

**NOMINATIONS OF DR. TEVI TROY,
DAVID H. McCORMICK, PETER B. McCARTHY,
KERRY N. WEEMS, AND CHARLES E.F. MILLARD**

HEARING

BEFORE THE

COMMITTEE ON FINANCE

UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

ON THE

NOMINATIONS OF

DR. TEVI TROY, TO BE DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES; HON. DAVID H. McCORMICK, TO BE UNDER SECRETARY FOR INTERNATIONAL AFFAIRS, U.S. DEPARTMENT OF THE TREASURY; PETER B. McCARTHY, TO BE ASSISTANT SECRETARY FOR MANAGEMENT AND CHIEF FINANCIAL OFFICER, U.S. DEPARTMENT OF THE TREASURY; KERRY N. WEEMS, TO BE ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES; AND CHARLES E.F. MILLARD, TO BE DIRECTOR OF THE PENSION BENEFIT GUARANTY CORPORATION

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JULY 25, 2007
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WEDNESDAY, JULY 25, 2007

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10 a.m., in room SD-215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Bingaman, Kerry, Wyden, Stabenow, Salazar, Grassley, Hatch, Lott, Smith, Crapo, and Roberts.

OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The committee will come to order.

In the book of Deuteronomy, Moses instructed the 12 tribes of Israel on how to choose officials. Moses told them to choose people who are “wise, understanding, and respected.”

Today we are here to consider the nominations of five people to become high officials in the Federal Government. We are here in the hope that the President has chosen people who are wise, understanding, and respected.

Before us today are the nominations of Dr. Tevi Troy, to be Deputy Secretary of Health and Human Services; David McCormick, to be Under Secretary for International Affairs at the Treasury; Kerry Weems, to be Administrator of the Centers for Medicare and Medicaid Services; Peter McCarthy, to be Assistant Secretary for Man-

agement and Chief Financial Officer at the Treasury; and Charles Millard, to be Director of the Pension Benefit Guaranty Corporation.

First, the Department of Health and Human Services is the largest non-defense agency in the Federal Government. Administering such a large organization with such a wide variety of issues is a huge responsibility.

Dr. Tevi Troy is the nominee to be the Deputy Secretary, the number-two man at HHS. Dr. Troy will have his hands full helping Secretary Leavitt to run the department that is home to CMS, FDA, the CDC, NIH, ACF, and probably a host of other three-letter acronyms. [Laughter.]

I expect Dr. Troy to be an impartial Administrator and put politics aside. He must make the right decisions, not just the politically popular ones. Americans will be counting on him to help keep them healthy.

Second, the Under Secretary for International Affairs at the Treasury is an important position, with responsibilities for many issues under this committee's jurisdiction. Mr. McCormick has an impressive background, and he comes highly recommended.

Two issues are of critical importance. This committee has been very concerned about China's under-valued currency. We are concerned that current law may not adequately address the relationship between fundamentally misaligned exchange rates and trade flows.

That is why I introduced landmark currency legislation with Senators Grassley, Schumer, and Graham last month. This committee will act on that legislation soon.

The Under Secretary will also have oversight over sanctions. I have long been frustrated by the lopsided focus of the Office of Foreign Assets Controls on Cuba. That office should have been focusing critical resources on sanctions against Iran. It should have been rooting out funding for terrorists.

I recently introduced legislation on Cuba trade, along with Senator Crapo and six other Finance Committee members. We need to get beyond counterproductive ideology. We need to do what is right for America's agriculture producers.

Third, Mr. Weems has been nominated to be Administrator of the Centers for Medicare and Medicaid Services, known as CMS. CMS is the agency within HHS that administers Medicare, Medicaid, and the Children's Health Insurance Program.

That means that CMS is responsible to more than 85 million beneficiaries who rely on the agency for their health care. The CMS Administrator is in charge of some of the most complex programs in our government. These programs make a huge difference in people's lives every day.

I am counting on Mr. Weems to be fair and even-handed. I do not believe that CMS has been putting beneficiaries' needs first recently, and that has to change.

HHS in general, and CMS in particular, have a duty to provide services to our country in a nonpartisan way. The programs within HHS are not political tools to be used at the whim of the administration.

Fourth is the Assistant Secretary for Management at Treasury. Mr. McCarthy is well-qualified to oversee the budget and management of all of the Treasury's offices and bureaus. His whole career has been devoted to managing the operations of large financial services organizations and their components.

The Department of the Treasury includes the Internal Revenue Service, the Office of Tax Policy, and others, and so the Assistant Secretary for Management has responsibility for developing the IRS budget and overseeing IRS operations.

Mr. McCarthy will, thus, have a role in taking on the \$345 billion annual tax gap, and it probably is even much larger than that. I expect Mr. McCarthy to fight to ensure that the budget provides the IRS with the tools and resources that it needs.

I expect him to work to ensure that the IRS can provide top-quality taxpayer service and fair enforcement. I expect him to be a hands-on leader who will support a credible and comprehensive plan to reach 90-percent voluntary compliance by 2017. I appreciate that Mr. McCarthy has agreed to take on this challenge, and I am looking forward to hearing his ideas to improve tax administration.

Finally, Mr. Millard. Mr. Millard is the first nominee for PBGC Director to be subject to Senate confirmation. Last year, Congress upgraded the position to a Presidential appointment, subject to Senate confirmation. We made it one of the few positions of government subject to confirmation by two committees, this committee and the HELP Committee.

The position's new status is recognition of how important we consider people's pensions. Both committees are concerned about the financial health of the PBGC, and the defined benefit pension system generally. I applaud Mr. Millard's willingness to take on this quite difficult position.

I look forward to hearing from all of you. I wish all of you good luck, and hope that, by your actions in your jobs, you all prove to be wise, understanding, and respected.

Senator Grassley?

Senator GRASSLEY. Mr. Chairman, I am just going to put my statement in the record. Thank you very much for the opportunity to be here. I have some questions that I will be asking of the witnesses.

The CHAIRMAN. Thank you, Senator.

[The prepared statement of Senator Grassley appears in the appendix.]

The CHAIRMAN. I am going to just introduce the panel, and then I know Senators wish to introduce certain nominees. We will do that as soon as I generally introduce the panel.

Senator ROBERTS. Mr. Chairman, could I make a unanimous consent request?

The CHAIRMAN. Certainly.

Senator ROBERTS. I would ask unanimous consent that I be recognized last, which is not unusual on this committee for me, at any rate, and be granted 20 minutes' time to answer some pertinent questions in regards to the bidding program for the durable medical equipment? And that way I would not take up the time of

other members, which I know is very valuable, and would try to get through my questions just as fast as possible.

The CHAIRMAN. I think we can work that out, Senator. You will certainly have 20 minutes. That is not going to be a problem.

Senator ROBERTS. I thank the Chairman.

The CHAIRMAN. The first witness is Dr. Tevi Troy, who has been nominated to be Deputy Secretary of Health and Human Services for the Department of Health and Human Services; then Hon. David McCormick, nominated to be Under Secretary for International Affairs for the U.S. Department of Treasury; next, Mr. Kerry Weems, nominated to be the Administrator of the Centers for Medicare and Medicaid Services; then Mr. Peter McCarthy, who has been nominated to be the Assistant Secretary for Management and Chief Financial Officer of the U.S. Department of Treasury; and then Mr. Charles Millard, who has been nominated to be the Director of the Pension Benefit Guaranty Corporation.

As I said, several Senators have asked to introduce nominees, and I will turn to you, Senator Bingaman, if you wish to.

Senator BINGAMAN. I think Senator Domenici was going to go first, if that is all right, Mr. Chairman. I will follow him.

The CHAIRMAN. All right. Thank you.

Senator, welcome to the committee.

**STATEMENT OF HON. PETE DOMENICI,
A U.S. SENATOR FROM NEW MEXICO**

Senator DOMENICI. Thank you very much. I do not come here very often.

The CHAIRMAN. Well, it is good to see you.

Senator DOMENICI. But when I am here, I recognize the great austerity of this committee, and I know all the great things that it does, and will do. I thank you for giving me just 2 or 3 minutes.

We happen to have a New Mexican appointed for a very big job, and he agreed to take it. At the end of the presidential term, when you take somebody who has been in public service for 35 years, with a family, three great children—and he will introduce them, as you usually give them that chance—and a wonderful wife, whom he met here in the Senate—that was a match made for heaven, but made in the Senate. [Laughter.] When I met him, my first question was, why would you do this to yourself? This is an incredibly difficult job at this stage of your career.

And, frankly, he is the most honorable and honest person that the President could have picked for this job. He truly believes he can do a good job, and pledges to do that and nothing else. He has no other motives. His background clearly justifies him for the job.

So, rather than go into any detail, I think you know me, most of you. I would not be here telling you, if I did not mean it, that this man is more than qualified and truly wants to take the job, and pledges nothing but good public service and wants nothing out of it other than to look back and say that he did the best job possible.

I do not think I can introduce a candidate who makes my job easier than this one, and I hope that your job of approving him is as easy as mine is in asking you to do that.

Thank you very much.

The CHAIRMAN. Thank you, Senator. You did not state his name. I presume you mean Mr. Weems. [Laughter.]

Senator DOMENICI. Mr. Weems.

The CHAIRMAN. Thank you for taking time out of your very busy day, Senator. Thank you so much for coming. We deeply appreciate it.

Senator DOMENICI. You are welcome. Thank you.

The CHAIRMAN. You are welcome.

Senator Bingaman?

**OPENING STATEMENT OF HON. JEFF BINGAMAN,
A U.S. SENATOR FROM NEW MEXICO**

Senator BINGAMAN. Mr. Chairman, thank you very much for letting me also say a word of endorsement of Kerry Weems for this important position. This is an important position. I think you pointed out, 85 million people depend on Medicare and Medicaid, and CMS is obviously the agency that we have a lot of interaction with because of that. Kerry Weems is well-qualified to take over this position.

He worked here in the Senate. When I first came to the Senate, he had just left. He worked for my predecessor, Senator Schmitt, here in the Senate and came from New Mexico. He grew up in Los Cruces much of his life, and then went to the University of New Mexico for his Master's in Business Administration after going to New Mexico State for his undergraduate work.

But he has worked in the Department of Health and Human Services since 1983 and is very much a career public servant in that regard. He worked for Republican and Democratic administrations. In 2000, he got the President's Award from then-President Clinton, and the Presidential Rank Award.

In 2005, he was appointed as Deputy Chief of Staff to Secretary Leavitt and has distinguished himself in that position. So, I think we are fortunate to have him able to take this position. It is late in this administration.

I think we are all aware that this is a difficult job to step into at this stage and make a constructive difference, but he is committed to doing that. So, I am glad to join Senator Domenici in urging his approval by this committee.

The CHAIRMAN. Thank you, Senator, very much.

I believe Senator Hatch would like to make an introduction.

**OPENING STATEMENT OF HON. ORRIN G. HATCH,
A U.S. SENATOR FROM UTAH**

Senator HATCH. Well, thank you, Mr. Chairman. I just want to welcome all five of you here today. I have high respect for each and every one of you, and we are hoping that your confirmations will go very smoothly. I am aware of you and appreciate the service that you have given and the background that you have obtained.

I would like to specifically introduce Dr. Tevi Troy to the committee this morning. He has been nominated by the President to be the Deputy Secretary for the Department of Health and Human Services, and he is currently the Deputy Assistant to President Bush for Domestic Policy. In that capacity he has been one of the

White House's lead domestic policy advisors, and he manages the domestic policy processes in the White House.

Dr. Troy has also served in the White House as a Special Assistant to the President and Deputy Cabinet Secretary, and as the White House Liaison to the Jewish Community. In that position, he was selected as a U.S. delegate to the Organization for Security and Cooperation in Europe Conference on Anti-Semitism in the spring of 2004. He was also detailed to the White House from the Department of Labor as Special Advisor to the White House Domestic Policy Counsel.

He began working in the Bush administration at the Department of Labor, where he was the Deputy Assistant Secretary for Policy, and earlier served as Director of the Department of Labor's Office of Faith-Based Initiatives.

Prior to joining the administration, Dr. Troy served as the Policy Director for former Senator John Ashcroft. He has also served as Senior Domestic Policy Advisor, and later Domestic Policy Director, for the House Policy Committee, chaired by former Congressman Christopher Cox.

He has also been the Herman Kahn Fellow at the Hudson Institute in Indianapolis and a researcher at the American Enterprise Institute in Washington. Dr. Troy earned a B.S. in Industrial and Labor Relations from Cornell University, and an M.A. and Ph.D. in American Civilization from the University of Texas at Austin. He has studied at the London School of Economics.

He is the author of "Intellectuals in the American Presidency: Philosophers, Jesters, or Technicians?" I do believe I deserve an autographed copy of that book. [Laughter.] I want to read that.

His experience and education have prepared him well to take over as Deputy Secretary of HHS. As Deputy Secretary, Dr. Troy will serve as the principal Deputy of Secretary Leavitt, a man I know a great deal about, and a very, very fine Secretary. I think we all feel that way.

But he will serve there with Secretary Leavitt in all matters affecting the Department, and perform continuing and special duties as the Secretary may assign, including the exercise of policy direction and general supervision over operating units not placed under other secretarial officers or other departmental officials.

Dr. Troy currently resides in Maryland with his wife Kami and four children, who are here with us today. We welcome them as well. We welcome the family members of all of you today.

With that, I present the nomination of Dr. Troy to the committee for consideration, and I appreciate you, Mr. Chairman, for moving ahead on these nominations. I do not think we could have five better people. Thank you so much.

The CHAIRMAN. All right. Thank you very much, Senator.

At this time I would like to ask Dr. Troy to begin. But before he does, do you want to introduce your family here?

Dr. TROY. Yes. Thank you, Mr. Chairman. I would be honored to. They are standing over here. Please rise. I have my wife, Kami, to whom I owe so much, my son, Ezra, my daughters, Ruth and Rina, and little baby Noah. I hope he does not cry this morning, sir. [Laughter.]

The CHAIRMAN. Well, thank you very, very much. I thank all of you. Government service is a sacrifice for everyone, not only the person serving, but also the person's family. We thank you all very much for undertaking this endeavor. Thank you.

Dr. Troy, you can begin.

**STATEMENT OF DR. TEVI DAVID TROY, NOMINATED TO BE
DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES,
DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASH-
INGTON, DC**

Dr. TROY. Thank you, Mr. Chairman.

The CHAIRMAN. And your full statement will be included in the record.

Dr. TROY. Well then, thank you. I will be brief then, since I know that that will happen. I appreciate that.

Thank you, Mr. Chairman, for this opportunity. Thank you, Senator Hatch, for that kind introduction; you will be sure to get an autographed copy of my book. I will be proud to give you one.

The CHAIRMAN. What about the rest of the committee? [Laughter.]

Dr. TROY. Any members who so desire who would actually read it, I would be happy to do so. [Laughter.]

Senator HATCH. I think they would all benefit from it, personally.

Dr. TROY. All right. Copies coming up.

Thank you for this opportunity. I would also like to thank President Bush and Secretary Leavitt for showing this faith in me. I really appreciate that.

As Senator Hatch noted, I have worked in this body before as a staffer, and I have also worked on the House side, and so I have a great appreciation and respect for this body and really look forward to working with you in my new capacity.

I was pleased to have this opportunity to introduce my family, who are so important to me. I am really excited for this opportunity to be here. I grew up in New York City in a time that was a very difficult period in the late 1970s when the city was on the verge of bankruptcy, there was graffiti, crime, urban unrest. It was a very difficult period.

At that very early age, it instilled in me a belief that there needed to be a better way. There is a strong desire for me to enter public service to help bring about that better way.

That belief in service was bolstered by two things. First of all, my family—both my parents are teachers in the New York city teachers union, teachers in the New York city schools—and also my Jewish upbringing. There is a Jewish principle of tikkun olam, which means improving the world, or constantly improving the world. It is a very important Jewish principle, and it has informed my thinking.

After going to college, I went to get a Ph.D. at the University of Texas, as Senator Hatch noted. I wrote a book on intellectuals of the presidency, as noted. That book was about how ideas get translated into action, how they get brought into politics.

Because of my belief in service, while interested in studying it, I also wanted to be involved. So I did move to Washington. I worked in the House and in the Senate. I have worked for the De-

partment of Labor, for the executive agencies, and for the White House. I found executive service, and government service in general, to be incredibly rewarding.

Now as I approach this new opportunity, my rabbi said to me that moving over to HHS gives me the opportunity to practice tikkun olam, or improving the world on a grand scale. That really is the case at HHS, which is a very large department, as the Chairman noted, but a department that really touches the lives and helps improve the lives of every American.

So I look forward to having this opportunity to work at HHS. I really look forward to having the opportunity to work with Secretary Leavitt, who is a very thoughtful and smart man. I am grateful for the faith he has shown in me, and I really hope to reward that faith while I am over at the Department.

So it is this overriding belief in service and in family that brings me here today, and I come here comforted, knowing that in this new capacity, should the Senate be willing to confirm me, I will go home every day to my wife and my four children, telling them that I have helped work to make this a better world.

Thank you for this opportunity.

The CHAIRMAN. Thank you, Dr. Troy.

[The prepared statement of Dr. Troy appears in the appendix.]

The CHAIRMAN. Mr. McCormick, you have an opportunity here to introduce your family, if you so choose.

Mr. MCCORMICK. Thank you, Senator. I would like to introduce my wife, Amy Richardson, and three of my four children: Ava. Put your hand up, Ava. Tess, the 4-year-old, and Elise.

The CHAIRMAN. Could as many as you can please stand so we can all see you? All right. Wonderful. Thank you. That is great. Thank you.

Mr. MCCORMICK. Thank you very much.

The CHAIRMAN. You bet. Thank you.

We wish you all very well. As Dr. Troy's family, the McCormick family as well.

Go ahead.

STATEMENT OF HON. DAVID H. MCCORMICK, NOMINATED TO BE UNDER SECRETARY FOR INTERNATIONAL AFFAIRS, U.S. DEPARTMENT OF THE TREASURY, WASHINGTON, DC

Mr. MCCORMICK. Mr. Chairman, Ranking Member Grassley, members of the Committee on Finance, thank you for the opportunity to be here today. I recognize what an important role this is, and, if fortunate enough to be confirmed, I will do my utmost to execute those responsibilities effectively.

I am honored that President Bush has nominated me to serve as the Under Secretary of Treasury for International Affairs and, if confirmed, to have the opportunity to work with Secretary Paulson, the Treasury staff, and others in the administration.

If confirmed, I would also look forward to the opportunity to work closely with this committee, because I know a number of the issues in this portfolio are of significant concern and interest to members of this committee, and I would look forward to working with your colleagues in the House of Representatives to advance U.S. economic interests at home and abroad.

My experiences as a senior member of the President's economic team, as a public company CEO, and as a veteran and former military officer have prepared me well for the position to which I have been nominated.

And if fortunate enough to be confirmed, I would work very hard on some of the most pressing issues of the day and focus on things such as addressing growing global imbalances, accelerating China's stable integration into the global economy, and ensuring that development assistance from the multilateral development banks is deployed effectively around the world.

I would also focus on advancing the President's vision for opening up foreign markets for U.S. goods and services and accelerating the transition of many developing countries to true market-based economies.

I would also continue to emphasize the critical importance of economic growth, good governance, and the rule of law in ensuring that all parts of the global economy can become vibrant and prosperous, while at the same time maintaining vigilance in trying to prevent future financial crises.

As I said, I am grateful to have the opportunity to be with you here today, and I look forward to answering any questions you might have. Thank you.

The CHAIRMAN. That is it?

Mr. MCCORMICK. Yes, sir.

The CHAIRMAN. All right.

[The prepared statement of Mr. McCormick appears in the appendix.]

The CHAIRMAN. All right. Mr. McCarthy, welcome to the committee.

Mr. MCCARTHY. Thank you, Mr. Chairman. My children are all grown up and living in faraway places, but I would like to introduce to you my wife of 35 years, Mary Calvert McCarthy, who is with me today.

The CHAIRMAN. Welcome, Mrs. McCarthy, very much. Thank you.

Why don't you proceed?

STATEMENT OF PETER B. MCCARTHY, NOMINATED TO BE ASSISTANT SECRETARY FOR MANAGEMENT AND CHIEF FINANCIAL OFFICER, U.S. DEPARTMENT OF THE TREASURY, WASHINGTON, DC

Mr. MCCARTHY. Mr. Chairman, Ranking Member Grassley, members of the Senate Finance Committee, thank you for the opportunity to appear before you here today. I am honored that the President has nominated me to serve as Assistant Secretary for Management at the Treasury Department, and I am grateful to you for taking the time to consider that nomination.

Mr. Chairman, the Assistant Secretary for Management and Chief Financial Officer at Treasury is responsible for internal management and policy in the areas of budgeting, planning, human resources, information technology, financial management, accounting, procurement, and administrative services.

It is incumbent upon this individual to maintain and improve the effectiveness and efficiency of, and cooperation among, the offices

and bureaus of the Department. I believe that my broad management experience in large financial organizations would enable me to successfully fulfill these responsibilities.

My career in banking and financial services spans more than 30 years and includes extensive practical experience in the financial management of complex business entities. Eighteen of those years were spent in expatriate assignments, primarily in the United Kingdom and Japan.

I have held senior positions across a wide variety of banking activities, including customer relationship management, credit and market risk management, corporate banking, capital markets product management, training, trading, Treasury operations, and administration.

I have had the opportunity to manage significant change, having opened, grown, and right-sized banking operations around the world to better meet customer expectations and improve efficiency and accountability.

Mr. Chairman, I would be grateful for the opportunity to apply the experience that I have gained and the skills that I have learned to the vitally important work of the Treasury. I look forward to the possibility of joining the dedicated cadre of career and appointed professionals at the Department in the various Treasury bureaus.

If confirmed, I will work hard to support Secretary Paulson's commitment to efficient and effective management practices, to responsible budgeting, and to strong internal controls. I will support the Secretary's commitment to strengthen policy guidance and approve oversight of information technology investments.

I will be attentive and responsive to the interests of your committee and of Congress in Treasury's performance and the administration of its programs and activities.

Mr. Chairman and members of the committee, I have never had the privilege of serving the government of the United States. To do so now in a management role for which I feel truly well-prepared would be a great honor. Thank you again for the opportunity to appear before this committee and for considering my nomination.

The CHAIRMAN. Thank you, Mr. McCarthy.

[The prepared statement of Mr. McCarthy appears in the appendix.]

The CHAIRMAN. Mr. Weems?

Mr. WEEMS. Thank you, Mr. Chairman. If I might, I would like to introduce my family, sir.

The Chairman. Absolutely.

Mr. WEEMS. They are here. First of all, my wife of 23 years, Jean, who is a former employee of Senator Grassley's.

Senator GRASSLEY. And a good employee. I would hire her back. [Laughter.]

Mr. WEEMS. As Senator Domenici noted, we did meet while coming to the Senate when we were employed here.

My son, Peter, who is at James Madison University; my daughter Claire, who is at George Mason; and finally, my daughter Anna, who is beginning her senior year in high school.

The CHAIRMAN. Oh. Good. Congratulations, all of you. Welcome to the committee, and good luck.

Why don't you proceed?

STATEMENT OF KERRY N. WEEMS, NOMINATED TO BE ADMINISTRATOR OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES, WASHINGTON, DC

Mr. WEEMS. Thank you, Senator. Thank you very much for holding this hearing today, and especially thanks to Senator Domenici and Senator Bingaman for introducing me.

I have worked with many of you. You know me from both Republican and Democratic administrations. I was first hired into the civil service in 1983. I became a manager during President George H.W. Bush's administration. Former HHS Secretary Donna Shalala signed my appointment to the Senior Executive Service, and President Clinton awarded me the Presidential Rank Award.

Former Secretary Thompson promoted me to Deputy Assistant Secretary for Budget, and from January 2003 to July 2005, I served as Acting Assistant Secretary for Budget, Technology, and Finance and as HHS Chief Financial Officer. More recently, I was Deputy Chief of Staff to Secretary Leavitt.

It is a privilege to be here today to apply for the job of CMS Administrator. One of the strengths I bring to this job is the ability to manage enormous budgets effectively.

CMS spends more than \$600 billion a year, more than Defense and more than many countries in the world. CMS determines access to health care for more than 90 million beneficiaries. Its payment decisions determine the quality of health care and when and how that care is provided. CMS's regulatory power is enormous, reaching into practically every aspect of health care.

Small programmatic changes have large consequences to individual providers. This is not simply a question of CMS flexing its regulatory muscle; it is also a question of being aware of those consequences. Indeed, many on this committee have urged me to be sensitive to CMS's regulations on a wide range of providers.

Much more is at stake than economics or politics. Beneficiaries' health and lives depend on these decisions. The person who steps into the Administrator's post also needs to have a broad, non-partisan understanding of health care delivery and where we need to go. Almost a quarter of a century of working at HHS has given me a long-term perspective that I believe is critical to leading CMS.

There has been a lot of change in health care in my 24 years of service. When I began in the Social Security Administration, then a part of HHS, there was an ashtray on every desk and smoking in every office. Today, CMS has a nationwide prevention campaign, including smoking cessation counseling.

When I started at HHS, the ink was barely dry on diagnostic-related groups. Today CMS is moving beyond DRGs, replacing volume-based payment systems with systems that recognize a patient's condition and the quality of their care. For example, on July 1, CMS began the Physician's Quality Reporting Initiative to reward initiatives for reporting on quality health care.

I hope soon to be able to send to this committee a CMS plan for value-based purchasing in the hospital setting, and Secretary Leavitt is making great progress with standards and certification on electronic health records.

I am aware that this committee and others have been frustrated by the lack of resolution and consistent information regarding the

Medicare Part D premium withhold. Mr. Chairman and Senator Grassley, if I am confirmed, you will have the same information that I do, and I will make it a top priority to fix these problems.

Much attention has been devoted to the baby boom generation and its imminent retirement. However, before they retire, the boomers have one great task ahead of them: caring for the generation that preceded them.

My own family offers examples of the issues these generations face. My father is on the Medicare prescription drug program and hit the coverage gap this year; I got a phone call. He and I worked together to get him the coverage he needs and the drugs that are best for him.

My vision for the prescription drug program is that every beneficiary and their caregivers have the information they need to choose the plan that is best for them and to get the care they need.

My mother may soon be faced with the need for a particular surgery. My vision for our health care system is that she, and every patient, has the right information to choose care that is accessible, coordinated, effective, and in the most appropriate setting.

My wife and her sister are caregivers for their mother who resides in a nursing home. Recently, my mother-in-law was injured in the nursing home, yet my wife has not received a satisfactory explanation from this particular facility, despite a request for a detailed incident report.

My vision for Medicare and Medicaid is one in which beneficiaries are protected, whether from unsafe nursing homes, unscrupulous insurance salesmen, fraudulent equipment providers, or bad medicine. If confirmed, I will intensify CMS oversight, and I expect you to hold me responsible for acting on abuses or inefficiencies discovered in the course of program oversight.

Throughout my more than 2 decades of public service at HHS, I have witnessed tremendous talent at CMS and at HHS. Let me tell you what I have learned in that time. I have learned to seek out experts and all those who have equities in an issue and listen to them. I have learned to follow the law, to weigh the evidence and the facts, and to render a decision. My pledge to you today is that I will pursue the facts and the law to guide my decisions and leadership.

Let me again say that it is an honor to have received the President's nomination, to thank you for holding this hearing, and I humbly submit my credentials for your consideration.

Thank you.

The CHAIRMAN. Thank you, Mr. Weems.

[The prepared statement of Mr. Weems appears in the appendix.]

The CHAIRMAN. Mr. Millard?

Mr. MILLARD. Good morning, Mr. Chairman. I have a large family. I have eight children, and my wife is expecting number nine. But they are young, and travel from New York to here was a little difficult. But I do have my oldest son Egan here, who is spending a few weeks with me in Washington, whom I would like to introduce.

The CHAIRMAN. Thank you very much. Good luck to you, Egan.

**STATEMENT OF CHARLES E.F. MILLARD, NOMINATED TO BE
DIRECTOR OF THE PENSION BENEFIT GUARANTY CORPORA-
TION, WASHINGTON, DC**

Mr. MILLARD. Chairman Baucus, Ranking Member Grassley, and members of the committee, thank you for giving me the opportunity to appear before you today.

I am honored and humbled that President Bush has nominated me to serve as the Director of the Pension Benefit Guaranty Corporation, and I appreciate your consideration of my nomination. Public service is a privilege which I hold dear, and I am sincerely grateful for this opportunity to serve, if I am confirmed.

For as long as I can remember, my parents taught my siblings and me that loving our neighbor meant taking action. My first experience of that action was marching for civil rights with my parents 40 years ago in Newark, NJ. The desire to serve has stayed with me since that time. I certainly hope that my children experience a similar example from my wife and me.

I have had the chance to serve as a VISTA Volunteer in Crown Heights, Brooklyn, and as a board member of the New York Urban League. In 1985, I worked in Chile for the Vicariate of Solidarity, a Santiago-based human rights organization.

I have served as a New York city councilman, and was then appointed by Mayor Rudolph Giuliani to be the president of the New York city Economic Development Corporation and chairman of the New York city IDA. I also worked as a legislative assistant in the early 1980s here on Capitol Hill for Congresswoman Millicent Fenwick of New Jersey.

My work in New York as head of EDC is worth noting because, like PBGC, the Economic Development Corporation was created as a corporation to manage governmental programs that are principally business-like in nature, produce self-sustaining revenue, involve numerous negotiated transactions, and require greater budget and other flexibility than a traditional government agency.

In addition to public service, my career in private life also helps me bring relevant knowledge and experience to the PBGC. I have been a practicing Wall Street attorney, representing large financial institutions. I have been a managing director involved in investment banking, public finance, and investment management with such firms as Lehman Brothers and Prudential Securities.

Most recently, I have been a partner in a more entrepreneurial real estate enterprise dealing with large, individual, and institutional investors regarding their investment allocations to real estate.

This diverse background in public and private life has given me experience in managing hundreds of people in a public environment and directing a large organization to higher achievement. I have also come to understand how individual corporations reach financial decisions and how many large institutions and pension funds make investment decisions.

PBGC and the defined benefit pension systems face considerable challenges in coming years. At the end of fiscal year 2006, PBGC's deficit stood at \$18.9 billion. The corporation controls assets worth approximately \$61 billion and faces liabilities of approximately \$80 billion on a present value basis. Also, PBGC estimates that

total under-funding in ongoing plans stood at \$500 billion at the end of fiscal year 2006.

The Pension Protection Act, passed last year by Congress and signed by President Bush, has made some significant improvements in the system that will enhance the soundness of the defined benefit system for millions of American workers. The corporation is currently implementing the PPA, including the development of a comprehensive set of regulations and other guidance as mandated by Congress.

Mr. Chairman, I would like to emphasize my personal commitment to PBGC's mission and purpose. It is PBGC's job to promote and maintain healthy plans, to negotiate in bankruptcy and other proceedings, to protect workers and their benefits, and, of course, when a plan must terminate, it is PBGC's job to pay those benefits. This requires constant vigilance to various corporate transactions, securities filings, and bankruptcy court proceedings.

It requires steadfast negotiations by PBGC on behalf of workers and their families to help avoid plan terminations, or at least to minimize their impact, and it requires responsible and effective investment and stewardship of the assets that are used to pay benefits to the insured beneficiaries of trusteed plans.

A corporation carries a tremendous responsibility, because the insured beneficiaries of trusteed plans that I just mentioned are actually real, individual human beings, people who have worked their whole lives to receive the retirement benefits that they have been promised and have earned, people who support families and who wait for the check from PBGC so they can sit at the kitchen table and pay their bills, people who are counting on PBGC to carry out its mission as given to it by you.

If confirmed in this position, I would welcome the opportunity to work with members of the Senate and the House, as well as your staffs, to make sure that we do the best job we can for these workers. I would be happy to answer any questions you may have.

Thank you.

The CHAIRMAN. Thank you, Mr. Millard.

[The prepared statement of Mr. Millard appears in the appendix.]

The CHAIRMAN. I am now going to ask three standard questions of each of the nominees. I will ask the first question of you, Dr. Troy, and then I am going to ask each of the other nominees if they also make the same commitment. Then I will go to question two, in the interest of time, and hopefully clarity.

Dr. Troy, is there anything that you are aware of in your background that might present a conflict of interest with the duties of office to which you have been nominated?

Dr. TROY. No, sir, Mr. Chairman.

The CHAIRMAN. Mr. McCormick?

Mr. MCCORMICK. No, sir, Mr. Chairman.

The CHAIRMAN. Thank you very much.

Mr. McCarthy?

Mr. MCCARTHY. No, Mr. Chairman.

The CHAIRMAN. Mr. Weems?

Mr. WEEMS. No, Mr. Chairman.

Mr. MILLARD. No.

The CHAIRMAN. Thank you.

Do you know of any reason, personal or otherwise, that would in any way prevent you from fully and honorably discharging the responsibilities of the office to which you have been nominated?

Dr. TROY. Definitely not, sir.

Mr. MCCORMICK. No.

Mr. MCCARTHY. No, sir.

Mr. WEEMS. No, sir.

Mr. MILLARD. No, sir.

The CHAIRMAN. Thank you.

Do you agree, without reservation, to respond to any reasonable summons to appear and testify before any duly constituted committee of Congress, if you are confirmed?

Dr. TROY. Yes, sir.

Mr. MCCORMICK. Yes, Mr. Chairman.

Mr. MCCARTHY. Yes, sir.

Mr. WEEMS. Yes, Mr. Chairman.

Mr. MILLARD. Yes, I do.

The CHAIRMAN. All right. Thank you.

I think it is not a secret that there is considerable concern that this administration tends to put politics above policy in many different areas. It is very concerning to me, personally.

You, Dr. Troy, mentioned public service, the noble service that it is, and I agree. All of us are really public servants. We are here to serve the country, the people we represent. I do in my capacity, Senator Grassley does; you do, we all do. We have a duty, almost a fiduciary duty, to the people we serve, not a duty to ideology or to partisan politics.

Rather, it is a duty that each of us holds, I think, especially in the agencies in which you will be probably serving, to fully remember your constituents—in HHS's case, beneficiaries; at Treasury, it is taxpayers—rather than the White House, rather than political pressure.

I expect you to be neutral, aggressive servants of the people you are working for, all of you. You will be, in the long run, able then to hold your head higher when you leave. You are not there permanently—none of us is. But when we all leave, we want to be very proud of what we did when we served our people.

So in that respect, Dr. Troy, as you know, former Surgeon General Richard Carmona said that he has been stopped by the White House from bringing certain science-based information to the public, and he said his speeches and reports were edited because they did not fit the President's political agenda.

What assurances can you give this committee that you will resist political pressures and do what is right based on science? Someone else can follow the facts and law. I assume you will follow the facts and law, too. So what assurance can you give this committee?

Dr. TROY. Thank you for that question, Mr. Chairman, and also for your comments about public service, which, as I said earlier, I hold in the highest regard.

I have been a public servant in the White House, but also in the executive agencies. The White House is part of my background, but it is not the totality of my background. I have also worked in Congress. I have a strong reputation on both sides of the aisle.

I have long built friendships on both sides of the aisle. With my Ph.D. background, I have always had a great interest in looking at the facts, in studying, in research in making sure we come to the right decision. I understand what the role of the agencies are in the process, and I pledge to undertake that role.

The CHAIRMAN. I appreciate that. We do not have a lot of time up here. Each of you has jurisdiction over an incredibly complex set of issues, so it is very difficult for us to ask lots of individual, specific questions. So that is why I am asking generally, just your attitude and the approach that you are going to take with your job.

Mr. Weems, I have had longstanding concerns about CMS using enormous pressures of the Office of the Administrator to advance the White House political agenda. I expressed great displeasure when CMS held a briefing on Medicare Advantage, basically pushing and promoting Medicare Advantage. It was an outrage.

To my surprise and dismay, a more egregious political stunt followed, even though we had a private meeting and I told you how concerned I was about that briefing. That stunt that followed was, the administration tried to make 5 million children disappear with an HHS study about the number of eligible, but unenrolled, children.

CBO says the study is not accurate. It is clearly a political document. What assurance can you give this committee that you will not indulge in such activities? In fact, if you are asked to do something like that, that you will stop it and you will be straight and forthright with us, not be political?

Mr. WEEMS. Thank you for the question, Senator. I will be brief. I sit before you today still as a career civil servant. I have, on many, many occasions, resisted political pressure when the right decision lay in front. I have no intention, if confirmed, of using the Administrator's office for political purposes.

The CHAIRMAN. And will you not let your office be used at all for political purposes?

Mr. WEEMS. Not within my—

The CHAIRMAN. Remembering the beneficiaries that you are serving.

Mr. WEEMS. That is what I would be there for, if confirmed. And within my power, I would not let my office be used for that purpose, sir.

The CHAIRMAN. Thank you. My time has expired.

Senator Grassley?

Senator GRASSLEY. Yes. My first question is about political pressure, to make sure that there is not political pressure from Congress. So, I am going to direct to Mr. McCarthy more a statement than a question.

As you know, I have shared the administration's strong support for the IRS's private debt collection program. It is a cost-effective way, I think, to deal with the tax gap. The Chairman always emphasizes the tax gap, and I agree with him 100 percent. This has been an effective tool in collecting taxes due and owing, and at the same time protecting taxpayers' rights.

It is my understanding that the current contracts are scheduled to end early next year. Given the lead time necessary for new contracts to be let, that process needs to be moving forward very rap-

idly. The Acting Commissioner of IRS has said that these requests for quotes would be "out by summer." Those are his words, not mine. However, there are only a few more Sundays left in summer and we have not heard a doggone thing.

I want your assurance that these requests for quotes will be out before July 31. I have no interest in the details of the request for quotes. That is the business of the IRS, and it would be inappropriate for me or any member of Congress to interfere in that process.

I would like your assurance that the IRS and Treasury are not allowing a member of Congress, or Congress generally, or maybe some very strong staff of appropriate committees in the Congress, to get involved at this point in the contracting process. That would be very irregular.

Before you respond, the law of the land is that there should be private debt collection programs. We passed that. I expect Treasury and the IRS to properly administer the current law and in no way restrict the program based on speeches from politicians.

Let me be more specific. It is my understanding that there is kind of a general rule that if there is debt collection below \$25,000, that the present staff of IRS just ignores that.

So we have put in place debt collection from the private sector to go after money that we would not otherwise go after. I do not know how much of the \$350 billion of the tax gap we talk about. It might be this \$25,000 or less. But we ought to go after it, and we are going after it with this program. We need to have more than two contracts out there.

So, will it get done?

Mr. MCCARTHY. Senator, thank you for that question. I know this is a very important matter for your committee and for the American taxpayer. The IRS has been managing, and continues to manage, this initiative strictly within the rule of law, as laid out by Congress in 2004.

My understanding is that the first cases were referred only last September, so it is still a relatively new initiative. But it is being successfully managed at this time. I believe that taxpayer surveys have indicated that the taxpayers are satisfied with the service that they are getting through these collection agencies, and every taxpayer does have the right to request that his or her return be returned to an IRS agent rather than being handled by a collection agent, if they so choose.

Also, I understand that it is a financially successful operation, at least so far. Sometime during fiscal year 2008, the monies that have been collected by these agents will match the appropriations that have been allocated.

Senator GRASSLEY. Yes. Can I ask you, are you going to put out these requests before summer is out, according to the IRS? I just kind of need a "yes" or "no" answer.

Mr. MCCARTHY. Sir, I am not in a position to say whether they will be out by July 31. I could only refer that question directly to IRS management, I think, if you wish me to.

Senator GRASSLEY. Well, if there is anybody here from congressional relations, I hope they know that the law is the law. It is going after money that would not otherwise be collected. You

should not be listening to a bunch of union bosses or a bunch of people on the other side of the Hill about whether this is a good program or not.

The Constitution establishes a system of checks and balances—I am leading up to Mr. Weems and Dr. Troy—that is intended to assure that the American people have fair, honest, and transparent government. We all know what a checks-and-balances system is.

In furtherance of our oversight responsibilities in Congress, we often ask the GAO to evaluate CMS's activities. In addition, we may ask the Office of Inspector General to get involved in things like that. This committee, however, has encountered a number of significant undue delays in response to its requests. A number of requests to HHS, for example, remain outstanding and the deadlines have long passed.

Mr. Weems, in your opening statement you said you will “intensify CMS oversight activities, and I expect this committee to hold me responsible for acting on abuse or inefficiencies discovered in the course of program oversight.” Your predecessors will tell you that I am going to hold you to that. You know me for doing that, and I appreciate that.

So, Dr. Troy and Mr. Weems, will you commit to working with Congress, GAO, and OIG in a timely and constructive manner to address the oversight and other needs of Congress, and will you encourage others to do so?

Dr. TROY. Yes, Mr. Chairman.

Senator GRASSLEY. Thank you.

Mr. WEEMS. Yes, sir.

Senator GRASSLEY. My time is up.

Mr. Crapo is next. I will have some further questions.

Senator CRAPO. Thank you very much.

I have questions for every member of the panel, but as you can see, we do not have enough time to get through our questions. So I am going to focus on you, Mr. Weems.

Mr. WEEMS. Thank you.

Senator CRAPO. I suspect you will get a lot of the questions. Actually, I have so many questions that I am going to just tell you the categories and then probably get into what I can in the time I have, and submit some to you in writing.

I have questions on the hospital inpatient prospective payment system rule that I wanted to go over with you; also, on the ambulatory surgical center payment rule that was just issued; on the least costly alternative policy that CMS is pursuing, particularly with regard to certain prostate cancer drugs; the erythropoiesis-stimulating agent issue, where CMS has proposed a national coverage determination that I think may be too restrictive and cause some difficulties.

Just two more. A question on specialty hospitals and the manner in which CMS is approaching resolving those issues that we have been working on for so long. And then finally one that you and I have already talked about also, as well as some of these others, but the Xoponex issue and the question of whether CMS's decision recently to bundle multi-source and single-agent asthma and COPD drugs in the reimbursement code is being done properly.

So I am going to send you in writing more detailed questions on those six areas, but let me just focus in the time I have remaining on the ambulatory surgical center issue.

CMS released its payment rule recently. And by the way, I thought that the rule that was issued was a significant improvement over where we are currently, but, as I believe you know, it did not go as far as I had been asking. I am concerned about basically two problems.

First, the 65-percent reimbursement rate, I do not believe is going to be adequate. I would hope we would still have time to revise that proposed rule. A 75-percent reimbursement rate will be much more effective and will allow ambulatory surgical centers to better fulfill the medical needs that we want to see them accomplishing in our society. So, I encourage you to discuss that with me in the time that we have here.

Then the other major concern I have is that, although the proposed rule adds a number of new procedures that are authorized, instead of moving to the exclusionary list, which was to authorize all procedures except those specifically determined not to be proper for those types of facilities, instead the agency still seems to be wanting to go through and outline every procedure that can be authorized rather than approaching it from the exclusionary point of view.

I do want you to respond in the few minutes that we have left on those two issues, please.

Mr. WEEMS. Thank you. And for the others, I would be happy to respond in writing.

Ambulatory surgical centers are an essential part of our health care system. They offer alternative settings and perform what we believe is high-quality work. The reimbursement rate that we were led to in that rule, like many things we do in rules, is based on the evidence that is available.

Frankly, in cases like this, and also something that I am sure other members of the committee will want to discuss, the inpatient rule, we are led by the evidence presented by our Office of the Independent Actuary who makes these estimates.

We follow that. We attempt to follow the facts, but like most things we will keep an eye on the transition as we go through it. We will ensure that as we refine payments, that the reimbursement rate is correct. We certainly want to be responsive to your concerns.

Senator CRAPO. I think the data show otherwise, and I will visit with you about that. But in the short time we have remaining, what about the exclusionary approach rather than listing every authorized procedure?

Mr. WEEMS. On August 23, 2006, CMS proposed in the *Federal Register* (71 FR 49635) a revised payment system for ambulatory surgical centers (ASCs) to be implemented effective January 1, 2008, in accordance with section 626(b) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). Among many other things, the rule proposed a new "exclusionary" approach for revising the ASC list of covered surgical procedures beginning CY 2008. CMS proposed to evaluate surgical procedures to identify those that could pose a significant safety risk or that

would be expected to require an overnight stay when performed in ASCs, and that would, therefore, be excluded from Medicare payment under the revised ASC payment system. Using that exclusionary method, CMS developed a list of surgical procedures viewed to be safe for Medicare beneficiaries in ASCs and appropriate for Medicare payment.

CMS noted in the August 2006 proposed rule that they had given careful consideration to recommendations made by the Medicare Payment Advisory Commission (MedPAC) in its March 2004 Report to Congress, which suggested that the current "inclusive" list of procedures be replaced with an "exclusionary list." CMS also noted considerable consultation and discussion with members of ASC trade associations and physicians regarding the criteria that would be used to identify procedures for payment under the revised ASC payment system. CMS agreed that adoption of a policy similar to that recommended by MedPAC would serve both to protect beneficiary safety and increase beneficiary access to procedures in appropriate clinical settings, recognizing the ASC industry's interest in obtaining Medicare payment for a much wider spectrum of services than is now allowed. Therefore, in the August 2006 proposed rule, CMS proposed that, under the revised ASC payment system for services furnished on or after January 1, 2008, Medicare would allow payment to ASCs for any surgical procedures performed in an ASC, except those surgical procedures that we determine are not payable under the ASC benefit.

CMS has not yet issued the final rule implementing these regulations, but has received and reviewed thousands of comments in preparation for final policy decisions and publication of the final rule.

Senator CRAPO. All right. I appreciate that. Thank you very much. We ended up with a few seconds left over.

The CHAIRMAN. Thank you.

Next is Senator Roberts, but I think Senator Roberts wants to reserve all of his time for a little later on.

Next on the list is Senator Wyden.

Senator WYDEN. Thank you, Mr. Chairman.

My thanks to all of you. Dr. Troy, I always like to hear somebody talking about being in the tikkun olam business and perfecting the world.

My questions as well are primarily for you, Mr. Weems. Let me start with something you and I talked about in my office. Under the Healthy Americans Act that Senator Bennett and I have proposed, we would like to start a revolution in health care. That is to move away from sick care and put a much stronger focus on health care and prevention.

Towards that end, we are advocating a legislative change that would allow your Department, for the first time, to reduce premiums for seniors, the outpatient premiums, when they stop smoking, lower their blood pressure, engage in the preventive kind of practices.

You gave me a good answer to this question in my office, and I would like to hear you on the record: would you support a change like that that we are advocating in our bipartisan bill to reward prevention?

Mr. WEEMS. Senator, you have my personal support on that. I have been an advocate for that inside our own councils in HHS. I believe that good evidence-based preventive measures should be rewarded. In fact, there is a friend of mine who is here today whose own private insurance requires him to go through a physical. He has to manage his blood pressure and all that to get a lower premium.

I believe it makes good business sense, but moreover I think it will improve the health of our beneficiaries by moving the incentives in the right direction for the beneficiaries, but also for the health care system.

Senator WYDEN. It is going to help transform American health care, and I appreciate your answer and I appreciate your advocacy.

The second question I want to ask you about deals with private sector health care. I note Senator Lott, Senator Roberts, a number of us are talking about the future of American health care, and we really want to ensure that our citizens have private sector choices.

That is what the Healthy Americans Act is built around. But I am very concerned about a new area that has come up where it seems that there are some abusive practices. That is this question of the private fee-for-service option under Medicare Advantage.

And as you know, there have been some pretty well-documented marketing abuses. What concerns me is, seniors are getting ripped off, and also this is giving a bad name to private sector health care.

What steps, if any, would you take to reign in these abuses in private fee-for-service plans that we have seen come out in the last 6 months?

Mr. WEEMS. Senator, as I said in my opening statement, it is my intent to intensify oversight. We are going to take a close look at the CMS organization, at how that happens. Right now, much of the oversight happens in the regions.

I need to either, if confirmed, be in a position to hold my regional directors responsible for that or to centralize that and to have that brought back as a normal part of business in the Administrator's life of, what are we doing about oversight today? That is my promise to you.

Specifically on private fee-for-service, we need to really dig in on the way that marketing happens. We need to have secret shoppers out there. I also think that we need to breathe life into the Memorandum of Understanding that we have with many States on how agents and brokers conduct themselves in the marketplace.

Senator WYDEN. We will work closely with you on that, because seniors clearly have been exploited. Those of us who believe in private sector health care and believe there are good private sector options especially want to have this corrected because it is going to be a key part of any bipartisan reform effort.

The third area I want to ask you about is, absent legislative action, physicians are looking at the prospect of a 10-percent cut in Medicare reimbursement. This is an enormous issue with respect to access to health care for seniors, particularly in rural areas—and in urban areas.

You all will have a lot of discretion and a lot of opportunities to advocate policies in this area. What changes are you looking at with respect to dealing with what could be a huge crisis, an ex-

panded set of problems for seniors getting access if physician reimbursement is cut again?

Mr. WEEMS. Senator, thank you for the question. I think that what many refer to as the “doc fix” or the “SGR fix” really gives us a remarkable opportunity to work together on some of the things that need to begin to happen in the reimbursement system. We need to find a way to pay for quality, not just to pay for more. That, I believe, is one of the things that we need to work into the SGR fix.

I also believe it represents an opportunity for us to think clearly about, what is the role of electronic health records? Should that be a part of what we do? In the end, I look at it as an opportunity to work with this committee to in some way summon forth the future of health care in the physician’s office.

Senator WYDEN. My time has expired, but I am planning to support the nominee. I look forward to working with all of you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Smith?

Senator SMITH. Thank you, Mr. Chairman.

Sorry you are being picked on, Mr. Weems. You and I also met and we discussed the “all or substantially all” policy related to Medicare Part D. I asked you what CMS was going to do about ensuring that plans cover these six protected classes.

I am still not clear what steps CMS is going to take or is taking to ensure that the plans actually follow the guidance that you provide. I consistently hear reports that plans do not cover all or substantially all of these protected classes and that beneficiaries have to go through lengthy appeals processes.

Can you tell me what is happening and what CMS is going to do?

Mr. WEEMS. Well, Senator, I share your concern in that area. I have to say, following our meeting I went back and checked through CMS on this. At least what I am hearing, Senator, is we are not hearing the same things. I think we need to reach back and find these discrete cases and bring them forward, individual cases, look at them and see what happened. That is in the particular.

In general, as I said to this committee, we are going to intensify oversight. That means we are going to get counts, we are going to talk to the plans about the number of appeals, why there are appeals. If there are systematic problems, sir, we are going to find them, and we are going to root them out.

Senator SMITH. I appreciate that.

CMS recently announced that all beneficiaries who receive extra help with their drug costs would be able to change their prescription drug plans on a monthly basis. Senator Bingaman and I support that. We have legislation to accomplish that very thing.

However, allowing these beneficiaries to change plans monthly will require CMS, the Social Security Administration, and prescription drug plans to update information in the enrollment system in a timely manner. You and I talked about the tremendous lack of communication or difficulty existing between CMS and Social Security.

I am wondering what steps you are doing to ensure that beneficiary enrollment information is updated in the enrollment system so that it is timely, so that it can accommodate the new policy on monthly plan switching.

Mr. WEEMS. Thank you for that, Senator. As I told you and I will just tell the rest of the committee, I used to work at the Social Security Administration. The way their computers work is a lot different than the way CMS's work. In Social Security, they like computing an annual benefit, dividing it by 12, and sending out a check. They do not have to deal with deductibles and co-payments and many of the things that CMS has to. So, there is just a problem with the systems talking.

Now, having said that, if confirmed, one of my first acts will be to work on this premium withhold problem, to work with the Social Security Administration. If we need a change in the business process of premium withhold, then let us make that change.

If we need a change in the business process of moving people from plan to plan, then we are going to make that change. If people also fall into the holes of premium withhold, we are going to find a way to get them out quickly and get back either the money that we owe them or to find some way that they can make restitution to the government. It is a problem, I acknowledge, but it is going to be a very high priority, as I said in my testimony, to fix this.

Senator SMITH. Mr. Chairman and Senator Grassley, this is an issue that, frankly, has come to my attention repeatedly, that CMS and the Social Security Administration almost speak different languages because their computers are so different. Social Security's computer systems are antiquated, which is a generous term to describe them.

This may be an area where we need to make an investment so they can speak the same language, because, with all that we are doing now with Medicare Part D and enrollment and plan switching, they just simply are not able to function together. I think it would be appropriate for our committee to help lead a change so that they can have similar systems that coordinate in a way that is workable for the American people who depend on these programs.

Thank you.

The CHAIRMAN. I would say, your point is very well taken. Some of it gets down to just budget requests in the amounts that the Appropriations Committee grants and the Congress grants. For example, I know in SSA it is a whole other problem. There are insufficient resources and administration with respect to disabilities. I think that part of the problem is just budget requests. They are inadequate and insufficient. Congress, I think, frankly, has not been as aggressive as they could, and should, be.

Senator SMITH. We need to be.

The CHAIRMAN. Thank you.

Senator Lott?

Senator LOTT. Thank you, Mr. Chairman.

And thank you all for being here. Congratulations on your nomination. I certainly will support your confirmations, and I wish you the best in the job you have ahead.

I, too, would like to address a few questions to Mr. Weems. I think it is obvious here that all of us, and others not here, have problems with CMS, the way it responds to our concerns and how it deals with critical health care issues in America.

Now, I am going to be gentle with you because you have your family here, and it is a lovely family. We appreciate you and your service over 24 years. I enjoy these meetings when we have a baby crying in the crowd. It relaxes us all a little bit.

But there are clearly problems at your agency, the one you are going to head. You know that. Now, part of the problem is us. Quite often, you have to comply with the law, the damnable law that we passed, which puts you in straightjackets quite often.

I also suspect that you are always under pressure by us and by OMB to control the costs, control the costs. But some of the decisions just do not make common sense, and sometimes just getting a decision is the problem.

I hope you will try to get a proper balance here, reign in your bureaucracy, make a decision. Or if you need legislative assistance, tell us. So, like the others, because of limited time—and I am not going to go through the specific questions here, but I am going to mention two or three of them because you will be hearing from me. I, of course, represent Mississippi and I am from the Mississippi Gulf Coast. We are still wrestling with the recovery from Hurricane Katrina. A lot of people and a lot of agencies have helped us. The government has been very good. I am not here to whine or complain.

However, I must say the distribution of the funds through HHS—and a lot of them involve CMS, obviously—to the Mississippi Gulf Coast, in my opinion, in the health care area have not been fair. It is really making it difficult for us to address the financial problems caused by Katrina with the lost opportunity in the misallocation of critically wage-indexed relief.

I do not begrudge the other States in the region, but when you have almost \$200 million to distribute and one State gets \$161 million and my State gets \$23 million and the third State gets \$10 million, there is a problem here. So I just want to make sure that you understand that we are going to expect a better allocation of those funds or some allocation of funds to help us with this wage-indexed relief problem we have on the Mississippi Gulf Coast.

Mr. WEEMS. Senator, not to interrupt, but that is something I would be happy to look into. But let me say that I was in Gulfport 72 hours after the storm.

Senator LOTT. And you know what a good job Gulfport Memorial did, which was a critical service to people who could not go anywhere else.

Mr. WEEMS. That is right. The way the people pulled together there, literally in something that looked like the result of a war. I mean, I remember very vividly the water tower twisted and lying on the ground. It was just really a remarkable scene. So, I would love to work with you on this.

Senator LOTT. I think the problem in this case was actually HHS, your superiors. But you can have input and you can help us in the future.

We have problems like, you have rules that actually seem to contradict each other. There is one particular county where Rush Health Systems out of Meridian wants to build a hospital in an adjoining county. One rule says it cannot be within 35 miles of another critical access care facility, and another one says it cannot be built within 15 miles of a secondary road. So they meet the criteria of one, but not on the other one, and therefore they are denied.

So here is a case where, clearly, this would be constructive and helpful for a lot of people to have access to health care, and they want to do it, they feel like it makes financial sense, and they are being denied. We have a serious problem with long-term acute care hospitals. You are about to come down with a ruling that is going to be devastating.

I am running out of time. I wanted to get to the PBGC too, to inquire about the recent legislation involving American Airlines, Continental, and the special pension provision they have. Obviously it is going to cost PBGC, or they are not going to pay about \$2 billion. I just want to express my concern about that. I plan to work with the Chairman and the Ranking Member in dealing with that problem.

Last but not least, Mr. Weems, in the broader sense, here is a critical example. We are getting deluged in my offices with complaints about delays in reimbursement. CMS is constantly dragging its feet on refunding money that has been deducted from Social Security checks for Medicare Part D. I think that is what Senator Smith was talking about.

Additionally, when a third-party payee is involved in reimbursing folks, it can take years to get a lien released. At a very minimum, find a way to address these payments. You cannot have people go months or years where you do not have to get reimbursed. Whatever the problem is, I cannot believe it is just a computer decision. Somebody needs to make a decision. I am getting complaints regularly from my State offices, from the men and women who work in this area, that there is a real problem here, a growing problem, and I hope you will quickly address that.

Mr. WEEMS. I will, sir.

Senator LOTT. Thank you very much.

The CHAIRMAN. Thank you very much, Senator.

Senator Kerry?

Senator KERRY. Thank you very much, Mr. Chairman.

I apologize to the witnesses, but I am chairing another hearing of the Small Business Committee and I have to go back to that. But I did want to inquire of Mr. Weems a few questions directly relating to Massachusetts, and a couple of others, if I may.

Mr. Weems, as you are aware, the financing of the Massachusetts health care reform program, which is unique and has been praised by President Bush and by the Secretary and others, is dependent in large part on the Medicaid waiver.

It is very important to us, critical to the State and the future of this program, that that waiver be renewed and strengthened before it expires in less than a year. We have 135,000 previously uninsured citizens who now have health coverage, and the cost of a quality health insurance plan in the Commonwealth has actually been reduced significantly.

So I know the Governor has informed us that they have already submitted the first phase of the 3-year extension application. So could you share with me, perhaps, (1) your views on the Massachusetts initiative; (2) the waiver renewal itself; and (3) can you commit that we are going to receive adequate funding with the prompt approval and back payment for the Certified Public Expenditures (CPE) methodology?

Mr. WEEMS. Thank you, Senator. First of all, I believe that health care reform in Massachusetts was a remarkable thing. It certainly fits the norms and values of that State, and I think that is what is particularly remarkable about it. Other States might choose to do it differently, but I certainly applaud it.

I have heard from CMS that negotiations are going well on the waiver, that they have received material and do expect a favorable outcome. That always takes time. It takes negotiation.

Then, lastly, on the CPE issue, we understand that Massachusetts has submitted material that has been requested that happened in the last several days, and it is the staff's belief that that material would make the waiver approvable.

Senator KERRY. Would make it?

Mr. WEEMS. It would be.

Senator KERRY. Well, that is good to hear, obviously.

Do you anticipate that, under the new waiver, it is going to recognize a reasonable increase in the expenditures over the length of the waiver period?

Mr. WEEMS. Yes, I do. I do.

Senator KERRY. And we can hold you to that, right?

Mr. WEEMS. Yes, sir.

Senator KERRY. With respect to another issue that has arisen, the State Medicaid agencies have been implementing the citizenship documentation requirement. You may have been asked about this, I am not sure.

But we are finding out that numerous studies were conducted where the Medicaid agencies, private researchers, the Congressional Research Service, the GAO report, and others—the GAO report was released just yesterday—found that thousands of individuals, especially children, have had their Medicaid denied, delayed, or terminated despite being eligible U.S. citizens.

So I would like to ask you, you are aware of this, obviously. Do you have plans and can you guarantee to us that you are going to take steps to make certain that these barriers to U.S. citizens getting eligible benefits will be removed?

Mr. WEEMS. Yes. And let me say, Senator, these reports are very concerning to me. Let me reflect on my own experience. I grew up in southern New Mexico. In my 1st grade class, all of us were United States citizens, but actually very few of us spoke English at home.

I grew up probably with many of the people who might be being denied benefits today as a citizen. I find that unacceptable. The agency needs to find a way to be responsive to the Congress, who laid out the law, but make sure that our rules do not erect these kinds of barriers.

I think it is going to take working State by State with the State Medicaid directors to make sure that our guidance is clear, to make

sure that the documentation and evidentiary requirements are clear, but it is achievable.

Senator KERRY. Well, that is good to hear, obviously. We really hope you can focus on that quickly, because it is just a terrible outcome and does not speak well to any of our efforts to try to follow through on these things.

Finally—I think, finally. Where am I on my time? Just about running out.

The CHAIRMAN. We have more people. I am going the other direction, in fact.

Senator KERRY. I am going in the other direction. Well, can I get it in quickly?

The CHAIRMAN. Certainly.

Senator KERRY. In the other direction. Could you just share with me, on the changes for the home health care reimbursements which go to 3 million Americans, we have all been pushing, trying to reduce the cost of institutionalized care, and to keep people out of costlier settings.

Now we are getting people into these home care situations. But I am very concerned that the payment is going to go down automatically, 2.75 percent for each year over 3 years on the suspicion of case mix creep.

The evidence seems to suggest that we are saving money, doing the job we want to do, and I am not sure what that definition is going to do. So we are very concerned about that, and I hope I am not missing something here.

But could we count on you to correct the CMS proposal to the degree that that may, in fact, work against the interests of what we are trying to achieve?

Mr. WEEMS. Of course. Caring for beneficiaries in the home is, many times, best. We do not want to erect barriers to that. I would be happy to work with you, Senator, to make sure we get a rule-making agreement.

The CHAIRMAN. I thank the Senator.

Senator KERRY. Is the record going to be open, Mr. Chairman?

The CHAIRMAN. Yes, it will be. In fact, I am going to ask that witnesses answer written or oral—there may be more oral questions, but witnesses may receive written questions. In order to expedite the committee's consideration, I ask that you reply to those written questions as quickly as possible.

I might note that the committee will not act on the nomination while the answers to such questions are still outstanding.

Senator KERRY. Thank you very much, Mr. Chairman.

Thank you, Mr. Weems. Appreciate it. Good luck to all of you.

The CHAIRMAN. Senator Grassley?

Senator GRASSLEY. I want to go back to Mr. Weems and Dr. Troy on a subject dealing with legislation I got passed 20 years ago called the False Claims Act.

These amendments resurrected the False Claims Act and provided real penalties against those who defraud the Federal Government. As a result, this act has helped the Federal Government recover over \$20 billion that would otherwise be lost to fraud and abuse, including programs in Medicare and Medicaid.

Just last year I continued this effort by adding a monetary incentive in the Deficit Reduction Act for our 50 States, if they want to, to pass their own False Claims Act.

The DRA also requires that any provider receiving more than \$5 million annually from Medicaid inform their employees about the False Claims Act.

To the two of you, will you both, in your positions, commit today to vigorously support the False Claims Act, the anti-kickback law, the Stark law, and other Federal laws that are used to investigate, prosecute, and suppress fraud at CMS and other HHS programs? Mr. McCarthy? I am sorry. Dr. Troy?

Dr. TROY. Yes, sir, I do.

Senator GRASSLEY. All right.

Now, Mr. Weems?

Mr. WEEMS. Yes, Senator Grassley,

Senator GRASSLEY. Will you do your best to ensure that your Department does everything in its power to eliminate fraud and abuse from the programs that it administers?

Dr. TROY. Yes, sir.

Mr. WEEMS. Yes, sir, I will. It is very important.

Senator GRASSLEY. Thank you.

Will you and your staffs cooperate fully with the Department of Justice, the HHS Office of Inspector General, and whistleblowers to investigate, prosecute, and suppress fraud?

Dr. TROY. Yes, sir, I will.

Mr. WEEMS. Yes, Senator.

Senator GRASSLEY. Thank you.

And in regard to that, can I emphasize feeling that, since you are new, maybe you have not heard me say that we do have whistleblower protection laws. Taking into consideration that even you in your position, as close as you are to the bureaucracy, you cannot know every instance of fraud and mismanagement, and that you ought to pay some attention to whistleblowers.

I emphasize that because whistleblowers tend to be viewed as skunks at a picnic and they are not very welcome. There is a great deal of peer pressure to go along, to get along. You folks at the highest ranks of your agencies can either encourage that or discourage it by not just your words, but how your response might be when somebody tells you there is something wrong.

There are too many agencies that are worried about their public relations and they see a whistleblower as interfering with their public relations. They want to look good, and maybe something the whistleblower brings to you does not look good. Every time I have seen an agency try to suppress information, it seems to me they end up getting egg on their face.

Now, I speak mostly about FDA or mostly about FBI in regards to that. I do not have anything against your agencies, per se, in regards to that, but it happens. So I hope you will pay some attention to bad news when you get it.

Further, would you ensure that your Department cooperates with State governments that prosecute False Claims Act cases for Medicaid fraud under the States' False Claims Act, assuming a State has passed one?

Dr. TROY. Yes, sir, I will.

Senator GRASSLEY. All right.

Will you work to pass clear, uniform regulations outlining the procedures for paying States an increased share of Medicaid recoveries when they bring the False Claims Act under the qualifying State False Claims Act? And before you probably say yes, I want to remind you that the encouragement to States to pass it was the bonus that they are going to get. If you do not know that, that is what the law says. So, go back to my question.

Mr. Weems?

Mr. WEEMS. Yes, Senator.

Senator GRASSLEY. Dr. Troy?

Dr. TROY. Yes, sir.

Senator GRASSLEY. All right.

And, finally, will you agree to take no administrative initiatives that would weaken the effectiveness of the False Claims Act or other laws and authorities used to investigate, prosecute, and suppress fraud in your areas of jurisdiction?

Mr. Weems?

Mr. WEEMS. Yes, sir.

Senator GRASSLEY. Dr. Troy?

Dr. TROY. Yes, sir.

Senator GRASSLEY. Yes.

And I now turn to Senator Roberts for his 20 minutes. If staff would remind members that maybe came for the first round, Senator Roberts has his 20 minutes uninterrupted, so that they understand that he has that time. A first-timer would normally have their time after Senator Roberts.

Go ahead, Senator Roberts.

Senator ROBERTS. Thank you, Senator Grassley.

Senator GRASSLEY. You are going to have to adjourn the hearing, because I am going to go.

Senator ROBERTS. I am going to ask unanimous consent to pass legislation to provide a 90-day moratorium on the home health care provider regulations. And since I will have the gavel and Mr. Weems and I will vote "yes"—[Laughter.]

Senator GRASSLEY. Do not forget, it takes 11 for a quorum. [Laughter.]

Senator ROBERTS. I have counted all of the witnesses and their families. [Laughter.]

Do not start the 20 minutes yet. Who is the timer? Where is the timer? Right in front of me. Right now. All right, go.

**OPENING STATEMENT OF HON PAT ROBERTS,
A U.S. SENATOR FROM KANSAS**

Senator ROBERTS. I want to thank Chairman Baucus for this hearing. Thank you all for coming. Twenty-four years at HEW, Mr. Weems. You come from the age of ashtrays and HCFA. I remember serving in the House when Mr. Joe Califano, HCFA, and HEW issued a ruling that said that three doctors had to approve all Medicare payments every 24 hours or they would not be paid. We have over 100 hospitals in Kansas, and 83 are critical access hospitals. We were outraged by that.

All of a sudden, I decided I would be for that because I figured if we could get three doctors out there in rural America, we would

just chain them to the desk and then we would have family practitioners or some doctors out there, at any rate.

I am the chairman of the Rural Health Care Caucus, co-chaired with Senator Harkin, ably led formerly by Craig Thomas, whom we lost just several weeks ago, a great man. I was the first Rural Health Care Caucus chairman in the House. This was back when you were at HHS or HEW, or maybe here on Capitol Hill, I do not know.

It was basically formed up by rural members who got tired of bloodying their knuckles on the door of HEW and not being able to get an answer, and so then we formed together in sort of a posse, and I think it worked out pretty good.

Great nominees. Thank you all for coming. Thank you for your time. Impressive backgrounds, very handsome families.

Mr. Weems, you met Jean up here, what, 24 years ago?

Mr. WEEMS. Yes.

Senator ROBERTS. I met my wife, Franki, about 34 years ago here on Capitol Hill, so we have something in common. I regret the obligation I have to ask some tough questions, but they are not personal. I want to emphasize that. If you read my bio in *Congressional Quarterly*, it says that I am "pleasant but irascible." [Laughter.]

Mr. WEEMS. I will try to stay on one side of that.

Senator ROBERTS. We will start on that note.

Mr. Weems, I want to thank you for your courtesy call. We asked you to come, you did. We met. We discussed several concerns that many of us have with how CMS is implementing—or more accurately, not implementing—the competitive bidding program for what is called the durable medical equipment currently being implemented by CMS in 10 different metropolitan areas across the country which affect hundreds of health care providers and thousands of their employees.

You come highly recommended. You cannot be any better recommended than by Senator Domenici and Senator Bingaman, both outstanding Senators. Senator Domenici is revered here.

So it is not really fair. Senator Domenici said, why would you take this? You know, you are in the briar patch. It is not fair, but there you are.

So I am going to ask you some questions. As you and my colleagues know, I am not a big fan of this program. The Kansas City area is included in the first round of implementation, so I have learned first-hand of serious, and in some cases really inconceivable, problems with this program.

First, we need some legislative changes to improve the program. I was going to ask Senator Grassley and Senator Baucus for their help in this respect, and I think they will be helping. But I think there are some areas, sir, where CMS can make improvements without any Congressional intervention, but you need time to accomplish this.

Now, my request to you is to take immediate action on these changes, as the deadline for providers to submit their bid closes this Friday, July 27. You have already extended it by 2 weeks. I think that is a mission impossible. If they cannot get on the Help Web, I doubt if you can either. I think a 90-day delay is very cru-

cial and very important, and I am going to ask you that about four times.

I know you are going to listen to our concerns, because you already have. I know you are going to commit to making these necessary improvements for your nomination to move forward. I am extremely troubled about the potential impact that this program will have on our home health care providers and the Medicare beneficiaries they serve.

My fears are coming true. Some of my biggest frustrations I have heard from our providers in Kansas center on their inability just to submit a bid through the website or get their questions answered by the contractor.

I am going to play Butch and Sundance. Who is this guy? CBIC. Is that Palmetto?

Mr. WEEMS. CBIC stands for the Competitive Bidding Implementation Contractor website. CMS has contracted with Palmetto GBA, the CBIC, to conduct certain functions relating to the administration of the DMEPOS Competitive Bidding Program.

Senator ROBERTS. I have news for you. With all of these complaints that I have here, and from a 7-State organization that represents home health care providers—and they are piling up in my office now, now that they know that they at least have one Senator and several others on the committee—and they are coming in so fast and furious. With these stories, I would not have that contractor. I would not have the contractor.

Many have told me they are ready to throw in the towel. Sharks are in the waters. Basically they call it now the CMS price. The sharks know that they are not worth what they used to be because they will not be able to get a bid and they will not have any Medicare, and the mom-and-pop exemption does not work. Some of them are about to give up.

So I think you have at least recognized some of these problems. You have extended the deadline twice at the last minute. But the Chairman and the Ranking Member did ask you again for a 90-day delay in the bidding process as a result of the problem. So I request, I support, I second this request. I plead to you to do this.

Now, the complaints that I have here from suppliers across the Nation who have contacted me with their problems in trying to submit a bid through the website or simply get a question answered, these are unsolicited. I am going to give you a shortened list. I am not going to give them all; we would be here all afternoon. You would miss lunch and your families would be upset, and the kids would be crying, and we do not want that.

But these are personal complaints. They are also some complaints from the Midwest Association for Medical Equipment Services led by Mrs. Rose Sheffhauser, who has done an excellent job. She has submitted a whole series of these situations.

So I am going to submit all of these complaints, literally pleas for help, to you. I ask that you provide an immediate response to me in this committee before Friday. I do not think you can do that. That is why I am asking for the 90 days.

All right. A typical “what on earth is going on” complaint comes from a supplier in Kansas on July 5. This company completed and submitted their bid to CMS. Five days later, their bid was rejected

and returned to them because the system would not accept zeroes on the application form. So if you type in “zeroes” or “none,” sorry, the computer will not accept it.

The application requires that suppliers state how many products they sold in 2006, and then how many of these products were sold to Medicare beneficiaries in that particular Metropolitan Statistical Area (MSA), in this particular instance, the Kansas City MSA that has 128 home health care providers.

This supplier had not billed Medicare for any products in the power wheelchair category in 2006, so they put down a “zero,” which was not accepted. That was a red flag. When this supplier called the help desk to ask what to properly do to submit the bid, the help desk replied, “Well, I guess you have to put down a 1, or maybe a 2, or maybe a 3.”

This response was confirmed by CMS on a follow-up. This means that because of CMS’s website and the application form problems, of which there are many, CMS is forcing and openly encouraging suppliers to lie and manipulate their Medicare numbers.

Now, that is incredible. How on earth can you achieve accurate cost containment with this kind of falsified information simply because the computer will not take it or it is a contractor problem?

A second sample complaint comes from the same supplier. After she and her staff devoted countless hours in preparing their bid, their information was somehow lost by the contractor’s website. Now, this is not a stand-alone incident. This has happened many, many, many, many times all across the country.

Frantically calling the contractor, trying to figure out what to do next, this supplier was informed that she would have to re-do the application that took a whole day with three people, but that she should also make sure to reboot her computer every 15 minutes in order for the information to be properly stored and accepted by the website, i.e., Palmetto. Strong finger; a lot of patience, all right. So every 15 minutes, she has to hire somebody to reboot. That is ridiculous.

It was redone. This supplier, or a member of her staff, diligently rebooted the computer. So, doubtlessly, we have a bunch of home health care providers trying to employ people to simply press the “reboot” thing.

This reminds me of the TV show—I do not watch it, my kids do—“Lost.” It is the TV show, “Lost,” where the inhabitants on the island are forced to press the button in the underground station every 108 minutes to save the world. Well, they are going to save their company by rebooting every 15 minutes.

Another story. A Cincinnati provider had been trying to log on to the bid website with no success. Called the help desk. The help desk responded, they are so backed up, there is no guarantee her call would be handled prior to the bidding deadline on July 20. Not a very good message.

Another story, all too commonplace. This supplier had been trying since July 6 to enter their bid on the website. As of July 12, 1 day before the original deadline, this person was unable to enter their network or the individual supplier bid, gate closed, no entry.

The applicant had gotten no further than part A of the form, which the website repeatedly tells them is incomplete. The appli-

cant has entered the same information approximately 20 times a day.

This supplier called the help line several times that week, and the help desk would ask copious amounts of questions, but then the caller said that the servers were down. The help desk also promised this applicant they would return their call, but they never received a return call.

When the applicant asked the help desk again, the help desk suggested for the applicant to log on that evening sometime after midnight when the server traffic would be lighter. After midnight! That is like Charlie Brown waiting for the Great Pumpkin.

My next complaint is a transcript from a call between a supplier and a CMS official. It was not secretly taped. That person knew this, and it is all on the record so there is nothing wrong with this.

Caller:

“I have a very quick question, but it is very simple: How do I get a password straightened out for getting a bid ID? And I know we’re past the window, but I have been on the phone with the help desk now for the better part of last week.

“Every time we input the information, it was saying our Social Security number was already in use, and we have gone up and down the line with the help desk. As of today, they seem to have stopped helping us and say that the window is closed for getting the bidder IDs issued.”

CMS Official:

“Well, yes, the window is closed. The registration period ended on the 7th.”

Caller:

“Okay. But we have gone ahead and done what we were supposed to do. There was apparently some trouble tickets written and we’re waiting on having that resolved. So you’re saying that because it wasn’t resolved in the time period, that’s the end of it?”

CMS Official:

“Yeah, well, whatever. The trouble was to have been resolved by the 7th. You had until the 7th, and that was the deadline for actual registration.”

Caller:

“Again, so if they weren’t able to resolve it at your end, then I’m basically out?”

CMS Official:

“Ah, yes. I don’t know what the problems were, but if you were not successfully registered by the deadline—actually it was extended by a week—you’re not registered.”

Now, I could keep going with these complaint stories. That is clearly unacceptable. The MAMES Association has here, system problems. They have 11 of them. I am not going to read them because I am not going to take up the time. Bid instructions, lack of details, cumbersome. They have six examples of that. Then we have providers being cut out of the bidding process. The number is rather astounding. Then we have the product category issue.

Samples being provided came from the following locations: Cincinnati, Cleveland, Dallas, Kansas City, Miami, Riverside, Orlando, Pittsburgh, Maryland, Kentucky, industry consultant on competitive bidding, a national company submitting bids on all CBAs, regional companies submitting bids on several CBAs. I am tempted to say, remember Jack Benny, also from Cucamonga, but I am not going to do that.

Assuming—and I know you want to do this—you cannot change these before Friday. Assuming you cannot, can you provide an appropriate extension of the application deadline to correct these technical problems in order to give our providers a fair shot and honor the request by the Chairman and the Ranking Member for 90 days?

Mr. WEEMS. Senator, thank you for that. I take issue with absolutely nothing that you have said. I have heard of—

Senator ROBERTS. Well, how about a “yes” or “no?” I have 5 minutes left and I have some real stuff coming down the road here.

Mr. WEEMS. First of all, at this juncture I am not running CMS.

Senator ROBERTS. I know that. I know that.

Mr. WEEMS. So I cannot make that commitment to you.

Senator ROBERTS. I will send it upstairs.

Mr. WEEMS. All right. I am happy to do that.

Senator ROBERTS. All right. Thank you.

Other concerns CMS must address before the program can move forward. Patient impact. This is a big issue. A big issue. I am concerned that the program has no mechanism to review or assess patient impact with the quality of care as a result of the program. Shouldn't the program that will impact some of the frailest seniors track how they fare under it?

Now, the one person that I relied on for advice for over 30 years as a staffer and a member of the House and the Senate in Hutchinson, KS, America, sold out. I do not know the figure, but we call it the “CMS sell-out.”

You are going to get down to the Big Three and then see how much money you save. And she was amazing. She would go out into the countryside and visit virtually every one of the Medicare beneficiaries that she served. I do not know if the person who bought her home health care providership will do that or not.

She is now a consultant to help people through all the paperwork. She just gave up. She said, “I'm just going to give up.” Is there any patient impact quality of care assessment? So that is one that I really think we have to think about.

I have strong reservations about how this program will work, especially for patients in the rural and small MSAs. You have an MSA in Kansas that stretches all the way past Lawrence, all the way past other areas that should certainly qualify as a mom-and-pop and a rural providership.

Hopefully you can guarantee to me that patient access, choice, and services will be the same for the beneficiaries in the small and rural MSAs as they currently experience.

Third, accreditation. As I mentioned, the bidding process ends on Friday. How can the bidding process proceed while a number of potential suppliers' applications for accreditation, which is needed to

participate, are still pending? That is a repeat of something I have emphasized.

Fourth, small supplier participation. It is important for the program that small suppliers participate. Now, CMS could allow networks, have small suppliers form up a network so that they could really keep up with all this. They would not have to have somebody hitting the “reboot” button every 15 minutes.

But the formation of networks is seriously impeded by antitrust prohibitions. So we need to issue guidance to help suppliers to overcome these barriers, and I think the networks certainly represent a good idea.

You need to provide written explanations or remedies for providers whose applications for participation were rejected due to technical reasons. Is there any transparency? So, if you do not get the bid or you cannot get an application, can you at least give them a reason why as opposed to just saying “no” or “your bid was not accepted?” We need the transparency.

Here is a big-time issue: savings certification. Can, and will, CMS provide any detailed data on the administrative costs of creating this new bureaucracy to implement this program? Can you provide data showing that this program will, in fact, provide significant savings in the Medicare program?

This happened at the 11th hour and 59th minute during these negotiations. We all know the story. We all know the member of Congress who did this. Many of us were not aware of the implications.

Senator Lott indicated that that is our responsibility. It is. But, if you add on the cost of the contractor and all that is going on throughout the home health care world, I am not sure that it is going to achieve the budget savings so much as push that cost onto Medicaid, or just fee-for-service, in which case I am not sure that the Medicare beneficiaries will be served.

I talked to you about the extension. You have already responded to that. There is another issue I want to talk about. In your proposed rule for inpatient prospective payment for 2008, CMS proposed something called—and Senator Kerry has mentioned this—a behavioral offset that would reduce payments to hospitals by \$24 billion over 5 years.

As I said, we have over 100 hospitals, 83 critical access hospitals. This will impact my State by over \$20 million in 2008. The centerpiece of this rule is something called a “behavioral offset” that is clearly, I think, an overage.

Now, the troubling piece of this offset is that it is based on expectations or “suspensions” of hospitals’ future coding activity rather than on real evidence. Suspensions? Are we basing cuts on suspicions of how a hospital may act or not act? That reminds me of that song, “Suspicious Minds” sung by Elvis. Maybe he came back to HHS. Maybe he is over there somewhere singing “Suspicious Minds” on hospitals.

We did not direct CMS to do this. You were told not to do this. Senator Salazar and I led an effort in the Senate. We have 61 of our colleagues telling CMS prospective behavioral “suspicious” offsets was the wrong approach. Congress should have been consulted. The Chairman and Ranking Member of this committee also

sent their own letter. So, I hope you can respond to this, and I hope you can respond to it in the best way.

My final comment is this, and I am down to four seconds. Under the banner of deficit reduction, I fear we are making some serious mistakes for the future of our seniors and Medicare, and I simply ask that CMS and this committee take a step back and look at the potential patient impact before moving forward on programs to save money in Medicare, which, in fact, are not saving money but are endangering the rural health care delivery system.

I thank you again for your time today. I know we can work on these issues. I do not know of anybody who is better qualified to do this, but boy, we are in a briar patch.

I want to read one other thing from MAMES that just came in. Oh. I have one other little item that popped up here that staff just gave me. I am 50 seconds over time; that is pretty good for me.

CMS originally thought that you were going to receive thousands of bids at one time. The expectation was around 9,000. I have spoken to a company in Cincinnati, OH—this comes from one of the associations—who submitted their bid on July 16, and the number was 706 for all 10 MSAs.

Now if that is the case and we have extended this for 2 weeks, and you wanted 9,000 people to submit bids and we are at 706, and I am going to guess in the next 2 weeks you have a whole bunch more, but certainly not 9,000, I do not know what is going to happen to those other folks. We have 128 in Kansas, and I will bet you that a third of them do not even know they are supposed to do this. The other two-thirds who have tried to do it, I am not too sure any of them really made it.

Then when you get to the end result, I asked somebody at CMS in Kansas City—I cannot remember, staff did, I did not—how many bids do you think are going to be awarded? Oh, about five. Five in the whole metropolitan service area? That leaves 123 without any Medicare.

What on earth do we do with patients? Not only the providers and their employees, but the patients? That is madness. You are not going to achieve any savings. Those people are going to go and get pushed onto Medicaid or they are not going to even receive the care, and then they will be put in the hospital. You know what happens then. So, I am terribly concerned about it, as you can indicate.

Here is one last comment:

“I called the CBIC Help Line. I held for 30 minutes. I was greeted by Nancy Smith, who is probably a good person. What should have been a simple question was rephrased 10 different ways to me, with the same answer each time.

“I requested clarification of supplier capacity units on rental items and gave a hypothetical scenario so that I could determine if I am calculating my service capacity correctly. The answer each time, without waver, was ‘CMS allows us to say 1 unit, 1 month rental.’

“I completed my bid on two product categories, I printed the summary to verify the information on the service area section. The question on the bidding application is completely different from the way it is asked in the summary.

“I managed to get clarification from CMS; however, due to the ambiguity on the bid application, I will now have to go back and amend my answers and attempt to re-certify all over again. The system continues to throw me out without saving my changes, even though I press the ‘update’ button, so it looks like another very long night.”

Another Charlie Brown night.

“I am not sure if these are issues that you need to hear about, but they have caused me, just today, an entire work day of grief. I have worked diligently for months now trying to prepare, between serving my community’s DME needs. I am a small company, six people.”

I cannot find the second line. But she says:

“You know, I think I am going to sell out.”

That is not right.

That is the end of my statement or my rant, and I appreciate a person of your quality and your commitment to try to fix this. Let us get the 90 days. Let us get the legislation changed. Let us save money and let us help the Medicare beneficiaries.

Thank you, sir.

Mr. WEEMS. Thank you, sir.

Senator ROBERTS. My time has expired.

The committee now stands adjourned. I thank all the witnesses and the patience of their families.

[Whereupon, at 11:54 a.m., the hearing was concluded.]

A P P E N D I X

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

Statement of Senator Chuck Grassley Senate Finance Committee Nomination Hearing July 25, 2007

Thank you, Mr. Chairman.

First I want to welcome Dr. Tevi Troy, who has been nominated to be Deputy Secretary of the Department of Health and Human Services. Dr. Troy has a diverse background in domestic policy issues and has held impressive positions in academia, Congress and the Federal government. These experiences will assist Dr. Troy in meeting the numerous and significant roles he will play in the Deputy Secretary's office.

I also want to welcome David McCormick to the Committee. Based on his distinguished résumé, I can see why the President nominated him to be Under Secretary of the Treasury for International Affairs. In addition to currently serving as the President's principal advisor for international economic policy, he earned a Ph.D. from Princeton in economics and foreign policy after serving our country as an Army officer. He's also worked as the CEO of a global technology organization. If confirmed, I look forward to working with Dr. McCormick on the pressing international economic issues we face, including with respect to currency exchange rates.

Our next witness will be Peter McCarthy, nominated to be Assistant Secretary for Management and Chief Financial Officer of the U.S. Treasury. Originally from Wisconsin, Mr. McCarthy has accumulated a great deal of management experience that will help him succeed in this challenging position.

Next we have Mr. Kerry Weems, nominee for the Administrator of the Centers for Medicare and Medicaid Services. For over 20 years, Mr. Weems has held numerous career positions in the Federal government. He started out as a budget analyst and worked his way up the ranks to hold senior level positions. Mr. Weems was serving as HHS Deputy Chief of Staff before his nomination. With such a distinguished career, there is no doubt that Mr. Weems knows the ins and outs of running a Federal agency.

Our final witness will be Charles Millard. The nation's defined benefit plan system is in distress. The PBGC is currently carrying a deficit. If a significant number of defined benefit plans are terminated, the PBGC may be unable to insure the pension benefits of hard-working Americans, resulting in a taxpayer bailout of the pension plan system. Now more than ever the PBGC needs a Director. Chairman Baucus and I recognized this need and introduced legislation creating the position.

Now this Committee has the opportunity to confirm this very important position for the first time. I look forward to hearing from Mr. Millard.

Thank you all for spending time with us today.

Senator Joseph I. Lieberman
Senate Finance Committee Introduction of Tevi D. Troy
Nominee for Deputy Secretary for the Department of Health and Human Services

Good morning, Chairman Baucus, Ranking Member Grassley. Thank you for giving me the opportunity to introduce Tevi Troy to your Committee for this confirmation hearing on his nomination to become the Deputy Secretary for the Department of Health and Human Services.

I'm proud to support his nomination and would like to welcome his personal "department of HHS," his wife and four children, to today's hearing.

I have the pleasure of knowing Mr. Troy and his family outside of the professional world, as we have attended the same synagogue over the years. While I can speak to his strong personal character, his vast professional experience speaks for itself – and I believe it is the combination of the two that brings him before your committee today.

Mr. Troy's education background includes degrees in Industrial and Labor Relations as well as American Civilization.

His work in domestic policy includes senior positions with the House Policy Committee, Senator John Ashcroft, and the Department of Labor's Office of Faith Based Initiatives.

Mr. Troy also served as Deputy Assistant Director for Policy in the Department of Labor, as well as Special Adviser to the White House Domestic Policy Council.

In his current capacity as Deputy Assistant to the President for Domestic Policy, Mr. Troy has been managing and leading the White House's domestic policy processes. Over the course of his long career, his work has spanned from health information technology to food and drug safety to welfare reform.

Ultimately, HHS deals with family issues – the things we discuss at the kitchen table – such as health care, social security, and how we deal with the aged.

I believe Mr. Troy's extensive involvement and leadership in family issues has prepared him to take on the role of Deputy Secretary for the Department of Health and Human Services.

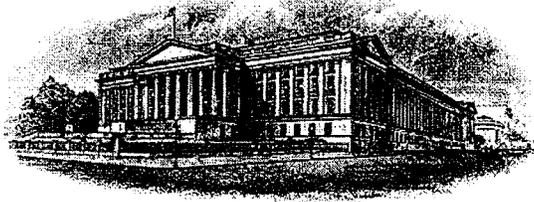
The HHS building is named after a great crusader for social programs – and one of my personal heroes – Hubert Humphrey. Humphrey put in perspective what I see as the charge of HHS when he said:

"The moral test of Government is how that Government treats those who are in the dawn of life, the children; those who are in the twilight of life, the elderly; and those who are in the shadows of life, the sick, the needy and the handicapped."

Certainly, we hope that this critical division of the administration will be in the hands of leaders who are both compassionate and wise, leaders who understand that the "moral test of Government" is far more significant and consequential than any litmus test of partisanship.

I believe sitting before you is a young man who will be sensitive to the concerns we raise around our kitchen tables, who will bring the competence and experience needed for success in the moral test of our government, and who will do so with the best interests of those Americans in the dawn, twilight, and shadows of life in mind.

Tevi Troy is truly an admirable candidate for this position and I recommend the Committee vote to send his nomination to the Senate. Thank you.



U.S. TREASURY DEPARTMENT OFFICE OF PUBLIC AFFAIRS

**STATEMENT OF PETER B. MCCARTHY
NOMINEE FOR ASSISTANT SECRETARY FOR MANAGEMENT
U.S. DEPARTMENT OF THE TREASURY
BEFORE THE SENATE FINANCE COMMITTEE**

Chairman Baucus, Ranking Member Grassley, members of the Senate Finance Committee, thank you for the opportunity to appear before you today. I am honored that the President has nominated me to serve as Assistant Secretary for Management at the Treasury Department, and I am grateful to you for taking the time to consider my nomination.

Before I make a brief statement to the Committee, I would like to introduce to you my wife of 35 years, Mary Calvert McCarthy, who is with me here today.

Mr. Chairman, the Assistant Secretary for Management and Chief Financial Officer at Treasury is responsible for internal management and policy in areas of budgeting, planning, human resources, information technology, financial management, accounting, procurement, and administrative services. It is incumbent upon this individual to maintain and improve the effectiveness and efficiency of, and cooperation among, the offices and bureaus of the Department. I believe that my broad management experience in large financial organizations will enable me to successfully fulfill these responsibilities.

My career in banking and financial services spans more than 30 years and includes extensive practical experience in the financial management of complex business entities. Eighteen of those years were spent in overseas assignments, primarily in the United Kingdom and Japan. I have held senior positions across a wide variety of banking activities, including customer relationship management, credit and market risk management, corporate banking and capital markets product management, trading, training, treasury, operations and administration. I have had the opportunity to manage significant change, having opened, grown, and right-sized banking operations around the world to better meet customer expectations and improve efficiency and accountability.

Mr. Chairman, I would be grateful for the opportunity to apply the experience I have gained and the skills I have learned to the vitally important work of the Treasury Department. I look forward to the possibility of joining the dedicated cadre of career and appointed professionals at the Department, and in the various Treasury bureaus. If confirmed, I will work hard to support Secretary Paulson's commitment to efficient and effective management practices, to responsible budgeting, and to strong internal controls. I will support the Secretary's commitment to strengthen policy guidance and improve oversight of information technology investments. I will be attentive and responsive to the interests of

your Committee and of Congress in Treasury's performance and administration of its programs and activities.

Mr. Chairman and members of the Committee, I have never had the privilege of serving the government of the United States. To do so now, in a management role for which I feel truly well prepared, would be a great honor. Thank you again for the opportunity to appear before this committee and for considering my nomination. I would be pleased to answer any questions.

**SENATE FINANCE COMMITTEE
STATEMENT OF INFORMATION REQUESTED OF NOMINEE**

A. BIOGRAPHICAL INFORMATION

1. Name: (Include any former names used.)
Peter Brian McCarthy
2. Position to which nominated:
**Assistant Secretary (Management and Chief Financial Officer)
The Department of the Treasury**
3. Date of nomination:
April 10, 2007
4. Address:

5. Date and place of birth:

6. Marital status:

Married

7.

8. Education: (List secondary and higher education institutions, dates attended, degree received, and date degree granted.)

**Southern Methodist University
Dallas, Texas
08/73 to 08/74
Master of Business Administration (08/74)**

**Cornell University
Ithaca, New York
09/68 to 05/72
Bachelor of Arts (05/72)**

**Shorewood High School
Shorewood Wisconsin
09/64 to 06/68
High School Diploma (06/68)**

9. Employment record: (List all jobs held since college, including the title or description of job, name of employer, location of work, and dates of employment.)

**Deputy Managing Director
Institute of International Finance
Washington, DC
12/02 to 12/06**

**Senior Vice President & Area Head – Europe, Middle East and Africa Area
First Chicago NBD Corporation/Bank One Corporation
London, England
01/97 to 11/01**

Senior Vice President & Area Head – Asia Pacific Area
First Chicago Corporation/First Chicago NBD Corporation
Tokyo, Japan
08/93 to 01/97

Senior Vice President & Senior Credit Officer
First Chicago Corporation
Chicago, Illinois
01/88 to 07/93

Vice President & Country Manager – UK and Ireland
First Chicago Corporation
London, England
08/85 to 12/87

Vice President & Division Head
Chase Manhattan Bank
London, England
07/80 to 08/85

Area Credit Officer – Europe, Middle East & Africa Area
First Chicago Corporation
London, England
01/79 to 07/80

Operations Manager – Dublin Branch
First Chicago Corporation
Dublin, Ireland
09/77 to 01/79

Head of Foreign Exchange Marketing
First Chicago Corporation
New York, New York
09/76 to 09/77

Associate/Assistant to Head of International Department
First Chicago Corporation
Chicago, Illinois
09/74 to 09/76

Management Trainee
Sears, Roebuck & Company
Dallas, Texas
08/72 to 08/73

10. Government experience: (List any advisory, consultative, honorary, or other part-time service or positions with Federal, State or local governments, other than those listed above.)

None

11. Business relationships: (List all positions held as an officer, director, trustee, partner, proprietor, agent, representative, or consultant of any corporation, company, firm, partnership, other business enterprise, or educational or other institution.)

None currently

12. Memberships: (List all memberships and offices held in professional, fraternal, scholarly, civic, business, charitable, and other organizations.)

**Carmi Country Club
Carmi, Illinois**

**National Presbyterian Church
Washington, DC**

**Phi Gamma Delta Fraternity
Lexington, Kentucky (National Headquarters)**

13. Political affiliations and activities:

- a. List all public offices for which you have been a candidate.

None.

- b. List all memberships and offices held in and services rendered to all political parties or election committees during the last 10 years.

None.

- c. Itemize all political contributions to any individual, campaign organization, political party, political action committee, or similar entity of \$50 or more for the past 10 years.

None.

14. Honors and Awards: (List all scholarships, fellowships, honorary degrees, honorary society memberships, military medals, and any other special recognitions for outstanding service or achievement.)

None since college.

15. Published writings: (List the titles, publishers, and dates of all books, articles, reports, or other published materials you have written.)

None.

16. Speeches: (List all formal speeches you have delivered during the past five years which are on topics relevant to the position for which you have been nominated. Provide the Committee with **two** copies of each formal speech.)

None.

17. Qualifications: (State what, in your opinion, qualifies you to serve in the position to which you have been nominated.)

The position of Assistant Secretary (Management and Chief Financial Officer) is an internal management role principally charged with maintaining and improving the effectiveness and efficiency of, and cooperation among, units operating within the U.S. Treasury Department.

My broad management experience in large financial organizations makes me well qualified to ably fill this position. I am comfortable in line functions, staff positions, and complex matrix situations. I have a proven ability to motivate teams and manage significant change, having successfully opened, grown, consolidated, downsized and closed business units around the world. Moreover, as a banker, manager and long-term expatriate (some eighteen years in overseas assignments), I have developed a thorough understanding of the domestic and international functions and mission of the United States Treasury Department.

Since assuming my first managerial responsibilities in 1974, my entire career has been devoted to managing individuals, teams, products, risks, systems, budgets, and constituent relationships (including customers, auditors, regulators, and media) in a professional context of banking and international finance. It would be an honor for me to apply my resulting financial knowledge and managerial expertise to the position of Assistant Secretary.

B. FUTURE EMPLOYMENT RELATIONSHIPS

1. Will you sever all connections with your present employers, business firms, associations, or organizations if you are confirmed by the Senate? If not, provide details.

None to sever.

2. Do you have any plans, commitments, or agreements to pursue outside employment, with or without compensation, during your service with the government? If so, provide details.

No.

3. Has any person or entity made a commitment or agreement to employ your services in any capacity after you leave government service? If so, provide details.

No.

4. If you are confirmed by the Senate, do you expect to serve out your full term or until the next Presidential election, whichever is applicable? If not, explain.

Yes.

C. POTENTIAL CONFLICTS OF INTEREST

1. Indicate any investments, obligations, liabilities, or other relationships which could involve potential conflicts of interest in the position to which you have been nominated.

None.

2. Describe any business relationship, dealing or financial transaction which you have had during the last 10 years, whether for yourself, on behalf of a client, or acting as an agent, that could in any way constitute or result in a possible conflict of interest in the position to which you have been nominated.

None.

3. Describe any activity during the past 10 years in which you have engaged for the purpose of directly or indirectly influencing the passage, defeat, or modification of any legislation or affecting the administration and execution of law or public policy. Activities performed as an employee of the Federal government need not be listed.

None.

4. Explain how you will resolve any potential conflict of interest, including any that may be disclosed by your responses to the above items. (Provide the Committee with **two** copies of any trust or other agreements.)

Any potential conflicts of interests will be identified and resolved in accordance with the terms and conditions of my ethics agreement with the Department of the Treasury, which is documented by letter to Bernard Knight, Jr., Assistant General Counsel (General Law & Ethics) and Designated Agency Ethics Official. Should any potential conflict of interest arise in the future, I will seek guidance from a Treasury ethics official.

5. **Two** copies of written opinions should be provided directly to the Committee by the designated agency ethics officer of the agency to which you have been nominated and by the Office of Government Ethics concerning potential conflicts of interest or any legal impediments to your serving in this position.

6. The following information is to be provided only by nominees to the positions of United States Trade Representative and Deputy United States Trade Representative:

Have you ever represented, advised, or otherwise aided a foreign government or a foreign political organization with respect to any international trade matter? If so, provide the name of the foreign entity, a description of the work performed (including any work you supervised), the time frame of the work (e.g., March to December 1995), and the number of hours spent on the representation.

Not Applicable.

D. LEGAL AND OTHER MATTERS

1. Have you ever been the subject of a complaint or been investigated, disciplined, or otherwise cited for a breach of ethics for unprofessional conduct before any court, administrative agency, professional association, disciplinary committee, or other professional group? If so, provide details.

No.

2. Have you ever been investigated, arrested, charged, or held by any Federal, State, or other law enforcement authority for a violation of any Federal, State, county or municipal law, regulation, or ordinance, other than a minor traffic offense? If so, provide details.

a. **Arrested in Pierce County, Washington for hitchhiking
One evening in jail. 06/70.**

b. **Arrested for building a campfire in Salinas County, California
Suspended sentence. 07/70.**

3. Have you ever been involved as a party in interest in any administrative agency proceeding or civil litigation? If so, provide details.

No.

4. Have you ever been convicted (including pleas of guilty or *nolo contendere*) of any criminal violation other than a minor traffic offense? If so, provide details.

See question #2 above.

5. Please advise the Committee of any additional information, favorable or unfavorable, which you feel should be considered in connection with your nomination.

Not applicable.

E. TESTIFYING BEFORE CONGRESS

1. If you are confirmed by the Senate, are you willing to appear and testify before any duly constituted committee of the Congress on such occasions as you may be reasonably requested to do so?

Yes.

2. If you are confirmed by the Senate, are you willing to provide such information as is requested by such committees?

Yes.

**Senate Finance Committee
Nomination Hearing
July 25, 2007
Questions for the Record for Mr. McCarthy**

Questions from Chairman Baucus

Question 1:

Mr. McCarthy, the tax gap, the difference between the taxes legally owed and the taxes timely paid, is estimated by the IRS to be \$345 billion each year. You are nominated for a position that has many IRS oversight responsibilities, including information technology, financial management, and human capital and workforce management. Each of these areas of responsibility has a direct effect on voluntary tax compliance and the size of the tax gap.

- a. To what extent do you consider the tax gap to be a cause for concern?

Response:

I believe the tax gap is a serious issue, and I know that the Treasury Department and the IRS take it very seriously.

- b. What do you think is a realistic percentage goal for voluntary compliance within the next five years and ten years? To what extent do you support the use of a credible and comprehensive plan, with benchmarks and measures, to increase compliance?

Response:

I understand that the Treasury Department released a comprehensive strategy for reducing the tax gap in September 2006, and that the Secretary has recently informed the Committee that a report is forthcoming that will cover efforts to implement the strategy and also will discuss specific near-term and longer-term actions that will be undertaken. I share the Secretary's view that a voluntary compliance goal over the next five or ten years must be based on such actions that can realistically be taken to achieve that goal. In addition, the IRS needs to improve its ability to measure progress in reaching such a goal.

- c. During the first 90 days of your tenure, what will be your top five priorities to improve tax administration and increase voluntary compliance?

Response:

If confirmed, I look forward to working closely with the IRS on: (a) the agency's FY 2009 budget request, including funding for enforcement, research, taxpayer service, and information technology, which are integral to reducing the tax gap; (b) improving the

IRS' information technology resources, especially through Business Systems Modernization; and (c) securing adequate human capital to support the IRS' mission. In addition, I am committed to helping the IRS keep taxpayer information carefully safeguarded at all times. Overall, I will work to ensure that the Treasury Department's oversight of the IRS continues to result in effective and efficient administration of our tax laws.

d. What will be your long-term priorities to improve tax administration?

Response:

The priorities listed in the previous question are both immediate and long-term objectives that I will pursue, if confirmed.

e. How will you make a difference at the IRS, both in the short-term and the long-term? What will be your legacy?

Response:

If confirmed, I would expect my most important short-term contributions to be in the area of IT project management. As a matter of urgency, I intend to reestablish the Treasury Department's Executive Investment Review Board, with the Deputy Secretary serving as Chairman and the Assistant Secretary for Management serving as a Vice Chairman. I also intend to hire at the earliest possible date a new Treasury Department Chief Information Officer, who will also serve as a Vice Chairman of the Review Board. While all Treasury offices and bureaus will benefit from these changes, nowhere will the benefit be greater than at the IRS. Given the enormous challenges faced by the IRS in terms of new systems initiatives and the Business Systems Modernization program, immediate and deep involvement by senior Department management, in terms of IT strategic direction, IT capital planning, and IT project oversight, will represent significant improvement.

In the longer term, if confirmed, I would expect to spend considerable time on human capital issues at the IRS. The demographics of the IRS workforce, particularly in the IT area, suggest that greater emphasis on retention and recruiting will be of utmost importance. I look forward to working closely with IRS management and the Treasury's Chief Human Capital Officer to bring the Department's full training, recruiting, and performance-measurement resources to bear on IRS human resource functions.

I would hope my legacy would reflect an ever-deepening partnership between the Department and the IRS, not only in the contexts of IT and HR management, but across the full range of IRS operational matters.

Question 2:

Former IRS Commissioner Charles Rossotti said in his September 2002 report to the IRS Oversight Board that a "yearly increase in the IRS operating budget sufficient to support about a 2 percent per year increase in staffing, together with productivity gains from

successful technology modernization, could close the gap in both service and enforcement over about a five-year period.”

- a. To what extent do you agree with Mr. Rossotti’s assessment of IRS funding?

Response:

I recognize that, in light of budget constraints and competing priorities to protect our borders, our nation’s leaders are faced with difficult decisions on how to balance increased funding for federal programs and deficit reduction. However, I understand that the IRS delivers a 4 to 1 return on investment. We should not disregard that investments in IRS will help reduce the tax gap and bring in additional revenue needed to fund our federal programs. The IRS five-year Strategic Plan provides a roadmap for formulating IRS resource requirements needed to achieve its goals and objectives, including those of reducing the tax gap. Consistent with this plan, I believe the FY 2008 Budget includes funding for additional resources and legislative proposals that support IRS efforts to reduce the tax gap. It also includes important investments in information technology, primarily through the Business Systems Modernization program, that will yield long-term productivity increases.

- b. The IRS says it gets a 4 to 1 return on investment for every dollar spent on enforcement.
 - i. To what extent do you think the IRS budget should be treated differently than other agency budgets since every dollar spent brings in even more money?

Response:

The IRS provides 95 percent of the Federal Government’s revenue and in that respect the IRS is unique in that its programs are responsible for collecting the revenue that funds almost all federal programs. Accordingly, I do believe the IRS budget should be considered in the context of its unique ability to generate revenue.

- ii. To what extent do you support a five-year IRS budget process that would give the agency the ability to make long-term plans to improve tax compliance?

Response:

Based on what I have learned thus far, I do not believe it is appropriate to do a five-year budget for the IRS. The IRS operates in a dynamic environment where external factors such as new legislative changes, taxpayer demands for internet services and other electronic media, taxpayer use of abusive tax avoidance transactions, an increasingly diverse population, globalization of the business world, and terrorism have a major impact on the strategic priorities of the IRS and the resources needed to achieve its goals. The annual budget process, guided by the IRS 5-year strategic plan, enables the IRS to react to changes while at the same time maintaining a consistent long-term strategy.

- c. To what extent are you willing to make a commitment to increase transparency in the IRS budget process so the IRS Oversight Board and the IRS have the ability to weigh-in more effectively on IRS budgets?

Response:

The Department recognizes the importance of the IRS' mission and has supported and promoted its budget requests to the Administration and Congress. I understand the IRS works closely with the Oversight Board to ensure transparency of its budget process as well as ongoing program performance. As part of the annual budget formulation process, the IRS provides to the Oversight Board the information and data necessary to make informed budget decisions. The IRS has advised that it also briefs the Oversight Board on the overall request, enabling further clarification of Board questions prior to receiving final Board-approval of the IRS's budget request. In addition, my understanding is that the IRS keeps the Board regularly informed of IRS program and performance issues via quarterly briefings and issuance of Business Process Review reports. If confirmed, I look forward to supporting these principles.

Question 3:

Section 9503 of P.L. 105-206, the Internal Revenue Service Restructuring and Reform Act of 1998, authorizes the Secretary of the Treasury to establish, fix the compensation of, and appoint individuals to, designated critical administrative, technical, and professional positions needed to carry out the functions of the Internal Revenue Service. The Secretary's authority is limited to forty positions with terms not to exceed four years. The authorization exists for a period of ten years after the date of enactment and expires on July 22, 2008. This provision is commonly referred to as the "IRS critical pay program."

- a. How effective do you consider the critical pay program to be? Using specific examples, describe whether and to what extent the individuals hired under the critical pay program provided value to the IRS commensurate with their compensation.

Response:

I understand that there has been considerable variation in the types of positions at the IRS for which the authority has been used in response to the IRS' changing leadership needs. Use of this authority enables the IRS to recruit executives with skills critical to the agency's technological, security, research, and business reengineering activities. I am told by the IRS that this authority has contributed to the following initiatives and accomplishments:

- The development and successful implementation of the "Son of Boss" settlement initiative, which was due in large part to the leadership the Commissioner's Senior Advisor, a critical-pay appointee. This initiative has resulted in the successful recovery of more than \$3.7 billion from more than 1,200 taxpayers.

- The provision of critical support by a critical-pay executive in the development and delivery of a new Integrated Financial System in 2005 in a manner that enabled the IRS to deliver on a timely basis all FY 2005 financial accounting deliverables to GAO. Thus, the IRS was able to retain its “clean audit opinion” – a significant accomplishment for an organization during its first year of implementing a new financial system.
- During the 2005 filing season, Services and Enforcement experienced a very positive year due to the leadership of another critical-pay appointee, exceeding most of its objectives in the IRS Strategic Plan and making significant contributions to deterring tax abuse, enforcing the tax laws, and providing high quality customer service.
- The successful launch in 2004 of the “Modernized e-File” IT project was due in large part to another critical-pay appointee. This program allows businesses to submit their tax returns electronically. More than 250,000 returns have thus far been processed through this system, resulting in efficiencies that have saved taxpayers approximately \$18 million.
 - b. To what extent could the IRS have attracted candidates with the requisite skills, knowledge and abilities without the streamlined critical pay program?

Response:

I understand that the IRS’ ability to attract top talent without streamlined critical pay would have been limited. After almost 8 years of experience using the streamlined critical pay authority, the IRS has found it to be an enormously useful tool in recruiting highly talented top executives from private industry to complement the skills of its internal leadership team in meeting the challenges of providing top quality tax administration. This talent has greatly contributed to many of the IRS’ accomplishments in addressing the tax gap through improved compliance and enforcement efforts in recent years.

- c. Do you believe the critical pay authorization should be renewed? What changes would you recommend to the program?

Response:

Yes, I believe the critical-pay authority should be extended and I understand that the Administration’s FY 2008 budget request proposes to extend this authority. I support the extension of this authority as it affords the IRS an avenue to continue making progress toward achieving its strategic goals. The need is particularly acute in the areas of information technology, security, research, and support for reengineering of processes.

I am informed that, as the IRS has made use of the authority, it has identified statutory impediments as well as internal issues. There are several changes that would require a statutory change to improve the program. The IRS is now unable to extend the contract of a critical pay appointee, even though the individual may be in the middle of

completing an important project, and there is a good business case to extend the appointment to the completion of an assignment. Also, the current statute does not allow the use of critical pay for an individual previously employed by the IRS. While I agree with the IRS that the authority should not be used to manipulate the system to permit a current employee to leave the IRS only to return for more pay, there are instances where it would be beneficial for the IRS to hire an individual who has previously worked for the IRS, left for an extended period, acquired critical expertise and/or proficiency, and later agrees to return under the streamlined critical pay authority. Such flexibility would provide an added incentive for such an individual to return to the IRS, where he or she is familiar with the business practices and corporate culture.

- d. Of the 40 authorized critical pay positions, how many currently are vacant? How many of the vacancies does the IRS intend to fill?

Response:

I have been informed by the IRS that it currently has 21 Streamlined Critical Pay Executives on board and 19 vacant positions. Of the 19 vacant positions, the IRS is actively recruiting for 6 positions.

- e. If authorization is not renewed, how will the IRS adapt its staffing to accommodate the vacancies created by the expiration of critical pay? What would be the effect on tax administration if authorization is allowed to expire?

Response:

I am advised that the extension of the authority is extremely important. Without the pay flexibility that it affords, the IRS' ability to recruit and retain executives of the same caliber as those recruited under streamlined critical pay authority would be severely hampered and potential negative consequences on IRS programs and services could be severe. This authority is especially critical to the Business Systems Modernization program – probably the most challenging and important operational program at the IRS. If confirmed, I look forward to working with Congress to continue this important tool for the IRS.

Question 4:

All political employees who have worked with Treasury's career staff have been impressed with the exemplary abilities and professionalism of the career employees. Unfortunately, there have been times during this Administration, when morale among these outstanding civil servants has been low. The Assistant Secretary for Management is the Treasury Department's senior personnel office. What creative steps can you take as Assistant Secretary to keep on top of the morale level of the Department's career?

Response:

I have the utmost respect for the Department's career professionals and support staff. I realize that the Department has experienced a great deal of change in the last several years, especially in Departmental Offices, and that change in any form can sometimes

have an adverse impact on employee morale. I am very aware of the effects of change on employees, having managed large financial organizations which have undergone dramatic organizational and cultural shifts.

As I looked into this issue at Treasury, I was pleased to learn that the results of the Federal Human Capital Survey reflect improvement in the Department's job satisfaction scores since the survey's initial administration in 2002. Specifically, the Departmental Office's response to the question "Considering everything, how satisfied are you with your job?" has improved each year of the survey: 61.2% responded positively in 2002 (baseline), 67% responded positively in 2004, and 72.7% responded positively in 2006. Indeed, many key indicators of job satisfaction reflect that the Department is clearly headed in the right direction. I am encouraged by these trends.

If confirmed as the Department's senior personnel officer, I will endeavor to leave the Department and the Department's work force in even better condition than it is as I arrive. I have accomplished that in other large organizations, and I look forward to bringing my experience and skills to the Department. My overriding objectives will be to enable the Department to increase employee engagement and to make Treasury an employer of choice able to attract and retain the best and brightest. Supportive initiatives may include improvements to telework policies and practices, expanded training and development opportunities, and workforce analysis and succession planning, to include an emphasis on increasing workforce diversity. Finally, I have found that employees perform at their best if they know what is expected of them, are allowed to use their talents and skills to full advantage, and are rewarded for good work. I plan to work toward those values and objectives if confirmed.

Questions from Ranking Member Grassley

Question 1:

As you know, I've shared the administration's strong support for the IRS private debt collection program. It is a cost-effective way to deal with the tax gap and has been effective in collecting tax due and owing while protecting taxpayers rights.

It is my understanding that the current contracts are scheduled to end early next year. Given the lead time necessary for new contracts to be let, that process needs to be moving forward very rapidly. The acting Commissioner for the IRS said that these requests for quotes (rfq) would be out by Summer. However, there are only a few more Sundays in Summer left and we haven't heard anything.

Please tell me the specific date on which the rfq's will be issued.

Response:

Since Congress authorized the use of private collection agencies (PCAs) in 2004, the IRS has been working to implement the PCA program, taking steps to ensure that it is

managed appropriately and that taxpayer rights are fully protected. I have been informed that the IRS is currently placing collection cases with two contractors. In doing so, I understand that the IRS is working to ensure that those contractors are fully utilized, and that timely and appropriate steps are taken to maintain this important program. I have consulted with the IRS about a possible schedule for requests for quotes, and no specific date has yet been set. If confirmed, I will work with the IRS to be sure that this important tool continues to be used to help collect unpaid taxes.

Question 2:

Mr. McCarthy, the Treasury Inspector General for Tax Administration (TIGTA) has just released yet another report expressing concern over Internal Revenue Service delays in implementing one of its computer systems during its modernization efforts. The Customer Account Data Engine (CADE) is intended to be a cornerstone of the IRS's plan to modernize its systems and services. A major benefit of CADE, other than replacing outdated legacy files and databases, is that it replaces a weekly processing cycle with a daily processing cycle. This means that instead of tax refunds being processed and mailed weekly, they will be processed and mailed daily. This is a huge benefit for taxpayers – especially for those who depend on their refunds to pay overdue bills and other debts.

But, instead of ensuring that this project received the priority that it was due, TIGTA found that a pattern of deferring Project requirements to later releases and missing release deployment dates has continued from the Project's beginning in 1999. Eight years and hundreds of millions of dollars later, the CADE project is unacceptably over budget and behind schedule, in both target dates and functionality. This pattern cannot continue.

So I would like to ask you, Mr. McCarthy, what will you do to help oversee the modernization efforts at the IRS? I want IRS computer modernization and IT programs to be a priority – I am tired of hearing reports of poor IRS oversight of its contractors, of modernization efforts being delayed and over budget, and of fraud detection systems that were not even functioning during the 2006 processing year. Mr. McCarthy, you have held some very impressive positions during your career. I would like you, assuming you are confirmed to this position, to take on the personal responsibility of improving the IRS's record on their modernization and IT efforts – especially the CADE project which is so important to individual taxpayers.

Response:

The continuing progress of the IRS Business Systems Modernization effort, including the successful development of CADE, is a matter of exceptional importance to the IRS and to the Treasury Department. If confirmed, I fully expect to assume an active personal management role in these matters, and to ensure significantly deeper involvement of other senior Department management through the reestablishment of the Executive Investment Review Board and the appointment of a new Chief Information Officer for Treasury.

With specific regard to CADE, it is my understanding that since the TIGTA audit was completed in April, important steps have been taken to stabilize the development process and to deliver some functionality. While more work remains, over 11 million individual 2006 returns have now been processed on the CADE system, as have over \$11 billion in tax refunds. In order to achieve this stabilization, a number of critical decisions have been implemented. Among other things, IRS project managers have been placed in direct control of the project, replacing contractors. Moreover, a fixed-price contract has been negotiated with the contractors for the next two module releases to mitigate risk of cost overruns, and the timing of those releases has been re-baselined to reflect realistic expectations. I support these decisions.

With regard to the broader modernization effort, if confirmed, I look forward to supporting IRS steps to:

- Lift IRS IT skill sets by actively hiring project managers, systems engineers and operations specialists, and utilizing the Critical Pay Program authority.
- Place IRS professionals in charge of key initiatives and gradually reduce the number of projects managed by contractors.
- Sharpen processes for large scale project management, and place much greater emphasis on early warnings and improved upward communications.

Questions from Senator Snowe

Question 1:

Mr. McCarthy, the Assistant Treasury Secretary for Management and Chief Financial Officer has a wide swath of responsibilities. The Assistant Secretary advises the Treasury Secretary on the development and execution of the Treasury Department's budget. The incumbent also advises the Secretary on the internal management of the Department and its bureaus. In addition, the Assistant Secretary oversees Department-wide management programs, including human resources, information and technology management, financial management and accounting, strategic planning, performance budgeting, and procurement. Mr. McCarthy, if you are confirmed, you will obviously have a lot of different priorities all competing for your attention. What do believe are the most pressing issues facing the Assistant Secretary for Management and Chief Financial Officer's portfolio and what do you intend to do to address those issues? Put another way, I am sure you have identified management issues facing Treasury. What specifically do you hope to accomplish during your first three months at Treasury?

Response:

I have worked hard to learn as much as possible about the mission of the Department and the challenges it faces, and I believe that I am prepared if confirmed to hit the ground running.

Specifically, I expect my most important short-term accomplishments will be in the area of IT project management. As a matter of urgency, I intend to reestablish the Treasury

Department's Executive Investment Review Board, with the Deputy Secretary serving as Chairman and the Assistant Secretary for Management serving as a Vice Chairman. Also in the short-term, I intend to hire a new Treasury Department Chief Information Officer, who will also serve as a Vice Chairman of the Review Board.

Beyond these immediate priorities, I expect to spend considerable time over the next three months preparing Treasury's FY 2009 budget request, with particular attention to ensuring appropriate funding for key IRS programs that are integral to addressing the tax gap. Given the challenges and critical missions of the IRS and all of the Treasury bureaus, I believe that the deep involvement of senior Department management in the budget formulation process is critical to success. If confirmed, my intention is to move quickly to strengthen this involvement and oversight.

Finally, if confirmed, I expect to become actively involved in the imminent rollout of Treasury's new Strategic Plan for 2007-2012, and in establishing the Performance Management programs that will link individual objectives and responsibilities to the Department's evolving mission.

Question 2:

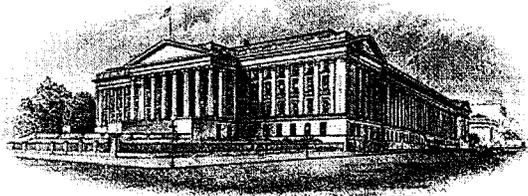
Mr. McCarthy, the Assistant Treasury Secretary for Management and Chief Financial Officer is, among many other responsibilities, charged with information and technology management. Like Senators Grassley and Baucus, I was deeply concerned by a July 13 Treasury Inspector General for Tax Administration (TIGTA) report, Vital Decisions Must Be Made to Ensure Successful Implementation of Customer Account Data Engine Capabilities, that found that implementation of the Internal Revenue Service's Customer Account Data Engine (CADE) has been plagued by delays and poor planning, and that the IRS has yet to implement essential processing requirements. CADE, which is supposed to manage taxpayer accounts and meet taxpayer needs, is intended to be a cornerstone of the IRS' plan to modernize its systems and services. By the end of FY 2007, the IRS will have spent nearly \$234 million on CADE. Mr. McCarthy, I understand that the IRS has agreed with TIGTA's recommendations to begin to reform CADE? What do you intend to do to oversee the process to ensure that CADE works and serves taxpayers as intended? Do you plan to take any steps beyond what TIGTA has recommended to ensure the success of the CADE project?

Response:

The IRS has agreed with TIGTA's recommendations on how to improve CADE development, and has provided a timeline for implementation of corrective actions to address those recommendations.

If confirmed as Assistant Secretary, among my first actions would be to delve deeper into the history of CADE and other key IRS IT modernization projects, examine current progress, identify issues, and develop options for improvement. I have been told that the IRS has taken some significant steps to address issues on CADE, to include moving program leadership for CADE back to the IRS from the contractor, embedding additional technical and tax administration subject matter experts on the program, revamping the

requirements development process, and renegotiating the contract with Computer Sciences Corporation so that the contractor bears much more of the performance risk. That being said, I need to ensure that the proper processes, controls, and oversight are in place for CADE and other critical IT programs across Treasury. To the degree I find any additional deficiencies in CADE development, I would work with IRS to ensure these are immediately addressed. Further, I would be involved in monthly reviews to monitor progress of the corrective actions to address the TIGTA recommendations, and to assess the ongoing health of the CADE and the larger IRS IT program.



U.S. TREASURY DEPARTMENT OFFICE OF PUBLIC AFFAIRS

STATEMENT OF DAVID H. MCCORMICK NOMINEE FOR UNDER SECRETARY OF THE TREASURY FOR INTERNATIONAL AFFAIRS TO THE U.S. SENATE COMMITTEE ON FINANCE

Chairman Baucus, Ranking Member Grassley, and members of the Committee on Finance, thank you for the opportunity to appear before you today. I am honored that President Bush has nominated me to serve as Under Secretary of the Treasury for International Affairs and, if confirmed, to have the opportunity to work with Secretary Paulson, the Treasury staff and others in the administration. I'd also like to take a moment to thank my wife Amy and our four children - who are here today - for their unwavering support for my public service.

If confirmed, I also look forward to working closely with this committee, the United States Senate, and your colleagues in the House of Representatives to advance U.S. economic interests at home and abroad.

My experiences as a senior member of the President's economic team, as a public company CEO, and as a former military officer have prepared me well for the position to which I have been nominated.

In my first role in government as Under Secretary of Commerce for Export Administration, I led a 250-person organization responsible for balancing the promotion of U.S. technology exports with the imperative of protecting our national security by controlling the transfer of militarily-sensitive technologies. In this position, I coordinated with other government agencies consulted actively with members of Congress and their staffs, worked closely with the business community, and engaged senior foreign officials in reaching agreement on multilateral approaches for satisfying both of these objectives.

This experience has been crucial to my success as the President's principal White House advisor for international economic policy with responsibilities closely aligned with those of the Under Secretary of Treasury for International Affairs. In my current role, I have led the US-Japan sub-cabinet economic dialogue, directed White House involvement in policies affecting foreign investment in the United States, and coordinated U.S. policy regarding multilateral debt relief, the President's U.S. AIDS Initiative, and the Millennium Challenge Account. I have also served as the President's personal representative for major economic summits such as those of the US-EU, APEC, and the G8.

My experiences in the private sector too are relevant to the responsibilities of the Under Secretary of Treasury. As a consultant serving Global 2000 companies, I worked with senior executives to develop and execute strategies for improving the growth and performance of their businesses. As an entrepreneur and public company CEO, I helped build and lead a profitable 1,000+ person technology organization with 25 offices worldwide. During this time, I collaborated with business leaders around

the globe, and I witnessed firsthand their challenges in maintaining competitiveness in times of accelerating change.

Prior to my business career, I was a veteran of the first Gulf War and I served for five years as an active Army officer. From this experience, I learned the importance of setting a clear direction for an organization, communicating clearly and often, and leading by example. I followed this service with formal training in economics and foreign policy, receiving a Ph.D. from Princeton in 1996. Since that time, I have written regularly on economic, national security, and business-related issues.

I'm confident that based on these experiences I have the capacity to take on the responsibilities of Under Secretary and execute them successfully. If confirmed, I will immediately focus on pressing issues such as addressing growing global imbalances, accelerating China's stable integration into the global economy, and ensuring that development assistance from the multilateral development banks is deployed effectively around the world. I will also focus on advancing the President's vision for opening foreign markets for U.S. goods and services and accelerating the transition of many developing countries to true market-based economies. I will emphasize the critical importance of economic growth, good governance, and the rule of law in ensuring that all parts of the global economy can become vibrant and prosperous, while at the same time maintaining vigilance to try to prevent future financial crises.

Mr. Chairman, Senator Grassley, I am grateful for this opportunity to appear before you today. I would be pleased to answer any questions you and other members of the Committee may have.

**SENATE FINANCE COMMITTEE
STATEMENT OF INFORMATION REQUESTED OF NOMINEE**

A. BIOGRAPHICAL INFORMATION

1. Name: (Include any former names used.): David H. McCormick
2. Position to which nominated: Under Secretary of Treasury for International Affairs
3. Date of nomination: May 2007
4. Address:

5. Date and place of birth:
6. Marital status:
Married
- 7.

8. Education: (List secondary and higher education institutions, dates attended, degree received, and date degree granted.)

- Princeton University	9/1992 to 9/1996	M.P.A and Ph.D.	9/1996
- United States Military Academy	9/1983 to 5/1987	B.S. Mechanical Engineering	5/1987
- Bloomsburg Senior High School	9/1979 to 5/1983	Diploma	5/1983

9. Employment record: (List all jobs held since college, including the title or description of job, name of employer, location of work, and dates of employment.)
- Deputy National Security Advisor, National Security Council, 1650 Pennsylvania Avenue, NW, Suite 374, Washington, DC 20504, 8/2006-Present
 - Under Secretary for Export Administration, U.S. Department of Commerce, 1401 Constitution Avenue, NW, Washington, DC 20230, 10/2005-8/2006
 - President and Director, Ariba, Inc., 210 Sixth Avenue, Pittsburgh, PA 15222, 7/2004-8/2005
 - FreeMarkets, Inc., 210 Sixth Avenue, Pittsburgh, PA 15222

CEO	2/2003-6/2004
President	10/2002-1/2003
EVP, Worldwide Operations	1/2001-9/2002
SVP, Core Business Markets	11/1999-12/2000
 - Consultant, McKinsey & Company, 301 Grant Street, Pittsburgh, PA 15219, 9/1996-10/1999
 - Student/Preceptor, Princeton University, Preceptor, Robertson Hall, Prospect Avenue, Princeton, NJ, 8/1992-8/1996
 - Research Assistant/Intern, International Peace Academy, 777 United Nations Plaza, New York, New York, 10017, 6/1993-8/1993
 - Captain, United States Army, 5/1987-2/1992
10. Government experience: (List any advisory, consultative, honorary, or other part-time service or positions with Federal, State or local governments, other than those listed above.)
- None.
11. Business relationships: (List all positions held as an officer, director, trustee, partner, proprietor, agent, representative, or consultant of any corporation, company, firm, partnership, other business enterprise, or educational or other institution.)
- Ariba, Inc., President and Director, 210 Sixth Avenue, Pittsburgh, PA 15222, 7/2004-8/2005

- FreeMarkets, Inc., 210 Sixth Avenue, Pittsburgh, PA 15222
 - CEO 2/2003-6/2004
 - President 10/2002-1/2003
 - EVP, Worldwide Operations 1/2001-9/2002
 - SVP, Core Business Markets 11/1999-12/2000
- McKinsey & Company, Consultant, 301 Grant Street, Pittsburgh, PA 15219, 9/1996-10/1999

12. Memberships: (List all memberships and offices held in professional, fraternal, scholarly, civic, business, charitable, and other organizations.)

Organization	Office held (if any)	Dates
Allegheny Conference on Community Dev.	Board Member	7/2004-9/2005
Pittsburgh Technology Council	Board Member	7/2004-9/2005
The Duquesne Club	Member	2/2002-4/2007
Pittsburgh Parks Conservancy	Board Member	12/2001-9/2005
Manchester Bidwell Corporation	Board Member	7/2000-9/2005
Pittsburgh World Affairs Council	Board Member	1/2001-9/2005
The New Idea Factory	Chairman	Spring 2000
Council on Foreign Relations	Term Member	1999-2004
French-American Foundation	Young Member	1999-2000

13. Political affiliations and activities:

- a. List all public offices for which you have been a candidate.

None.

- b. List all memberships and offices held in and services rendered to all political parties or election committees during the last 10 years.

None.

- c. Itemize all political contributions to any individual, campaign organization, political party, political action committee, or similar entity of \$50 or more for the past 10 years.

See Schedule A.

14. Honors and Awards: (List all scholarships, fellowships, honorary degrees, honorary society memberships, military medals, and any other special recognitions for outstanding service or achievement.)

- Henry Crown Fellow, Aspen Institute, 2003

- Young Leader, French-American Foundation, 1999
- Earhart Fellowship for academic excellence, H.B. Earhart Foundation, 1996
- Bronze Star Medal for Meritorious Service, Operation Desert Storm, 1991
- Honor Graduate and Merrill Leadership Award, US Army Ranger School, 1988
- Eastern Collegiate Athletic Association Award for Academic and Athletic Excellence, 1987

15. Published writings: (List the titles, publishers, and dates of all books, articles, reports, or other published materials you have written.)

"A Fresh Look at Innovation and Security", *Science*, volume 313, number 5795, September 29, 2006.

"Exports to China Must not be Used to Develop the Military", *The Financial Times*, June 9, 2006.

"Export Controls Aren't to Blame for the Trade Deficit with China", *The Mercury News*, May 8, 2006.

"The UAE: A Gulf Region Success Story" (Reprint of a Speech Given to the American Business Council of Dubai), *Liberty*, issue 15, April 2006.

"Technology Leadership is Key to Security", *The Financial Times*, December 12, 2005

"Exports to China Must not be Used to Develop the Military", *The Financial Times*, June 9, 2006

"Let's Roll Against Saddam Hussein", *Los Angeles Times*, February 28, 2002

"Trouble in the Ranks", with John Hillen, *The San Diego Union-Tribune*, July 23, 2000

"Hospital, Heal Thyself" with Paul Mango and Michael Figliuolo, *The McKinsey Quarterly*, vol. 1, 2000

"Illusions of Airpower", *The Pittsburgh Post-Gazette*, July 14, 1999

"The Draft Isn't the Answer", *The New York Times*, February 10, 1999

The Downsized Warrior: America's Army in Transition, New York University Press, 1998

"From Peacekeeping to Peacebuilding: Restructuring Military and Police Institutions in El Salvador" in *Keeping the Peace: Multidimensional UN Operations*, Michael Doyle, Ian Johnstone, Robert Orr, eds., Cambridge University Press, 1997

"Relationships Between the State and the Armed Forces", a published essay based on a Ditchley Foundation Conference held at Ditchley Park, Oxfordshire, England (report No. 96/8), June 1996

"A Downsized, Down and Out Army", *Christian Science Monitor*, March 26, 1996

"A Perilous Precedent: The U.S. Military and the War on Drugs", *Journal of Public and International Affairs*, vol. 5, Spring 1994, pp. 36-63

"A Soldiers Sacrifice" (Letter to the Editor), *Press Enterprise*, February 23, 1991

16. Speeches: (List all formal speeches you have delivered during the past five years which are on topics relevant to the position for which you have been nominated. Provide the Committee with **two** copies of each formal speech.)

"Results-Based Development: The Bush Administration's Transformation of Foreign Assistance", Princeton University, Princeton, NJ, April 12, 2007

"The Future of Export Controls", American Association of Exporters & Importers Annual Conference, New York, NY, June 12, 2006

"Win-Win High Technology Trade With China", Center for Strategic and International Studies, Washington, DC, June 9, 2006

"America and Hong Kong in the 21st Century", American Chamber of Commerce, Hong Kong Special Administrative Region, May 17, 2006

"Technology Leadership and America's Competitiveness", St. Vincent College Duquesne Club Lecture Series, Pittsburgh, PA, May 8, 2006

"The UAE: A Gulf Region Success Story", American Business Council, UAE, March 9, 2006

"India and the United States: An Emerging Global Partnership", World Economic Forum India Economic Summit 2005, New Delhi, India, November 28, 2005

"An Agenda for Change in Export Controls", Update 2005 Conference on Export Controls and Policy, Washington, D.C., October 24, 2005

17. **Qualifications: (State what, in your opinion, qualifies you to serve in the position to which you have been nominated.)**

My experiences as a senior government official and a public company CEO along with service in the military and my educational training have prepared me well for the position to which I have been nominated, Under Secretary of Treasury for International Affairs.

My first role as a government official was as the Undersecretary of Commerce for Export Administration. In this capacity, I led a 250-person organization responsible for balancing the interests of the business community in promoting exports with the Government's imperative of protecting our national security by controlling the trade of sensitive technology. In this position, I coordinated with other agencies across the government, consulted actively with members of Congress and their staffs, worked closely with the business community, and engaged senior foreign officials in reaching agreement on multilateral approaches to technology controls.

This experience has been crucial to my success as Deputy National Security Advisor for International Affairs where I currently serve as the President's principal White House advisor for international economic policy. Many of my responsibilities are very relevant to the Undersecretary of Treasury for International Affairs. In this role, I lead the US-Japan sub-cabinet dialogue on bilateral economic integration, direct White House involvement in policies affecting foreign investment in the United States, and coordinate U.S. policy in the developing world regarding multilateral debt relief, the President's U.S. AIDS Initiative, and the Millennium Challenge Account. Additionally, I serve as the President's personal representative for major leader economic summits to include the US-EU Summit, APEC, and the G8.

My experiences in the private sector are also relevant to the responsibilities I would assume if confirmed as Undersecretary of Treasury. As a Consultant at McKinsey, Inc. serving Global 2000 companies across a range of industries, I learned to develop and execute strategies for growth and improved performance. Later in my career as an entrepreneur and public company CEO, I helped build and lead a profitable 1000+ person technology organization with 25 offices around the world. During this time, I worked closely with business leaders across industries and around the world, and I have witnessed firsthand the challenges they face in leading their companies in difficult and unpredictable capital markets, protecting highly valued intellectual property as they expand their businesses abroad, and maintaining global competitiveness through times of accelerating change.

Prior to my business career, I served for five years as an active duty Army officer. As a lieutenant in the 82nd Airborne Division, I led combat paratroopers in the wake of the Cold War at a time when the Army was fundamentally rethinking the threat

and its mission for the future. My unit was one of the first to deploy to Saudi Arabia and then Iraq following Saddam Hussein's invasion of Kuwait in 1990. During these formative years, I learned the importance of setting a clear direction for an organization, communicating clearly and often, and leading by example. I followed my military service with more formal training in economics and foreign policy, receiving a Ph.D. from Princeton University in international affairs in 1996. Since that time, I have written articles and a book and spoken publicly on a range of national security, economic policy, and business-related issues.

It is an honor to be nominated by the President for the role of Under Secretary of Treasury for International Affairs. This position is of critical importance and has enormous implications for the conduct and effectiveness of international economic policy. While there is undoubtedly much to learn if confirmed for this role, I am confident that I have the ability and the experience to take on these responsibilities and execute them successfully.

B. FUTURE EMPLOYMENT RELATIONSHIPS

1. Will you sever all connections with your present employers, business firms, associations, or organizations if you are confirmed by the Senate? If not, provide details.
Yes.
2. Do you have any plans, commitments, or agreements to pursue outside employment, with or without compensation, during your service with the government? If so, provide details.
No.
3. Has any person or entity made a commitment or agreement to employ your services in any capacity after you leave government service? If so, provide details.
No.
4. If you are confirmed by the Senate, do you expect to serve out your full term or until the next Presidential election, whichever is applicable? If not, explain.
Yes.

C. POTENTIAL CONFLICTS OF INTEREST

1. Indicate any investments, obligations, liabilities, or other relationships which could involve potential conflicts of interest in the position to which you have been nominated.

None.

2. Describe any business relationship, dealing or financial transaction which you have had during the last 10 years, whether for yourself, on behalf of a client, or acting as an agent, that could in any way constitute or result in a possible conflict of interest in the position to which you have been nominated.

None.

3. Describe any activity during the past 10 years in which you have engaged for the purpose of directly or indirectly influencing the passage, defeat, or modification of any legislation or affecting the administration and execution of law or public policy. Activities performed as an employee of the Federal government need not be listed.

None.

4. Explain how you will resolve any potential conflict of interest, including any that may be disclosed by your responses to the above items. (Provide the Committee with two copies of any trust or other agreements.)

I do not believe the above responses suggest any conflict of interest. However, should any circumstance arise that would involve even an appearance of a conflict of interest, I would consult with the Treasury Department's Legal Counsel to find an appropriate resolution of the issue.

5. Two copies of written opinions should be provided directly to the Committee by the designated agency ethics officer of the agency to which you have been nominated and by the Office of Government Ethics concerning potential conflicts of interest or any legal impediments to your serving in this position.
6. The following information is to be provided only by nominees to the positions of United States Trade Representative and Deputy United States Trade Representative:

Have you ever represented, advised, or otherwise aided a foreign government or a foreign political organization with respect to any international trade matter? If so, provide the name of the foreign entity, a description of the work performed (including any work you supervised), the time frame of the work (e.g., March to December 1995), and the number of hours spent on the representation.

N/A

D. LEGAL AND OTHER MATTERS

1. Have you ever been the subject of a complaint or been investigated, disciplined, or otherwise cited for a breach of ethics for unprofessional conduct before any court, administrative agency, professional association, disciplinary committee, or other professional group? If so, provide details.

No.

2. Have you ever been investigated, arrested, charged, or held by any Federal, State, or other law enforcement authority for a violation of any Federal, State, county or municipal law, regulation, or ordinance, other than a minor traffic offense? If so, provide details.

No.

3. Have you ever been involved as a party in interest in any administrative agency proceeding or civil litigation? If so, provide details.

See Schedule B.

4. Have you ever been convicted (including pleas of guilty or *nolo contendere*) of any criminal violation other than a minor traffic offense? If so, provide details.

No.

5. Please advise the Committee of any additional information, favorable or unfavorable, which you feel should be considered in connection with your nomination.

Nothing to report.

E. TESTIFYING BEFORE CONGRESS

1. If you are confirmed by the Senate, are you willing to appear and testify before any duly constituted committee of the Congress on such occasions as you may be reasonably requested to do so?

Yes.

2. If you are confirmed by the Senate, are you willing to provide such information as is requested by such committees?

Yes.

**Senate Finance Committee
Nomination Hearing
July 25, 2007
Questions for the Record for Mr. McCormick**

Questions from Senator Snow:

Question 1:

Because of a persistent – and rising – current account surplus, China has accumulated record levels of foreign exchange reserves. At the end of 2006, China's foreign exchange reserves exceeded \$1 trillion, up more than 30 percent from the end of 2005, and the People's Bank of China continues to intervene in the foreign exchange markets to buy up an additional \$20 billion per month.

When the Chinese Government announced it was de-pegging the Renminbi from the U.S. dollar in July 2005, it said that henceforth it would be using a reference basket of foreign currencies to manage the currency. However, although China has never announced the composition of its reference basket, there is no possible combination of currencies that could describe the movement of the RENMINBI since 2005. Considering China's steady accumulation of foreign exchange reserves and the continued intervention of the central bank in the foreign exchange markets, what evidence can be produced to suggest China is not manipulating the value of its currency? What do you feel it is most appropriate administration response to such manipulation?

Response:

China must make many reforms to its economy to ensure stability and future growth, and we are working with them to accelerate the pace of these reforms. It is in China's interests to do so. In particular, a more flexible currency would make China's domestic macroeconomic policy more effective and help rebalance the Chinese economy towards greater household consumption and less reliance on investment and exports for growth.

The Treasury Department and this Administration have been aggressively pressing China to move faster to allow its currency to appreciate, and to adopt a number of other reforms that would rebalance its economy. The currency issue is a central part of the Strategic Economic Dialogue (SED) with China that was established by President Bush and President Hu last August. In fact, the renminbi (RMB) has appreciated by over nine percent since the end of the dollar peg in July 2005. Since the SED began, the pace of appreciation is three times as fast as in the first year of that policy. We are having some effect, although the pace is still not rapid enough.

In addition, at the urging of the Administration, the IMF recently adopted reforms that will permit firmer surveillance in areas such as insufficiently flexible exchange rate

regimes or weak macroeconomic policies that do not adequately support the exchange rate regime.

The most recent currency report concluded that while the renminbi is undervalued, China did not meet the technical requirements for designation under the terms of Section 3004 of the Omnibus Trade and Competitiveness Act of 1988 during the period covered by the report. The Treasury Department was unable to determine that China's exchange rate policy was carried out for the purpose of either preventing effective balance of payments adjustment or gaining an unfair competitive advantage in international trade

China needs to move more rapidly to introduce greater flexibility of its exchange rate. The intensive dialogue that the Administration has with China under the SED and firmer IMF surveillance are the best means for bringing this about.

Question 2:

The Chinese Government recently announced that it will be setting up a foreign exchange reserve investment agency along the lines of Singapore's Temasek Holdings. An estimated 70 percent of China's foreign exchange reserves are currently invested in U.S. Treasuries or other low-risk U.S. dollar-denominated bonds, one important factor that has kept U.S. interest rates low. The State Administration of Foreign Exchange has previously indicated an interest in diversifying out of U.S. dollars, but in doing so, it faced the dilemma of such a move leading to U.S. dollar depreciation and an erosion of the value of China's U.S. dollar-denominated assets. Although it is not clear how large the fund will be -- market expectations are that it will be around \$200 billion -- or how it will invest its assets, it is clear that it will be investing more in non-U.S. dollar assets. Even if these investments are initially very small, this new policy approach could lead to an acceleration of U.S. dollar depreciation and higher interest rates. If China begins to sell down its U.S. dollar-denominated assets, what are the implications for the U.S. dollar? For interest rates?

Response:

Foreigners invest in our securities because the United States financial markets are the deepest, most liquid and most efficient in the world. A decision to hold U.S. assets represents a vote of confidence in the strength and future of the U. S. economy.

At the end of May 2007, Chinese residents are estimated to have held around \$840 billion of portfolio investment in the United States, of which \$407 billion is in Treasury securities. The holdings of China's residents represent 4.6% of Treasury obligations. More than \$500 billion worth of Treasuries, an amount greater than the estimated holdings of Treasury by Chinese residents, are bought and sold in cash markets every day. Daily turnover of Treasury repurchase agreements is about \$1.3 trillion. Moreover Treasuries only constitute 15 percent of non-financial credit demand in the US economy.

Questions from Senator Cantwell**Question 1:**

Mr. McCormick, as Under Secretary of Treasury for International Affairs you will be responsible for international monetary affairs and trade and investment policy. You will be handling the U.S. economic relationship with key emerging powers like China.

Washington state and China have been good trading partners. Whether it has been airplanes, software, or coffee, there are been many tremendous opportunities in China for companies from my state. Last year, China was the top export market for Washington state. I would like to see the U.S. exporting more goods and services related to clean energy to China.

What opportunities do you see in China and what can the U.S. government do to keep U.S. – China relations on a positive track?

Response:

The prosperity of the United States and China is tied together in the global economy. In today's interdependent world, U.S. exports and U.S. employment opportunities are affected by how well our major trading partners are doing. When any major economy, including China, grows rapidly, its growth benefits the overall global economy. For example, in 2006, China was America's 4th largest export market with a growth rate of 32 percent from 2005. If a major economy such as China were to falter, it would put a drag on global growth and demand for U.S. exports. It is for this reason that China's continued economic growth is of vital importance to the United States.

Bigger domestic markets and more success for China mean expanded markets, a higher standard of living and more jobs in the United States. It also means greater choices for U.S. consumers and higher returns for U.S. investors.

A positive relationship with China also presents important opportunities to work together on energy policy and to preserve and protect our environment.

We continue to believe that the most productive way to for us to engage with China is through a robust dialogue. Accordingly, we have launched the SED with the Chinese through the Strategic Economic Dialogue.

Through the SED, we have advanced our goals in several ways. We have created a unique forum in which the U.S. government speaks with a single voice to the highest levels of China's government. By bringing together the heads of key ministries and agencies, this approach breaks down bureaucratic stovepipes and resistance, particularly on issues that require consensus of various agencies to make progress. Additionally, the SED, as a communication channel, enables both the United States and China to prioritize issues and manage tensions in our relationship.

The SED has helped China and the United States come to a better, shared understanding about the direction of policy reform that must take place in China, including on currency. However, we continue to have disagreements over the pace of that reform, and we take every opportunity to stress to our Chinese counterparts the importance of moving more quickly to adopt greater currency flexibility, liberalize their markets, and implement a broad reform agenda that supports rebalanced growth.

Question 2:

Mr. McCormick, as Under Secretary of Treasury for International Affairs you will be responsible for U.S. participation in international financial institutions like the World Bank. You will also be coordinating economic policies with the finance ministers of other G-7 countries. Therefore, you will have an important role in our efforts aimed at reducing and eliminating global poverty.

Many constituents in my state care are very concerned about reducing global poverty. The Initiative for Global Development (formerly called the Seattle Initiative) has working to leverage the strengths of the business community in the fight against global poverty.

What is the Bush administration's strategy to eliminate extreme global poverty where individuals live on less than \$1 per day?

Response:

The Administration's approach to this issue builds on the 2002 Monterrey Consensus, which emphasizes national responsibility, rule of law, governments' accountability to their people, and sound economic policies.

The President's ambitious trade agenda seeks to remove barriers to trade so developing countries can more readily compete and grow through their own efforts. As an example of the positive results that can be achieved through free trade, two-way U.S.-African trade has more than doubled since the first full year of the African Growth and Opportunity Act, reaching \$71.3 billion in 2006. This includes a two-fold increase in non-oil AGOA imports from Africa – including apparel, manufactured products, and processed food items – as well as a doubling of U.S. exports to sub-Saharan Africa.

We also provide official development assistance (ODA) through bilateral programs and multilateral institutions. In fact, the United States is the single largest provider of such assistance in the world (\$22.6 billion in 2006). This means we have more than met President Bush's 2002 Monterrey Commitment to increase ODA by 50 percent by 2006. President Bush also led the international effort to provide 100% debt relief to the world's poorest, most heavily indebted countries through the Multilateral Debt Relief Initiative, so that these countries can devote more resources to the acute development needs of their people.

Consistent with our results-based approach, the Administration supports increased assistance to countries that have demonstrated that they can use that aid effectively. This philosophy serves as the foundation for the President's Millennium Challenge Account

initiative and our support for performance-based allocations at the multilateral development banks. The Administration also believes it is vitally important to provide assistance to address special threats to growth and prosperity in developing countries, such as HIV/AIDS and other diseases. In this area, United States leadership through the President's Emergency Plan for Aids Relief (PEPFAR) and the President's Malaria Initiative have been particularly effective and have spurred multilateral action around the world.

Finally, it is important to note that foreign aid is only one component of U.S. contributions to the economic development in poor countries. U.S. private investment, grants, remittances and trade, all of which contribute to increased growth and improved living standards in developing countries, significantly exceed our foreign aid expenditures.

Salazar Question 1*Offshore Tax Havens*

The Finance Committee recently held a hearing with regard to offshore tax abuses. At that hearing, we examined a finding by the General Accounting Office that providing the IRS with additional flexibility to pursue offshore tax cheats could help increase compliance. Specifically, the GAO found that the current 3-year statute of limitations on investigations into tax returns that include offshore transactions is insufficient.

- **Do you agree that extending the existing statute of limitations could help the IRS crack down on offshore tax cheats?**

Answer

I understand from my colleagues in the Office of Tax Policy that the Treasury Department views offshore tax evasion as an important issue. As part of the Treasury Department's multi-faceted approach for dealing with this issue, the Office of Tax Policy is examining some of the proposals to extend the statute of limitations. Proposals to extend the statute of limitations raise several issues, however. One is the specific scope of the problem. Internal Revenue Code section 6501(c)(1) provides an unlimited statute of limitations in the case of false or fraudulent returns. Does the difficulty lie with distinguishing between fraudulent and non-fraudulent conduct? If one does consider extension of the statute of limitations, how much of an extension is necessary without impinging on the need for certainty? What should be the triggers for an extended statute of limitations? Would the extended statute of limitations apply to the particular offshore transaction or apply to the entire return? These are issues that Treasury's Office of Tax Policy is carefully evaluating.

- **Do you agree that preventing people from evading our tax laws by hiding assets offshore is an important part of the effort to promote fairness?**

Answer

While I am not a tax expert, I understand that the Treasury Department and the Internal Revenue Service aggressively go after offshore tax evasion. One way is by using the United States' existing tax information exchange agreements. Another way is through information reporting and penalty provisions. The Administration's FY 2008 budget proposal included several proposals to strengthen and increase existing penalty provisions, including those applicable to tax return preparers and the failure to file a return. I understand that the Small Business and Work Opportunity Tax Act of 2007 included versions of several of these proposals, including provisions modifying the collection due process procedures for employment tax liabilities, broadening the scope of the present-law tax return preparer penalties, and imposing a penalty on any taxpayer filing an erroneous claim for refund or credit. More specifically for offshore transactions,

my colleagues in the Office of Tax Policy continue to consider whether additional reporting and penalties in this area would assist in achieving greater compliance.

Salazar Question 2

I am a cosponsor of legislation recently introduced by Senators Baucus, Grassley, Schumer, and Graham to improve the way we respond to fundamentally misaligned foreign currencies that exacerbate our trade balances and make it harder for American businesses to compete in the global economy.

- **Do you agree that this legislation will provide the Treasury Department with the tools it needs to respond to currency misalignments?**

Answer

As Secretary Paulson has stated, we particularly respect the efforts and intent of the Senate Finance Committee. However, we do not believe the approaches taken in the bill would strengthen the hand of the United States in achieving essential economic reforms in China. The proposed bill distances the U.S. from a multilateral approach, and raises serious concerns regarding US compliance with international rules governing antidumping investigations.

**STATEMENT OF
CHARLES E.F. MILLARD
NOMINEE TO BE THE DIRECTOR
PENSION BENEFIT GUARANTY CORPORATION
BEFORE THE
SENATE FINANCE COMMITTEE
July 25, 2007**

Chairman Baucus, Ranking Member Grassley, and Members of the Committee:

Thank you for giving me the opportunity to appear before you today. I am honored and humbled that President Bush has nominated me to serve as the Director of the Pension Benefit Guaranty Corporation, and I appreciate your consideration of my nomination. Public service is a privilege which I hold dear and I am sincerely grateful for this opportunity to serve.

Before my formal statement, and with your indulgence, I would like to introduce members of my family who are here with us today. My wife, Gwen, who performs her own public service every day as the manager of the small population center that is our family. Without her conviction, support and love, I would be unable to take on this new responsibility. In addition, my sons Egan, Conor and Daniel, daughters Mary, Christine and Maureen, as well as my sisters Marylou and Meg.

For as long as I can remember, my parents taught my siblings and me that loving our neighbor meant taking action. My first experience of that action was marching for civil rights with my parents 40 years ago in Newark, New Jersey. And the desire to serve has stayed with me since that time. I certainly hope that my children experience a similar example from my wife and me.

I have had the chance to serve as a VISTA Volunteer in Crown Heights, Brooklyn, and as a Board member of the New York Urban League. In 1985, I worked in Chile for the Vicariate of Solidarity, a Santiago-based human rights organization. I have served as a New York City Councilman and was then appointed by Mayor Rudolph Giuliani to be the President of the New York City Economic Development Corporation (EDC) and Chairman of the New York City Industrial Development Agency. I also worked as a Legislative Assistant in the early 1980s for Congresswoman Millicent Fenwick of New Jersey.

My work in New York as head of EDC is worth noting because, like PBGC, EDC was created as a corporation to manage governmental programs that are principally business-like in nature, produce self-sustaining revenue, involve numerous negotiated transactions, and require greater budget and other flexibility than a traditional government agency.

In addition to public service, my career in private life also helps me bring relevant knowledge and experience to PBGC. I have been a practicing Wall Street attorney representing large financial institutions, and I have been a Managing Director involved in investment banking, public finance and investment management with firms such as Lehman Brothers and Prudential Securities. Most recently, I have been a partner in a more entrepreneurial real estate enterprise, dealing with large individual and institutional investors regarding their investment allocations to real estate.

This diverse background in public and private life has given me experience in managing hundreds of people in a public environment and directing a large organization to higher achievement. I have also come to understand how individual corporations reach financial decisions and how many large institutions and pension funds make investment decisions.

PBGC's insurance program currently protects the pensions of over 40 million Americans. The corporation receives no funds from general tax revenues. Rather, it is financed by insurance premiums paid by plan sponsors as well as by assets from terminated plans, recoveries from companies that sponsored those plans, and investment income from these assets.

When an underfunded plan terminates, PBGC becomes trustee, taking over the assets and paying benefits. The corporation is now trustee of approximately 3,700 terminated plans. In Fiscal Year 2006, the corporation paid more than \$4 billion to over 612,000 retirees and beneficiaries in trustee plans. There are about another 550,000 people who will receive payments in the future upon retirement. These are workers who depend on the PBGC, and I fully appreciate the necessity for prudent decisions and management of this agency. Workers who receive benefits from the PBGC have already been let down by their pension plan; they should not be let down again by the pension guarantor.

PBGC and the defined benefit pension system face considerable challenges in coming years. At the end of FY 06, PBGC's deficit stood at \$18.9 billion. The corporation controls assets worth approximately \$61 billion and faces liabilities of approximately \$80 billion (on a present value basis). Also, PBGC estimates that total underfunding in on-going plans stood at \$500 billion at the end of FY 06.

The Pension Protection Act, passed last year by Congress and signed by President Bush, has made some significant improvements in the system that will enhance the soundness of the defined benefit system for millions of American workers. The corporation is currently implementing the PPA, including the development of a comprehensive set of regulations and other guidance as mandated by Congress.

Mr. Chairman, I would like to emphasize my personal commitment to PBGC's mission and purpose. It is PBGC's job to promote and maintain healthy plans, to negotiate in bankruptcy and other proceedings to protect workers and their benefits and, of course, when a plan must terminate, it is PBGC's job to pay those benefits. This requires constant vigilance of various corporate transactions, securities filings, and bankruptcy court proceedings. It requires steadfast negotiations by PBGC on behalf of workers and their families to help avoid plan terminations or minimize their impact. And it requires responsible and effective investment and stewardship of the assets that are used to pay benefits to the insured beneficiaries of trustee plans.

The corporation carries a tremendous responsibility because the "insured beneficiaries of trustee plans" I just mentioned are actually real, individual human beings – people who have worked their whole lives to receive the retirement payments that they have been promised and have earned, people who support families, and who wait for the check from PBGC so they can sit at the kitchen table and pay their bills, people who are counting on PBGC to carry out its mission as given to it by you.

If confirmed in this position, I would welcome the opportunity to work with members of the Senate and the House, as well as your staffs, to make sure that we do the best job we can for these workers.

I would be happy to answer any questions you may have.

Thank you.

SENATE FINANCE COMMITTEE
STATEMENT OF INFORMATION REQUESTED OF NOMINEE

A. BIOGRAPHICAL INFORMATION

1. Name: (Include any former names used.) Charles E. F. Millard
2. Position to which nominated: Director, Pension Benefit Guaranty Corporation
3. Date of nomination: May 3, 2007
4. Address:

5. Date and place of birth:
6. Martial status:
Married
- 7.

8. Education: (List secondary and higher education institutions, dates attended, degree received, and date degree granted.)
- Bergen Catholic High School
Oradell, New Jersey
- College of the Holy Cross
Worcester MA
Attended 9/75 – 5/79
Degree: B.A. Honors degree, cum laude, Phi Beta Kappa
- Columbia Law School
New York, NY
Attended 9/81 – 1/82, 1/83 – 5/85
Degree: J.D.
9. Employment record: (List all jobs held since college, including the title or description of job, name of employer, location of work, and dates of employment.)
- VISTA Volunteer, Crown Heights Progress Council, Brooklyn, NY 9/79 – 9/80
Trainee, Coca-Cola Company, Mexico City, Mexico, 2/81 – 6/81
Legislative Assistant, Representative Millicent Fenwick, Washington, DC 2/82 – 1/83
Human Rights Analyst, Vicariate of Solidarity, Santiago, Chile, 9/85 – 12/85
Associate Attorney, Davis Polk & Wardwell, New York, NY, 2/86 – 4/91
New York City Councilmember, 1/92 – 12/95
Managing Director, Cambridge Partners (investment banking), NY, NY 3/95 – 9/95
President, New York City Economic Development Corporation, 12/95 – 6/99
Managing Director, Prudential Securities, New York, NY 6/99 – 5/00
Managing Director, Lehman Brothers, New York, NY 6/01 – 6/04
Managing Director, Broadway Real Estate Partners, New York, NY 7/04 – present
President, BP Direct Securities, New York, NY 1/05 – present
10. Government experience: (List any advisory, consultative, honorary, or other part time service or positions with Federal, State or local governments, other than those listed above.)
- All listed above

11. Business relationships: (List all positions held as an officer, director, trustee, partner, proprietor, agent, representative, or consultant of any corporation, company, firm, partnership, other business enterprise, or educational or other institution.)
 - Consultant to Victory Schools, 2000
 - Board of Directors, Bion Dairy, 2006-07 (to be resigned)
12. Memberships: (List all memberships and offices held in professional, fraternal, scholarly, civic, business, charitable, and other organizations.)

Membership in civic, social, charitable, etc., organizations

Current:

Board of Trustees, Mercy College, Dobbs Ferry, New York. Mercy College provides secondary education to many welfare recipients and others who lack secondary education opportunities.

Board of Directors, New York League of Conservation Voters

Advisory Board, St. Aloysius School, Harlem

Board of Directors, Greenwich Leadership Forum, small organization focusing on business leadership and faith in the workplace

Parks Commission, Borough of Fenwick, Old Saybrook, Connecticut (summer home)

Finance Committee, Resurrection Parish, Rye, New York

Knight of the Holy Sepulchre, Roman Catholic leadership organization

Member, Winged Foot Golf Club, Mamaroneck, NY

Member, The Honors Course, golf club in Chattanooga, Tennessee

Member, The Century Association, New York, NY

Board of Advisors, Gary Klinsky Children's Centers, a Brooklyn-based, after-school program

Former:

Pregnancy Care Center, New Rochelle, NY, a pregnancy counseling and single mother residential program, 2003-06

Racquet and Tennis Club, New York, NY, 2002-2006

New York Urban League, Board of Directors, late 1980s

13. Political affiliations and activities:
 - a. List all public offices for which you have been a candidate.
 - New York City Council, 1991, 1993
 - U.S. Congress, 1994
 - Fenwick Board of Burgesses, Old Saybrook, Connecticut (withdrawn)

- b. List all memberships and offices held in and services rendered to all political parties or election committees during the last 10 years.

Various New York State and New York County Republican Committees
Finance Committee, Rudy Giuliani Presidential Committee, Dec. 2006 –
April 27, 2007

- c. Itemize all political contributions to any individual, campaign organization, political party, political action committee, or similar entity of \$50 or more for the past 10 years.

July 2002, Friends of John Faso, \$500
June 2003, Bush-Cheney, \$2,000
November 2003, Westchester County Republican Committee, \$1,000
February 2004, New York County Republican Committee, \$1,000
June 2004, Friends of Jeanine Pirro \$1,000
June 2004, Manger for Congress, \$250
June 2005, People For Linda Doherty, \$200
May 2006, Solutions America PAC, \$5,000
June 2006, Swann for Governor, \$500
October 2006, Talent for Senate, \$500
October 2006, Tennessee Senate Committee, \$500
October 2006NY-24, Victory Committee, \$500
October 2006, Friends of Clay Shaw, \$500
October 2006, Bachman for Congress, \$500
October 2006, Rob Simmons for Congress, \$500
October 2006, Friends of Mike Sodrel, \$500
October 2006, Jim Gerlach for Congress, \$500
October 2006, Joint Candidates Committee \$500

(This represents the immediate prior five years; I have not been able to locate check stubs for the previous five years, but am still searching.)

14. Honors and Awards: (List all scholarships, fellowships, honorary degrees, honorary society memberships, military medals, and any other special recognitions for outstanding service or achievement.)

Knight of the Holy Sepulchre

15. Published writings: (List the titles, publishers, and dates of all books, articles, reports, or other published materials you have written.)

I have written dozens of Op-Ed columns and some Book Reviews and have done my best to list them all here. All are from NY Post unless otherwise noted.

Eliot & NY's Economy, November 8, 2006
 New York GOP's Road Back, November 14, 2006
 Ballot Boxing, November 5, 2006
 NJ Gay Games, October 30, 2006
 Riverside's Terror Rally, October 18, 2006
 A Real, Honest Woman, September 29, 2006
 & A Not So Exciting GOP, Sep. 13, 2006
 SOx and the City, Sep 18 2006
 Con Edison, Our Creature, July 31, 2006
 From Slave to Senator, approx Aug 2006
 GOP Crossroads, NY party's puzzle, May 30, 2006
 Chris Quinn's Radical Reform, May 11, 2006
 Gay Marriage Non-Debate, approx Sep 2006
 Budgeting in Wonderland, Apr. 28, 2006
 Budgeting By Cookie Jar, Aug. 22, 2006
 Mike's PA Mistake, April 13, 2006
 When Bias Kills, Mar. 20, 2006
 "Street Fight" Sequel Ahead, March 3, 2006
 Fatal Misfocus, Feb. 19, 2006
 Flanking Eliot, Feb 9, 2006
 Don't Forgive TWU's Friends, Dec. 22, 2005
 The City Council: Get Set For Worse, Nov. 23, 2005
 Helping More Wisely, NYC & The Homeless, Dec. 24, 2005
 From The Top, ACS's policy problem, Jan. 18, 2006
 ACS's Wrong-Headed Reforms, Feb. 1, 2006
 Council Frenzy, Dec. 27, 2005
 The Wrong Focus, Freddy's Big Mistake, oct31, 2005
 Four-Time Losers, Nov. 9 2005
 A Happy Failure, NY GOP Needs Primary, Dec.13, 2005
 Let Silverstein Do His Thing, Oct. 27, 2005
 Why The Vallones Like Mike, Oct.17, 2005
 Independent Voice, Oct. 3, 2005
 Weiner's Wimpout, Sep. 15, 2005
 Real Issues, Sep 13, 2005
 NYC's Primary: The New Orleans Test, approx. early Sep., 2005
 After Pataki, Aug. 26, 2005
 A Primary Fight NY's GOP Needs, Aug. 16, 2005
 What Mayor Needs: Good Tunnel Vision, Aug 1, 2005
 Pataki's Plan B Puzzle, Jul 15, 2005
 Too Many Cooks, May 15, 2005

Bay Ridge Boy Could KO Kofi, Jun 24, 2005
 Watch Your Right, Mike, Jun 21, 2005
 Not Just A Stadium, Jun3, 2005
 Columbia's Bigotry, Hate-filled ban on ROTC, Apr. 14, 2005
 Importing Pols, Apr.29, 2005
 Whiner Weiner Chases Jobs, Apr.5, 2005

Why I'm Not Marching On Washington, New York Times, May, 16, 1992
 As Democrats Seek Blame, Cities Suffer, Los Angeles Times, summer 1992
 Stop the Porn Explosion, New York Times, Jan. 29, 1993
 Op-Ed Column in New York Times regarding Legal Aid Society, fall 1995
 Republicans' Compassion, Christian Science Monitor, summer 1992
 A \$30-Billion Pie in the Face, Newsday, June 4, 1992

Pinochet Stays, Can Chile's New president Hold off the Dictator?, Cleveland Plain Dealer, December 19, 1989
 In Chile, Fraud Doesn't Wait For Election Day, Newsday, June 28,1988
 Baltic Fever: It Can Happen here, Newsday, May 17, 1990
 In Chile, Fraud Occurs Long Before the Balloting, Chicago Tribune, June 10,1988
 Is Democracy Coming To Chile?, St. Louis Post-Dispatch, approx. summer 1989
 Chile's Democrats Pray for Pope's Moral Support, Los Angeles Times, Mar. 30, 1987
 Pinochet is Gone! Long Live Aylwin!, San Francisco Chronicle, approx. summer 1989
 Despite Chile's Loud No to Pinochet, Change Won't Come Overnight, Atlanta Constitution, Oct. 9, 1988
 Pinochet Risks Further Chaos, New York Times, Sep. 21, 1986
 Reagan: Put the Pressure on Pinochet, Christian Science Monitor, July 18, 1986

I wrote three other articles that I recall but have not been able to locate. Two were for the New York Sun and one was for National Review Online. One Sun article discussed the Laci Peterson double murder indictment as relates to fetal homicide. The other discussed one of the Bush-Kerry presidential debates. The National Review Online article discussed Rosa Parks and Wellington Mara, who died at about the same time.

16. Speeches: (List all formal speeches you have delivered during the past five years which are on topics relevant to the position for which you have been nominated. Provide the Committee with two copies of each formal speech.) NONE
17. Qualifications: (State what, in your opinion, qualifies you to serve in the position to which you have been nominated.)

The PBGC exists at the intersection between government and business. More specifically, PBGC interacts regularly and sometimes in a transactional capacity, with private businesses, and at the same time, the PBGC itself operates like a large financial institution. I have held senior roles in organizations that provide both experiences.

As President of the New York City Economic Development Corporation, I directed numerous negotiations on behalf of New York City with counter parties in the real estate

and financial world. These interactions dealt with the negotiation of business terms in the highly visible arena of New York politics and government. I had to have a complete understanding of the business terms involved as well as the ability to supervise multiple teams involved in multiple transactions simultaneously. Obviously, the PBGC is involved in a similar multiplicity of simultaneous negotiations as well.

The PBGC also requires leadership on issues relating to the implementation of the PPA. At the EDC I also was required to operate within various legislatively prescribed areas.

On the private sector side of the equation, my work at Lehman Brothers, Broadway Partners, and Prudential Securities has given me insight into U.S. capital markets. I have addressed issues of asset allocation and the investment of large pools of assets. I have been involved in significant investment banking efforts and have interacted directly on issues of investment policy, risk management and asset allocation with large institutions of the magnitude of PBGC.

When it comes to matters of policy direction, I have reported to a chief executive (the Mayor) but been responsive to oversight by the legislature of the city and, having been a legislator myself, I understand the importance of oversight and legislative policy making.

Finally, as a matter of management, I have successfully run a large organization composed of hundreds of employees, and can point at specific, measurable enhancements to the organization's bottom line, due in significant part to certain of my efforts.

B. FUTURE EMPLOYMENT RELATIONSHIPS

1. Will you sever all connections with your present employers, business firms, associations, or organizations if you are confirmed by the Senate? If not, provide details.

I intend to sever all connection with my current employer except insofar as I have deferred compensation due as stated elsewhere in this document.

2. Do you have any plans, commitments, or agreement to employ your services in any capacity after you leave government service? If so, provide details.

I have no commitment or agreement with any party for future employment, and have made no specific plans after my service in this position comes to an end.

3. Has any person or entity made a commitment or agreement to employ your services in any capacity after you leave government service? If so, provide details.

None.

4. If you are confirmed by the Senate, do you expect to serve out your full term or until the next Presidential election, whichever is applicable? If not, explain.

If confirmed, I expect to serve until the next President is elected.

C. POTENTIAL CONFLICTS OF INTEREST

1. Indicate any investments, obligations, liabilities, or other relationships which could involve potential conflicts of interest in the position to which you have been nominated.

My current employer, Broadway Partners could seek investment from the PBGC (though it has not done so in the past).

2. Describe any business relationship, dealing or financial transaction which you have had during the last 10 years, whether for yourself, on behalf of a client, or acting as an agent, that could in anyway constitute or result in a possible conflict of interest in the position to which you have been nominated.

None

3. Describe any activity during the past 10 years in which you have engaged for the purpose of directly or indirectly influencing the passage, defeat, or modification of any legislation or affecting the administration and execution of law or public policy. Activities performed as an employee of the Federal government need not be listed.

None.

4. Explain how you will resolve any potential conflict of interest, including any that may be disclosed by your responses to the above items. (Provide the Committee with two copies of any trust or other agreements.)

I will consult with agency counsel with the expectation that I will recuse myself from participating in such matters.

5. Two copies of written opinions should be provided directly to the Committee by the designated agency ethics officer of the agency to which you have been nominated and by the Office of Government Ethics concerning potential conflicts of interest or any legal impediments to your serving in this position.

6. The following information is to be provided only by nominees to the positions of United States Trade Representative and Deputy United States Trade Representative:

Have you ever represented, advised, or otherwise aided a foreign government or a foreign political organization with respect to any international trade matter? If so, provide the name of the foreign entity, a description of the work performed (including any work you supervised), the time frame of the work (e.g., March to December 1995), and the number of hours spent on the representation.

N/A

D. LEGAL AND OTHER MATTERS

1. Have you ever been the subject of a complaint or been investigated, disciplined, or otherwise cited for a breach of ethics for unprofessional conduct before any court, administrative agency, professional association, disciplinary committee, or other professional group? If so, provide details.

No.

2. Have you ever been investigated, arrested, charged, or held by any Federal, State, or other law enforcement authority for a violation of any Federal, State, County, or Municipal law, regulation, or ordinance, other than a minor traffic offense? If so, provide details.

No

3. Have you ever been involved as a party in interest in any administrative agency proceeding or civil litigation? If so, provide details.

No.

4. Have you ever been convicted (including pleas of guilty or nolo contendere) of any criminal violation other than a minor traffic offense? If so, provide details.

No

5. Please advise the Committee of any additional information, favorable or unfavorable, which you feel should be considered in connection with your nomination.

E. TESTIFYING BEFORE CONGRESS

1. If you are confirmed by the Senate, are you willing to appear and testify before any duly constituted committee of the Congress on such occasions as you may be reasonably requested to do so?

Yes.

2. If you are confirmed by the Senate, are you willing to provide such information as is requested by such committees?

Yes.

Senate Finance Committee
Nomination Hearing
Questions for the Record for Mr. Millard
Submitted August 31, 2007

Questions from Chairman Baucus

1. **What do you see as the mission of PBGC? If every defined benefit pension plan in America terminated with workers and retirees receiving their benefits either through insurance annuities or PBGC guarantees and the PBGC had sufficient assets to satisfy its obligation to pay guaranteed benefits, would you consider the PBGC a success?**

One of PBGC's missions under section 4002 of ERISA is to "encourage the continuation and maintenance of voluntary private pension plans for the benefit of their participants."

If every defined benefit ("DB") pension plan in the nation terminated, PBGC could be viewed as having failed in this mission. However, each company must determine if the costs and benefits of voluntarily providing a DB plan are appropriate for, and best suited to, the firm achieving its business model goals. For many companies, a DB plan is an important compensation tool that allows them to attract and retain workers with needed skills. For workers, DB plans provide a predictable and secure retirement income.

Competitive and vibrant markets require that companies have a broad range of choices on how DB plans are established and operated. DB plans should continue to be a viable option for employers that determine they want to provide such plans, and I hope workers will continue to see that a DB plan can be a valuable part of their overall compensation packages.

2. **A recent article in the Washington Post (Sunday, July 15) about United Airlines flight attendants contrasted the reductions in current and retirement income for these rank and file workers with a reported \$40 million pay package for the CEO in 2006.**
 - **In the process of negotiating a distress plan termination, could PBGC help effect an outcome that gives injured participants a share of post-plan termination company gains?**

When an underfunded pension plan is terminated, PBGC makes a snapshot valuation of its assets and benefit liabilities on the termination date. The Corporation can also file claims for the full amount of unfunded benefits as of that date. Any recovery obtained is shared with plan participants under a statutory formula.

In many cases, plan assets (or expected recoveries) are sufficient to allow retirees and others to receive benefits exceeding normal ERISA guarantee levels. ERISA specifies that PBGC, not participants, must shoulder any post-termination losses

or gains. Participants receive a fixed level of benefits even if asset values fall. For the same reasons, post-termination asset gains do not increase benefit levels. Thus, the amount PBGC pays participants is not directly linked to the success or failure of the company that sponsored the plan. Also, most plan terminations involve sponsors that either liquidate or dissolve, so there are no post-reorganization gains.

In a minority of cases, a plan sponsor successfully reorganizes under chapter 11 of the Bankruptcy Code. PBGC's claim in these cases often is paid largely in stock of the reorganized entity, and that stock is treated like all other PBGC recoveries. By statute, these gains (or losses) are credited (or suffered) by PBGC.

By negotiating the best deal it can with the debtor and creditors' committee, and obtaining approval of the bankruptcy court, PBGC can and does limit losses to retirees, workers and the pension insurance system.

- **In the PPA (Pension Protection Act of 2006) we limited funding of executive compensation if pension plans for rank and file are not well funded. Do you have suggestions for other legislative changes to enable more fair treatment of workers' benefits?**

Executive compensation is generally under the jurisdiction of the Internal Revenue Service ("IRS"). With respect to matters under PBGC's jurisdiction, any action that enables the Corporation to obtain a full recovery on its claim for unfunded benefits in a chapter 11 case would benefit workers whose pension benefits are cut. I would be pleased to work with all the appropriate congressional committees to identify impediments to such recoveries.

3. **GAO's recent report on the governance of PBGC suggests the organization lacks the clear delineation of responsibility necessary for effective accountability and oversight. The report also recommends that Congress consider expanding PBGC's board of directors to include members with useful knowledge and experience, and the time to devote attention to PBGC.**
 - **What steps do you intend to take to improve PBGC's governance process?**
 - **What do you think are the pros and cons of expanding the board of directors?**

My experience in both the private and public sectors has taught me the importance of good corporate oversight, especially the need for constant communication between management and the board of directors. GAO makes a number of observations on good governance practices that accord with my experience. I look forward to working with PBGC's Board of Directors to address issues noted in the GAO report.

Some of these issues will include more frequent communication with the Board members and their representatives, in addition to by-laws changes that can bring expanded Board oversight.

4. **PPA permitted hedge funds to hold a larger portion of pension assets without subjecting the fund to ERISA requirements.**
- **Do you think hedge and private equity funds are suitable investments for defined benefit pension plans?**
 - **Does the offshore location of private equity and hedge fund investments create any special problems for PBGC when a plan is trustee?**

Title I of ERISA, which is administered by the Department of Labor, does not prohibit pension plans from investing in hedge funds, private equity, real estate or other kinds of investments that may have a different regulatory framework than the securities laws. Instead, ERISA places the duty on plan fiduciaries to make prudent investment decisions, to invest diversely, and to act solely in the interests of the participants and beneficiaries of the plan. This duty requires fiduciaries to understand the nature of an prospective investment, including its risks, potential returns, fees and expenses, investment strategy, and similar characteristics, in order to determine the prudence of the investment and whether it comports with the law and the plan's investment goals. It is important to note that fiduciaries are personally liable for losses to the plan resulting from a breach of this duty. ERISA generally prohibits a pension plan fiduciary from maintaining ownership of plan assets outside U.S. district court jurisdiction. When PBGC becomes trustee of a terminated plan, it takes over the plan's assets, which may include (and in a few instances, have included) hedge fund investments. To date, PBGC has been able to liquidate these investments in a timely manner.

As with other DB plan investments, PBGC has insurance exposure to direct or indirect investments in hedge funds. Plans may invest in hedge funds to pursue strategies that may increase return. Those investments can be effective in mitigating some risks. However, they can also increase other risks. PBGC has an interest in the transparency of investments made by plans it insures.

Questions from Ranking Member Grassley

1. **The GAO released a report last week indicating that the PBGC governance structure needed improvements to ensure policy direction and oversight. Specifically, the GAO highlighted tension and confusion between the PBGC and the DOL in directing the PBGC's operations. Do you believe that the PBGC should be provided more authority under ERISA to direct and administer its operations, and if so, what changes would you recommend?**

The GAO report identified a number of areas where responsibilities for PBGC governance could be better documented and clarified. I am working with the PBGC Board in reviewing and responding to these findings. As the Board noted in its response to the GAO report, potential revisions to PBGC's by-laws are under review. I am also looking at improving the documentation of the Corporation's policies and procedures to eliminate uncertainty over roles and responsibilities.

- 2. The GAO also recently asked Congress to consider expanding the PBGC's board of directors. In your opinion, do you believe that such a move is needed? If the board was expanded, what types of people would you recommend be placed on the board?**

My experience in both the private and public sectors has taught me the importance of good corporate oversight, especially the need for constant communication between management and the board of directors. GAO makes a number of observations on good governance practices that accord with my experience. I look forward to working with PBGC's Board of Directors to address issues noted in the GAO report.

Some of these issues will include more frequent communication with the Board members and their representatives, in addition to by-laws changes that can bring expanded Board oversight.

- 3. As you know, the Pension Protection Act of 2006 established a PBGC director and provided that the position would "administer" the PBGC in accordance with the policies of the board. As the first director under this law, how would you define your role and responsibilities? Do you believe that the director position has adequate authority to administer PBGC, and if not, what authorities are needed? What are your thoughts on the director's relationship with the PBGC's Inspector General?**

My understanding is that the director's authority to administer PBGC encompasses responsibility for the Corporation's management, including its personnel, organization and budget practices. In addition, it is the director's obligation, under PPA, to implement the policies established by PBGC's Board. With respect to the Inspector General, under the current board structure, the IG has the ability to deal directly with the Board.

- 4. Currently, the PBGC Inspector General is required to report directly to the PBGC Board of Directors; specifically to the Secretary of Labor as Board Chair. However, the GAO recently found that there are no formal protocols outlining this requirement. Do you believe that this reporting relationship is appropriate? If not, why?**

With a Board composed of three Cabinet Secretaries, PBGC's Board does not have an audit committee. In such a situation it is appropriate for the IG to report to the Board.

- 5. To what extent do you believe the PBGC's Trust Fund investment portfolio is adequately distributed between fixed income assets and equities?**

I intend to review PBGC's investment policy, and consult closely with the Corporation's financial advisors, Advisory Committee, and the Board (which has authority over investment policy) in assessing any proposals for change.

As you know, PBGC has revolving funds containing premiums, and trust funds containing both assets that the Corporation takes over when it becomes trustee of a terminated plan and liability recoveries from employers for plan underfunding. Approximately 25 percent of PBGC's assets are currently in revolving funds that must be invested in U.S. government securities and are currently invested in special-issue Treasury bonds. The trust funds can be invested more broadly.

PBGC's current investment policy focuses heavily on limiting risk by investing the majority of the Corporation's assets in long-duration fixed income securities. I believe that the possibility PBGC could narrow its deficit by investing more significantly (but prudently) in equities should not be overlooked. However, I do not wish to pre-judge the outcome of our current review.

6. Do you think that changes to the PBGC's overall investment portfolio could better position PBGC to address its accumulated deficit? If so, what measures are you considering to address the PBGC's continued deficit?

Changes in PBGC's investment policy have the potential to have a positive effect on PBGC's deficit, but I am not suggesting that the corporation invest its way out of its deficit. As I indicated above, we are currently reviewing the investment policy, and I do not wish to pre-judge the outcome of that review.

In contrast to potential changes in investment policy, many of the other measures needed to address PBGC's existing deficit and improve future financial experience will require legislation.

One such measure would be to provide the PBGC Board with authority to set the variable rate premium ("VRP"), which would help both address future claims and fund the existing deficit over a period of years. The Administration's FY 2008 budget provision on this topic would also make the VRP rate applicable to a plan's total unfunded liabilities.

There are other possible ways to address the situation, and I look forward to working with all the appropriate congressional committees and the Board to improve the financial condition of the pension insurance program.

7. Under the Early Warning Program, the PBGC monitors certain companies with underfunded defined benefit pension plans to identify corporate transactions that could jeopardize pensions and to arrange suitable protections for those pensions and the pension insurance program. In what ways, if any, could the PBGC improve its ability to identify potentially troubled defined benefit plans? In what areas, if any, do you believe the PBGC could improve oversight of troubled defined benefit plans?

The Early Warning Program looks to identify sponsors who may be unable to maintain their pension plans. Unfortunately, PBGC's ability to identify potentially troubled sponsors was adversely affected by a change in PPA. Section 4010 of ERISA requires certain plan sponsors and their controlled group members to provide PBGC with information about the plan funding status and financial

information about the businesses themselves. Before PPA, 4010 filings were required of all controlled groups sponsoring plans with aggregate unfunded vested benefits ("UVBs") exceeding \$50 million. This meant that 4010 filings were required for most sponsors of large underfunded plans, even if the plans were reasonably well funded on a percentage basis.

PPA replaced the \$50 million UVB test with a funding percentage test: starting in 2008, filing under 4010 will be required if any plan of the controlled group is less than 80 percent funded. Due to this change, many companies will be exempt from 4010 filings. This includes many companies whose plans pose a significant risk to the pension insurance system and for which, before PPA, filing was required. A legislative change reverting to the prior method (even with a \$75 or \$100 million threshold) would significantly enhance PBGC's efforts to monitor risk or, if needed, take protective action.

- 8. The GAO recently reported on confusion over the legal roles and responsibilities of attorneys within the PBGC, and explained that the management structure of the PBGC's legal support does not ensure that advice of a chief legal officer is provided to the director on significant issues. To what extent do you agree with the GAO's findings and their recommendation that the PBGC provide for all legal functions to be overseen by a single chief legal officer with full authority to delineate the duties of each legal office and a direct reporting relationship to the director?**

In addition to reviewing the GAO report on PBGC's legal services structure, I have had the opportunity to work with that structure since my appointment as Interim Director. The Corporation has instituted processes and procedures for its legal offices that facilitate greater communication and co-operation. I will continue to monitor the situation closely and will not hesitate to restructure the organization if I feel I am not getting appropriate legal advice in an effective and efficient manner.

- 9. The PBGC has very limited regulatory or enforcement authority over ongoing plans; the authority the PBGC does have relates to certain employer reporting requirements and to determining whether a plan should be terminated to protect the insurance program. Do you believe that the PBGC should have increased enforcement authority? If so, what authorities do you think the PBGC needs?**

Regulatory and enforcement authority over ongoing plans is primarily the responsibility of EBSA (DOL) and the Employee Plans office (IRS/Treasury). PBGC does have certain regulatory and enforcement authority, including the ability to initiate plan termination to protect the pension insurance system. In addition, the Corporation has authority to seek protections in certain "downsizing" cases, and to perfect and enforce liens for missed minimum funding contributions. The latter two provisions are of limited effect, and termination is a blunt instrument that may have adverse consequences for plan participants.

Certain items within the Administration's February 2005 pension reform proposal that were not enacted in PPA would have strengthened PBGC's ability to exercise

its existing regulatory tools, such as permitting the Corporation to perfect its liens for missed contributions after a plan sponsor has filed for bankruptcy. I look forward to working with all the appropriate congressional committees and the PBGC Board on these issues.

10. Because the PBGC needs staff with expertise in corporate finance and private sector pensions, what steps would you take to ensure that the PBGC is positioned to attract and retain the type of expert financial, actuarial, and legal staff it needs to conduct its mission?

PBGC has lost staff members to other federal agencies that are not constrained by the GS pay scale, and anticipates that it will continue to do so. In addition, because the executives of government corporations are not eligible to be in the Senior Executive Service (“SES”), but are Senior Level (“SL”) employees, our executives have fallen behind the SES agencies, which received an increase in the pay cap that was not extended to SLs. I understand the Office of Personnel Management is working with Congress to remedy this latter discrepancy; remedial action would aid PBGC in executive recruitment and retention. In addition, GAO is currently conducting a review of the Corporation’s compensation system and the challenges PBGC faces in recruiting and retaining talented professionals. I look forward to reviewing GAO’s recommendations when its report is complete.

11. The PBGC relies heavily on the use of third party contractors in carrying out its mission. To what extent do you believe it is appropriate for the PBGC to use outside contractors, and how will you distinguish between those positions and functions that are inherently governmental and those that can be contracted out? How will you ensure that such outside contractors are held accountable? How will you ensure that the PBGC has the ability to appropriately administer its current and future contracts? What mechanisms, if any, are needed to ensure that the PBGC’s contractors are representing the best interests of the PBGC on behalf of insured workers and retirees? What mechanisms, if any, are needed to ensure that contractors advising the PBGC on acquisition and financial matters do not have conflicts-of-interest?

Because PBGC’s workload can fluctuate dramatically with changes in the economy, it is important to have flexibility in adding to and subtracting from our workforce. This aspect of our business makes outside contracting an important management tool for the Corporation.

Government employees set directions and make decisions, while contractors provide expert and technical advice. OMB has provided guidance on what constitutes inherently governmental functions that PBGC has since incorporated into its contracting policies. To successfully oversee contractors, we need to ensure that succession planning is in place so that institutional knowledge and required skill sets are not lost over time. There also need to be well-written statements of work that hold contractors accountable, and well-trained project

managers to enforce these standards. PBGC has a strong conflicts of interest policy that applies not only in the selection process but throughout performance to ensure that all potential conflicts are fully disclosed and dealt with appropriately. I intend to fully enforce this policy, and to hold myself and all employees and contractors to the highest ethical standards.

12. Federal agencies have proven vulnerable to loss of personal privacy information. PBGC collects privacy data from participants and so would be a natural target for identity thieves. One of PBGC's internal control reportable conditions is information security. What is PBGC doing to protect privacy data and comply with OMB's requirements?

PBGC has taken numerous steps to help ensure that privacy data and other Personally Identifiable Information ("PII") are properly protected and handled. Issues involving PII are identified, referred for action and monitored by the Privacy and Security Committee, which includes as members senior officials from our information technology and legal functions.

The Corporation has upgraded and updated intrusion detection systems, antivirus protections, and firewalls, and uses encryption technology to protect PII on its networks and laptops. We have also established an incident response team to deal with any attempts at unauthorized access. Consistent with recent OMB guidance, PBGC is updating its guidelines on employee access to and use of sensitive information, and will be issuing a plan by the end of the fiscal year to minimize, if not eliminate, the unnecessary use of Social Security numbers.

13. The Constitution established a system of checks and balances intended to ensure the American people of fair, honest and transparent government. Congressional oversight of executive branch operations is a linchpin of the checks and balances system. Oversight of government programs and activities require the review of documents and interviews with agency officials, and it is critical that we have timely access to the documents and agency officials to inform our work.

I agree.

14. In furtherance of our oversight responsibilities, we often ask GAO to evaluate federal government programs and activities. In addition, we may ask inspector generals to follow up on complaints regarding specific agencies and/or programs. Will you commit to working with the Congress and the GAO in a timely and constructive manner to address the oversight and other needs of the Congress, and will you encourage others to do so?

Yes, I do commit to such and will encourage others to do so.

Questions from Senator Lott

1. Mr. Millard, I wanted to ask you about a pension-related provision that was enacted earlier this year as part of the Emergency War Supplemental bill. In

particular, I am referring to section 6615, which I understand is a multi-billion dollar pension give-away to one or two airlines. As you know, the Finance Committee has jurisdiction over pension issues. Yet, it is my understanding that no Member of this Committee has offered public support or claimed personal responsibility for inserting the provision in the War Supplemental. In fact, Chairman Baucus and Senator Grassley sent a letter to the CEOs of American Airlines and Continental Airlines, questioning the provision. Does section 6615 have the effect of allowing these two airlines to systematically underfund their workers' pensions? And can you provide an estimate of the total amount of skipped pension payments for American and Continental Airlines under the provision?

Section 6615 provides funding relief to sponsors of plans of commercial airlines and airline catering companies that have not frozen their pension benefits. It does so by allowing the plans to measure their liabilities using an 8.25 percent discount rate rather than the significantly lower corporate bond rates that they would have been required to use under PPA as enacted. Using a higher discount rate lowers liabilities significantly. Depending on plan demographics, a 200 basis point increase in the discount rate could reduce liabilities by 20-25 percent. As a result, a plan that is significantly underfunded using a corporate bond rate could appear to be at or near a surplus position using a discount rate of 8.25 percent.

Based on information that PBGC received prior to passage of the Supplemental bill, PBGC estimated that this provision will reduce the minimum required contributions for American Airlines and Continental Airlines by over \$2 billion over the next ten years relative to what they would have to contribute under the regular funding rules. The bulk of the reduction will be for the American Airlines plans.

Other airline/catering firms may also be eligible for this funding relief, but we believe that the amount of relief would be much smaller in the aggregate than the relief granted American and Continental.

Questions from Senator Snowe

- 1. I am deeply concerned about the deficits in the PBGC program. According to the PBGC's 2006 Annual Report, between its single-employer and multiemployer programs, the PBGC's combined net position as of September 30, 2006, was -\$18.88 billion. Although that was a \$4.2 billion net improvement over the PBGC's deficit as of September 30, 2005, it is clear that the PBGC faces a significant shortfall. According to the annual report, "The Corporation has sufficient liquidity to meet its obligations for a number of years; however, neither program at present has the resources to fully satisfy the PBGC's long-term obligations to plan participants." Mr. Millard, as you know, last year, Congress passed the Pension Protection Act of 2006. Among its numerous provisions, the Act sought to shore-up pension funding and make permanent termination premiums of \$1,250 that companies must remit to the PBGC for each of three years when those firms terminate their pension plans. Given the PBGC's large shortfall, I would like your view as to whether the Pension Protection Act went far enough toward ensuring that**

plans are funded, and that the PBGC can pay benefits if those plans are terminated? What else can Congress do to ensure that retirees can count on their pension benefits? As I mentioned, the PBGC's annual report indicates that the Corporation has resources to pay benefits for "a number of years"? Can you quantify what "a number of years" means and when we will have to consider additional changes to the PBGC program?

PPA improved the situation, especially with respect to the new benefit limitations. One major goal of the legislation is to stop companies from continuing to make promises to their employees that cannot be kept. The PPA also improved the accuracy of the measurement of plan assets and liabilities, and strengthened the minimum funding rules. However, most of these new rules have not yet taken effect under the phase-in provisions of the statute.

I would like to reiterate that giving the PBGC Board authority to adjust the variable rate premium would be helpful in addressing the existing deficit in the pension insurance system.

There are too many factors involved to determine a reliable single estimate of when PBGC might lack sufficient resources to pay benefits when due. These factors include how well funded future trustee plans are, how many plans are trustee, what percentage of participants in future trustee plans are already in pay status, what our investment returns are, what future interest rates are, and what future premium income is. Unlike Social Security, where revenues and expenses are reasonably predictable, PBGC is heavily impacted by catastrophic (very large) claims whose timing and size cannot be reliably predicted. All these factors cast doubt on the reliability of a single estimated date, but as PBGC noted in its 2006 Annual Report, the Corporation has sufficient liquidity to meet its obligations for a number of years.

2. **The Pension Protection Act of 2006, which Congress passed last August, made the position of PBGC director confirmable by the Senate. This Committee, as well as the Health, Education, Labor, and Pensions Committee, have joint jurisdiction over the director's nomination. Previously, the PBGC had an executive director who was selected by the Chairman of the PBGC's Board, the Secretary of Labor. Mr. Millard, understanding that you have only been interim director of the PBGC since May 23, do you believe that you have all the statutory authority necessary to carry out all of your responsibilities as PBGC director? Put another way, did Congress neglect to give you additional powers that you feel would be helpful when we passed the Pension Protection Act last year?**

It would be helpful for PBGC to have additional tools to better manage risk and minimize loss to plan participants and the pension insurance system. Two areas of particular concern arise from missed pension contributions during bankruptcy. The Corporation can perfect liens for missed contributions outside of bankruptcy, but once in bankruptcy, companies can miss contributions without consequence, as both United Airlines and US Airways did before terminating their plans. Allowing PBGC to perfect liens after bankruptcy, and expressly mandating that required minimum contributions be paid as administrative expenses after bankruptcy, would address this problem.

Questions from Senator Kerry

1. What role do you think defined benefit plans play in our pension system?

As noted previously, DB plans play an important role in the pension system, both as a source of retirement income for workers and their beneficiaries, as well as a workforce recruitment tool for businesses.

DB plans typically pay benefits as an annuity for life, and thus, they reduce the risk that a worker will outlive his retirement income. If an employer determines a need to reduce its labor force, temporary retirement incentives can be offered in its DB plan to encourage workers to leave. Morale and productivity of remaining workers are not as likely to fall when such early retirement “windows” are provided as when the employer conducts a general workforce reduction.

For a number of reasons, DB plans have been covering a declining share of the work force over the past 25 years. Still, more than 20 million wage and salaried workers in private industry are covered today by DB plans. These plans remain a key source of retirement income for 44 million workers and retirees. Congress took important steps in PPA -- such as encouraging cash balance and other hybrid plans -- that can help to strengthen DB plans.

2. Do you think pension plans that are covered by the PBGC should be required to diversify their investments? Do you think that there should be limits on the amounts that private pension plans can invest in hedge funds?

Pension plans covered by PBGC have been required to diversify their investments under ERISA section 404(a)(1)(C) for over 30 years. Responsibility for enforcing this provision, and all of ERISA’s fiduciary rules, rests primarily with EBSA (DOL).

The question of whether there should be limits on private pension investments in hedge funds also falls under EBSA’s authority. EBSA guidance already requires ERISA fiduciaries, in exercising their duty of prudence, to consider diversification, liquidity and risk/reward tradeoffs in making investment decisions, including hedge fund and private equity investments.

3. Do you think Congress should amend ERISA to require pension plan sponsors to report the number of hedge funds they use or the amount of money invested in them?

Currently, plans with 100 or more participants must list all assets and investments of the plan on their annual Form 5500. A pending final regulation making changes to the Form 5500 will require very large plans with 1,000 or more participants (plans more likely to pose significant risk to the insurance system) to provide additional information breaking those listed assets into categories, such as equities, bonds, real estate, etc. Hedge funds would be assigned to a certain category depending on how these entities invested plan assets.

- 4. I have heard from a small business that is concerned about its withdrawal liability. This business participates in a multiemployer plan and it plays by all the rules, but due to circumstances beyond their control they have seen their withdrawal liability increase every year. Do you think reforms need to be made to multiemployer plans beyond what was included in the Pension Protection Act of 2006?**

Withdrawal liability payments into multiemployer plans can be crucial to the benefit security of workers and retirees. Withdrawal liability payments help ensure that retirees receive their full plan benefit and do not suffer reductions. They also tend to equalize the burden between continuing employers and withdrawn employers, thus helping to prevent cost shifting among competitors. If plan assets become depleted, plans have to obtain financial assistance loans from PBGC to pay benefits at guaranteed levels, which can be well below promised benefit amounts.

The multiemployer plan funding reforms in PPA should help improve the funded status of these plans, which has declined in recent years. Improved funding will reduce withdrawal liability for employers that leave these plans in the future. We should give the new law time to work and then reassess the need for additional legislation in light of that experience.

STATEMENT OF SENATOR GORDON H. SMITH

U.S. Senate Finance Committee
Public Hearing on Confirmations
July 25, 2007

Thank you, Chairman Baucus and Ranking Member Grassley for holding today's hearing. It is a great honor to be before this distinguished panel of nominees as they present their testimony to members of the Finance Committee.

I look forward to hearing from Mr. Kerry N. Weems, nominated to be Administrator of the Centers for Medicare and Medicaid Services (CMS) in the Department of Health and Human Services (HHS); Dr. Tevi David Troy, nominated to be Deputy Secretary of HHS; The Honorable David H. McCormick, nominated to be Under Secretary for International Affairs in the U.S. Department of the Treasury (Treasury); Mr. Peter B. McCarthy, nominated to be Assistant Secretary for Management and Chief Financial Officer, Treasury; and Mr. Charles E. F. Millard, nominated to be Director of the Pension Benefit Guaranty Corporation (PBGC).

This hearing is an important opportunity to hear directly from the nominees on their vision for changes and improvements to their respected agencies. Following the testimonies, I look forward to questioning Mr. Weems, the nominee for CMS Administrator. Ensuring the strength and sustainability of the Medicare and Medicaid programs, which will be under Mr. Weems' purview, defines much of the job of the CMS Administrator. I would like to share some issues with Mr. Weems that I feel need to be addressed to improve the programs and see how we can work together to achieve these goals.

CMS administers the Medicare and Medicaid programs, which provide health care to about one in every four Americans. Medicare provides health insurance for more than 42 million elderly and disabled Americans. Medicaid provides health coverage for some 44 million low-income persons, including 21 million children, and nursing home coverage for low-income elderly. Mr. Weems will have a great responsibility running these programs and I wish him great success.

For the last several years, as a member of the Finance Committee and former Chairman and now Ranking Member of the Aging Committee, I have been closely monitoring CMS and how the agency has handled issues of concern to beneficiaries and myself, many of which remain unresolved. I would like to take this opportunity to discuss several of these issues that I hope Mr. Weems will be swift to correct once he takes the helm of the agency.

In 2005, I had a number of conversations with Dr. Mark McClellan, former CMS Administrator, about prescription drug plans covering vital drugs used to treat conditions

like mental illness, HIV/AIDS and cancer. In response, CMS created sub-regulatory guidance that encourages plans to cover “all or substantially all” drugs in six protected classes. As we know, sub-regulatory guidance is not binding, and many plans do not follow it, even though CMS claims that they enforce the guidance through the contracts they negotiate with each prescription drug plan. Earlier this year, I discussed this issue with Mr. Weems, but I was not given a clear indication on what changes CMS will make with the guidance and how the agency will better enforce it. In response, I have crafted a bill that would codify this policy.

Second, just recently, CMS announced that it will allow any beneficiary who receives the low-income subsidy (LIS) to change prescription drug plans on a monthly basis. Prior to this announcement, only dual eligible beneficiaries had the ability to change plans monthly. Because I felt this initial policy was inadequate, I filed a bill last Congress and again this year that would allow all LIS beneficiaries to change their plan options. However, the bill would limit plan switching to up to two times a year. While, I am supportive of CMS’s recent decision, monthly plan switching involves a great deal of communication between CMS, the Social Security Administration (SSA) and prescription drug plans to be successful. Many beneficiaries have experienced problems accessing their medications because CMS has had a number of problems communicating changes with SSA and plans in a timely manner. I am concerned that allowing even more beneficiaries the option of monthly plan switching will only make the situation worse. I would like to hear from Mr. Weems what CMS is doing to ensure that enrollment information updates occur in the system in a timely manner so that beneficiaries do not experience problems accessing their medications.

I also am exceedingly frustrated with the multiplicity of problems that persist, some of which could have been avoided all together, and certainly should have been corrected by now, but have not, due to technical and administrative inefficiencies. CMS can and must improve communications among its own divisions, with outside agencies such as SSA, and with beneficiaries. For example, beneficiaries have been experiencing inconsistencies in information when they call 1-800-MEDICARE call centers with questions, as well as major delays as they try to disenroll from Medicare Advantage (MA) plans.

Currently, I am leading what has been a two and a half year investigation into 1-800-MEDICARE call centers that include call center visits, and review of call center scripts for a myriad of MA and prescription drug benefit issues. During the most recent round of test calls, my staff asked standard questions about the MA disenrollment process and received inconsistent responses to the questions. CMS informed me that they have acted to update call center scripts and train staff. However, as with Part D premium withhold problems, MA disenrollment information update processes at call centers are seriously lagging. CMS maintains there is no backlog, yet I continue to receive complaints from plans, State Health Insurance Programs (SHIPs) and advocacy groups regarding beneficiaries that have been waiting for months for their disenrollment to be processed.

I certainly appreciate the hard work of CMS to diligently solve these problems. But at the end of the day many of the problems are the result of CMS policy and administrative inefficiencies. On June 29, 2007, I wrote a letter to Leslie Norwalk, acting CMS Administrator, outlining these issues.

I have high expectations for a CMS Administrator. The CMS Administrator is in charge of some of the most complex programs in the federal government. These programs make a huge difference in people's lives every day and it is the duty of the CMS Administrator to protect these people. I have a number of additional suggestions and concerns that I look forward to discussing further with Mr. Weems regarding ways to improve Medicare's programs and CMS' systems to better serve beneficiaries. I look forward to Mr. Weems' answers to my questions today and to working with him closely in the future.

**STATEMENT BY DR. TEVI TROY
NOMINEE FOR DEPUTY SECRETARY
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
BEFORE THE SENATE FINANCE COMMITTEE
July 25, 2007**

Mr. Chairman, Senator Grassley, and members of the Committee,

Thank you for inviting me to appear before you today as the nominee for Deputy Secretary of Health and Human Services. I appreciate your scheduling this hearing during this busy time. I would also like to thank the members of the Committee for meeting with me earlier this month. I found our conversations informative and helpful, and appreciate your commitment to the health and public service mission of this Department.

Before I begin my remarks, I would like to take a moment to introduce my family.

Mr. Chairman, I am honored and humbled that the President has chosen to nominate me for this important position. I am grateful to the President and to Secretary Leavitt for their trust and confidence, and for this opportunity to continue to serve our country. If I am confirmed, you may be assured that I will work to fulfill this trust on behalf of the American people.

Mr. Chairman, I have a written statement that I would ask be included in the record, but would just like to share a few things now about my background and my understanding of the HHS mission and the important role of the Deputy Secretary.

I was born and raised in New York City. My mother and father were teachers with a lifelong commitment to public service. As teachers, they instilled in me a love for learning and for sharing knowledge. I have been lucky enough to follow in my parents' footsteps and spend my career in public service.

I began my career as a Ph.D. candidate in American Civilization at the University of Texas. During that time, I taught students and authored a book on the American Presidency that analyzed the different ways that Presidents identified and implemented new ideas, and interacted with those in academia, public policy, politics and the media.

Although I enjoyed teaching and writing, I did not find life in academia to be fully satisfying. Simply put, I wanted to do more; I wanted to do my part to make things better for all Americans. I credit my parents and my upbringing with giving me an abiding belief in the importance of public service: to your country, to your family, to your fellow man.

So I decided to come to Washington, where I learned first-hand how ideas are translated into action. I have been fortunate enough to have worked in the House, the Senate, the Department of Labor, and the White House. These experiences not only helped prepare me for the position for which I have been nominated, but instilled in me a tremendous respect for our system of government, including the important role Congress plays.

When I was nominated to be Deputy Secretary, my Rabbi sent me a letter reminding me of the importance of the Jewish concept of “Tikkun Olam” or “repairing the world.” He said that this appointment would give me the opportunity to practice *tikkun olam* on a grand scale. I’ve thought about his comment a lot recently in the context of the Department of Health and Human Services and its mission.

The Department of Health and Human Services (HHS) touches the lives of every American, from the elderly and infirm to the young and healthy. HHS has improved the lives of millions of Americans and it plays a critical role in helping America meet its obligation to help take care of the poor, the disabled, and the elderly. It reaches out to more than 40 million low-income and disabled Americans with Medicaid and it serves millions with our nationwide network of Community Health Centers. HHS also helps provide persons of low income with energy to heat their homes, give disadvantaged children an early start in education, and prepare for medical emergencies including possible terrorist acts.

Within this important agency, the Deputy Secretary is responsible for overseeing policy development for all initiatives and programs. The Deputy also serves as the Regulatory Policy Officer for HHS, overseeing the development and approval of regulations and significant guidance.

The next Deputy Secretary will have the privilege of working closely with Secretary Mike Leavitt and the dedicated professionals at HHS to advance the Department’s mission. I have enjoyed working with the Secretary over the last few years during my tenure at the White House – most recently on the HealthierUS Initiative to prevent disease, improve physical fitness, and promote community health and wellness. Secretary Leavitt is an innovative thinker and former governor who is driven by a desire to ensure we find the best ways to promote the health of all Americans.

Each of my public service experiences has reinforced my belief that one voice and one person’s actions can make a difference. Inherent in the concept of *tikkun olam* is the simple truth that our individual responsibilities to repair the world can be combined to change the world for every one of God’s creatures.

When I return home from work each day and see my wife and our four children, I walk in the door knowing I have a responsibility to build a better world for the next generation. By working together, by using the powers of government, and by improving the service of the Department of Health and Human Services, I believe I can do my part to assist HHS in its important mission and help improve the health and well-being of all Americans and the generations to come.

Thank you again for the opportunity to be here, Mr. Chairman. I look forward to answering your questions.

**SENATE FINANCE COMMITTEE
STATEMENT OF INFORMATION REQUESTED OF NOMINEE**

A. BIOGRAPHICAL INFORMATION

1. Name: (Include any former names used.) Tevi David Troy
2. Position to which nominated: Deputy Secretary, Department of Health and Human Services
3. Date of nomination: Wednesday, May 3, 2007
4. Address:

5. Date and place of birth:
6. Marital status:
Married
- 7.

8. Education: (List secondary and higher education institutions, dates attended, degree received, and date degree granted.)
Ramaz Upper School; 09/1981 – 06/1985; High School Diploma awarded 06/1985
Cornell University; 08/1985 – 05/1989; BS awarded 05/1989

London School of Economics; 09/1987 – 06/1988; General Course Degree awarded 06/1988
 University of Texas, Austin; 09/1992 – 12/1996; Masters awarded 05/1994 and PhD awarded 12/1996

9. Employment record: (List all jobs held since college, including the title or description of job, name of employer, location of work, and dates of employment.)
- American Enterprise Institute; Researcher; Washington, DC; 12/1989 – 08/1992
 - University of Texas; Teacher's Assistant; Austin, TX; 09/1993 – 09/1994 & 09/1994 – 05/1995
 - Hudson Institute; Herman Kahn Fellow and then Research Fellow; Washington, DC; 09/1995 – 08/1996
 - House Republican Policy Committee; Domestic Policy Director; Washington, DC; 09/1996 – 07/1998
 - Office of Senator John Ashcroft; Policy Director; Washington, DC; 07/1998 – 01/2001
 - Joint Economic Committee; Senior Economic Analyst; Washington, DC; 01/2001 – 01/2001
 - U.S. Department of Labor; Director of the Office of Faith-Based and Community Initiatives, Deputy Assistant Secretary for Policy; Washington, DC; 01/2001 – 04/2003
 - The White House; Special Assistant to the President and Deputy Cabinet Secretary; 05/2003-05/2004
 - Bush/Cheney 2004 Re-Election Campaign; Deputy Director of Policy; Washington, DC; 06/2004 – 11/2004
 - Self-Employed; 11/2004 – 03/2005; served as consultant to Concepts Inc., The Limited Inc., Navigators Inc., Paramount Capital Inc., and Rabin, Sheves, Lipkin-Shahak & Birger Inc. (RSLB).
 - The White House; Deputy Assistant to the President for Domestic Policy; Washington, DC; 03/14/2005 - Present
10. Government experience: (List any advisory, consultative, honorary, or other part-time service or positions with Federal, State or local governments, other than those listed above.)

Delegation Member of The Organization for Security and Co-operation in Europe
Anti-Semitism Conference, April 28-29, 2004- Berlin

11. Business relationships: (List all positions held as an officer, director, trustee, partner, proprietor, agent, representative, or consultant of any corporation, company, firm, partnership, other business enterprise, or educational or other institution.)

Self-Employed; 11/2004 – 03/2005; served as consultant to Concepts Inc., The Limited Inc., Navigators Inc., Paramount Capital Inc., and Rabin, Sheves, Lipkin-Shahak & Birger Inc.(RSLB).

Paid Speeches/Lectures:

"The Bush Administration," The Limited, November 2004.

"The Bush Administration," Columbus Bar Association, December 2004.

"The Bush Administration," WestLB Bank, December 2004.

"The Bush Administration," Gerber Capital Management, January 2005.

"The Bush Administration," Krupin-O'Brien, January 2005.

"The Structure of the Executive Office of the President" Washington Campus, January 2005.

"The Structure of the Executive Office of the President" University of Pennsylvania in Washington, February 2005.

"Church-State Relations," (panel discussion), Jewish Council for Public Affairs, March 2005.

"The Bush Administration," Stern College students, March 2005.

"The Structure of the Executive Office of the President" Washington Campus, March 2005.

12. Memberships: (List all memberships and offices held in professional, fraternal, scholarly, civic, business, charitable, and other organizations.)

Member of Keshet Israel Synagogue, 1996 – 2001

Member of the Kemp Mill Synagogue, 2002 – current

Associate Member of the Young Israel Shomrei Emunah, 2003 – current

Former member of the Capitol Jewish Forum.

No offices held at any of the above

13. Political affiliations and activities:

a. List all public offices for which you have been a candidate.

None

b. List all memberships and offices held in and services rendered to all political parties or election committees during the last 10 years.

Bush/Cheney 2004 Re-Election Campaign; Deputy Director of Policy; Washington, DC; 06/2004 – 11/2004

Volunteer for John Ashcroft for Senate, 2000 campaign; took one week's vacation time to work on Jewish outreach in the campaign office in Missouri.

c. Itemize all political contributions to any individual, campaign organization, political party, political action committee, or similar entity of \$50 or more for the past 10 years.

Bush '04 - \$1018

Bush '00 - \$500

14. Honors and Awards: (List all scholarships, fellowships, honorary degrees, honorary society memberships, military medals, and any other special recognitions for outstanding service or achievement.)

Fellowships: University Fellow, University of Texas; Salvatori Fellow, Heritage Foundation; Publius Fellow, Claremont Institute; Herman Kahn Fellow, Hudson Institute; Claude R Lambe Fellow, Institute for Human Studies.

Young Leadership Award, American Friends of Lubavitch

15. Published writings: (List the titles, publishers, and dates of all books, articles, reports, or other published materials you have written.)

Books

Intellectuals and the American Presidency: Philosophers, Jesters, and Technicians, (Lanham: Rowman & Littlefield, 2002)

Dissertation: *Ideas in Action: The White House Intellectual*, 1996, University of Texas.

Articles

Review of Right Turns, *National Review Online*, January 28, 2005.

"A Rich Tradition," *National Review Online*, June 7, 2004.

Review of The Truth of Power: Intellectual Affairs in the Clinton White House, *The Wall Street Journal*, September 13, 2001.

Arthur Schlesinger, *Worthy Adversary*, *Policy Review*, February/March, 2001.

"My Boss the Fanatic," *The New Republic*, January 29, 2001.

"Ehud Barak, Arabist," *National Review online*, December 11, 2000.

"The Family Man," *National Review online*, December 1, 2000.

"The Desert Chamberlain," *National Review online*, November 29, 2000.

"Al Gore's Game of Life," *Rising Tide*, with James Carter, Fall 2000.

"Risky Schemes: Gore's Proposals Would Sure Make LBJ, FDR Proud," *Investor's Business Daily*, with James Carter, September 28, 2000.

"George W. and the Intellectuals," *Washington Times*, September 14, 2000.

Review of The Paradox of American Democracy : Elites, Special Interests, and the Betrayal of the Public Trust, *Perspectives in Political Science*, Spring, 2000.

"Does Public Care About Tax Cuts?" *Investor's Business Daily*, with James Carter, May 10, 2000.

"Flatten the IRS," *Investor's Business Daily*, with James Carter, January 7, 2000.

Review of Freedom From Fear, *Washington Times*, July 4, 1999.

"The Right Moment," Review of The Conservative Revolution, *The Wall Street Journal*, April 27, 1999.

"From Left to Right: The Punditry of Max Lerner," *The Weekly Standard*, March 8, 1999.

Review of Whatever It Takes, *Perspectives in Political Science*, Winter, 1997.

Review of Reconstructing America, *Washington Times*, November 1, 1997.

"Downsizing: Myth and Reality," *Journal of Commerce*, May 14, 1996.

Frequent book reviewer for the *Indianapolis Star* in 1995 and 1996; titles include Primary Colors, The Nightingale's Song, Showdown, On the Brink, Neo-conservatism, Partners in Power, and Storming the Gates.

"What Dole Might Have Told the NAACP," *Knight-Ridder News*, July 25, 1996.

"Prague-lodytes," *National Review*, October 19, 1992.

"An Intern's Eye View of Washington," *Washingtonian*, August, 1992.

"Faster Hollywood! Kill! Kill!" *Reason*, July/August, 1992.

Review of The Power and the Glitter, *Crisis*, September 1991.

"The Fanny Hill Phenomenon," *The American Enterprise*, March/April, 1991.

16. Speeches: (List all formal speeches you have delivered during the past five years which are on topics relevant to the position for which you have been nominated. Provide the Committee with **two** copies of each formal speech.)

I have given over 100 speeches over the last six years as a representative of the Bush Administration, from both the White House and the Department of Labor. While working for the Bush campaign from June to November of 2004, I also gave numerous speeches, largely to Jewish organizations.

Most common topics include:

- American Competitiveness Initiative- general talking points attached
- The President and the Jewish Community- general talking points attached
- The Bush Administration- general talking points attached

Formal speech given to NYU Law School at the NYU World Financial Policy Forum; 4/11/07- speech attached

I have also given the following speeches in my own name, and not representing the administration or the Bush campaign (not done from formal, prepared talking points):

"Intellectuals and the American Presidency" (book talk)

- The Heritage Foundation, May 16, 2002
- Helsing/Pinkerton Book Luncheon, May 16, 2002
- American Friends of Lubavitch, May 15, 2002
- American Enterprise Institute, May 18, 2002

"The Bush Administration,"

- The Limited, November 2004
- Columbus Bar Association, December 2004
- West LB Bank, December 2004
- Gerber Capital Management, January 2005
- Krupin-O'Brien, January 2005
- Stern College students, March 2005

"The Structure of the Executive Office of the President"

- Washington Campus, January 2005
- University of Pennsylvania in Washington, February 2005
- Washington Campus, March 2005

"Church-State Relations," (panel discussion), Jewish Council for Public Affairs, March 2005.

17. Qualifications: (State what, in your opinion, qualifies you to serve in the position to which you have been nominated.)

As the Deputy Assistant to the President for Domestic Policy, I have been responsible for managing strategy and policy processes for all domestic policy issues. I have worked to build consensus across the Administration in order to effectively implement the President's agenda.

While at the Domestic Policy Council, I have worked closely with HHS policy issues and initiatives – including health information technology; public health, disease prevention; fitness; food and drug regulation; welfare; and family services.

Previously, I served as Deputy Cabinet Secretary at the White House. In this role I was responsible for coordinating policy efforts and logistics with Cabinet agencies and White House offices.

I also have significant experience in managing regulatory policy at the cabinet level. While at the Department of Labor, I was responsible for overseeing the department's regulatory processes, including the review of existing and proposed regulatory efforts.

I have extensive speaking experience on behalf of the administration and feel that I am well prepared to represent Secretary Leavitt and the Department of

Health and Human Services in official capacity and public fora.

B. FUTURE EMPLOYMENT RELATIONSHIPS

1. Will you sever all connections with your present employers, business firms, associations, or organizations if you are confirmed by the Senate? If not, provide details.

Will continue relationship with present employer (the Federal government).
Otherwise, yes I will sever all connections, but have none.

2. Do you have any plans, commitments, or agreements to pursue outside employment, with or without compensation, during your service with the government? If so, provide details.

No.

3. Has any person or entity made a commitment or agreement to employ your services in any capacity after you leave government service? If so, provide details.

No.

4. If you are confirmed by the Senate, do you expect to serve out your full term or until the next Presidential election, whichever is applicable? If not, explain.

Yes.

C. POTENTIAL CONFLICTS OF INTEREST

1. Indicate any investments, obligations, liabilities, or other relationships which could involve potential conflicts of interest in the position to which you have been nominated.

To avoid any conflicts or appearance of conflicts, I have agreed to divest various holdings and take other action as outlined in my ethics agreement (attached).

2. Describe any business relationship, dealing or financial transaction which you have had during the last 10 years, whether for yourself, on behalf of a client, or acting as an agent, that could in any way constitute or result in a possible conflict of interest in the position to which you have been nominated.

None- but pursuant to my ethics agreement, I will consult with department ethics consultant to make sure no conflicts of interest arise.; however, this is the list of

clients I had during my brief career as a private consultant: Concepts Inc., The Limited Inc., Navigators Inc., Paramount Capital Inc., and Rabin, Sheves, Lipkin-Shahak & Birger Inc. (RSLB).

3. Describe any activity during the past 10 years in which you have engaged for the purpose of directly or indirectly influencing the passage, defeat, or modification of any legislation or affecting the administration and execution of law or public policy. Activities performed as an employee of the Federal government need not be listed.

None

4. Explain how you will resolve any potential conflict of interest, including any that may be disclosed by your responses to the above items. (Provide the Committee with **two** copies of any trust or other agreements.)

I do not believe there are any such conflicts of interest, but I will follow the advice of the Department's ethics officials should such potential conflicts arise.

5. **Two** copies of written opinions should be provided directly to the Committee by the designated agency ethics officer of the agency to which you have been nominated and by the Office of Government Ethics concerning potential conflicts of interest or any legal impediments to your serving in this position.

Attached.

6. The following information is to be provided only by nominees to the positions of United States Trade Representative and Deputy United States Trade Representative:

Have you ever represented, advised, or otherwise aided a foreign government or a foreign political organization with respect to any international trade matter? If so, provide the name of the foreign entity, a description of the work performed (including any work you supervised), the time frame of the work (e.g., March to December 1995), and the number of hours spent on the representation.

N/A

D. LEGAL AND OTHER MATTERS

1. Have you ever been the subject of a complaint or been investigated, disciplined, or otherwise cited for a breach of ethics for unprofessional conduct before any court, administrative agency, professional association, disciplinary committee, or other professional group? If so, provide details.

No

2. Have you ever been investigated, arrested, charged, or held by any Federal, State, or other law enforcement authority for a violation of any Federal, State, county or municipal law, regulation, or ordinance, other than a minor traffic offense? If so, provide details.

No

3. Have you ever been involved as a party in interest in any administrative agency proceeding or civil litigation? If so, provide details.

Yes. Civil suit of Cyril and Rama George in the D.C. Superior Court. They were tenants who defaulted on payment. Case filed 4/20/2000; court ruled in our favor on 1/11/01, but we were never paid.

4. Have you ever been convicted (including pleas of guilty or *nolo contendere*) of any criminal violation other than a minor traffic offense? If so, provide details.

No

5. Please advise the Committee of any additional information, favorable or unfavorable, which you feel should be considered in connection with your nomination.

None

E. TESTIFYING BEFORE CONGRESS

1. If you are confirmed by the Senate, are you willing to appear and testify before any duly constituted committee of the Congress on such occasions as you may be reasonably requested to do so?

Yes

2. If you are confirmed by the Senate, are you willing to provide such information as is requested by such committees?

Yes

Senate Finance Committee
Hearing on Nominations, Wednesday, July 25, 2007
Response to Questions for the Record, by Dr. Tevi Troy

The Honorable Chairman Baucus

1)

Question:

Dr. Troy, last week, former Surgeon General Richard Carmona said that the current administration repeatedly stopped him from bringing science based information to the public on major health care issues such as embryonic stem cell research, alternatives to abstinence only sex education, and the effects of second hand smoke. He went on to say that his speeches and reports were edited because they didn't fit the president's political agenda. What assurances do I have that you will ensure that the Department uses only the best science available to make policy decisions and will put the interests the Department's beneficiaries first? Will you remain independent and neutral in the face of political and industry pressure?

Answer:

I believe it is critical that policy decisions be guided by a full understanding of the best science available. If confirmed, one of my goals as Deputy Secretary would be to work to ensure that we use the best science and put beneficiaries first. I will continue to remain an independent actor.

The Honorable Senator Grassley

1)

Question:

Health information technology can play a major role in reducing medical errors and improving the quality of health care. You have helped with White House efforts to promote adoption of health IT. Many people believe that significant federal funding will be required for more widespread adoption of health IT by physicians and other providers. However, the Administration's position and that of the Department of Health and Human Services has been that providers should adopt health IT as a "normal cost of doing business" to ensure patients receive high quality care.

- How do you envision working with the Centers for Medicare and Medicaid Services to coordinate the Department's efforts to foster the adoption of health IT with CMS' efforts to improve quality in Medicare?
- Do you agree that more federal funding should be provided to encourage physicians and other providers to adopt health IT?
- From your vantage point, are there additional steps that you think Medicare could take to foster more widespread adoption of health IT, especially by physicians and other providers with small practices and those in rural areas with limited resources?

Answer:

If confirmed, I intend to make sure the President's executive order on health IT is fully implemented by CMS. I would work with CMS to develop the right incentives for adoption of health IT and evaluate the appropriate payment mechanisms for delivering those incentives.

I believe that continued federal investment is critical to the development and adoption of interoperable health IT. CMS is supporting the adoption and effective use of health information technology by physicians through the Doctor's Office Quality - Information Technology (DOQ-IT) project and Medicare Care Management Performance (MCMP) demonstrations, these demonstrations are efforts that I intend to support and develop as necessary. In addition, I plan to work with stakeholders and the Department to determine if there are additional steps that CMS could take to encourage more widespread adoption among small and rural providers.

2)

Question:

As Deputy Secretary, you would serve as the Chief Operating Officer for the Department of Health and Human Services. HHS is responsible for numerous programs intended for the health and well-being of all Americans. Policy decisions concerning the operation of HHS programs can result in different impacts for Americans in urban versus rural areas. This Committee has done much to ensure that Americans in rural areas benefit from HHS programs as much as those in urban areas.

As Deputy Secretary, how would you ensure that Americans in rural areas will benefit from HHS programs?

Answer:

This is a critical issue, and I am committed to ensuring that HHS continues to work to improve the health and well-being of Americans who live in rural areas. Today, a number of programs help rural areas. The Administration has invested significantly to expand the number of Community Health Centers and to support the National Health Service Corps, which provide significant assistance to rural areas. In addition, as you know, Medicare serves a significant amount of rural Americans, and I am committed to ensuring that Medicare and other HHS policy decisions constantly take into account the needs of rural patients, to ensure that they have access to quality and affordable health care. I am supportive of the work these and other programs are doing and hope to continue work to ensure that Americans in rural areas benefit from HHS programs.

3)

Question:

As Deputy Secretary, you would serve as the Regulatory Policy Officer for the Department of Health and Human Services. The work of this Department benefits all Americans and its regulations can significantly impact individuals and businesses alike. The regulatory process has not been without criticism. Some have voiced considerable concern about the regulations' development process and whether stakeholders are truly able to participate. Others are concerned that regulations may be burdensome and they actually pose barriers for affected parties to carry out their responsibilities.

As Deputy Secretary, how would you assess and, if necessary, reform the regulatory process at HHS?

Answer:

As you know, HHS conducts a broad range of programs mandated by Congress to protect and promote the health and well-being of all Americans, focused especially on those least able to help themselves. The Department's regulatory efforts include: Medicare, Medicaid, support for public health preparedness, biomedical research, substance abuse and mental health treatment, assurance of safe and effective drugs and other medical products, food safety, financial assistance to low income families, Head Start, services to older Americans, and direct health services delivery. I believe that we must ensure that these regulatory processes work efficiently and encourage public participation. If confirmed, I would work with each of the Department's operating divisions to ensure that these regulatory processes are as efficient and transparent as possible.

4)

Question:

As you may or may not know, there are two outstanding subpoenas at the HHS issued by the Committee, one of which requests documents and a privilege log of any documents that are withheld from the Committee and the other requests access to a line agent who is presently employed by the FDA.

We have been told that we may not have access to Agent Robert West because he is a line agent. HHS has articulated from time to time that this instruction is being given to HHS from, among others, the Department of Justice. However, I am troubled by this excuse because this Committee has had access to line agents in the past, including line agents at the FDA and at the FBI. In fact, Attorney General Gonzales himself confirmed last year when he testified before the Judiciary Committee that the Department of Justice has in the past provided to Congressional committees and their staff members, access to line attorneys, line FBI agents, assistant US attorneys and investigators.

- What is your position about this Committee receiving access to line agents at the HHS? Please be specific.

Answer:

I recognize that Congress has a strong interest in information that aids its legislative function. If confirmed, I am committed to finding ways to work with Congress to accommodate its needs, while protecting appropriate Executive Branch interests.

Question:

- I have asked for the names of the attorneys at both the HHS and the Department of Justice who are providing advice and counsel regarding this Committee's access to line agents, and to date we have not received those names. Please provide those names to us.

Answer:

I am not at the Department and am not familiar with the names of Justice Department or HHS attorneys who have been consulted. As I have stated, I am committed to finding ways to accommodate Congressional inquiries, and will look into this if confirmed.

Question:

- During the course of a meeting that I had at the HHS, when I requested access to Agent West, I was advised that Agent West could only speak to me if he formally declared himself a whistleblower under the law. Now that does not make sense to me. Why does a federal employee need to declare himself a whistleblower to talk to me; nonetheless that is what I was told. When I asked for an explanation, I was told that was what the Department decided. Accordingly, do you believe that a federal employee, who is a line agent, needs to declare himself or herself a whistleblower to speak to Congress? Please provide to me a detailed explanation of your position. In addition please set forth for me an outline and chronology of where that position came from, including who was involved in the development of that decision? Please be very specific.

Answer:

I do not believe that a federal employee who is a line agent needs to declare himself or herself a whistleblower to speak to Congress. With respect to your question on the Department's position, I was not at the Department at that time and am unfamiliar with the background behind the decision. As I have stated, I am committed to finding ways to accommodate Congressional inquiries.

Question:

- During your time in the White House, did you ever participate in any discussions addressing this Committee's ability to receive information from the HHS, including but not limited to the FDA and CMS? If so, please describe those discussions.

Answer:

No.

Question:

- Are you aware that in response to requests for documents, this Committee has received hundreds of pages stating that pages have been removed, such as "57 pages removed," or "43 pages removed?" Other documents have whole pages, paragraphs or sentences redacted with no explanation as to why. Sometimes documents are marked redacted; other times they are not marked, even when it is evident that information is missing. Do you think document submissions like these are responsive to Committee requests? Please explain in detail. What is your position on producing a privilege log of documents withheld and why? Will you commit to providing to the Committee a privilege log by September 1, 2007?

Answer:

I am not at the Department and am unfamiliar with the specific circumstances you describe. In general, I believe the Department should strive to find a way to provide the Committee with the information it needs to conduct oversight activity in aid of its legislative function, while also preserving the legitimate Executive Branch interests at stake. I commit to working with the Committee in ensuring that the Department is responsive to its requests, consistent with these principles. I believe there are ways to accommodate legitimate Congressional interests without compromising important Executive Branch interests. For example, there may be circumstances in

which providing a listing of withheld documents would meet the Committee's legitimate oversight needs.

5)

Question:

We are aware that a Memorandum of Understanding was executed some time ago between the Office of Inspector General at the Department of Health and Human Services and the Food and Drug Administration. Among other things that MOU transferred a number of responsibilities from the HHS OIG to the FDA. Questions have arisen as to whether or not FDA is notifying OIG about investigations to the extent promised in the MOU and whether or not FDA has been thorough and effective when investigating its own employees. Accordingly we would appreciate your responses to the following questions:

- Please describe for the Committee your views about the continued need for this MOU and whether or not it has been appropriately implemented?
- Are you aware of any issues that have come up regarding whether or not all appropriate cases have been referred to OIG, particularly all matters involving the potential violation of criminal conflicts of interest statutes by FDA employees? If so, please describe those issues in detail. Please determine whether or not all appropriate cases have been referred to HHS OIG pursuant to the MOU; particularly all matters involving the potential violation of criminal conflicts of interest statutes by FDA employees?
- What actions will you take to ensure that HHS OIG will have access to the docket of all FDA's cases so that it can be sure that it can provide the proper oversight and monitoring of FDA's compliance with the MOU? At this time the HHSOIG does not have access to the FDA docket.

Answer:

I am not familiar with the Memorandum of Understanding that you referenced. If confirmed, I would hope to review the MOU and any issues surrounding it in consultation with the HHS Office of Inspector General and the Food and Drug Administration, and seek the input of Congress, in order to ensure that the Memorandum of Understanding continues to serve its purpose and that it is being effectively implemented.

6)

Question:

The Senate Committee on Finance has an ongoing inquiry into allegations of mismanagement at the National Institute of Environmental Health Sciences (NIEHS), one of the institutes within the National Institutes of Health. This Institute falls directly under the purview of the HHS. Specifically, the press reported that the NIEHS director, David Schwartz, was allowed to testify in asbestos cases and made over \$150,000 while running the NIEHS. This occurred even after NIH supposedly strengthened their conflict of interest policies in 2004.

- Would you please share with the Committee your views regarding waivers being granted for the purpose of permitting federal employees to engage in outside activities? Do you believe there should be limitations on the amount of income an employee can receive

from outside entities while one is employed by the federal government? If so, what is that sum?

Answer:

First, I hold myself to the highest ethical standards and have similar expectations for those around me. As you know, under regulations promulgated by the Office of Government Ethics, federal employees are generally permitted to engage in certain, prescribed types of outside activities, after receiving permission to engage in such outside activities. There are important reasons that outside activities should be permitted, consistent with all legal and regulatory standards and subject to strong oversight. As you know, there are limits on income for certain levels of federal employees, which I believe is appropriate. If confirmed, I would consult with the Department's legal and ethics experts, as well as other interested parties, to further explore this issue.

Question:

- Do you believe that information regarding the outside activities and income derived by federal employees should be readily available to Congress and to the public? Please explain your position in detail.

Answer:

I believe that transparency is a critical principle that must inform any consideration of this issue. As you know, such information is publicly available for many federal employees today. I believe that we should seek to maintain a balance between the public's right to know and individual privacy.

Question:

- The Committee is reviewing, and has reviewed in the past, the outside activities of senior-level NIH employees, among other HHS officials. The HHS OIG found that between 2001 and 2003, 40 percent of NIH senior-level employees received approval for 319 outside activities, in which NIH officials were compensated for nearly half of those events. The OIG also determined that NIH's ability to review outside activities is limited. What is your position on HHS senior-level employees being paid for participating in outside activities such as teaching or consulting?

Answer:

I believe that outside activities, such as teaching, are important and should be permitted, consistent with all legal, ethical and regulatory standards and subject to strong oversight. If confirmed, I would consult with the Department's legal and ethics experts, as well as other interested parties, to further explore this issue.

Question:

- Do you believe that NIH and HHS have adequate mechanisms in place to ensure that senior-level officials involved in outside activities maintain impartiality in their Federal capacities? If yes-please explain; if not please identify what improvements you would like to implement.

Answer:

I am aware that NIH created new ethics regulations in August 2005 that sought to improve the ability to ensure and maintain appropriate ethical safeguards for employees. If confirmed, I would consult with the Department's legal and ethics experts, Congress and other interested parties, to assess the adequacy of these regulations.

The Honorable Senator Snowe

1)

Question:

Every child deserves nurturing parents and a safe and loving home to call their own. Unfortunately, there are thousands of children throughout the country whose parents are unable to care for them. Children shuffled around in foster care face emotional, behavioral and academic challenges. This situation is exacerbated by a shortage of licensed homes, and a child welfare workforce that experiences a turnover rate of 20 percent in public agencies and 40 percent in private agencies. Everyone can agree that the way we fund the Title IV-E Child welfare program is in desperate need of reform. Due to the eligibility restrictions linked to outdated pre-welfare reform income standards, the level of federal support for children through Title IV-E is consistently eroding away over time. Today, only 50 percent of all children in foster care are supported with federal funds based on current eligibility. Clearly we should improve this program to better suit the needs of the vulnerable children it serves. Several states have obtained federal waivers to test "assisted guardianship" programs as part of their efforts to help achieve more permanency in the foster care system. In fact, I have joined Senator Hilary Clinton in introducing legislation that gives grandparents and other relatives some of the same support and services that are currently available to foster parents. The Administration has long sought to block grant the Title IV-E Child welfare program, citing increased flexibility for states. Those opposed to the President's proposal argue that turning Title IV-E into a block grant will make it a vulnerable target for cuts in difficult budget years, citing the Administration's proposed cuts to the Social Services Block Grant over the past several years as a prime example. Simply maintaining the status quo on child welfare is just not good enough for these vulnerable children. As Deputy Secretary of Health and Human Services, how will you work to achieve meaningful progress on child welfare reform in the Administration's remaining 18 months in office?

Answer:

Title IV-E child welfare programs are an important element of the safety net and protect some of our most vulnerable citizens, abused and neglected children. If I am confirmed, I hope to work with Congress to improve these programs for children by increasing flexibility for States in using IV-E funds. The President's proposal for a Child Welfare State Option is one alternative that would assist states to stabilize the funding base for their child welfare systems while permitting them to fund preventive services that are not currently allowable within the program. In addition, I am very excited about the President's proposed research-based initiative to put nurses in the homes of first time mothers to provide social services and health counseling. This is the sort of experimental program that many States are incorporating in their child welfare efforts, but that Federal IV-E dollars are prohibited from funding. Clearly, financing for foster care, adoption assistance, and related child welfare programs must remain a federal priority, and I am committed to working with Congress to ensure that the vulnerable populations these programs serve are protected.

2)

Question:

Last August marked the 10 year anniversary of welfare reform. We can all agree that we want to build on the momentum of falling caseloads by transitioning families off welfare and into economic self-sufficiency. Yet it is not good enough simply to say we want to reduce the number of families on welfare. I believe that good jobs should be the priority – jobs that will lead toward financial independence and finally break the intergenerational cycle of dependency on public assistance. In order to accomplish this, we must give families the necessary tools to make them a success. For some people that means job training, for others, that could mean dealing with barriers to employment like substance abuse or domestic violence, and for others, that might mean access to education that will secure them a good job and that will get them off and keep them off of welfare. The Parents as Scholars program has been a success in Maine and has helped thousands of low-income parents to obtain a post-secondary degree and thereby significantly reduce their need for TANF in the future. I have concerns that there is a misunderstanding about how the program works. Last June, the preamble to the interim final rules regarding the TANF reauthorization stated that the “TANF program was never intended to be a college scholarship program for postsecondary education.” The Parents as Scholars program does not operate as a scholarship program, meaning it does not pay for the tuition of participants. Instead TANF funds are used to provide parents the supports, like child care and transportation, which they need to attend and stay in school. These are exactly the same types of supports as parents engaged in other “work activity” receive. Parents in the program take advantage of other sources of funding for tuition or take out loans. Assistance with tuition is provided in very rare occasions. Without the support services that parents receive, it would be impossible for them to juggle the responsibilities of caring for their children and school. In addition, the Deficit Reduction Act did not compel HHS to establish a definition of vocational educational training that excludes all baccalaureate degrees. How can HHS better incorporate education and training programs to truly help lift welfare families out of poverty?

Answer:

One of the most important goals of welfare reform was to help people become self sufficient. TANF has been a truly remarkable example of a successful federal-State partnership. Millions of parents have left welfare for work, reducing the TANF rolls by nearly 60 percent while also achieving great improvements in a range of outcomes for low-income families and children.. I appreciate your personal commitment to strengthening the TANF program, and agree that education can be an important component to help people achieve self sufficiency. If confirmed, I will work with Congress to ensure that States have the resources and flexibility they need to meet their TANF work participation requirements and build upon the program’s historic success improving outcomes for participants and their children.

Senate Finance Committee
Hearing on Nominations, Wednesday, July 25, 2007
Response to Questions for the Record, by Dr. Tevi Troy

The Honorable Senator Stabenow:

1)

Question:

The CDC-funded WISEWOMAN program currently provides free heart disease and stroke screening to low-income uninsured women in 14 states, including Michigan.

Since Congress established this program as a demonstration program in 1993, it has been very helpful in helping women reduce their risk for heart disease and stroke. In fact, 3 out of 4 women screened by the program have at least one risk factor for cardiovascular disease.

I believe we need to put more emphasis on prevention of disease by expanding the WISEWOMAN program to all 50 states, and I have introduced legislation, the HEART for Women Act, that would do that. What is HHS' plan for expanding this program?

I am concerned that only 13 states receive funding to actually implement state-tailored programs and only another 20 states receive planning grants under the CDC's State Heart Disease and Stroke Prevention Program, despite the fact that heart disease, stroke and other cardiovascular diseases remain the No. 1 killer in every state and we know how to prevent these often deadly and disabling diseases.

During the recently completed national competition for funds under this program, 49 states applied but only 33 states were funded. Michigan was one of the fortunate 4 states to be added to the program for a planning grant—the first states added to the program since 2002.

Please tell the Committee how HHS plans to make this program available to all 50 states?

Answer:

As you know, current legislation caps the number of WISEWOMAN sites. Next year, states will have the opportunity to re-compete for WISEWOMAN programs after a new Funding Opportunity Announcement is released.

Concerning CDC's State Heart Disease and Stroke Prevention Program, CDC has been able to provide funding to 33 states plus the District of Columbia. This is in addition to a new funding opportunity, called "Optional Funding for Capacity Building." This new award provides States the ability to support demonstration interventions and thereby reach more people. CDC has reported that Michigan is one of the states that has received an Optional Funding for Capacity Building award.

I share your commitment to addressing the risk of heart disease and stroke, and hope to continue work to accomplish this.

The Honorable Senator Cantwell:

1)

Question:

Mr. Troy, I have long been committed to supporting the health care workforce and encouraging education to strengthen the pool of people coming into the workforce. This will be an enormous challenge to the nation as baby boomers age and the need for care grows exponentially.

When I meet with hospital officials, they often tell me how the lack of allied health professionals affects the care that patients receive. I have introduced legislation to create greater opportunities in the allied health professions and improve patient care, spur job growth and help boost our economy.

I also sponsored the National Health Service Corps (NHSC) Loan Repayment Act to bring more doctors and nurses to rural and underserved communities.

There is more HHS can be doing both to serve rural and underserved areas and to prepare for the coming needs of the baby boomers.

What strategy would you pursue at HHS to ensure that patients, especially in rural and underserved areas, have access to a qualified health care workforce?

Answer:

If confirmed, I would work to continue the Secretary's focus of targeting HHS resources on those programs which have the most successful track record in improving and increasing health care services and personnel in our Nation's most underserved areas and communities. These efforts would include seeking increased resources to expand our Nation's system of Community Health Centers, including the extension of the Health Center Program into rural America through the high poverty initiative, and support for the National Health Service Corps (NHSC) and nursing programs that provide direct patient care in rural and underserved areas. Further, I believe it is vital that we continuously evaluate the current health care needs of our most vulnerable communities, and that health care plans and services be adjusted according to these needs and any other changes in their environment.

The Honorable Senator Ensign:

1)

Question:

We need to act quickly to complete the long overdue work to improve efficiencies and reduce medical errors. What is the most significant barrier to making the dramatic changes necessary?

Answer:

I share your commitment to improving the quality of health care for all Americans, and I believe there are key steps that we can take to accomplish this goal. One of these steps includes the passage of medical litigation reform, which the President has supported, consistent with legislation that you have proposed. We can also make steps through successful implementation of the Patient Safety and Quality Improvement Act of 2005, which was passed to remove barriers to a culture of quality improvement. Finally, I hope to continue work that is presently underway to support the development and adoption of interoperable health information technology that can improve health care quality.

2)

Question:

I believe we need to develop and encourage the use of best practices and clinical practice guidelines so that doctors and patients have the information they need to make appropriate clinical decisions. How can health information technology facilitate the use of best practices?

Answer:

As you know, the widespread adoption of interoperable health information technology holds significant potential to improve health care quality for all Americans. One of the many ways that such technology can improve health care quality is by including and reminders for providers based on consensus, scientifically-validated best practices and quality measures. I am excited by the potential of health IT to improve health care quality and look forward to working with Secretary Leavitt to continue to make progress in this area.

3)

Question:

I am concerned about the rising cost of health care. Altogether, medical liability adds billions to the cost of health care each year – which means higher health insurance premiums and higher medical costs for all Americans. The direct cost of medical liability coverage and the indirect cost of defensive medicine increase the amount the federal government must pay for Medicare, Medicaid, the State Children’s Health Insurance Program, Veterans’ Administration Health Care, health care for federal employees, and other government programs. What is the direct and indirect cost of our current medical liability system? What can be done to reduce the amount of taxpayer’ money the federal government spends in this area?

Answer:

I share your concern about the rising costs of health care. The current medical liability climate imposes significant costs on both public and private health care programs, whether through high medical liability insurance premiums that increase overhead, or through encouraging defensive medicine practices. Perhaps even more important than the direct costs imposed by the system are the perverse incentives that prevent the sharing of information vital to eliminating the medical errors that cause patient injury. Furthermore, the medical liability system is costly, combative, time consuming, and fails to compensate patients injured by medical errors in a timely fashion.

The President supports meaningful liability reform that puts patients rather than lawyers first; that provides quick compensation for injured patients; that encourages the open sharing of information needed to prevent medical errors and improve quality of care; and that discourages frivolous lawsuits that drive up costs and hamper caring hands from delivering the right care at the right time.

4)

Question:

I am interested in the President’s proposal to expand Health Savings Accounts (HSA). The President’s proposal would make these accounts more accessible to individuals with lower incomes, and more portable so that both the HSA and the high-deductible health plan can go with a person when they change jobs or move. Las Vegas is booming in terms of population growth. What do you think needs to take place to ensure that Americans moving to Nevada can bring their HSA and high-deductible health plan with them? In addition, it appears to me that the bulk of the HSA business is with plans and national brokers. How can further encourage the HSA concept in the small business community?

Answer:

I share your interest in ensuring the availability of affordable, quality health care, and agree that health savings accounts (HSAs) can play a key role in this effort. Health care costs continue to rise rapidly in the United States. Empowering health care consumers, rather than third party payers, to play a more direct role in their health care decisions would help to stem this trend. A health care system that is more market-oriented and consumer driven will help control costs and result in health care that is more affordable and accessible. This goal can be facilitated by making HSAs more flexible and increasing the incentive for individuals to change to HSA-eligible coverage.

In fact, your question focuses on one of the principal advantages of HSAs over non-HSA coverage – the HSA’s portability. The workforce in the U.S. is much more mobile than in other industrial countries. Under traditional health coverage, an employee must adapt to a whole new regime when he or she goes to another job. With an HSA, the individual’s account balance can be used wherever the individual may work or live.

**Senate Finance Committee
Nomination Hearing
July 25, 2007
Additional Question for the Record for Mr. Troy**

Question from Senator Salazar

- 1) With respect to the Medicare Part D program, there have been concerns about turnaround for pharmacy reimbursement from the plans participating in the program. This is extremely important for small community and rural pharmacies that need these funds to remain financially stable. I have heard from several Colorado pharmacies who feel strained by the slow reimbursement. One even closed its doors. I have worked with my colleagues on several legislative proposals to improve these payment guidelines, including requiring the plans to reimburse pharmacies within 14 days of the billing being submitted. Do you believe the Medicare Part D program and the plans participating in it could improve their pharmacy reimbursement deadlines? I know in Colorado our Medicaid program is able to provide prompt payments, so I would think private plans could do the same.

Answer: I share your concern about the importance of prompt payment. As you know, Medicare Part D is a market-based program that relies on private insurance companies to deliver prescription drug benefits to Medicare beneficiaries. If confirmed, I would look into this issue to ensure that Plan sponsors are honoring their contracts, although we should not dictate specific payment terms.

**Statement for
Kerry N. Weems
Nominee for Administrator for the Centers for Medicare & Medicaid Services
Before the Senate Committee on Finance
July 25, 2007**

Chairman Baucus, Senator Grassley, thank you for holding this hearing today, and for the Committee's consideration of my nomination to be Administrator of the Centers for Medicare & Medicaid Services. I am Kerry Weems, a 24-year veteran of the Department of Health and Human Services.

Recently, my wife Jean and I celebrated our 23rd wedding anniversary. Over those 23 years, she has stood by me—even after hearing for the thousandth time: "I'll be leaving in another 15 minutes." I would also like to introduce the rest of my family to the Committee. Peter is a senior at James Madison University. Claire is a sophomore at George Mason University. Anna will commence her senior year in high school this August.

I have worked with many of you, who know me from both Republican and Democratic Administrations. I was first hired under President Reagan in 1983. I became a manager during President George H.W. Bush's Administration. Former HHS Secretary Donna Shalala signed my appointment to the Senior Executive Service, and President Clinton awarded me the Presidential Rank Award. Former Secretary Thompson promoted me to Deputy Assistant Secretary for Budget, and from January 2003 to July 2005, I served as Acting Assistant Secretary for Budget, Technology and Finance and as HHS Chief Financial Officer. Most recently, I was Deputy Chief of Staff to HHS Secretary Mike Leavitt.

It's a privilege to be here today applying for the job of CMS Administrator. One of the strengths I bring to this job is the ability to manage enormous budgets effectively. CMS spends more than \$600 billion a year—more than Defense; more than many countries of the world.

CMS determines access to health care for more than 90 million beneficiaries. Its payment decisions determine the quality of that health care and where and how that care is provided.

CMS's regulatory power is enormous, reaching into practically every aspect of health care. Small programmatic changes can have large consequences to individual providers. This is not simply a question of CMS flexing its regulatory muscle, it's also a question of being aware of these consequences. Indeed, many on this Committee have urged me to be sensitive to CMS regulations on a wide range of providers. Much more is at stake than economics or politics—beneficiaries' health and lives depend on them.

The person who steps into the Administrator's post also needs to have a broad, **nonpartisan** understanding of health care delivery in this country, and where we need to go. **Almost a quarter century of working at HHS has given me a long-term perspective that I believe is critical to leading CMS.**

There has been a lot of change in health care in my 24 years of service. When I began at the Social Security Administration, there was an ashtray on every desk and smoking in every office. Today CMS has a nationwide prevention initiative, including smoking cessation counseling.

When I started at HHS, the ink was barely dry on diagnostic-related groups. Today, CMS is moving beyond DRGs—replacing volume-based payment systems with systems that recognize a patient's condition and the quality of their care. For example:

- On July 1, CMS began the **Physicians Quality Reporting Initiative** to reward physicians for reporting on quality care.
- I hope to be able to send to this Committee a CMS plan for **Value-Based Purchasing in the hospital setting**.
- Secretary Leavitt is making great progress with standards and certification for **electronic health records**.

I am aware that this Committee and others have been frustrated with lack of resolution and consistent information regarding the Medicare Part D premium withhold. **Mr. Chairman and Senator Grassley, if I am confirmed, you will have the same information that I do, and I will make it a top priority to fix these problems.**

Much attention has been devoted to the baby-boom generation and its imminent retirement. However, before they can retire, the boomers have one great task ahead of them—caring for the generation which preceded them. My own family offers examples of the issues these generations face.

My father is on the Medicare prescription drug program and hit the coverage gap this last year. He and I worked together to get him the coverage and medications best for him. **My vision for the prescription drug program is that every beneficiary and their caregivers have the information they need to choose the best plan and get the best care they need.**

My mother may soon be faced with the need for a particular surgery. My vision for our health system is that she—and every patient—has the right information to choose care that is accessible, coordinated, and effective; and in the most appropriate setting.

My wife and her sister are caregivers for their mother who resides in a nursing home. Recently my mother-in-law was injured, yet my wife has not received a satisfactory explanation from this particular facility, despite a request for a detailed incident report.

My vision for Medicare and Medicaid is one in which beneficiaries are protected—whether from unsafe nursing homes, unscrupulous insurance salespeople, fraudulent equipment providers or bad medicine. **If confirmed, I will intensify CMS oversight, and I expect you to hold me responsible for acting on abuses or inefficiencies discovered in the course of program oversight.**

Throughout my more than two decades of public service at HHS, I have witnessed tremendous talent and dedication at HHS and CMS. I have learned to seek out experts and all those with equities in the issue and listen to them, to follow the law, to weigh the evidence and the facts, and to render a decision. **My pledge to you today is that I will pursue the facts and the law to guide my decisions and leadership.**

Again, let me say it is an honor to have received the President's nomination to this position. I would be pleased to answer any questions at this time.

###

7.

8. Education: (List secondary and higher education institutions, dates attended, degree received, and date degree granted.)

Secondary School: San Marcos Baptist Academy, San Marcos, Texas
September 1970 – June 1974, High School Diploma

College: New Mexico State University, Las Cruces, New Mexico
September 1974 – December 1978, BA and BBA

University of Texas, Austin, Texas
September 1979 – December 1979
(work toward MBA)

University of New Mexico, Albuquerque, NM
June 1980 – May 1981, MBA

George Mason University, Fairfax, Virginia
August 1984 – May 1987
(additional graduate work in economics)

9. Employment record: (List all jobs held since college, including the title or description of job, name of employer, location of work, and dates of employment.)

United States Senate:

Senator Harrison Schmitt, Legislative Assistant, May 1981 – August 1982

Senate Committee on Appropriations, L/HHS/E Subcommittee,
Professional Staff member, August 1982 – February 1983.

United States Department of Health and Human Services:

Social Security Administration, Budget Analyst/Program Analyst, May
1983-August 1988

Office of the Secretary, Office of Budget:

Program Analyst, August 1988-April 1991

Chief, Budget Planning Branch April 1991 – May 1994

Acting Director, Division of Budget Planning and Management,
May 1994 – March 1996

Director, Division of Budget Planning and Management,
March 1996 – January 2001

Acting Deputy Assistant Secretary for Budget, January 2001 – June
2002

Deputy Assistant Secretary for Budget, June 2002 – January 2003.

Office of the Assistant Secretary for Budget, Technology and Finance
Acting Assistant Secretary/Principal Deputy Assistant Secretary,
January 2003 – July 2005.

Immediate Office of the Secretary
Deputy Chief of Staff, March 2005 – present.

All employment was in Washington, DC with exception of the period May 1983 -
March 1985 which was in Baltimore, MD.

10. Government experience: (List any advisory, consultative, honorary, or other part-time service or positions with Federal, State or local governments, other than those listed above.)

Same as above

11. Business relationships: (List all positions held as an officer, director, trustee, partner, proprietor, agent, representative, or consultant of any corporation, company, firm, partnership, other business enterprise, or educational or other institution.)

Montessori School of Northern Virginia. My children attended pre-school, and I served on the board in the mid-90's. I no longer have a relationship with the school.

12. Memberships: (List all memberships and offices held in professional, fraternal, scholarly, civic, business, charitable, and other organizations.)

Sideburn Run Recreation Association (neighborhood pool and recreation association. Open membership.) I've been a member since 1989 and served on the board of directors 1996 - 2000.

American Association of Program and Budget Analysts. I was a member and served on the board from March 2001 to March 2002.

13. Political affiliations and activities:

- a. List all public offices for which you have been a candidate.

None

- b. List all memberships and offices held in and services rendered to all political parties or election committees during the last 10 years.

None

- c. Itemize all political contributions to any individual, campaign organization, political party, political action committee, or similar entity of \$50 or more for the past 10 years.

None

14. Honors and Awards: (List all scholarships, fellowships, honorary degrees, honorary society memberships, military medals, and any other special recognitions for outstanding service or achievement.)

Presidential Rank Award, awarded by the President of the United States for "sustained superior accomplishments" – 2000

Senior Management Citation, awarded by the Secretary of HHS "in recognition of outstanding leadership" – 1993

15. Published writings: (List the titles, publishers, and dates of all books, articles, reports, or other published materials you have written.)

"Disabled Worker Beneficiaries and Disabled SSI Recipients: A Profile of Demographic and Program Characteristics" (with John McCoy) Social Security Bulletin, May 1989

16. Speeches: (List all formal speeches you have delivered during the past five years which are on topics relevant to the position for which you have been nominated. Provide the Committee with **two** copies of each formal speech.)

I have not given what I would call formal speeches. Over the course of my career, I have given a large number of informal talks. Most of these have been to HHS employees, other Federal employees, including Congressional staff, Native American groups, and educational groups. Typically the talks have been on budget issues or on budget and performance linkage. None involved prepared remarks beyond an outline or talking points.

17. Qualifications: (State what, in your opinion, qualifies you to serve in the position to which you have been nominated.)

I have been employed by the Department of Health and Human Services for 24 years. During that time it has been my privilege to lead the management of the HHS budget, to act as the Department's chief financial officer, and to assist in managing the day-to-day operations of HHS. I possess the experience of effectively managing large budgets and large organizations as well as extensive experience helping shape health and public health policy.

B. FUTURE EMPLOYMENT RELATIONSHIPS

1. Will you sever all connections with your present employers, business firms, associations, or organizations if you are confirmed by the Senate? If not, provide details.

My present employer is the US Department of Health and Human Services, so I will not sever that relationship.

2. Do you have any plans, commitments, or agreements to pursue outside employment, with or without compensation, during your service with the government? If so, provide details.

No

3. Has any person or entity made a commitment or agreement to employ your services in any capacity after you leave government service? If so, provide details.

No

4. If you are confirmed by the Senate, do you expect to serve out your full term or until the next Presidential election, whichever is applicable? If not, explain.

Yes

C. POTENTIAL CONFLICTS OF INTEREST

1. Indicate any investments, obligations, liabilities, or other relationships which could involve potential conflicts of interest in the position to which you have been nominated.

See attached ethics agreement.

2. Describe any business relationship, dealing or financial transaction which you have had during the last 10 years, whether for yourself, on behalf of a client, or acting as an agent, that could in any way constitute or result in a possible conflict of interest in the position to which you have been nominated.

None

3. Describe any activity during the past 10 years in which you have engaged for the purpose of directly or indirectly influencing the passage, defeat, or modification of any legislation or affecting the administration and execution of law or public policy. Activities performed as an employee of the Federal government need not be listed.

None

4. Explain how you will resolve any potential conflict of interest, including any that may be disclosed by your responses to the above items. (Provide the Committee with **two** copies of any trust or other agreements.)

See attached ethics agreement.

5. **Two** copies of written opinions should be provided directly to the Committee by the designated agency ethics officer of the agency to which you have been nominated and by the Office of Government Ethics concerning potential conflicts of interest or any legal impediments to your serving in this position.

See attached ethics agreement.

6. The following information is to be provided only by nominees to the positions of United States Trade Representative and Deputy United States Trade Representative:

Have you ever represented, advised, or otherwise aided a foreign government or a foreign political organization with respect to any international trade matter? If so, provide the name of the foreign entity, a description of the work performed (including any work you supervised), the time frame of the work (e.g., March to December 1995), and the number of hours spent on the representation.

N/A

D. LEGAL AND OTHER MATTERS

1. Have you ever been the subject of a complaint or been investigated, disciplined, or otherwise cited for a breach of ethics for unprofessional conduct before any court, administrative agency, professional association, disciplinary committee, or other professional group? If so, provide details.

No.

2. Have you ever been investigated, arrested, charged, or held by any Federal, State, or other law enforcement authority for a violation of any Federal, State, county or municipal law, regulation, or ordinance, other than a minor traffic offense? If so, provide details.

No.

3. Have you ever been involved as a party in interest in any administrative agency proceeding or civil litigation? If so, provide details.

No.

4. Have you ever been convicted (including pleas of guilty or *nolo contendere*) of any criminal violation other than a minor traffic offense? If so, provide details.

No.

5. Please advise the Committee of any additional information, favorable or unfavorable, which you feel should be considered in connection with your nomination.

None

E. TESTIFYING BEFORE CONGRESS

1. If you are confirmed by the Senate, are you willing to appear and testify before any duly constituted committee of the Congress on such occasions as you may be reasonably requested to do so?

Yes.

2. If you are confirmed by the Senate, are you willing to provide such information as is requested by such committees?

Yes.

Senate Finance Committee
Hearing on Nominations, Wednesday, July 25, 2007
Response to Questions for the Record, by Kerry Weems

The Honorable Chairman Baucus

1)

Question:

Are you familiar with the CMS Care Management for High Cost Beneficiaries Demonstration?
How are the awardees performing under this initiative?

Answer:

This demonstration consists of six different projects and care management models, one of which has notified CMS of its desire to terminate participation in the demonstration. So far, overall savings in claims costs are substantially lower than the fees paid to date.

2)

Question:

What trends has CMS seen to date under the Demo regarding (a) utilization of hospital admissions and ER visits, and (b) savings in hospital and ER claims costs?

Answer:

To date, CMS has limited data on performance with respect to reductions in hospital admissions, emergency department visits, and savings in hospital and ER claims costs.

3)

Question:

It is my understanding that because the patients in the target population of the demonstration are some of the sickest and frailest Medicare beneficiaries, there has been a greater attrition rate than other demonstration projections. In order for the demonstration to produce viable results, isn't it important for the enrollment to remain at the original level of approximately 15,000 beneficiaries? Would you require any additional authority to approve the enrollment of additional patients in the Demonstration?

Answer:

The number of beneficiaries participating in this demonstration varies widely from site to site. Of the five sites that are continuing in the demonstration, three are provider-based organizations with between 2,000 and 5,000 beneficiaries each. Their performance is being measured by comparing Medicare claims costs of beneficiaries in the treatment group with Medicare claims costs of beneficiaries in similar practices to the demonstration providers. The remaining two sites use randomization to establish treatment and control groups whose Medicare claims costs will be compared. One of these projects has a treatment group population of about 4,000 beneficiaries; the other has a treatment group population upwards of 20,000 beneficiaries.

I understand that CMS does not have any readily available evidence that the attrition rate for beneficiaries in this demonstration is higher than that of beneficiaries in other care management, care coordination or disease management demonstrations or pilots currently being conducted by CMS. I have been told that the sample sizes for all of these projects are sufficient to allow for a meaningful evaluation of the effectiveness of the demonstration interventions. CMS has

authority to increase the number of beneficiaries participating in these projects if it were necessary to ensure the validity and reliability of our evaluation of the demonstration.

4)

Question:

In light of CMS' proposed NCD for ESAs, what plans does CMS have to ensure that enough blood is available to allow for the management of chemotherapy- induced anemia through blood transfusions for Medicare beneficiaries with cancer in the absence of ESA therapies? Does CMS plan to create a special reserve of blood for Medicare beneficiaries and if so, how many units does it plan to dedicate to Medicare beneficiaries with cancer? Please detail those plans and address variations in blood usage in different geographic areas and, in some instances, during certain times of the year.

Answer:

The safety of Medicare beneficiaries is paramount to this Administration. That is why CMS promptly opened this NCD, in response to the FDA Black Box warning, to assess whether there is sufficient evidence to conclude that ESA treatment is not reasonable and necessary for beneficiaries with certain clinical conditions, either because of a deleterious effect of the ESA on their underlying disease or because the underlying disease increases their risk of adverse effects related to ESA use.

As you know, the public comment period for the proposed NCD closed on June 13, 2007. Input on the proposed NCD was received from interested public parties on all sides of this issue, including the physician community, patient groups, and manufacturers. Currently, CMS is carefully reviewing all of the comments and will take them into account in developing the final NCD, which has a statutory due date of August 12, 2007. Although CMS has not yet released the final NCD, I understand that the Agency does not anticipate the need for an increase of blood transfusion because of the NCD.

5)

Question:

What impact on the hospital in-patient system does CMS project resulting from requiring tens of thousands of Medicare beneficiaries with cancer currently treated in the ambulatory treatment setting to treat their anemia with blood transfusions, requiring a 6-8 hour hospital visit every 2-3 weeks? Has CMS considered the impact on Federal spending by cost-shifting cancer patients from the ambulatory to the in-patient setting?

Answer:

Please be assured that CMS is carefully reviewing all of the comments submitted on the proposed NCD and will take them into account in developing a final NCD. Although CMS has not yet released the final NCD, I understand that the Agency does not anticipate the need for an increase of blood transfusion because of the NCD, nor does the Agency expect a shift from the ambulatory to inpatient setting for treating cancer patients.

6)

Question:

Does CMS intend to shift cancer care out of the community, ambulatory setting and back to the hospital? Does CMS believe that an acute care hospital is a better setting for the treatment of cancer patients than the community setting? What are CMS' projected increases to Medicare Part A and the Part B HOPPS resulting from this forced shift of service? What are CMS' projected

increases to Medicare payments for blood transfusions and iron toxicity treatments as a result of this change?

Answer:

Please be assured that CMS is carefully reviewing all of the comments submitted on the proposed NCD and will take them into account in developing a final NCD. Although CMS has not yet released the final NCD, I understand that the Agency does not anticipate a shift in cancer care from the community and ambulatory settings to the hospital as a result of the NCD. Thus there would be no changes to projected spending in inpatient or outpatient spending or transfusions and iron toxicity treatments.

7)

Question:

What accommodation will CMS make to ensure that cancer patients receive the ESAs CMS believes are safe for their use during the period CMS administrative personnel deem necessary to put in place a CED program?

Answer:

The public comment period for the proposed NCD closed on June 13, 2007. Input on the proposed NCD was received from interested public parties on all sides of this issue, including the physician community, patient groups, and manufacturers. Input was received on the issue you raised. Currently, CMS is carefully reviewing all of the comments and will take them into account in developing the final NCD.

8)

Question:

Is CMS aware that the length of chemotherapy regimens often exceeds 12 weeks? Is there evidence to show that chemotherapy-induced anemia is no longer likely after 12 weeks of chemotherapy?

Answer:

CMS has not yet released the final NCD for use of ESAs in cancer and related neoplastic conditions. I understand that input on these points was received during the public comment period. CMS is carefully reviewing the comments received and will take them into account in developing a final NCD, which has a statutory due date of August 12, 2007.

Is CMS aware that many cancer patients who receive chemotherapy require more than one course of chemotherapy? Is there evidence to show that chemotherapy-induced anemia is not likely in a second or subsequent course of chemotherapy?

Answer:

CMS has not yet released the final NCD for use of ESAs in cancer and related neoplastic conditions. I understand that input on these specific points was received during the public comment period. CMS is carefully reviewing the comments received and will take them into account in developing a final NCD, which has a statutory due date of August 12, 2007.

9)

Question:

What accommodation will CMS make in its NCD to allow cancer patients living at high altitudes to utilize ESA therapy at the initiation point their physicians believe is best for them?

Answer:

Input on the proposed NCD was received from interested parties during the public comment period. This input will be taken into account as CMS develops a final NCD, which has a statutory due date of August 12, 2007.

10)

Question:

Yesterday, the GAO General Counsel sent a letter to Secretary Leavitt questioning the legality of the Section 1115 waivers that Secretary Leavitt has granted to Florida and Vermont for their Medicaid programs. GAO found that the waivers inappropriately waived Medicaid requirements for medically necessary care and requirements for cost-sharing and allowed questionable financing arrangements. I have long had concerns about HHS' Medicaid waiver policy and GAO's letter is alarming. What will you do as CMS Administrator to correct the problems GAO has identified with the Florida and Vermont Medicaid waivers? Will you commit to me that these problems will be addressed?

Answer:

I have not seen the letter from the GAO General Counsel to Secretary Leavitt. I will carefully review the letter and look into the concerns it raises. I will address any problems that I determine need to be addressed.

11)

Question:

The CMS Administrator is above all responsible for protecting beneficiaries. So it concerns me when CMS officials promote political ideas, with little regard for protecting beneficiaries. Recently I've seen CMS express bias for private plans, provide lax oversight, and act more like a partner rather than a regulator. What assurances do I have that as CMS Administrator you will lead the agency in putting beneficiaries first? Will you remain independent and neutral as Congress considers alternative policies affecting Medicare and private plans?

Answer:

If confirmed as Administrator, my role will be to put beneficiaries first. I can pledge to you that their interests will guide me in any decisions that I make.

12)

Question:

Mr. Weems, can you tell me how you will ensure that all contractors will meet the mission of the agency? How many contractors does the agency have? How will you personally ensure that the agency will solve outstanding problems with premium withholding and disenrollment associated with prescription drug and Medicare Advantage plans? What will you do to reign in the abusive marketing tactics of private fee-for-service plans?

Answer:

Although health care delivery in the United States has evolved with four decades of advances in medicine and technology, the contracting portion of Medicare's FFS administrative structure has not. The reforms mandated by Congress in the Medicare Modernization Act of 2003 grew out of the gradual realization that Medicare's ability to deliver more efficient and effective services to beneficiaries and health care providers and meet future programmatic challenges is hampered by a number of restrictions and weaknesses in the current administrative system. Section 911 of the MMA contains several important changes to Medicare's administrative structure that will make

contracting dynamic, competitive, and performance-based and ensure the program is more responsive to the needs of its beneficiaries and health care providers.

In the current environment, CMS continues to focus on oversight of Medicare contractor operations and activities. CMS is continuously develops, refines, and improves the methodologies for populating review teams, refines and updates the Contractor Performance Evaluation (CPE) reviews protocols, and identifies improved methodologies for drawing CPE review samples. Contractor oversight will be further improved by the centralization of evaluation results to an "Evaluation Results Data Repository" maintained by CMS. Contracting reform is expected to increase competition among Medicare contractors and result in service improvements for Medicare providers and beneficiaries and the Medicare program.

Number of contractors: At present, CMS contractors include 23 fiscal intermediaries (FIs) and 17 carriers that process FFS claims. FIs process claims for Medicare Parts A and B for facilities and carriers process claims for Medicare Part B, in particular for physician, laboratory and other services. In addition, four fiscal intermediaries serve as regional home health intermediaries (RHHIs) and four carriers serve as durable medical equipment regional carriers (DMERCs). To date, four DME MAC contracts have been awarded. Three have successfully completed their implementation/transition activities and are fully operational; the fourth is currently in the implementation/transition phase. The first A/B MAC began claims processing operations on September 30, 2006.

As we work to fully implement our contracting reform initiative, CMS will reduce its number of contracts from 40 to 15. Contracting reform represents a fundamentally new approach to working with the Medicare contractors that provide Medicare claims processing services. Instead of managing 40 cost-based contracts, CMS will manage 15 truly competitive, performance based contracts for new entities known as Medicare administrative contractors or MACs.

These 15 MAC contracts will integrate Part A and Part B claims processing workloads (that is, these contractors will handle both hospital and physician payments). In addition, CMS plans to have four contractors administer payments to home health and hospice providers, and four contractors administer payments to durable medical equipment suppliers. Successful implementation will result in substantial Medicare trust fund savings from more accurate and effective payments.

In addition, CMS has a national network of 53 Quality Improvement Organizations (QIOs), responsible for each U.S. state, territory, and the District of Columbia. QIOs work with consumers and physicians, hospitals, and other caregivers to refine care delivery systems to make sure patients get the right care at the right time, particularly patients from underserved populations. The Program also safeguards the integrity of the Medicare trust funds by ensuring that payment is made only for medically necessary services, and investigates beneficiary complaints about quality of care.

Finally, CMS contracts private health plans to offer benefits under the Medicare Advantage and Part D prescription drug benefit.

Premium withhold: I am personally committed to improving business processes within CMS such as premium withhold by taking a top-down review. CMS takes the premium withhold issues very seriously, and has been working to resolve all outstanding 2006 issues, as well as to implement changes to the premium withhold process to ensure that such problems do not occur

again. Our primary concern on both premium withhold is ensuring that beneficiaries swiftly receive benefits to which they are entitled.

Marketing oversight: Effective oversight of marketing activities requires collaboration between CMS and the States. To that end, we have partnered with the National Association of Insurance Commissioners to develop a memorandum of understanding (MOU) that facilitates information exchanges and enforcement collaboration between CMS and State departments of insurance.

13)

Question:

Mr. Weems, I would like to discuss CMS' proposed changes for hospital payment rates in 2008. CMS proposed to improve the hospital payment system in 2008 by providing higher payments to hospitals that treat sicker patients. While I commend this, I am concerned that CMS also proposes to cut hospitals by 4.8% over the next two years. This cut is based on CMS' speculation of how hospitals will behave under the new payment rules and could be detrimental to hospitals, particularly in rural areas. Senator Grassley and I wrote to CMS urging the agency not to make these cuts, as did 63 other Senators. Given this level of concern, we would appreciate your comments on this topic.

Answer:

The proposed rule, which was released on April 13, builds on the framework established over the last few years to implement the most significant revision of Medicare's inpatient hospital rates since 1983. The rule proposes to improve payment accuracy under Medicare's hospital inpatient prospective payment system (IPPS) by adopting Medicare Severity Diagnosis-Related Groups, or the MS-DRGs, which would increase the total number of DRGs from 538 to 745. I understand that the CMS Office of the Actuary determined that such a significant expansion in the number of DRGs could lead hospitals to improve coding and documentation in order to have a case group assigned to a DRG with a higher payment. As discussed in the proposed rule, without an adjustment to the IPPS rates to account for this expected case mix growth, the change to these severity-based DRGs would not be budget neutral. Because the Social Security Act requires that CMS not increase or decrease payments when making modifications to the DRG system, the rule included a proposed budget neutrality adjustment.

I am aware that many in Congress have expressed concerns regarding this adjustment. As you know, the public comment period on the proposed rule closed on June 12, 2007. CMS is currently in the process of reviewing all the comments submitted, taking them into account in drafting the final rule, which will be published August 1. I expect the final rule will strive to achieve a balance between the comments received and the Agency's obligation to comply with the statute and safeguard the Medicare Trust Funds.

The Honorable Senator Grassley

1)

Question:

The Tax Relief and Health Care Act which passed in December eliminated the five percent cut in physician fees scheduled to take effect in January and froze physician fees at the 2006 level. CMS has estimated that the Medicare physician fee update for 2008 will be -9.9 percent. The current physician payment sustainable growth rate formula, known as the SGR, is fundamentally flawed. We know that fixing the SGR formula permanently will cost hundreds of billions of dollars. How would you envision reforming Medicare physician payment in a fiscally responsible way?

More specifically, please give us your views on whether you would favor retaining the SGR formula as is, revise the SGR formula, or adopt a different method to update physician fees in the Medicare program. If you believe Congress should revise the SGR formula or adopt a different method for updating physician fees in the Medicare program, please provide specifics.

Answer:

Over the last five years, Congress has intervened to prevent the implementation of the negative updates resulting from this formula. CMS will continue working with Congress as well as physician groups to identify payment methods that help improve the quality and efficiency of care in a way that does not increase costs for taxpayers or Medicare and its beneficiaries. The Medicare program needs to compensate physicians appropriately for the services they provide to Medicare beneficiaries, while balancing how the program pays. CMS believes that the early work on the Physician Quality Reporting Initiative program is one of those reforms that could help lead us to a point where we can promote improved quality and efficiency in patient care.

2)

Question:

Health information technology can play a major role in reducing medical errors and improving the quality of health care. However, the position of the Administration and the Department of Health and Human Services has been that providers should adopt health IT as a "normal cost of doing business" to ensure patients receive high quality care.

Recently, HHS announced that only ten percent of physician offices have adopted electronic health record systems that meet Institute of Medicine criteria.

- As CMS Administrator, how would you coordinate CMS' efforts to improve quality in Medicare with H-H-S' efforts to foster the adoption of health IT?

Answer:

First of all, if confirmed, I intend to make sure the President's executive order on health IT is fully implemented by CMS. Second, I would make full use of CMS demonstration authority to develop the right incentives for adoption of health IT, and evaluate the appropriate payment mechanisms for delivering those incentives.

- What steps would you plan to take with the Physicians Quality Reporting Initiative, or PQRI, to foster more widespread use of health IT? Do you support providing incentives for structural measures, such as use of electronic health records and e-prescribing, by physicians and other health professionals?

Answer:

The PQRI establishes a financial incentive for eligible professionals to participate in a voluntary quality reporting program. CMS is currently working with physician specialty groups to develop the expanded set of PQRI measures for 2008, and to meet the statutory requirement of including structural measures, such as the use of electronic health records or electronic prescribing technology. CMS recently proposed the addition of structural measures in the proposed Medicare Physician Fee Schedule for Calendar Year 2008, and is also exploring the possibility of opening registry-based and EHR-based reporting for 2008. I look forward to working with you on exploring the feasibility of including these measures in PQRI.

- What additional steps do you think Medicare could take to encourage more physicians to adopt health IT, especially physicians in small or solo practices and those in rural areas with limited resources?

Answer:

CMS is supporting the adoption and effective use of health information technology by physicians through the Doctor's Office Quality - Information Technology (DOQ-IT) project. The goal of DOQ-IT, which is managed by Medicare Quality Improvement Organizations (QIOs), is to improve the quality of care and safety for Medicare beneficiaries by promoting greater availability of high quality affordable health information technology (HIT) and by providing assistance to physician offices in adopting and using such technology. Under the 8th SOW, QIOs are required to implement DOQ-IT within each state. As part of the DOQ-IT requirements, QIOs are expected to recruit five percent of all primary care practice sites in the state and to provide assistance with HIT adoption and use to generate electronic clinical information, care management implementation and reporting of electronic clinical information.

The Medicare Care Management Performance (MCMP) demonstration, authorized by Section 649 of the MMA, is a 3-year pay-for-performance demonstration with physicians in small- and medium-sized physician practices. The goal of the demonstration is to promote the adoption and use of HIT to improve the quality of patient care for chronically ill Medicare patients. Doctors who meet or exceed performance standards established by CMS in clinical delivery systems and patient outcomes will receive bonus payments for managing the care of eligible Medicare beneficiaries. Because the implementation of an electronic health record (EHR) and the ability to use it to facilitate the redesign of clinical practices can be critical to improving the quality of care, physicians in this demonstration will be eligible to receive additional incentive payments for implementing a CCHIT-certified EHR and reporting the clinical performance data electronically.

3)

Question:

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required the Secretary to establish a competitive bidding program for durable medical equipment. Suppliers have had significant problems in accessing the CMS website to register and submit bids for the first phase of the program. The deadline for registering was July 7, 2007, and the deadline for submitting bids is now Friday, July 27th. Chairman Baucus and I have asked CMS to extend these deadlines an additional 90 days.

- What steps would you direct CMS to take to ensure that suppliers are able to register on the new Competitive Bid Submission System website, get timely responses to their questions, and submit their bids on the website?

Answer:

CMS is committed to the effective implementation of this important new Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) competitive bidding program, which will result in improved quality and greater value for Medicare and its beneficiaries. CMS has been working diligently to ensure that suppliers have the information necessary to submit their bids.

However, I acknowledge that there have been technical issues with the bid submission software. Therefore, CMS has been carefully monitoring the system and has moved

promptly to correct issues as they have been identified. The toll-free help desk has worked closely with individual suppliers to resolve specific problems they have had using the system. In response to supplier requests, CMS has provided a 2-week extension of the bidding window. With this extension, we believe that suppliers will have sufficient time to submit their bids. Currently, there are no outstanding calls to the toll-free help desk from suppliers requiring assistance with the on-line bidding system. As with all technical issues, I am committed to a top to bottom review of business practices.

- Small suppliers have asked CMS for guidance in forming bidding networks to avoid potential antitrust concerns. Such networks will be essential for many small suppliers who are unable to service an entire bidding area, as required. Given the fast-approaching deadline, when would you plan to have CMS provide guidance on this issue and how would you envision that guidance would be provided to the many suppliers who might need to form networks in order to bid?

Answer:

The Medicare Modernization Act of 2003 requires that, in developing procedures relating to bids and the awarding of contracts, CMS "take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program." In the development and implementation of this program, CMS has created numerous provisions to protect small suppliers and ensure they have an opportunity to participate. For example, many commenters on the competitive bidding proposed rule expressed concern about potential antitrust violations that could occur under the proposed network policies. In fact, one commenter submitted a specific example of a supplier attempting to form a network for the purpose of manipulating Medicare's price. We considered these comments carefully and, while not practical to re-state the body of antitrust law in a Medicare regulation, designed the final network provisions in a way that limits exposure to potential conflict with antitrust laws.

- How would you plan to address the numerous problems that have arisen in CMS's implementation of the competitive bidding program? Do you believe that suppliers have had enough time to develop and submit bids or would you direct CMS to extend the current deadlines?

Answer:

CMS is committed to the effective implementation of this important new Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) competitive bidding program, which will result in improved quality and greater value for Medicare and its beneficiaries. CMS has been working diligently to ensure that suppliers have the information necessary to submit their bids.

4)

Question:

Almost a year ago, CMS developed a Strategic and Implementing Plan on Physician Investment in Specialty Hospitals. We know that some of the actions in this document are being implemented or considered, but we do not know if or when CMS intends to implement the rest of the proposed actions detailed in the plan. As CMS Administrator, what would be your plans and your timeline for achieving each of the proposed actions in the strategic and implementing plan?

Answer:

I would be glad to give an update on some of the many things CMS is doing in this area. CMS recently published a final rule revising the payment system for Ambulatory Surgical Centers (ASCs) and plans to publish the fiscal year 2008 inpatient hospital prospective payment system final rule, requiring disclosure of physician ownership and making refinements to selected diagnosis related groups (DRGs), in August. These DRG refinements should reduce the incentive for allegations that they had heard that some specialty hospitals are “cream skimming” to treat less sick patients. CMS is working to better align physician and hospital incentives, and will publish the hospital value-based purchasing plan required by the Deficit Reduction Act of 2005 (DRA) shortly. CMS is collecting data on hospital ownership and compensation arrangements with physicians, which will significantly enhance our ability to detect and prevent fraud and abuse, to take appropriate enforcement actions, and to promote voluntary compliance with the Federal fraud and abuse statutes.

5)

Question:

The Quality Improvement Organization program is of great concern to me. These entities receive over \$400 million a year to perform a wide range of important responsibilities such as investigating poor quality care and providing technical assistance for quality improvement. The Institute of Medicine, The Government Accountability Office, and Department of Health and Human Services Office of Inspector General have all examined various aspects of this program and have raised serious issues such as the overall effectiveness of this program as well as the apparent lack of accountability in these organizations.

Do you agree that the QIO program needs to be reformed? If so, as the CMS Administrator, what steps would you take to bring both accountability and effectiveness to the QIO program?

Answer:

I agree that the CMS should continue to take a hard look at the QIO program. I understand the Agency undertook an intensive internal review of the QIO Program beginning the fall of 2005. As a result of the IOM study and the internal Agency review, CMS has determined that there is a need for improvement of the program to enable it to effectively promote high quality, efficient, and person-centered care for Medicare beneficiaries.

CMS is currently undertaking the following activities to strengthen the QIO program:

- Strengthening evaluation design to better assess the impact of the program,
- Strengthening financial oversight and establishing requirements for QIO board governance to assure appropriate use of contractor funds and the representation of key constituencies,
- Increasing competition for QIO contracts,
- Enabling QIOs to release information to beneficiaries about QIO findings related to their complaints,
- Directing QIOs to focus on the local achievement of national quality and efficiency goals, to improve care for beneficiaries with significant medical needs,
- Directing QIOs to support local initiatives to develop and use information on quality and cost to help beneficiaries, their caregivers, and their health professionals make better choices about their treatment options, and self-care.

6)

Question:

When you were the HHS acting deputy assistant secretary for the budget, you worked creatively within the HHS hiring system – by rewriting job descriptions and posting them on private sector websites - to attract job candidates who never before would have considered becoming government budget analysts. That suggests that you are willing to think a little outside the box, even while working inside the box, to get things done.

There are a whole host of actions that CMS could take to improve administration of the Medicare and Medicaid programs. What creative processes or ideas might you have in mind if you become CMS administrator that would improve how the agency functions?

Answer:

I have some creative new ideas, but I also want to go back to some of the old ideas of oversight and accountability. If confirmed, I will intensify CMS oversight across programs, and I expect you to hold me responsible for acting on abuses or inefficiencies discovered in the course of program oversight.

7)

Question:

There have been numerous reports of enrollees in Medicare Advantage Private Fee for Service being denied service upon presentation of their insurance card at their health care providers. It seems likely that the providers may be confused and assume the enrollee is in a PPO or HMO plan with which the provider does not contract.

Do you have ideas for what CMS could do to make it more clearly to providers that under Private Fee for Services' deeming authority, providers will be paid the standard Medicare fee-for-service rate and will not be at a financial disadvantage in treating these enrollees?

Answer:

Outreach to providers is critical to the success of private fee-for-service. CMS already has in place a website to facilitate provider access to plan terms and conditions. They also have developed a brochure designed for providers, which explains the PFFS rules. They are requiring all organizations offering PFFS plans, beginning October 1, 2007 when marketing begins for the 2008 benefit year, to have a provider outreach program in place. I plan to continue actions of this nature to promote better provider understanding.

8)

Question:

One goal of the dual-eligible Special Needs Plans was to integrate Medicare and Medicaid covered services to provide more coordinated health care for beneficiaries. However, it does not appear that states have encouraged integration, and, indeed, it appears that in many instances, beneficiaries are not benefiting from better coordination of care. In some states, it appears that the states may not fully understand the program and the value it could bring to beneficiaries.

- How would you plan to have CMS encourage state collaboration with Medicare Special Needs Plans?

Answer:

Special Needs Plans (SNPs) are new products in the Medicare program. CMS has a strong network of partners across the country, established channels for communicating with the States, and a state-of-the-art website that we have use to educate interested

parties about new features of Medicare. I would envision using this established infrastructure, and enhancing it as needed, to promote better understanding of SNPs by the States, our partners, and beneficiaries.

- What process will you use to assess CMS's current efforts to educate states about the Special Needs Plan program and its goals?

Answer:

The success of all of programs CMS administers depends on accurate, timely, and adequate information for beneficiaries and their caregivers, our partners, and the States. I would assess our current efforts in consultation with internal CMS experts – including our workgroup on Medicare/Medicaid and the Office of External Affairs – as well as the States and other interested parties.

- If you were confirmed, would you expect to expand and intensify outreach to the states to encourage them to contract with Special Needs Plans?

Answer:

In general, yes, but how we would undertake this would depend on the outcome of our assessment of current outreach efforts, as well as States' readiness and ability to contract with special needs plans.

- Finally, what tools do you think CMS could consider to promote integration of services? For example, should CMS consider requiring Special Needs Plans to have contracts with the states before approving their applications?

Answer:

That would certainly be one option for dual eligible and institutional Special Needs Plans, but I would need to assess beneficiary impact and States' readiness and ability to contract with special needs plans before instituting such a requirement. Effective education and outreach to States, our partners, providers, and beneficiaries about this very new plan option in Medicare would be a good first step towards promoting integration with special needs plans, as well as the issue of whether we have current authority to impose such a requirement, before undertaking to impose it.

9)

Question:

In the Deficit Reduction Act, we changed the federal upper limit for reimbursement for prescription drugs to 250% of the lowest Average Manufacturer Price or AMP, and we also required the Secretary to share these data with States on a monthly basis. It is my understanding that CMS is sharing these data with the states, but will not make the data public until some 18 months after the statutory deadline. Do you believe CMS has the authority to delay release of AMP data for 18 months?

Answer:

I would like to reiterate that my priority as Administrator would be to uphold all aspects of the laws affecting the Medicare, Medicaid and SCHIP programs. As you know, the Deficit Reduction Act of 2005 (DRA) contained important provisions to increase transparency in Medicaid drug pricing and provide states with the tools they need to improve the accuracy of their drug reimbursements. The DRA revised the definition of the average manufacturer price (AMP) and required CMS to provide AMP data to States on a monthly basis beginning July 1, 2006 and

post AMP data on a website at least quarterly. While CMS had access to AMP data on July 1, 2006, this data did not reflect the revised definition of AMP. As a result, CMS shared the concern expressed by many in the retail pharmacy industry and some members of Congress, that the AMPs should not be released until they can reflect the revisions made by the DRA, including the changes in regulation required by the DRA. If you have specific concerns about the release of this data, I would be happy to work with you on them. CMS is committed to providing AMP data to the public once the final rule becomes effective and manufacturers have submitted data that is reflective of the new AMP definition.

10)

Question:

We have seen a number of press reports of rogue insurance agents using abusive sales practices to sell Medicare plans – Part D and Medicare Advantage – in which they misrepresented the plans' benefits to seniors, forged seniors' signatures, cross-sold products, and so on. The states would like greater authority to regulate MA and PDP plans, as they have with Medigap. But this is a federal program, and CMS should be sanctioning plans and helping the states find and discipline the rogue agents.

- Do you plan to assess whether CMS has adequate capacity to monitor and penalize abusive sales practices?

Answer:

I am committed to strong oversight of all CMS programs. As part of that commitment, I would, if confirmed, assess CMS resources available for oversight efforts, including monitoring and penalizing abusive sales practices.

- Would consideration of CMS capacity for overseeing plan marketing include an assessment of whether CMS needs a more explicit set of marketing guidelines for plans and agents? How would you decide who might create such guidelines if they are determined to be necessary?

Answer:

CMS continually reassesses its program guidelines, and marketing guidelines for plans and agents would be no exception. Any revisions would be made in consultation with interested parties, such as State insurance commissioners and the NAIC.

- Do you have opinion on what role states should have in protecting Medicare beneficiaries from abusive sales techniques?

Answer:

Effective oversight of marketing activities requires collaboration between CMS and the States. To that end, CMS has partnered with the National Association of Insurance Commissioners to develop a memorandum of understanding (MOU) that facilitates information exchanges and enforcement collaboration between CMS and State departments of insurance.

- States require insurers to tell them what agents are working on their behalf (a practice called appointment). Would you plan to ensure that CMS gets a list of each plan's agent appointments? If so, do you think it makes sense to share these lists with the states?

Answer:

CMS is exploring options for gathering this information directly from plans, and intend to make it available to the states via a website or other means.

- Understanding that the states discipline rogue agents, would you establish a process to determine what additional measures CMS should take against the plans on behalf of whom these agents worked?

Answer:

Yes. Effective oversight requires strong collaboration between CMS and the States. Within this framework, CMS will exercise its authority to discipline plans for the misconduct of their agents where appropriate.

11)

Question:

The HHS OIG determined that 25 percent of ambulance transports did not meet Medicare program requirements in Calendar Year 2002 resulting in an estimated \$402 million of improper payments. While I understand that this figure has improved in the last few years, there is still significant work to be done.

Question:

- What is the CMS current estimate of improper payments for ambulance transports, per year, since 2002?

Answer:

Fiscal Year	Error Rate (%)	Projected Improper Payments (dollars in millions)
(Mid-year Report) 2007	(gross) 2.2	75.3
2006	(gross) 2.3	75.7
2005	(gross) 5.1	156.7
2004	(gross) 3.7	122.8
2003	(net) 8.8	268.2

Gross = overpayments + underpayments; Net = overpayments – underpayments.

- CMS indicated that it is encouraging ambulance contractors to obtain documentation from ambulance suppliers and third party providers to determine that transports are meeting program requirements for post-payment review. In addition, CMS also indicated that it is educating suppliers and third party providers who initiate ambulance transports about the appropriate use of the benefit. What is the current status of these efforts? Please provide a detailed explanation of all steps CMS is taking to ensure integrity for this benefit.

Answer:

CMS closely monitors billings for ambulance services since those services have consistently shown up as a high-risk area for improper payments. Thanks to a combination of provider education, tightened policies and aggressive oversight by the carriers the improper payment rate for ambulance services has decreased from a high of

8.8 percent in FY 2003 to 2.3 percent in FY 2006. This is a reduction of nearly 193 million dollars

The two areas which remain a problem are insufficient documentation or claims submitted for services that are medically unnecessary. CMS has been very aggressive in working with its contractors and law enforcement to address the issue of medically unnecessary transports. However, this continues to be a high vulnerability area and one where CMS will continue to exercise vigilant oversight.

12)

Question:

As you know, the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) benefit has received considerable attention from this Committee. Specifically, as Chairman and Ranking Member, I have examined the processes associated with the implementation of this benefit and how CMS ensures that fraud and abuse are prevented and rooted out appropriately.

While CMS and the H-H-S O-I-G have made significant progress towards this end, there is still much work to be done.

- Given the highly vulnerable nature of DMEPOS suppliers, do you believe that C-M-S needs to take any additional action to prevent fraud and abuse outside of the measures currently taking place? In other words, does C-M-S need to do anything different or anything more?

Answer:

CMS has recently taken additional actions to prevent fraud and abuse among DMEPOS suppliers. The HHS and the CMS announced plans in the beginning of this month to implement a two-year demonstration project involving the Medicare enrollment of DMEPOS suppliers. The goal of this project is to strengthen CMS's ability to detect and prevent fraudulent activity and will focus specifically on DMEPOS suppliers in South Florida and the Los Angeles area. CMS will evaluate the effectiveness of this demonstration project and determine if the processes and procedures used can and should be implemented in other parts of the country as a means of deterring fraudulent conduct.

We are in the process of taking several more aggressive actions in this area. CMS believes these actions demonstrate positive steps forward to help prevent Medicare fraud, waste, and abuse from DMEPOS suppliers. In August 2006, CMS established quality standards that all DMEPOS suppliers must comply with in order to receive Medicare Part B payments and to obtain and retain a supplier billing number. CMS also implemented DMEPOS accreditation standards, which ensures that DMEPOS suppliers meet CMS' quality standards. In addition, CMS is in the process of addressing the posting of surety bonds in DMEPOS suppliers. CMS is also revisiting the NSC's contractual requirements to enhance the number of unscheduled site visits required by the NSC. Finally, CMS is developing a provider enrollment regulation that will propose revised deactivation requirements for inactive Medicare billing numbers of DMEPOS suppliers. This proposed regulation will give CMS more authority to deactivate numbers that have been inactive for a prolonged period of time.

- Please provide to the Committee C-M-S' most recent statement of work with the National Suppliers Clearinghouse.

Answer:

National Suppliers Clearinghouse's statement of work is attached.

13)

Question:

As you know, the Committee has been vigorous in its oversight of Quality Improvement Organizations, which are supposed to ensure that medical care is reasonable and medically necessary, provided in the most economical setting, and meets professionally recognized standards. During the course of my oversight activities, these organizations are occasionally less than helpful – and sometimes downright uncooperative. On this point, I have two questions:

- What is your position on QIOs refusing to provide information or documents to the Senate Committee upon request?

Answer:

It is my understanding that the QIOs are expected to provide information and documents to the Congress upon request, and it would be my policy to do so consistent with the law.

- What is your opinion on Congress including in a QIOs statement of work a requirement that they provide Congress certain information upon request?

Answer:

I would not object to including such a requirement to ensure that QIOs provide information and documents to the Congress upon request, in a manner consistent with the law.

14)

Question:

The Nursing Home Compare Website was developed in order to provide the public with information relating to the quality of Medicare and Medicaid-certified nursing homes. With this information, the public has the ability to view deficiency information about certain homes they may be considering. While I believe that this is a positive and important step, I am concerned with the HHS OIG's findings which indicate that there is a significant percentage of incomplete information about nursing homes' survey results and complaint histories.

- Please provide the status of efforts currently underway by CMS to ensure and certify that all information submitted to the Compare Web site is accurate and complete.

Answer:

I share your strong commitment to providing the public with information related to the quality of Medicare and Medicaid-certified nursing homes. In regard to the OIG study, OIG found that "nineteen percent of nursing homes had one or more surveys missing on *Nursing Home Compare*." Most of those "missing surveys" were not missing at all but reflected the editing-out of duplicate deficiency tags. With regard to the nursing home for which OIG found that the most recent survey had not been posted, I understand CMS has taken a number of actions:

1. Communicated with States the importance of timely data entry of survey results, and checking for accuracy of data,
2. Made accurate data entry an element of the State Performance Standards System (SPSS),

3. Enforced State performance expectations by deducting funds from the State survey & certification budget in the event that a survey has not been performed, or documented in the CMS information system (which is the database used for *Nursing Home Compare*).
4. Provided States with management information tools to monitor surveys and data entry during the course of the year.

I am committed to working with you to ensure that that America's elderly and disabled receive the high quality nursing home care they need and deserve.

15)

Question:

What creative processes or ideas might you have in mind if you become C-M-S administrator that would improve how the agency functions?

Answer:

While I have several new ideas, equally importantly I would plan to refocus the agency on some of the older guiding principles of strong oversight and accountability. If confirmed, I will intensify CMS oversight across programs, and I expect you to hold me responsible for acting on abuses or inefficiencies discovered in the course of program oversight.

16)

Question:

Will you, as Administrator of CMS, commit today to vigorously support the False Claims Act, the Anti-Kickback Act, the Stark law, and other federal laws that are used to investigate, prosecute, and suppress fraud in CMS programs?

Answer: Yes

17)

Question:

Will you do your best to insure that CMS does everything in its power to eliminate fraud and abuse from the programs it administers?

Answer: Yes

18)

Question:

Will you and your staff cooperate fully with the Department of Justice, the HHS Office of Inspector General, and whistleblowers to investigate, prosecute, and suppress fraud in Medicare and Medicaid?

Answer: Yes

19)

Question:

Will you ensure that CMS cooperates with state governments that prosecute FCA cases for Medicaid fraud under a state FCA?

Answer: Yes

20)

Question:

Will you ensure that CMS pass clear, uniform regulations outlining the procedures for paying states an increased share of Medicaid recoveries when they bring an FCA under a qualifying state FCA?

Answer: Yes

21)

Question:

And, finally, will you agree to take no administrative initiatives that would weaken the effectiveness of the False Claims Act or other laws and authorities used to investigate, prosecute, and suppress fraud in Medicare and Medicaid?

Answer: Yes

22)

Question:

Will you commit to working with the Congress, GAO and the HHS OIG in a timely and constructive manner to address the oversight and other needs of the Congress, and will you encourage others to do so?

Answer: Yes

23)

Question:

What specific steps will you take to ensure that the Congress, GAO and HHS OIG receive access to the information and agency officials we need to carry out reviews of CMS programs and activities, and to ensure that information is provided in a timely manner?

Answer: I am aware that this Committee and others have been frustrated at times with a lack of consistent access to information on a number of issues, such as information regarding the Medicare Part D premium withhold. If I am confirmed, I would make available to the Committee the same information as I have on the Part D premium withhold issue. I also pledge to cooperate with the GAO and HHS OIG and to provide access to information for purposes of CMS program and activities reviews, provided that information requests are received through established channels that allow us to process them appropriately.

Do you foresee any issues in providing particular categories of CMS information to Congress or GAO? If so, what are the issues and how will you address them?

Answer:

I do not foresee any issues with providing CMS information to Congress or GAO, consistent with applicable law. Should issues arise, the Agency should seek to find a way to provide the Committee with the information it needs to conduct its oversight activity while also preserving the legitimate Executive Branch interests at issue. I commit to working with the Committee to ensure that the Agency is responsive to its requests, consistent with any legitimate Executive Branch interests that may be implicated.

The Honorable Senator Roberts

1)

Question:

Deadline/Problems. Please see the attached document listing all of the technical problems suppliers have encountered while trying to submit a bid under the DMEPOS competitive bidding program. I would like an immediate response on how CMS will address these problems. In addition, I request that CMS provide a 90-day extension of the deadline in order to provide enough time to address all of the problems and allow suppliers ample opportunity to submit their bids. I would like an immediate response from CMS on their intentions for an extension of the deadline and when suppliers would be notified of this extension.

Answer:

The Centers for Medicare & Medicaid Services (CMS) is committed to the effective implementation of this important new Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) competitive bidding program, which will result in improved quality and greater value for Medicare and its beneficiaries. CMS has been working diligently to ensure that suppliers have the information necessary to submit their bids.

However, I acknowledge that there have been technical issues with the bid submission software. Therefore, CMS has been carefully monitoring the system and has moved promptly to correct issues as they have been identified. The toll-free help desk has worked closely with individual suppliers to resolve specific problems they have had using the system. In response to supplier requests, CMS has provided a 2-week extension of the bidding window. With this extension, we believe that suppliers will have sufficient time to submit their bids. Currently, there are no outstanding calls to the toll-free help desk from suppliers requiring assistance with the on-line bidding system. We are paying close attention to the concerns that we have heard and continue to hear. I recognize the importance of this issue and look forward to working with you to address any problems.

2)

Question:

Patient Impact. I am concerned that the program has no mechanism to review or assess patient impact and quality of care as a result of the program. Shouldn't a program that will impact some of the frailest seniors track how they fare under it?

Answer:

First and foremost, CMS is committed to protecting beneficiary access and quality of care. Toward that end, CMS conducted a demonstration program, in which patient impact and quality of care were assessed before continuing with widespread implementation of DME competitive bidding. The Medicare DMEPOS Competitive Bidding Program was mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("Medicare Modernization Act" or "MMA"), after demonstration projects in Texas and Florida that produced significant savings for beneficiaries and taxpayers without hindering access to DMEPOS and related services. In designing the competitive bidding program, CMS built on the experiences from those demonstrations.

3)

Question:

Small/Rural MSAs. I have strong reservations about how this program will work – especially for patients in small and rural MSAs. Mr. Weems - can you guarantee to me that patient access and

choice to DMEPOS items and services will be the same for beneficiaries in small and rural MSAs as they currently experience?

Answer:

CMS has the discretion to exempt from DMEPOS competitive bidding, rural areas and areas with low population density within urban areas that are not competitive unless there is national mail order market for a particular product. CMS has already used this discretion in the Riverside-San Bernardino-Ontario, CA metropolitan area for non-mail-order products include densely populated zip codes in the western part of Riverside County and the southwestern region of San Bernardino. Both counties also include sparsely populated areas in the mountains and desert. These areas are not included in the competitive bidding area for non-mail-order products because they have low population and allowed charges, are predominantly rural, are geographically distant from the center of the competitive bidding area, and are served by few suppliers.

The competitive bidding final rule also established a methodology for selecting contracting suppliers that requires the selection of a sufficient number of suppliers to meet the expected demand for the competitively bid items within a competitive bid area.

4)

Question:

Accreditation. As I mentioned, the bidding process ends on Friday. However, how can the bidding process proceed while a number of potential suppliers' applications for accreditation – which is needed to participate – are still pending?

Answer:

CMS is working with suppliers and the accreditation organizations to ensure that accredited suppliers are participating in the competitive bidding program. I understand that the accreditation organizations have the capacity to accredit the number of potential suppliers who are participating in the competitive bidding program.

5)

Question:

Small Supplier Participation. It is important for the program that small suppliers participate. CMS would allow them to form networks to bid and provide services within an entire MSA. However, formation of networks is seriously impeded by antitrust prohibitions. Why hasn't any guidance been issued to help suppliers overcome these barriers? What will CMS do to ensure guidance is issued to ensure these small providers can participate?

Answer:

The Medicare prescription Drug, Improvement, and Modernization Act of 2003 requires that, in developing procedures relating to bids and the awarding of contracts, CMS "take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program." In the development and implementation of this program, CMS has created numerous provisions to protect small suppliers and ensure they have an opportunity to participate. For example, many commenters on the competitive bidding proposed rule expressed concern about potential antitrust violations that could occur under the proposed network policies. In fact, one commenter submitted a specific example of a supplier attempting to form a network for the purpose of manipulating Medicare's price.

6)

Question:

Transparency. Suppliers that are denied participation for reasons other than the bid amount do not currently have any recourse to allow them to address the concerns and allow them to participate. Will CMS provide any written explanations/remedies for providers whose applications for participation were rejected due to technical reasons?

Answer:

CMS is working continuously with suppliers providing technical assistance during the bid window to ensure that their bid applications are complete and accurate.

7)

Question:

Savings Certification. Can and will CMS provide any detailed data on the administrative cost of creating this new bureaucracy to implement this program? Can CMS provide data showing that this program will in fact provide significant savings in the Medicare program?

Answer:

As CMS has shown in the impact analysis in the competitive bidding final rule, they anticipate that this program will provide significant savings to the Medicare program and to beneficiaries. That was certainly the experience in the demonstration projects conducted in Texas and Florida.

8)

Question:

Hospital IPPS. In its proposed rule for the inpatient prospective payment system for 2008, CMS proposed a behavioral offset that would reduce payments to hospitals by \$24 billion over 5 years. I have serious problems with this rule. Mr. Weems, Congress did not direct CMS to do this. In fact, we told you NOT to do this. Senator Salazar and I led an effort in the Senate and we were joined by 61 of our colleagues telling CMS that a prospective behavioral offset was the wrong approach and that Congress should have been consulted. The Chairman and Ranking Member of this committee also sent their own letter stating their concerns. Does CMS plan to listen to these Senators - and the 269 Members of Congress who wrote a similar letter, OR would you make a decision that goes against the will of Congress? Would you advise the Secretary to act against the will of the Congress even though it doesn't cost the government anything to wait, collect data and make a retrospective adjustment?

Answer:

The public comment period on the IPPS rule (CMS-1533-P) closed on June 12, 2007. CMS is currently in the process of reviewing all the comments and taking those into account in drafting our final rule, which should be published in the Federal Register in early August. The reforms in the IPPS rule are measured steps to improve the accuracy of Medicare's payment for inpatient stays to better account for the severity of the patient's condition.

I am aware that many in Congress have expressed concerns about the incorporation of behavioral offsets into the Medicare severity diagnosis-related groups (MS-DRGs); however, the statute requires that CMS not increase or decrease payments when adopting a DRG system. The new DRG system presents opportunities to improve documentation and coding to receive higher payments without a real increase in patient severity of illness. Without an adjustment to the IPPS rates to account for this case mix growth, the CMS Office of the Actuary has advised us that the proposed MS-DRGs would not meet the statutory budget neutrality requirement. The Office of the Actuary estimates an adjustment of 2.4 percent to the IPPS rates for each of FY 2008 and FY

2009 will be necessary to account for the anticipated improvements in coding and documentation. The final decision on this matter will appear in the final rule. CMS will revisit the adjustment in two years if projected and actual data are different.

9)

Question:

I would like you to respond on ways we can ensure that hospitals have the appropriate financial means and incentives to treat serious infections. As you know, Congress enacted a provision as part of last year's Deficit Reduction Act that requires CMS to identify certain preventable conditions, and reduces the amount of payment that otherwise would be available to treat these conditions unless they are present when the patient is admitted to the hospital. I understand the purpose of this provision is to use the threat of withholding payment to encourage hospitals to prevent conditions that are within their power to control, and that therefore should not be occurring in the first place. Classic examples would be so called "never events," like when a surgeon leaves an instrument inside a patient or operates on the wrong body part.

My concern is that applying a provision like this to serious infections could deprive hospitals of the resources they need to treat patients suffering from these infections. This could have very bad consequences not only for patient care, but also for the broader fight against antimicrobial resistance: if hospitals aren't using the most appropriate and effective therapies to treat a particular infection, they could end up contributing to the growing public health crisis of resistance. I'm particularly concerned about what would happen if CMS were to apply this provision to infections caused by antibiotic-resistant strains of bacteria, such as MRSA, that are increasingly common in our communities. CMS recognized in the recent Medicare inpatient proposed rule that it can be difficult or impossible for hospitals to prevent these infections, and that it is not always possible to determine whether these infections were acquired in the hospital or the community. I commend CMS for proposing not to cut payments to hospitals for treating patients with MRSA this year.

I was hoping you share my concerns, and will take great care in implementing this provision of the DRA to ensure that Medicare's inpatient payment system provides payment to hospitals that enables them to treat serious infections with the most appropriate means.

Answer:

Thank you for bringing this particular concern to my attention. As part of CMS' patient safety and quality care initiatives, the Agency is working diligently to reduce infections in hospitals, eliminate inappropriate care, and eradicate "never events." In addition, we are working to ensure that our payment policies are closely aligned with quality standards and aggressively pursuing new initiatives like MS-DRG payments to ensure that hospital payments more accurately reflect the severity of patient conditions. I look forward to working closely with you to address this growing area in public health.

Thank you.

The Honorable Senator Crapo

1)

Question:

Hospital Question-Background: This question will deal with the "behavioral offset" provision in the IPPS rule.

- I have some real concerns with this rule, but in particular I am concerned with the “behavioral offset” piece.
- Can you comment on this piece of the rule?

Answer:

The proposed rule, which was released on April 13, builds on the framework established over the last few years to implement the most significant revision of Medicare’s inpatient hospital rates since 1983. The rule proposes to improve payment accuracy under Medicare’s hospital inpatient prospective payment system (IPPS) by adopting Medicare Severity Diagnosis-Related Groups, or the MS-DRGs, which would increase the total number of DRGs from 538 to 745. I understand that the CMS Office of the Actuary determined that such a significant expansion in the number of DRGs would lead hospitals to improve coding and documentation in order to have a case group assigned to a DRG with a higher payment. As discussed in the proposed rule, without an adjustment to the IPPS rates to account for this expected case mix growth, the change to these severity-based DRGs would not be budget neutral. Because the Social Security Act requires that CMS not increase or decrease payments when modifying the DRG system, the rule included a proposed budget neutrality adjustment.

I am aware that many in Congress have expressed concerns regarding this adjustment. As you know, the public comment period on the proposed rule closed on June 12, 2007. CMS is currently in the process of reviewing all the comments submitted, taking them into account in drafting the final rule, which by statute must be published on August 1. I expect the final rule will strive to achieve a balance between the comments received and the Agency’s obligation to comply with the statute and safeguard the Medicare Trust Funds.

2)

Question:

ASC Question -Background: This question is in response to CMS’ announcement last week with regards to payments to ambulatory surgical centers (ASCs)

- Mr. Weems, I want to be sure that Medicare beneficiaries have adequate access to high quality surgical care. It is also clear that competition in health care should be encouraged.
- While I appreciate CMS's responsiveness in substantially expanding the services that ASCs can perform for Medicare beneficiaries, the proposed payment rate of 65% of HOPD is inadequate for many services to be viable at an ASC.
- Can you work with me and this committee to improve the payment rules for ASCs so that seniors have more choice of where to get their outpatient surgical care and competition in health care will be encouraged?

Answer:

Senator Crapo, I am well aware of your long-standing interest in increasing access and reducing unnecessary costs of health care, and I am happy to work with you and the Committee to ensure appropriate refinements to our payment system. We share a common goal in expanding access to medical treatments in appropriate care settings and I look forward to working with you on this issue in the future. I appreciate the time that you’ve put into drafting your bill to reform the method for determining Medicare payment rates for ambulatory surgical centers (ASCs) and expand the surgical services that can be provided there.

3)

Question:

Specialty Hospital Question -Background: CMS has taken actions to get the reimbursement right so that physician owned hospitals (specialty hospitals) don't have perverse incentives to focus on and overutilize certain services. Senator Crapo very much supports specialty hospitals and believes that CMS is moving in the right direction by trying to get the payments right (rather than banning such facilities).

- Mr. Weems, CMS has taken several steps recently to deal with concerns raised about physician owned hospitals. Could you please update me on the status of those activities? At this point in time, is the Administration still confident that the real issues in the debate are being addressed by the CMS actions?

Answer:

I would be glad to give an update on some of the many things CMS is doing in this area. CMS recently published a final rule revising the payment system for Ambulatory Surgical Centers (ASCs) and plans to publish the fiscal year 2008 inpatient hospital prospective payment system final rule, requiring disclosure of physician ownership and making refinements to selected diagnosis related groups (DRGs), in August. This is part of our strategic implementing plan required by the Deficit Reduction Act of 2005 (DRA). The inpatient payment rule, by modifying the DRG system, will more accurately account for severity and should address the allegations of "cream skimming" leveled against some specialty hospitals in the past. We also are working to better align physician and hospital incentives, and will publish the hospital value-based purchasing plan required by the DRA shortly. CMS is collecting data on hospital ownership and compensation arrangements with physicians, which will significantly enhance our ability to detect and prevent fraud and abuse, to take appropriate enforcement actions, and to promote voluntary compliance with the Federal fraud and abuse statutes.

4)

Question:

Xopenex Question - Background: CMS has recently decided to bundle the COPD drug Xopenex with generic albuterol in the same payment code.

- I, and many of my colleagues, are concerned that this bundling action will result in reduced access for patients, and have adverse effects on the clinical decisions of physicians.
- Are you willing to work with us on this matter to resolve it expeditiously?

Answer:

Senator, I am committed to ensuring that beneficiaries have appropriate access to [COPD] drugs, and I would be happy to work with you on this issue.

5)

Question:

Least Costly Alternative Question -Background: Some Medicare carriers have instituted a least costly alternative (LCA) policy for certain prostate cancer drugs. Many of the therapies in the class of drugs affected by these policies are single source drugs, or in other words, not therapeutically equivalent. In addition, Congress has set out detailed provisions for setting the amount to be paid for drugs and biologics. Finally, CMS coverage decisions based on cost seem

to be prohibited by the Social Security Act, and in any case may be detrimental to a patient's medical need and their physician's choice.

- Do you believe that physician administered drugs should be paid by Medicare consistent with section 1847A of the Social Security Act - the average sales price statute?
- If so, how is allowing carriers to continue the imposition of least costly alternative to a physician administered drug consistent with the ASP statute?

Answer:

CMS is aware that questions have been raised about the policy for applying LCA to drugs, and we take those issues seriously. At the same time, CMS also has concerns about whether it is good policy for CMS to pay for Lupron if other drugs can have the same beneficial effect at far lower cost. I am informed that CMS is looking at all of these issues carefully in light of all of the concerns raised, including the issues you have raised, and that CMS has not made a final determination at this time.

6)

Question:

Erythropoiesis Stimulating Agent (ESA) Question -Background: CMS has proposed a National Coverage Determination (NCD) for Medicare coverage of ESA use in non-renal indications (*i.e.*, cancer). The draft NCD would limit use of the ESA therapy to a maximum of 12 weeks per year. Yet the typical chemotherapy regimen last 16-18 weeks and many chemotherapy regimens last longer.

- Does the NCD policy on ESAs limit the therapy to a maximum of twelve weeks a year?
- Did CMS mean to do this, or is this a drafting error?
- Is CMS aware that the length of typical chemotherapy regimens exceeds 12 weeks? Is there evidence to show that chemotherapy-induced anemia is no longer likely after 12 weeks of chemotherapy?

Answer:

CMS pays close attention to Food and Drug Administration (FDA) Black Box warnings because the safety of Medicare beneficiaries is paramount. On March 9, 2007 the FDA issued a Black Box warning conveying serious concerns about potential dangers with the use of erythropoiesis stimulating agents (ESAs) in some types of cancer/oncology treatment.

CMS opened a national coverage decision (NCD) on March 14 to assess whether there is sufficient evidence to conclude that the use of ESAs is reasonable and necessary for beneficiaries with non-renal disease indications. Because of the great breadth of clinical evidence related to ESA use in the oncology setting, the scope of the national coverage analysis was narrowed in the proposed decision memorandum to evaluate the use of ESAs in cancer and related neoplastic conditions.

CMS published its proposed NCD on ESA use in cancer and related neoplastic conditions on May 14, 2007. In developing this proposed NCD, CMS clinical staff reviewed over 500 studies. A 30-day public comment period began on May 14 and ended on June 13, 2007.

CMS physicians are carefully reviewing and considering all of the comments received, and we will provide summaries of the public comments received and responses to the comments in the final decision memorandum and NCD, which is required by statute to be issued on or before

August 12, 2007. We received several comments on the issue you asked about, which will be addressed in the final NCD.

The Honorable Senator Bingaman

1)

Question:

In January of this year, the Administration issued a Medicaid rule that severely limits the ability of public providers to receive Medicaid payments and makes many other sweeping changes to the Medicaid program. This rule is a very blunt and broad instrument. It is purportedly intended to stamp out certain categories of Medicaid fraud, which by CMS' own admission may only be an issue in 3 states. As a result of the far-reaching nature of this rule, many states like New Mexico will lose hundreds of millions of dollars in federal Medicaid dollars. This would occur despite the fact that New Mexico and other states have worked hard to ensure the integrity of their Medicaid programs and have consistently received approval from CMS for the design and operation of their programs. Such a radical change in Medicaid policy is not justified and will drastically impact the ability of low-income Americans to receive life-saving Medicaid services. 65 Senators (including many members of the Finance Committee) and 263 House Members have gone on record in opposition to this devastating rule since it was proposed by the Administration. Congress demonstrated its disapproval and direct opposition to CMS' rule by including a one-year moratorium in the recent supplemental appropriations bill (P.L. 110-28). As originally contemplated in federal law, the moratorium would allow Congress a full year to develop legislation and policy as well as 60 days to act after the Administration completed and published a final rule following the expiration of the moratorium, if necessary. In blatant disregard for congressional intent surrounding the moratorium, CMS issued the final rule on May 25, 2007 – the same day that President Bush signed the one-year moratorium provision into law. The final rule still contains the most damaging components of the proposed rule, including severely limiting Medicaid payments to public and other safety net providers. What is your position on this regulation? How do you justify limiting the ability of public providers to receive above cost, while continuing to allow private providers to receive payments up to Medicare payment levels? Before this rule is implemented, how will you ensure that concerns that have been raised by both Congress and the larger healthcare community have been addressed?

Answer:

Let me say at the outset that, CMS intends to comply with the moratorium under the supplemental appropriations bill (P.L. 110-28). The final rule was published in the interest of transparency. CMS knew that Congress wanted to examine its policy with regard to intergovernmental transfers and out of deference to Congress' legitimate oversight role, the agency wanted to make those policies clear. CMS also wanted interested parties and the public to see the decisions that were made in responding to public comments on the proposed rule and believed that this could not have been done that after the President had signed the supplemental into law.

I appreciate that Medicaid is a vitally important program that serves very vulnerable populations. I am concerned by the perception that this Medicaid rule is intended to harm public providers; in fact, I understand it to protect health care providers. Governmentally-operated health care providers are assured the opportunity to receive full cost reimbursement for serving Medicaid-eligible individuals, instead of being pressured to return some payment to the State. And, non-governmentally operated health care providers, including many of the "public" safety net hospitals, are not affected by the cost limit provision of the rule.

In being a responsible steward for the Medicaid, Medicare and SCHIP programs, I believe it is important to promote transparency and accountability in financing and support efforts to maintain the integrity of the programs. During the one-year moratorium, I will work with you and the provider community to hear concerns about the rule that was published. If I find changes are needed, I will work to make sure they occur.

2)

Question:

State Medicaid agencies have been implementing the Medicaid Citizenship Documentation requirement, established by the DRA, since July 2006. When interviewed by the media, CMS officials -- and Secretary Leavitt -- have said that they are unaware of any problems states are experiencing as a result of the requirement. Yet, numerous studies conducted and published by state Medicaid agencies, private researchers, the Congressional Research Service, and a GAO Report released just yesterday have found that thousands of individuals -- especially children -- have had their Medicaid denied, delayed or terminated, despite being eligible U.S. citizens. These findings have received widespread media coverage. What will you do to ensure that CMS acknowledges and addresses the barriers eligible U.S. citizens are encountering as a result of the Medicaid citizenship documentation requirement?

Answer:

I certainly want to ensure that all individuals eligible for Medicaid are able to access the benefits to which they are entitled. I take any reports to the contrary very seriously and, if confirmed, I pledge to work with the States to ensure that they understand the Medicaid citizenship documentation requirements, including ways the State can help applicants and recipients obtain documentation. I want to hear about specific cases in which eligible individuals are denied benefits so CMS can investigate and address them.

3)

Question:

CMS officials have said that states have been given all the tools necessary to implement the citizenship documentation requirement so that eligible applicants and beneficiaries are not harmed. However, the CMS regulations issued July 2 continues to be more restrictive than required under the statute. For example, only original documents or those certified by the issuing agency are acceptable, and states are still prohibited from providing benefits to applicants who have demonstrated their eligibility based on all other eligibility factors but are still in the process of gathering their citizenship and identity documents. Will you re-evaluate the CMS guidance that has been issued to date to ensure that the CMS rule complies with the law but does not create unnecessary burdens for families, individuals and state agencies?

Answer:

Let me assure you that I have no intention of creating unnecessary burdens for families, individuals, and state agencies. In developing the citizenship documentation rule, CMS balanced the goals of helping Medicaid applicants and recipients and States comply with the new statutory requirement while continuing to protect the integrity of the Medicaid program. The rule thus provides a hierarchy of documents acceptable to establish citizenship and identity modeled after the Social Security Administration's longstanding policies. Through the Medicaid Transformation grants, CMS is also facilitating several state efforts to simplify citizenship documentation by conducting electronic verification and automating vital records. Nevertheless, I do want to hear any concerns about unnecessary burdens created and, if necessary, I will issue the appropriate guidance to address them.

4)

Question:

Reports from many states have indicated that the citizenship documentation requirement is a particular burden for people who are not living in the state where they were born. It can be very costly, time-consuming and confusing to try to obtain a birth record from another state and this can seriously delay Medicaid coverage for eligible individuals. What will you do to facilitate the implementation of a system for states to share birth records across state lines and also protect individuals from the harm induced by having to wait long periods of time or incur significant costs before they can obtain Medicaid coverage?

Answer:

I want to ensure that all individuals eligible for Medicaid are able to access the benefits to which they are entitled in a timely manner. I am very interested in your suggestion allow states to share birth records. In fact, several Federal agencies, including CMS, are working with the National Association for Public Health Statistics and Information Systems (NAPHSIS) on the Electronic Verification of Vital Events (EVVE) databank. The EVVE databank contains birth record information for all participating States. States would be able to electronically verify birth information for births in their own State and within other States.

I strongly encourage States to develop methods of working together to achieve efficient, effective ways of verifying citizenship and identity. The guidance that CMS has released provides a hierarchy of a variety of documents acceptable to establish citizenship and identity. Beyond birth records, these documents include U.S. passports and State-issued driver's licenses.

5)

Question:

Under the President's Healthcare proposal, Medicaid Disproportionate Share Hospital (DSH) payments would be redirected to pay for the cost of expanding health insurance. Please describe the current importance of Medicaid DSH payments to Safety-net providers. How would you ensure that such redirection of Medicaid DSH did not inadvertently destabilize the safety-net? Specifically, how would you sequence the shifting of Medicaid DSH payments with the creation of new health insurance coverage to preserve the ability of safety net providers to continue to serve vulnerable populations? If the President's proposal was fully adopted, would you still endorse some level of Medicaid DSH payments? What specific level of payments would you anticipate (e.g., what percentage of current payments would still be necessary)?

Answer:

Under the President's Affordable Choices proposal, States would develop proposals to make affordable health insurance available to their residents. As part of a proposal, a State could include information on how much of its DSH funds would be redirected to finance health insurance coverage and how much would remain for DSH payments. Massachusetts developed and implemented such a proposal last year. To the extent that a State wanted to adopt such a system, CMS would work closely with States as we review their proposals to make sure the proposal appropriately balances the need for the provision of affordable health insurance coverage with the maintenance of safety net providers to continue to serve vulnerable populations. Under the President's proposal, we had always envisioned that some Medicaid DSH dollars would remain in the system, in recognition of the fact that providers will always have some level of uncompensated care.

The Honorable Senator Kerry

1)

Question:

Mr. Weems, in 2004, MedPac called for the creation of certification criteria for long-term, acute-care hospitals, or LTACs, to assure that the right kind of patient is seen in the right kind of facility. It is now 2007 and CMS does not seem to be any further along in developing the criteria than it was three years ago when MedPac first raised the issue and the agency agreed to study it. In the meantime, CMS continues to make reimbursement and policy changes that have negatively impacted LTACs – decisions which even MedPAC has concluded are “crude” and “unsophisticated” methods.

As a result of the ongoing instability for this industry, a number of LTAC hospitals are facing considerable challenges, which, if unaddressed, will negatively impact on post-acute care service options for frail elders and other vulnerable populations. Absent agency action, a number of Senators on this Committee, including Mr. Conrad and Mr. Hatch and myself, support legislation which would create the criteria by statute. The bill approach been endorsed by the American Hospital Association and the two associations representing LTAC hospitals. Using this concern as an example, what can you tell us, Mr. Weems, about how this agency would perform under your leadership? Would you make it a priority to devote agency resources towards addressing policy and regulatory issues raised by the Congress and MedPac? Do you have any specific comments regarding CMS' development of certification criteria for LTAC hospitals?

Answer:

CMS has made extensive progress, and has devoted considerable Agency resources, towards addressing the concerns raised by the Congress and MedPAC regarding the development of certification criteria for LTCH hospitals. As Administrator, I would continue these efforts to explore and carefully assess the feasibility of developing and implementing patient-level and facility-level criteria for LTCHs. I would also continue to prioritize the development of a post-acute care patient assessment instrument that is designed to assess patients at hospital discharge to determine which post-acute care setting is most appropriate.

CMS awarded a contract to Research Triangle International, Inc. (RTI) to evaluate and determine the feasibility of implementing patient-level and facility-level patient criteria for LTCHs, and continues to review and evaluate the RTI recommendations. RTI has formed a technical expert panel (TEP) consisting of physicians who treat long-term care patients both in LTCHs and as inpatients in other provider settings to study the development of these criteria and assist in the development of a post-acute care assessment tool designed to ensure appropriate placement in a post-acute care setting. CMS just extended RTI's contract to focus specifically on the development of LTCH criteria. Furthermore, RTI is engaged in several other post-acute care projects evaluating different post-acute care settings, information from which will feed into the next level of their project.

CMS has also worked extensively with MedPAC and the industry throughout the RTI research process. The LTCH industry, along with their provider associations, attended the Technical Expert Panel meetings RTI hosted for CMS to openly discuss the overlapping populations treated by LTCHs, acute care hospitals, IRFs, and SNFs. The development of patient-level and facility-level criteria for LTCHs requires extensive research and careful consideration, and I would continue CMS' ongoing efforts to develop these criteria with Congress, MedPAC and the LTCH industry.

2)

Question:

As you may be aware, I have long supported expansion of home care opportunities for the elderly and disabled. Recently, I learned that CMS has proposed significant changes in the way it pays for the home health services that are provided to over 3 million Americans. It seems that much of the CMS proposal is appropriate. However, I am very concerned about the proposal to cut the payment rates by 2.75% over each of the next three years based on suspicions of something that is termed "case mix creep" which indicates that payment amounts have improperly increased. From what I can tell, the changes in home health care are just what we wanted to see happen. More patients are getting rehabilitation services, gaining independence, and staying out of more costly institutional care. Additionally, I understand that the cost of patient care on an annual per patient basis is stable or dropping and patient outcomes are continuing to improve. In a report by The Lewin Group, the data appears to indicate that the average case mix index has increased because more patients are coming to home health care for restorative care and that is the real explanation for the changes rather than inappropriate case mix creep.

What am I missing here? It just seems that home health care changes are working in ways that helps both the patients and Medicare. If you are confirmed as CMS Administrator, can I count on you to correct the CMS proposal?

Answer:

The proposed rule, which was released on April 27, includes the first refinements to Medicare's home health prospective payment system (HH PPS) since its inception in 2000. The proposals in this rule are designed to significantly increase the payment system's ability to more appropriately reflect the costs of home health care and consequently provide more accurate payments to home health agencies.

The proposed rule also contains an adjustment designed to account for changes in the case-mix that are not related to a home health patient's actual clinical condition. CMS analysis of the latest available home health claims data indicates a significant increase in the observed case-mix since 2000, and also indicates that this demonstrated case-mix increase is due to changes in coding practices and documentation rather than the treatment of more resource-intensive patients.

As you know, CMS is currently in the process of reviewing all the comments submitted regarding this proposed rule, taking these comments into account in drafting the final rule. I expect the final rule will strive to achieve a balance between the comments received and the Agency's efforts to ensure the accuracy of the HH PPS.

The Honorable Senator Conrad

1)

Question:

Prior to enactment of the MMA, hospitals in my state were receiving half the reimbursement of urban hospitals. The MMA took a step to close the gap. But many of my hospitals remain on the brink of closure. This is particularly alarming given the high quality of care that is provided in rural areas. In fact, North Dakota routinely ranks at the top in quality and at the bottom when it comes to spending. In my opinion, we need to find ways to reward providers, like those in North Dakota, who provide low-cost, high-quality care, not give them the least reimbursement and force them to close.

I would like to know your thoughts on the fact that rural providers often get the least reimbursement, but provide the highest quality. Specifically, will you support the extension of rural payment .

provisions that have helped level the playing field? What will you do to realign the payment structure to reward providers like those in North Dakota that provide the best care?

Answer:

The Centers for Medicare & Medicaid Services (CMS) has made a strong commitment to rural health issues and has made many significant regulatory and departmental reforms to address the needs of rural America.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) included a number of provisions to enhance beneficiary access to quality health care services and improve provider payment in rural areas. The provisions in the MMA continued two payment policy trends that have increased rural provider payment rates in recent years: (1) an expansion of opportunities for rural hospitals to receive cost-based payments from Medicare and (2) an increase in rural PPS payment rates so that they are closer to urban payment rates. These provisions include the creation of a new Physician Scarcity Area bonus payment program along with an updated Health Professional Shortage Area bonus payment program, which reward both primary and specialist care physicians for furnishing services in the areas that have the fewest physicians available to serve beneficiaries; the development of a graduated adjustment/add-on payment for low-volume hospitals; the redistribution of unused resident positions, with hospitals located in rural areas receiving top priority for such positions; and significant improvements to the Critical Access Hospital program, including increased payments to 101 percent of reasonable costs and flexibility to use up to 25 beds for acute care.

CMS has also been directed to conduct a number of demonstrations focused on the delivery of care in rural areas. For example, section 409 of the MMA established a demonstration to test the delivery of hospice care in rural areas; section 410A of the MMA established a 5-year demonstration for 15 hospitals in 10 states to test the advisability and feasibility of establishing Rural Community Hospitals; and section 434 of the MMA authorized a new demonstration project under which Frontier Extended Stay Clinics in isolated rural areas are treated as providers of items and services under the Medicare program.

Many of the provisions in the MMA were time limited but have been extended in later legislation, including the Deficit Reduction Act of 2005 (DRA) and the Tax Relief and Health Care Act of 2006 (TRHCA). CMS has worked expeditiously to implement all of the provisions in recent legislation, recognizing their importance to rural communities. Although the President's fiscal year (FY) 2008 Budget did not include proposals to extend the expiring rural provisions, CMS will continue to work with Congress to address disparities in rural reimbursement and to improve the quality and value of care delivered to all Medicare beneficiaries.

2)

Question:

I'd like to ask you a question about a specific hospital in North Dakota that is experiencing financial hardship. St. Joseph's hospital in Dickinson, North Dakota, is a medium-sized hospital that is critical to the health care safety net of Southwestern North Dakota. Without this hospital, thousands of North Dakotans and Montanans will be left to drive hundreds of miles to the nearest hospital. But the hospital is struggling to survive. It is too small to make it under the prospective payment system. Yet it cannot convert to a Critical Access Hospital.

The MMA established a demonstration program for hospitals experiencing similar situations. It's called the Rural Community Hospital Demonstration program. This demo gives hospitals cost-based reimbursement for inpatient services in an attempt to keep them viable. While 13 hospitals

were originally picked to participate, the number has dwindled to 9. My staff and I have been trying to work with CMS to see whether St. Joseph's would qualify, and I encourage you to look into reopening the demo to allow for more hospitals like St. Joseph's to take advantage of this assistance.

More broadly, do you have thoughts on ways to help these medium-sized hospitals that can't make it under PPS, but are prevented from converting to Critical Access?

Answer:

I support the commitment that the Centers for Medicare & Medicaid Services (CMS) have made in addressing rural health issues. They have made many significant regulatory and departmental reforms to address the needs of rural America.

I am aware of St. Joseph's interest in being part of the demonstration under section 410A of the MMA that established the Rural Community Hospital Demonstration. This is a 3-year demonstration that began in January 1, 2005. While I want to be clear that I recognize the critical importance of rural providers to ensure access to vital services for our rural beneficiaries, my understanding of the facts in this particular case is that St. Joseph's does not currently meet the statutory requirements for participation in the demonstration. The requirements for this demonstration, among other things, limits the number of acute care inpatient beds to less than 51., and St. Joseph's is currently listed as having about 100 beds.

In addition, CMS is now entering the final year of the 3-year demonstration, so the deadline for hospitals to apply to participate has long passed. So even if St. Joseph's were to significantly reduce its bed size, it is much too late for them to be included in this project. To my knowledge, CMS has never re-opened a demonstration to new applicants after the deadline had passed. To do so might be warranted in special cases, such as to enable CMS to answer research questions that might otherwise go unaddressed. In this case, however, with 2 of 3 years of the demo's statutory timeframe already complete, I would have concerns with compromising the value of the body of evidence we have already collected under the demonstration.

I want to work with you and the Congress to address disparities in rural reimbursement and to improve the quality and value of care delivered to all Medicare beneficiaries.

The Honorable Senator Bunning

1)

Question:

Mr. Weems, in 2004, MedPAC called for the creation of certification criteria for long-term, acute-care (LTAC) hospitals. After that MedPAC recommendation, CMS commissioned a study of how CMS might develop those criteria. Two years later, in 2006, CMS published an inconclusive study that made some generalized recommendations but did not do much to advance a new policy. CMS does not seem to be any further along in developing certification criteria than it was in 2004.

In the meantime, CMS continues to make reimbursement and policy changes.

A number of LTAC hospitals are facing considerable challenges going forward. What can tell you us about any thoughts you have about CMS's development of criteria for LTAC hospitals?

Answer:

CMS has made extensive progress, and has devoted considerable Agency resources, towards addressing the concerns raised by the Congress and MedPAC regarding the development of certification criteria for LTCH hospitals. As Administrator, I would continue these efforts to explore and carefully assess the feasibility of developing and implementing patient-level and facility-level criteria for LTCHs. I would also continue to prioritize the development of a post-acute care patient assessment instrument that is designed to assess patients at hospital discharge to determine which post-acute care setting is most appropriate.

CMS awarded a contract to Research Triangle International, Inc. (RTI) to evaluate and determine the feasibility of implementing patient-level and facility-level patient criteria for LTCHs, and continues to review and evaluate the RTI recommendations. RTI has formed a technical expert panel (TEP) consisting of physicians who treat long-term care patients both in LTCHs and as inpatients in other provider settings to study the development of these criteria and assist in the development of a post-acute care assessment tool designed to ensure appropriate placement in a post-acute care setting. CMS just extended RTI's contract to focus specifically on the development of LTCH criteria. Furthermore, RTI is engaged in several other post-acute care projects evaluating different post-acute care settings, information from which will feed into the next level of their project.

CMS has also worked extensively with MedPAC and the industry throughout the RTI research process. The LTCH industry, along with their provider associations, attended the Technical Expert Panel meetings RTI hosted for CMS to openly discuss the overlapping populations treated by LTCHs, acute care hospitals, IRFs, and SNFs. The development of patient-level and facility-level criteria for LTCHs requires extensive research and careful consideration, and I would continue CMS' ongoing efforts to develop these criteria with Congress, MedPAC and the LTCH industry.

2)

Question:

Mr. Weems, CMS is currently implementing a competitive bidding program for durable medical equipment in 10 MSAs. There has been some concern raised about some of the products included in the competitive bidding. One of these products is negative pressure wound therapy.

These products are used to treat complicated wounds, such as in a soldier who has been injured by an IED in Iraq or complicated wounds in fragile Medicare beneficiaries. These products are sophisticated medical devices, not simple canes and walkers. According to wound care experts that I've heard from, not all products are clinically equivalent. This could mean Medicare beneficiaries get less-expensive, ineffective products.

What will you do to ensure that Medicare beneficiaries continue to have access to clinically effective negative pressure wound therapy? And, why are these therapies even included in competitive bidding? Finally, how will CMS be monitoring the clinical impact of competitive bidding on beneficiaries and the financial impact of competitive bidding on the Medicare system as a whole?

Answer:

CMS will be monitoring all aspects of the competitive bidding program as it is implemented. The program is designed to reduce beneficiary out-of-pocket costs, improve the accuracy of Medicare payments, and ensure beneficiary access to high quality medical equipment and supplies.

As health care costs continue to rise, this new program is an opportunity to improve and modernize Medicare, using the competitive marketplace to obtain better value for beneficiaries and taxpayers. It builds upon the success of competitive bidding demonstration projects in Texas and Florida, which produced significant cost savings with uninterrupted beneficiary access to high quality medical items and supplies.

The bidding process is designed to ensure the availability of a wide variety of medical equipment and supplies for beneficiaries. More specifically, suppliers are required to furnish a particular brand name product when a physician specifically prescribes the brand name, consult with the physician or treating practitioner to find an appropriate alternative brand, or assist the beneficiary in locating a contract supplier that can furnish the brand name. When combined with the supplier quality standards and accreditation requirements that are already underway, this program will ensure that high quality medical equipment and supplies are available to Medicare beneficiaries who need them.

The product categories were chosen based on the total Medicare expenditures for the item, the growth in Medicare expenditures, the number of suppliers of the item, the savings potential and the findings of the OIG or GAO reports and studies. Negative pressure wound therapy was selected based on these criteria. CMS will of course closely monitor access to all therapies chose for participation in the competitive bidding program.

3)

Question:

The phase-in for the 75% Rule for Inpatient Rehabilitation Facilities has caused some rehab hospitals in my state to limit the number of patients they see, cut back on staff and some are even struggling to stay open. Fewer patients have access to inpatient rehab care, and this trend is expected to continue as the 65% threshold is implemented. Will you agree to work with us in Congress to support revising the rule so that people who need care at a rehab facility can get it? What is the agency doing or planning to do to revisit the list of diagnoses and clinical criteria for rehabilitation patients, as encouraged by MedPAC?

Answer:

CMS has made revisions in the past to the 75 percent rule based on research data and is committed to analyzing available data in order to improve rehabilitation care for Medicare beneficiaries. Earlier this year, CMS issued an update to a 2005 memorandum which analyzed the most recent data available on the IRF payment system. This updated memorandum illustrated how IRF admission and discharges practices have changed with the introduction of the PPS in 2002 and during the two-year suspension on enforcement of the 75 percent rule. In addition, CMS is currently working with the National Institutes of Health to foster research in the area of medical rehabilitation, which should provide more insight into the effectiveness of medical rehabilitation treatment.

I share your commitment in ensuring that specialized rehabilitation treatment is available for those Medicare beneficiaries with intensive rehabilitation needs and look forward to working with you to achieve this goal.

Senator Schumer

1)

Question:

In its proposed inpatient prospective payment system rule, CMS proposed to cut close to \$2 billion from New York State hospitals through a "behavioral offset." Do you believe CMS should prospectively reduce Medicare payments when they could be changed later to more accurately reflect behaviorally changes that result from the implementation of these new DRGs?

Answer:

The proposed rule, which was released on April 13, builds on the framework established over the last few years to implement the most significant revision of Medicare's inpatient hospital rates since 1983. The rule proposes to improve payment accuracy under Medicare's hospital inpatient prospective payment system (IPPS) by adopting Medicare Severity Diagnosis-Related Groups, or the MS-DRGs, which would increase the total number of DRGs from 538 to 745. I understand that the CMS Office of the Actuary determined that such a significant expansion in the number of DRGs could lead hospitals to improve coding and documentation in order to have a case group assigned to a DRG with a higher payment. As discussed in the proposed rule, without an adjustment to the IPPS rates to account for this expected case mix growth, the change to these severity-based DRGs would not be budget neutral. Because the Social Security Act requires that CMS not increase or decrease payments when modifying the DRG system, the rule included a proposed budget neutrality adjustment.

I am aware that many in Congress have expressed concerns regarding this adjustment. As you know, the public comment period on the proposed rule closed on June 12, 2007. CMS is currently in the process of reviewing all the comments submitted, taking them into account in drafting the final rule, which will be published August 1. I expect the final rule will strive to achieve a balance between the comments received and the Agency's obligation to comply with the statute and safeguard the Medicare Trust Funds.

2)

Question:

Hospitals in my state of New York collectively have been operating in the red for the last eight years. This negative fiscal climate has reduced the number of lenders willing to finance hospital projects and has increased the cost of borrowing. By freezing the capital update for urban hospitals and eliminating the large urban add-on for capital, CMS may be undermining the purpose of the capitol PPS. While you state that hospitals have high margins, how can you justify a capitol payment cut when my hospitals have difficulty attaining the capitol they need for important improvements?

Answer:

Recent analysis of inpatient hospital Medicare capital margins (the difference between payments and costs, divided by payments) for FY 1998 through FY 2004 suggests high margins. Thus, several adjustments currently provided under the Medicare inpatient prospective payment system may be unnecessary. For instance, the high capital margins for urban hospitals suggest the large urban add-on may not be necessary. Accordingly, CMS proposed to eliminate this adjustment to the capital rate for large urban hospitals. Further, the data suggest that the teaching and disproportionate share adjustments may also be unnecessary. CMS solicited comment on whether to discontinue these adjustments as well in the future.

I am aware that many in Congress have expressed concerns regarding the proposed elimination of these adjustments. As you know, the public comment period on the proposed rule closed on June 12, 2007. CMS is currently in the process of reviewing all the comments submitted, taking them into account in drafting the final rule, which will be published August 1.

3)

Question:

A recent Medicaid regulation would eliminate federal support for Medicaid Graduate Medical Education. Why is the Federal government reducing its investment in training doctors precisely at a time when there are already signs we are entering a physician shortage crisis?

Answer:

While I believe it is important for our nation to have access to a workforce of trained physicians, I also believe that CMS must abide by the statutory requirements set forth for the Medicaid program. Under section 1903(a)(1) of the Social Security Act, federal financial participation (FFP), is available to States for a percentage of amounts “expended . . . for medical assistance under the State plan.” The care and services that may be included within the scope of medical assistance under a Medicaid State plan are generally set forth in section 1905(a) of the Act.

Included in this list, for example, are inpatient and outpatient hospital services. Graduate medical education (GME) is not included in this list of care and services within the scope of medical assistance. CMS does not believe that it is consistent with the Medicaid statute to pay for GME activities either as a component of hospital services or separately. GME is not a health service that is included in the authorized coverage package. Nor is GME recognized under the Medicaid statute as a component of the cost of Medicaid inpatient and outpatient hospital services. To address these concerns, CMS issued a proposed rule on May 23, 2007 that proposed to eliminate the availability of federal matching funds for Medicaid payments for GME. States have the option of continuing to make GME payments to hospitals using other funding sources including state funds, national grants or requiring other local entities to participate in the funding of the state’s medical education program.

The Honorable Senator Snowe

1)

Question:

Today CMS is again engaged in an effort to modify the Inpatient Prospective Payment System (IPPS) for Medicare hospital reimbursement. This process – after attempts to revise IPPS last year - has become more problematic with the proposal by CMS to institute a “behavioral offset” – essentially to apply an “across the board” cut in reimbursement based on an assumption that hospitals will systematically “up code” procedures in order to receive excess reimbursement. Essentially, this assumes fraud on the part of providers. Yet rather than enforce sanctions on those who abuse the system, CMS proposes to apply a penalty to all – prospectively. And in fact, CMS seeks to take this same approach – the assumption of bad behavior on the part of providers – in other areas such as in home health. There is some real distortion when the Administration is announces a provider payment update of 3.3 percent – but that update is largely offset by projected 2.4 percent reductions in 2008 and 2009 for the “behavioral offset”. I know that over 60 of us in the Senate have communicated our concern to the Secretary regarding the outrageous application of a penalty before an act – and one applied to all regardless of their behavior. This proposal will harm the financial health of our hospitals – particularly those in rural communities. First, given that CMS is actually planning to penalize all providers, could you explain how this “behavioral offset” doesn’t simply encourage fraudulent upcoding, and second, what action

would you take as Administrator regarding institution of behavioral offsets – both as regards IPPS as well as those directed to other types of providers?

Answer:

The proposed rule, which was released on April 13, builds on the framework established over the last few years to implement the most significant revision of Medicare's inpatient hospital rates since 1983. The rule proposes to improve payment accuracy under Medicare's hospital inpatient prospective payment system (IPPS) by adopting Medicare Severity Diagnosis-Related Groups, or the MS-DRGs, which would increase the total number of DRGs from 538 to 745. I understand that the CMS Office of the Actuary determined that such a significant expansion in the number of DRGs could lead hospitals to improve coding and documentation in order to have a case group assigned to a DRG with a higher payment. As discussed in the proposed rule, without an adjustment to the IPPS rates to account for this expected case mix growth, the change to these severity-based DRGs would not be budget neutral. Because the Social Security Act requires that CMS not increase or decrease payments when modifying the DRG system, the rule included a proposed budget neutrality adjustment.

I am aware that many in Congress have expressed concerns regarding this adjustment. As you know, the public comment period on the proposed rule closed on June 12, 2007. CMS is currently in the process of reviewing all the comments submitted, taking them into account in drafting the final rule, which will be published August 1.. I expect the final rule will strive to achieve a balance between the comments received and the Agency's obligation to comply with the statute and safeguard the Medicare Trust Funds.

2)

Question:

While our hospitals struggle to serve Medicaid recipients, the Administration has proposed cutting an additional \$25 billion from this essential safety net. As you know, the Administration hoped to achieve this in part by capping Medicaid payments to public providers to cost, and restricting the options available to states for financing the non-federal share of their Medicaid programs. Hospitals believe this proposal will be devastating and that in order to maintain current levels of care; states would be forced either to raise new revenues or cut the program. So while I think we can all agree that we should be doing all we can to eliminate fraud in the program, I'm skeptical that these types of cuts will improve outcomes or services in Medicaid or among the uninsured. At the same time, the President has proposed his "Affordable Choices" initiative which the Administration has described might be financed, at least in part, through cuts in the disproportionate share hospital funds which are critical to institutions which serve a large number of Medicare and Medicaid beneficiaries. Hospitals have been a critical part of the health safety net, yet such funding reductions as outlined by the Administration jeopardizes their ability to serve Medicaid beneficiaries, as well as the uninsured and the under-insured. What do you envision as the replacement for such funding losses?

Answer:

I completely agree that hospitals are a critical part of the health safety net and I have no intention of disrupting the important care delivered in hospitals. The changes included in the Medicaid payment reform rule and the President's Affordable Choices proposal are targeted at providing options for affordable health care while maintaining the safety net for those who need it most.

I am concerned by the perception that the limitation to cost included in the Medicaid payment reform rule is intended to harm public providers; in fact, I understand it to protect health care

providers. Governmentally-operated health care providers are assured the opportunity to receive full cost reimbursement for serving Medicaid-eligible individuals, instead of being pressured to return some payment to the State. And, non-governmentally operated health care providers, including many of the “public” safety net hospitals, are not affected by the cost limit provision of the rule.

Under the President’s Affordable Choices proposal, States would develop proposals to make affordable health insurance available to their residents. As part of a proposal, a State could include information on how much of its DSH funds would be redirected to finance health insurance coverage and how much would remain for DSH payments. Massachusetts developed and implemented such a proposal last year. To the extent that a State wanted to adopt such a system, CMS would work closely with the States as we review their proposals to make sure the proposal appropriately balances the need for the provision of affordable health insurance coverage with the maintenance of safety net providers to continuously serve vulnerable populations. Under the President’s proposal, we had always envisioned that some Medicaid DSH dollars would remain in the system, in recognition of the fact that providers will always have some level of uncompensated care.

3)

Question:

We know that the number of Medicare beneficiaries will rapidly escalate in the coming years as the “baby boom” generation reaches retirement age. We face a stark shortage in medical professionals in the years to come. In rural states such as my own the situation is far more serious. Medicare and Medicaid are the dominant payers in my state, and that alone discourages physicians from setting up practice in Maine. So we work to overcome a clear disincentive for physicians to practice in our state, and we emphasize the many positives which counter the problem of low reimbursement from entitlement programs. One way we do so is to train physicians in our state. Graduate medical training programs benefit our states in so many ways - improving the practice of medicine, and training and recruiting new physicians. Yet over the past few years our graduate medical education programs are challenged as CMS has, through increasing aggressive enforcement, sought to disqualify GME reimbursements, and has thereby jeopardized graduate medical training programs. We face the threat of programs closing, and that will have a tremendous downstream effect on beneficiary access to care in rural states. One of the most frustrating aspects of this problem is that – as I have worked with my colleagues to legislate a solution – CMS has acted to enforce new fiscal rules which essentially change the budget baseline – making a legislative solution even more difficult. And that same approach now appears to be directed towards Medicaid support for teaching institutions. The net effect may be short term savings, with disastrous long term effects in terms of provider access. How would you, as the new CMS Administrator, act to prevent the erosion of graduate medical education programs which are so critical to developing our provider workforce?

Answer:

While I believe it is important for our nation to develop our provider workforce, I also believe that CMS must abide by the statutory requirements set forth for both the Medicare and Medicaid programs.

As you know, the Medicare program provides a substantial contribution to the training of physicians across the country by compensating hospitals for the direct and indirect costs incurred in training medical residents. In fiscal year 2007, Medicare is expected to pay hospitals more than \$8 billion in graduate medical education payments. I am committed to supporting

Medicare's role in training physicians, in order to ensure continued beneficiary access to high quality care.

With regard to the Medicaid program, under section 1903(a)(1) of the Social Security Act, federal financial participation (FFP), is available to States for a percentage of amounts "expended ... for medical assistance under the State plan." The care and services that may be included within the scope of medical assistance under a Medicaid State plan are generally set forth in section 1905(a) of the Act. Included in this list, for example, are inpatient and outpatient hospital services. Graduate medical education (GME) is not included in this list of care and services within the scope of medical assistance. CMS does not believe that it is consistent with the Medicaid statute to pay for GME activities either as a component of hospital services or separately. GME is not a health service that is included in the authorized coverage package. Nor is GME recognized under the Medicaid statute as a component of the cost of Medicaid inpatient and outpatient hospital services. To address these concerns, CMS issued a proposed rule on May 23, 2007 that proposed to eliminate the availability of federal matching funds for Medicaid payments for GME. States have the option of continuing to make GME payments to hospitals using other funding sources including state funds, national grants or requiring other local entities to participate in the funding of the state's medical education program.

4)

Question:

The issue of equity in payments is a critical one which we must address if we are to assure both reasonable compensation to providers and the long term fiscal health of Medicare. With your extensive budget experience, you appreciate that. I note that the President has been a major supporter of Community Health Centers, and has worked hard to support their expansion during his Administration. Yet today Federally Qualified Health Centers (FQHCs) – while allowed to serve Medicare beneficiaries – operate under a per-visit payment limit which results in centers often serving beneficiaries at a loss. Indeed 75 percent of FQHCs incurred some loss due to the payment cap, averaging nearly \$75,000 annually. When Congress established the FQHC program, it required that health centers be paid at a rate which would cover the cost of providing services. So on numerous occasions, I have raised the issue of the cap, and last year Senator Bingaman and I led a bipartisan group of 36 Senators in calling for the Secretary to examine adjustments to the payment methodology for health centers. The response was not encouraging, as we were told that, should CMS and HRSA find that "the limits negatively limit access to care, the Department will consider appropriate recalculation or adjustment at that time". Disturbingly, while the Administration deferred action here, it has continued to support and promote costly Medicare managed care - which MedPAC has told us will cost more than \$150 billion over traditional fee-for-service care over the next decade. Mr. Weems, here we have a real failure to respond meaningfully to a letter from over one third of the Senate. Is CMS waiting until the surge in our senior population swamps health centers, or until some centers reach the brink of insolvency, in order to assure they are paid at a rate that covers the cost of providing services?

Answer:

Ensuring Medicare beneficiary access to Federally Qualified Community Health Centers (FQHCs) and Rural Health Clinics (RHCs) is important. If confirmed, I would want to better understand how Medicare payments and the payment cap compare to audited FQHC costs, as well as how Medicare payments compare to costs in the RHC setting.

5)

Question:

Mr. Weems, you come to this nomination by an unusual route. It is more common that

appointees come from political or policy ranks, or perhaps from the medical profession. However, as you have spent decades in public service, you have a unique perspective – that of an expert in budgeting and finance. Today the fiscal challenges facing our entitlement programs – and particularly Medicare – are indeed daunting. And this year I joined many of my colleagues in expressing concern that the Administration’s approach to the fiscal health of Medicare appears very much one dimensional – the President proposed a period of repeated annual cuts in provider payments. Addressing the challenges facing Medicare requires more than budgeting, it involves changing processes. Not simply deciding arbitrarily to pay less, but, for example, knowing the efficacy of different treatments, so that Medicare can use value to set rational priorities. Yet the Administration budget largely ignores the need to prevent disease – and to better manage chronic disease – and it fails to ensure that we will have the health care workforce needed for an aging population. Simply put, as the number of seniors escalates with the aging of the boomer generation, we cannot use provider spending cuts to address Medicare costs – we will irreparably damage the system before such cuts ever bring costs in line adequately to counter the growth in beneficiaries. Critically, some have hypothesized that your nomination sends a message that the President will maintain his existing policy trajectory of spending cuts. Since you have worked so closely with the Secretary, and now sit as the nominee for Administrator, would you tell us how the next 18 months will be different in terms of the strategy at CMS, and if so, how?

Answer:

I agree that my path to this nomination is unusual, although it is a clear demonstration of my ability to analyze the facts, data, and law irrespective of the political affiliation of the Administration in power. I am honored to have worked so closely with several Secretaries of the Department of Health and Human Services (HHS) in recent years, and I believe the mutual respect and rapport that I already have with Secretary Leavitt will be beneficial in allowing me to advocate the needs and challenges faced by CMS.

In my tenure at HHS, it was my privilege to have led the Budget Office for a number of years. The budget, in formulation and in execution, may be the most policy-filled structure in government. It is often said that there is a policy hidden behind every budget number, and we all know the HHS Budget has many numbers within it. My experiences throughout HHS have taught me to fashion budget proposals with clear policy goals in mind, not simply budget savings. I have also learned to rely on experts and to weigh facts and evidence as policy goals are sought.

I agree that making Medicare solvent requires more than budget cuts. Without a doubt, behavior changes are also a critical part of ensuring the health and viability of the Medicare program for future generations of taxpayers and beneficiaries. Our current coordinated care efforts, chronic care demonstration programs, pay-for-performance and other quality initiatives are all aimed at investing in high quality preventative care, which is the only way to get ahead. I strongly believe that evidence-based preventative medicine should be rewarded; it not only makes good business sense but also encourages healthy behavior. If confirmed, I will continue CMS’ current focus on prevention, wellness initiatives, and disease management techniques that will reduce consumption and lower health care costs by changing beneficiary behavior, not merely lowering reimbursements.

Senate Finance Committee
Hearing on Nominations, Wednesday, July 25, 2007
Response to Questions for the Record, by Kerry Weems

The Honorable Chairman Baucus

1)

Question:

In GAO 07-587T, the Government Accountability Office estimated that over 21,000 Medicare physicians paid under Medicare Part B during the first nine months of 2005 owed about \$1 billion in unpaid Federal taxes. To improve compliance, the GAO recommended that the Centers for Medicare & Medicaid Services submit Medicare payments through the Federal Payment Levy Program.

1. To what extent do you concur with the GAO's findings and recommendations?

Answer:

Where tax debt is owed, Medicare believes it should be paid. CMS is actively working to facilitate collection of provider tax debt by participating on the Federal Contractor Tax Compliance taskforce (FCTC) to identify an automated way for CMS payments to be levied.

2. As Administrator of the Centers for Medicare & Medicaid Services, how will you address this problem? Will you make a commitment to take the steps necessary for CMS to process Medicare Part A & B payments through the Federal Payment Levy Program?

Answer:

CMS will continue to work closely with our partners at the Department of the Treasury (FMS and IRS) through the Federal Contractor Tax Compliance taskforce (FCTC) and other means to address the problem of unpaid tax debt of Medicare providers. CMS will commit to comply with the Federal Payment Levy Program by implementing the Non-Treasury Disbursement Office (NTDO) option, in which CMS will send an extract of its payees to FMS. In turn, FMS will determine if those payees have outstanding Federal debts, and will send CMS a file identifying the amounts. CMS will then remit Federal debts collected via offset to Treasury.

The Honorable Senator Kerry

1)

Question:

Hospital Reimbursement

Isn't it true that capital expenditures are long-term obligations and that drastically cutting these payments with less than 6-months notice amounts to pulling the rug out from under these hospitals and wreaking havoc with their capital planning? Shouldn't we be assisting hospitals with their long-term capital planning – so they can invest in not only improved patient care but also in things like environmentally-friendly, energy-saving building technology?

Answer:

Recent analysis of inpatient hospital Medicare capital margins (the difference between payments and costs, divided by payments) for FY 1998 through FY 2004 suggests high margins. Thus, several adjustments currently provided under the Medicare inpatient prospective payment system may be unnecessary. For instance, the high capital margins for urban hospitals suggest the large urban add-on

may not be necessary. Accordingly, CMS proposed to eliminate this adjustment to the capital rate for large urban hospitals. Further, the data suggest that the teaching and disproportionate share adjustments may also be unnecessary. CMS solicited comment on whether to discontinue these adjustments as well.

I am aware that many in Congress have expressed concerns regarding the proposed elimination of these adjustments. As you know, the public comment period on the proposed rule closed on June 12, 2007. CMS is currently in the process of reviewing all the comments submitted, taking them into account in drafting the final rule, which should be published in the Federal Register in early August. If confirmed, I would be happy to work with you on individual hospital concerns.

2)

Question:

Why is the administration proposing to cut IME payments to hospitals? These are funds that are used to ensure that we have a well-educated physician workforce to care for our Medicare patients. Shouldn't it come out of the excessively high payments to plans rather than the hospitals? Do you really think that Medicare Advantage plans are going to pass along the payment to hospitals? What evidence does the agency have to support this proposal? Please send me your data proving that MA plans do indeed pass along these payments to teaching hospitals.

Answer:

Under current law, CMS pays twice for IME: once directly to the hospitals, and once to health plans in their per-member per-month payments. It is CMS's expectation that, in the normal course of dealing with health plans, teaching hospitals would negotiate for payment terms with the health plans that adequately cover their expenses. While CMS does not track health plan distribution of their per-member per-month payments, CMS is confident that teaching hospitals would negotiate with a commercial insurer in their non-Medicare lines of business for teaching-related expenses. CMS believes that it is appropriate to expect the same type of negotiation in the Medicare context. By eliminating the current duplicate payments for IME, CMS can help improve Medicare's financial solvency and promise for future generations.

3)

Question:

Payment for Physician-delivered Pharmaceutical Treatments

Do you believe that physician administered drugs should be paid by Medicare consistent with section 1847A of the Social Security Act - the average sales price statute?

If so, how is allowing carriers to continue the imposition of least costly alternative to a physician administered drug consistent with the ASP statute? Does CMS think it has authority to not follow 1847 with respect to these drugs? If so, can you please explain what that authority is?

Answer:

Yes, I believe that physician administered drugs should be paid by Medicare consistent with the average sales price statute. CMS is aware that questions have been raised about the policy for applying LCA to drugs, and we take those issues seriously. At the same time, CMS also has concerns about whether it is good policy for CMS to pay for Lupron if other drugs can have the same beneficial effect at far lower cost. I am informed that CMS is looking at all of these issues carefully in light of all of the concerns raised, including the issues you raised, and that CMS has not made a final determination at this time.

4)

Question:

75% Rule

Several Medicare fiscal intermediaries are creating local coverage determinations based on the 75% Rule and doing an end-run around established medical necessity rules. As a result, fiscal intermediaries are looking at the 75% Rule and telling hospitals, even after the fact, that this patient or that patient isn't eligible for inpatient rehabilitation care. Physicians and hospitals are pushing back, noting that the care these patients are receiving does meet the established definition of medically necessary care. I point out this situation to you, Mr. Weems, to provide an opportunity for you to do the right thing and get a handle on what's going on with your fiscal intermediaries. Surely, CMS does not mean for eligible patients to be turned away by the inconsistent and unnecessarily restrictive standards of certain insurance claims processors. Tell me please how you plan on rectifying this situation so that patients who can and should be treated by an inpatient rehabilitation facility get the care their physician says they should receive?

Answer:

I share your commitment to ensuring that specialized rehabilitation treatment is available for those Medicare beneficiaries with intensive rehabilitation needs and am committed to working with you to achieve this goal. First and foremost, I will continue to highly prioritize the development of a post-acute care patient assessment instrument designed to assess patients at hospital discharge to determine which post-acute care setting is most appropriate. Such an instrument would be beneficial to providers as well as beneficiaries, and would help prevent situations of learning after-the-fact that a particular stay is not covered – a situation that I agree is extremely unfortunate and should be avoided. I also would be happy to discuss with you any particular concerns you have heard with specific fiscal intermediaries.

The phase-in of the 75% Rule is threatening access to care for many patients. We in Congress acknowledged the significance of this problem in the Deficit Reduction Act of 2005 by extending the 60% threshold for an additional year. Although that step preserved access for many patients, 88,000 patients have lost access to inpatient rehabilitation care in the first two years alone. Indeed, MedPAC has estimated that Medicare inpatient rehabilitation admissions would drop another 20 percent under the new 65% threshold. How will the Agency work with Congress to support revising the Rule?

Answer:

I share your commitment to ensuring that specialized rehabilitation treatment is available for those Medicare beneficiaries with intensive rehabilitation needs and am committed to working with you to achieve this goal.

CMS has made revisions in the past to the 75 percent rule based on research data and is committed to analyzing available data in order to improve rehabilitation care for Medicare beneficiaries. Earlier this year, CMS issued an update to a 2005 memorandum which analyzed the most recent data available on the IRF payment system. This updated memorandum illustrated how IRF admission and discharges practices have changed with the introduction of the PPS in 2002 and during the two-year suspension on enforcement of the 75 percent rule. In addition, CMS is currently working with the National Institutes of Health to foster research in the area of medical rehabilitation, which should provide more insight into the effectiveness of medical rehabilitation treatment.

MedPAC has characterized the current 75% Rule as "a blunt instrument." The 13 diagnoses used to identify patients simply do not identify all patients who need, can tolerate, and benefit from intensive rehabilitation. What is the agency doing, or planning on doing to revisit the list of diagnoses and clinical criteria for rehabilitation patients, as encouraged by MedPAC?

Answer:

One of the activities I am most enthusiastic about is the agency's ongoing work to develop a post-acute care patient assessment instrument, designed to assess patients at hospital discharge to determine which post-acute care setting is most appropriate. In addition, with respect to the 75 percent rule in particular,

CMS has made a number of revisions in the past based on research data and I am committed to continued analysis of available data in order to improve rehabilitation care for Medicare beneficiaries.

I would like information about the clinical evidence the agency is using to support its application of the 75% Rule. If CMS is trying to rationalize the post-acute care patients are receiving, the agency must base its decisions on solid research from the field. Congress has asked repeatedly for CMS to consult with clinical experts and work with stakeholders in an open format to update its decision-making. How is CMS producing evidence from clinical-based studies and research to refine the Rule? What kind of public forums is the agency using to identify the best practices in rehabilitation care? As MedPAC recently wrote to the CMS, I also urge the agency to be as open and transparent as possible in its analyses and deliberations, so that the rehabilitation community will fully understand the data and the logic supporting any changes in the qualifying criteria. I strongly suggest that CMS formally obtain input from those who provide and receive rehabilitation services. How are you planning on doing this?

Answer:

In attempting to promote research that better identifies the types of patients whose treatment needs require an IRF setting, I understand that CMS has collaborated with several crucial stakeholders to create a framework for future research. In addition, some examples of past research efforts that have informed recent work on the 75% rule include:

- At CMS's request, the National Center for Medical Rehabilitation Research at the National Institute of Child Health and Human Development (NCMRR/NICHHD) at the National Institutes of Health (NIH) convened a panel in February 2005 to develop a research agenda on appropriate settings for rehabilitation. [Agenda and summary report are attached].
- Recently, NCMRR/NICHHD also issued a notice on the NIH website recognizing the need to enhance the evidence base for clinical practice, with a commitment to work with providers and research groups to encourage the design of clinical studies that meet NIH standards. CMS also intends to work with researchers conducting NIH-approved studies so that they can meet their study objectives within the overall framework of the Medicare program benefit.
- Over the past year, CMS has been actively participating in various NIH panel discussions to foster research in the area of medical rehabilitation, with the goal to better identify typical characteristics of patients in need of the intensive rehabilitative services that only IRFs can provide.

It is important to note that CMS does not typically fund clinical trials or other clinical studies. However, NIH has expressed willingness to consider research proposals in this area if resources permit.

The Honorable Senator Lott

1)

Question:

As I stated at today's hearing, it is my opinion that some of Katrina funding allocations have not been balanced enough. How are hospitals in South Mississippi supposed to address the financial problems caused by Katrina with the opportunities lost in the misallocation of critical wage index relief? Do you agree with this and how can we address this going forward?

Answer:

I appreciate and share your concern with helping hospitals in South Mississippi remain financially viable. As you note, HHS has provided grant funding to the Gulf Coast region for purposes of wage index relief. The allocation of that grant was based on each eligible acute care hospital's and skilled nursing facility's share of total Medicare payments in the FEMA designated counties for 2006 (the latest and most complete year of Medicare billing data available to us). Recognizing the importance of continued relief to hospitals across the Gulf Coast, and certainly in South Mississippi, additional funding has been made available, including \$220 million in supplemental provider stabilization grants and additional workforce recruitment grants since January 2007. Out of the total \$2.8 billion in DRA funds, \$836.8 million was allocated to Mississippi. I know senior staff at CMS have made themselves available for technical assistance on various hospital reimbursement issues (e.g., wage index, GME) to Louisiana hospital executives working to rebuild, and I would be happy to offer the similar assistance to South Mississippi facilities, and to continue to work with you on recovery in South Mississippi.

2)

Question:

Rush Health Systems has been trying to build a hospital in Kemper County, which has no healthcare facility. CMS has a provision in their regulations stating two requirements. Kemper Co falls short of one requirement but meets the other. How can one rule basically override another in that of a county like Kemper County? How can a place meet one definition of critical, but not another?

Answer:

If confirmed, I would be happy to work with you on this issue to try to clear up any confusion or potential policy inconsistencies. From the information provided here, however, it is not clear what type of facility Rush Health Systems is attempting to build (e.g., critical access hospital, sole community hospital, etc), or which requirements are seemingly inconsistent. It may be possible that some of the rules in play are grant rules administered by an agency other than CMS, or even State laws, for example, as opposed Medicare regulations. Regardless, I pledge to listen to the concerns and help identify options for moving forward in a way that ensures access to needed health care in Kemper County.

3)

Question:

Mr. Weems, in 2004, MedPac called for the creation of certification criteria for long-term, acute-care (LTAC) hospitals. After that Medpac recommendation, CMS commissioned a study of how CMS might develop those criteria. Two years later, in 2006, CMS published an inconclusive study that made some very generalized recommendations but did not do much to advance a new policy. CMS does not seem to be any further along in developing certification criteria than it was in 2004. In the meantime, CMS continues to make reimbursement and policy changes which even MedPAC has concluded are "crude and unsophisticated." A number of LTAC hospitals are facing considerable challenges going forward. What can tell you us, Mr. Weems, about any thoughts you have about CMS' development of criteria for LTAC hospitals? A number of Senators, including Mr. Conrad and Mr. Hatch, have introduced a bill which would legislatively create criteria. The bill has been endorsed by the American Hospital Association and the two LTAC hospital associations. What would your position be on that legislation?

Answer:

CMS has made extensive progress and has devoted considerable Agency resources towards addressing the concerns raised by the Congress and MedPAC regarding the development of certification criteria for LTCHs. As Administrator, I would continue these efforts to explore and carefully assess the feasibility of developing and implementing patient-level and facility-level criteria for LTCHs. I would also continue to prioritize the development of a post-acute care patient assessment instrument that is designed to assess patients at hospital discharge to determine which post-acute care setting is most appropriate. As a

general matter, my preference would be to use regulations to develop patient-level and facility-level criteria

4)

Question:

In 1998, Congress extended who could receive hospice care to include, outside of cancer, other “non-curative illnesses” and lifted the 6 month limit, as long as a physician continued to certify the patient as having a terminal prognosis. However, with these changes, Congress did not remove or modify the Cap on the hospice provider to allow for increased spending. Doesn’t it seem counterintuitive to expand the types of patients that hospices can serve, yet not increase their cap? How are hospices supposed to provide services to more people with the same funding they’ve had since 1983?

Answer:

As you mentioned in your question, the Balanced Budget Act of 1997 (BBA) extended who could receive hospice care and lifted the six-month limit, as long as a physician continued to certify the patient as having a terminal prognosis. The BBA also made a number of changes to the Medicare hospice benefit including a restructuring of the Medicare hospice election periods. The changes were made to allow beneficiaries to revoke their hospice election to pursue curative treatments without jeopardizing future access to the Medicare hospice benefit.

Nonetheless, overall aggregate payments to a hospice are subject to a statutory cap amount. The cap is not a limitation on the payment per beneficiary, but is a limit on the total payment provided to a hospice for the year. This cap was established by law at the inception of the hospice benefit to limit program expenditures and to maintain the benefit’s orientation toward care in the individual’s home. The cap is updated annually for inflation and is applied in the aggregate, recognizing that lengths of stay for patients may vary. While I understand CMS is seeing an increase in the number of hospice providers exceeding the hospice cap, the Agency believes that the majority of hospices are able to provide appropriate hospice care within the hospice aggregate payment cap.

5)

Question:

As I mentioned this morning, my casework offices are deluged with cases of folks having problems reclaiming money that was deducted from Social Security for Medicare Part D and in the case of third party payees, getting liens released in a timely manner. How do you plan to address the delays in reimbursement so that citizens can continue to receive healthcare in a timely manner?

Answer:

I am personally committed to improving business processes within CMS such as premium withhold by taking a comprehensive top-down review. CMS takes the premium withhold issues very seriously, and has been working to resolve all outstanding 2006 issues, as well as to implement changes to the premium withhold process to ensure that such problems do not occur again. Our primary concern on both premium withhold is ensuring that beneficiaries swiftly receive benefits to which they are entitled. I fully intend to keep the Committee apprised of progress in this area.

The Honorable Senator Stabenow

1)

Question:

I want to ask you a question related to the agency’s proposed \$25 billion hospital cut which is part of the fiscal year 2008 proposed rule for Medicare hospital payments.

I am very concerned about this Administration's use of rule-making to cut payments to our health care providers. Members of Congress have made it clear that we do not support the provider cuts the President proposed in his budget; rule-making seems to be a back-door way of trying to cut providers.

If you were Administrator of CMS, would you pursue provider cuts through rule-making?

Answer:

Oftentimes what is characterized as a provider "cut" is in fact the result of our efforts to comply with the statutory budget neutrality requirement. We do not have the ability to waive or ignore that requirement.

2)

Question:

With respect to the hospital rule, I agree there is some logic in paying hospitals more when they treat sicker patients and less when they treat healthier patients.

My question though goes to the additional \$25 billion in cuts CMS proposed to take off the table on the assumption that hospitals will change the way they have coded bills. Twenty-five billion is an awfully big number, even for the Finance Committee. What specific analysis did the Agency do to develop that number?

Answer:

The proposed rule, which was released on April 13, builds on the framework established over the last few years to implement the most significant revision of Medicare's inpatient hospital rates since 1983. The rule proposes to improve payment accuracy under Medicare's hospital inpatient prospective payment system (IPPS) by adopting Medicare Severity Diagnosis-Related Groups, or the MS-DRGs, which would increase the total number of DRGs from 538 to 745. I understand that the CMS Office of the Actuary determined that such a significant expansion in the number of DRGs could lead hospitals to improve coding and documentation in order to have a case group assigned to a DRG with a higher payment. As discussed in the proposed rule, without an adjustment to the IPPS rates to account for this expected case mix growth, the change to these severity-based DRGs would not be budget neutral. Because the Social Security Act requires that CMS not increase or decrease payments when adopting a DRG system, the rule included a proposed budget neutrality adjustment. The necessary level of adjustment is supported by our internal analysis by the Office of the Actuary. CMS will revisit the adjustment in two years if projected and actual data are different, and we can make adjustments retrospectively as well as prospectively.

3)

Question

Did the Agency look at Michigan acute care hospitals or the acute care hospitals of any states represented on this Committee in making your estimate? I believe the hospitals I represent are coding claims accurately and completely and wonder about the assumption that hospitals will begin to code claims differently. Doesn't it make more sense to accumulate some actual claims experience and make adjustments based on hard evidence rather than guesswork?

Has CMS provided all of the analysis that is the basis for the \$25 billion cut? I would like to hear back from you if there is any additional data or analysis that supports such an enormous cut.

Answer:

The proposed rule, which was released on April 13, builds on the framework established over the last few years to implement the most significant revision of Medicare's inpatient hospital rates since 1983. The rule proposes to improve payment accuracy under Medicare's hospital inpatient prospective payment system (IPPS) by adopting Medicare Severity Diagnosis-Related Groups, or the MS-DRGs, which would

increase the total number of DRGs from 538 to 745. I understand that the CMS Office of the Actuary determined that such a significant expansion in the number of DRGs could lead hospitals to improve coding and documentation in order to have a case group assigned to a DRG with a higher payment. As discussed in the proposed rule, without an adjustment to the IPPS rates to account for this expected case mix growth, the change to these severity-based DRGs would not be budget neutral. Because the Social Security Act requires that CMS not increase or decrease payments when adopting a DRG system, the rule included a proposed budget neutrality adjustment.

I am aware that many in Congress have expressed concerns regarding this adjustment. As you know, the public comment period on the proposed rule closed on June 12, 2007. CMS is currently in the process of reviewing all the comments submitted, taking them into account in drafting the final rule, which should be published in the Federal Register in early August. I expect the final rule will strive to achieve a balance between the comments received and the Agency's obligation to comply with the statute and safeguard the Medicare Trust Funds.

With regard to the analysis conducted, the CMS Office of Actuary considered the recent experience of the State of Maryland with adopting a system similar to the MS-DRGs. When the actuaries compared how hospitals code Medicare claims in Maryland under their new system and nationally for the same time period using the current DRG system, they found that improved coding in Maryland increased payments by nearly 5 percent more than occurred nationally. This analysis was detailed in great length in the proposed rule to allow for public review and comment. Although MedPAC suggested a lower figure, I understand they supported the Agency's analysis and indicated that the figure represents a reasonable upward boundary for how much Medicare payments may increase as a result of improved coding.

4)

Question:

I am concerned about the lack of transparency in CMS decision-making and responsiveness to Congressional inquiries. For example, CMS released a rule earlier in the year that limited intergovernmental transfers (IGTs) under Medicaid. According to CMS, this rule would cut \$4 billion over 5 years from states, safety-net hospitals, nursing homes, and other providers. Yet CMS refused to release state-by-state impact when asked by the Finance Committee.

First, I would like the state-by-state specific data on the IGT rule. Given that CMS released a rule despite bipartisan congressional opposition and has had substantial time to determine the state-specific impact, this data should be available.

Second, as Administrator, what steps would you take to ensure that congressional inquiries are answered on a timely basis? Given the impact that many of rules will have on our states' Medicaid programs, that is a fair request.

Answer:

The CMS Office of the Actuary conducts the regulatory impact analyses and does not prepare estimates on a state-by-state basis. Thus, such data as you request is not available.

I appreciate the importance and value the relationship between CMS and the Congress. I will do all in my power as Administrator to ensure that Congressional inquiries are answered in a manner that is as timely as possible, and I expect that you will personally hold me to that commitment.

5)

Question:

I'd like to address Medicare physician payments. One of the most serious problems with the sustainable growth rate formula (SGR) is the inclusion of Part B drugs, whose rate of growth is beyond the control of physicians.

Does the Administration have any plans to remove Part B drugs from the SGR formula in the short term, or plans to find a long-term fix for the physician payment formula?

It has been argued that the Administration does not have the legal authority to take the drugs, but that position appears to differ from a discussion of this issue in the 2003 Medicare physician payment final rule. Can you explain this?

Doesn't the statement in the rule (from page 80027 of the December 31, 2002 Federal Register, see below) suggest that HHS has the authority to take the drugs out but has chosen not to do so?

"The statute provides the Secretary with clear authority to specify the services that are included in the SGR. Section 1848(f)(4)(A) of the Act indicates "the term 'physicians' services' includes other items and services (such as clinical diagnostic laboratory tests and radiology services) specified by the Secretary, that are commonly performed or furnished by a physician or in a physician's office". We disagree with the comments suggesting that the Secretary does not have the authority to include drugs in the definition of physicians' services for purposes of determining allowed expenditures, actual expenditures and the SGR. In reviewing section 1861(s) of the Act, we decided to include items and services in the SGR that are commonly furnished by physicians or in physicians' offices. Since "incident to" drugs covered under section 1861(s) of the Act are commonly furnished in physicians' offices, we are including these items in the SGR."

Answer:

The 2006 physician fee schedule final rule (page 70307 of the November 21, 2005 Federal Register) indicates:

"We have indicated in the past that retrospective removal of drugs from the SGR is statutorily difficult. For example, the statute requires the estimated SGR be refined twice based on actual data. We do not see a legal basis to re-estimate the SGR and allowed expenditures for a year after it has been estimated and revised twice. Further, as noted previously, our current estimate is that removing drugs retroactively from the SGR would not result in a positive update for 2006 or the succeeding few years"

The Administration does not plan to remove Part B drugs from the SGR formula in the short term. For the past 5 years, Congress has intervened to prevent the implementation of the negative updates resulting from this formula. CMS will continue working with Congress as well as physician groups to identify payment methods that help improve the quality and efficiency of care in a way that does not increase costs for taxpayers or Medicare and its beneficiaries. The Medicare program needs to compensate physicians appropriately for the services they provide to people with Medicare. But how the program pays also matters. We think the early work on the Physician Quality Reporting Initiative program is one of those reforms that could help lead us to a point where we can promote better quality care and more efficient care.

6)

Question:

Medicare Advantage plans are supposed to use the rebate dollars they receive from the government to offer additional benefits. However, it is my understanding that CMS does not explicitly track how private plans spend these rebates.

As Administrator, would you make a concerted effort to track the use of rebate dollars so Congress would have a clear understanding of how these monies are being spent and to verify whether or not the rebate payments are being passed along to beneficiaries?

Answer:

Plans are required in their bids to tell us how they are using rebate dollars. Rebate dollars are used primarily to reduce beneficiary cost sharing and premiums. In this regard, reduced premiums immediately provide beneficiaries with insurance coverage at a lower cost. In addition, surveys indicate that beneficiaries in MA plans have very high levels of access to services. However, I would be happy to work with you to explore means to collect additional data in this area.

7)

Question:

I've heard complaints from many seniors about documents that CMS uses to communicate with beneficiaries. The Medicare and You handbook is often criticized for not clearly distinguishing between traditional Medicare and private plans, leaving seniors confused about key differences.

Similarly, the Annual Notice of Change that is annually sent to beneficiaries does not clearly inform beneficiaries of their right to change plans or that their current plan is changing.

- How would you ensure that all CMS documents would better facilitate beneficiary understanding?

Answer:

I understand how critically important it is for these documents to be as simple and clear as possible. I know CMS has worked hard to improve the clarity and understandability of the publications and other documents for Medicare beneficiaries.

The 2007 Medicare & You handbook undergoes extensive consumer testing with beneficiaries and caregivers each year. Such testing helps to ensure that material is presented in a clear, comprehensive and objective manner. We also seek input from and consult with a wide range of organizations, advocacy groups, State Health Insurance Assistance Program counselors, other government agencies, and Congress. This year, we have reviewed and incorporated hundreds of comments on the handbook from various sources, resulting in reorganization of some information from the previous year's version. In addition, we have updated several navigational cues to increase the ease with which users find the information they need. All of these changes have tested well with our beneficiary audience.

With respect to the Annual Notice of Change, in response to comments the 2008 model notices include a very specific statement at the top of the first page that informs beneficiaries of their rights to switch plans and to compare the benefits, costs, and restrictions of the plans available in their area. If confirmed I would continue CMS's approach of reaching out to beneficiaries and key stakeholders for suggestions on how to improve those documents and investing significant resources in consumer testing with target audiences.

The low-income subsidy (LIS)-eligible population is an extremely difficult group to reach. Estimates range from 3.4 million to 4.7 million beneficiaries who are eligible for, but have not yet applied for this valuable subsidy.

- How do you propose to enroll this population in the benefits they are entitled to?

Also, CMS extended the LIS special enrollment period in 2007 so beneficiaries can apply for LIS and enroll in a plan without a premium penalty.

- As Administrator, would you extend the LIS special enrollment period for 2008?

Answer:

Beginning in 2005, CMS embarked on a multi-faceted campaign to reach out to the more than 42 million people with Medicare, with a special emphasis on reaching those beneficiaries potentially eligible for LIS. Medicare's partners, including grassroots organizations, local, State and Federal agencies, State Health Insurance Assistance Programs (SHIPs), the faith community, and individual volunteers sponsored and attended thousands of Medicare events and opportunities across the country for people to get personalized assistance.

Reaching beneficiaries who are eligible for the Medicare prescription drug low income subsidy (LIS) has been a top priority at CMS. If confirmed, I expect to personally devote considerable time to outreach – not just to beneficiaries, providers, and our partners, but also to the families and “informal” caregivers of beneficiaries.

Today, more than 10 million low-income Medicare beneficiaries are getting comprehensive drug coverage for little or no cost. CMS estimates that this is more than 70 percent of those beneficiaries potentially eligible for LIS. By any measure, enrollment in Medicare Part D is impressive and participation by LIS beneficiaries is unprecedented for a new public sector benefit program.

The work to identify and enroll beneficiaries in the LIS continues today. CMS continues to target potentially eligible LIS individuals with a multi-pronged education and outreach campaign that leverages existing information intermediaries and resources. Initiatives include direct mailings and targeted telephone calls to beneficiaries, along with local outreach from community groups, intergovernmental partners, and health care providers, including pharmacists. On July 25, 2007, CMS conducted an event for national, federal, state, and local partners who work with low-income Medicare beneficiaries. At this event, CMS released a LIS toolkit that provides important resources for partners to help beneficiaries learn about and apply for LIS. The contents of the outreach toolkit (includes updated data spreadsheets, interactive maps, and the photo novellas) was distributed to the over 200 partners in attendance, and is available online at the following address:
<http://www.cms.hhs.gov/Partnerships/Toolkits/itemdetail.asp?itemID=CMS1188820>

To remove barriers to enrollment for low-income beneficiaries, CMS waived the late enrollment penalty for 2006 and 2007. CMS has established a special enrollment period for all LIS beneficiaries and I will work to pursue ways to eliminate the late enrollment penalty for LIS-eligible beneficiaries in 2008.

8)

Question:

I'm sure you agree that it is extremely important for Medicare patients to have timely access to drugs and biological products for the treatment of cancer and other diseases.

Under current law, Medicare covers anti-cancer drugs if the indication for treatment is listed in one of three compendia; however CMS has issued a Proposed Rule to make needed revisions to the list of compendia used for Part B.

I am concerned, however, with the seemingly lengthy implementation schedule outlined in the Proposed Rule. It appears that the earliest that CMS intends to act to revise the list of compendia used for anticancer drugs is September 2008, despite an already extensive process having been undertaken.

Further, Congress must act to ensure that modifications of the list of compendia used for Medicare Part B occur at the same time for Medicare Part D.

Given that CMS has been studying this issue for more than two years, couldn't the agency implement these revisions more quickly than September 2008? That appears to be unnecessarily long, particularly given the urgency of appropriate treatment of a disease such as cancer.

I am aware that at least one cancer-specific compendium has already applied for inclusion to the currently mandated list. CMS's own Medicare Coverage Advisory Committee gave that compendium the best scores on each and every desirable characteristic of a compendium. Would it be possible to act now on that application if the compendium meets the criteria outlined in the Proposed Rule?

Answer:

Modification of the compendia list at 1862(t)(2)(B) must be achieved through notice and comment rulemaking. As you note, the agency has proposed that process as part of the Physician Fee Schedule proposed rule released on July 1 of this year, and that rule is scheduled to be finalized November 1, 2007. We welcome comments on the proposed rule, including suggestions regarding modifications or efforts to streamline the proposed process. We do believe that it is important to ensure that the process is open and transparent, and allows sufficient time for the public to provide input on compendia modifications.

Finally, given that approximately half of all new cancer drugs, including those in the pipeline, are oral anticancer products, I believe it is essential that the list of compendia used for Part D be as current as the compendia used for coverage determinations under Part B? Would you agree that compendia used for Part B should be listed under Part D as well?

Answer:

This is a complex issue that merits further study, and I would be happy to do that. The Part B compendia serve the needs of a different set of drugs and indications than the Part D compendia. For example, the Part B pharmaceutical coverage rules focus on DME products, medications administered incident to physician visits, or certain oral cancer drugs, anti-emetics for cancer treatment, and specific immunosuppressant medications. Part D coverage extends to a much broader set of drugs. I would like the opportunity to talk to experts and stakeholders, review the relevant evidence, and consider current experience with the Part B and D compendia, as well as the Medicaid compendia for that matter, before rendering a decision. I look forward to continuing a dialogue with you on this issue.

9)

Question:

I understand that you have a regulation pending that would cut about \$25 billion from hospitals; nearly \$104 million would be cut from hospitals in Michigan in FY08.

I am very concerned about this inpatient hospital payment rule, especially since the cuts do not seem to be based on solid evidence. If inappropriate coding is occurring, then CMS has the authority to recapture the money and should do so.

Has CMS provided all of the analysis that is the basis for the \$25 billion cut? I would like to hear back from you if there is any additional data or analysis that supports such an enormous cut.

Answer:

The proposed rule, which was released on April 13, builds on the framework established over the last few years to implement the most significant revision of Medicare's inpatient hospital rates since 1983. The rule proposes to improve payment accuracy under Medicare's hospital inpatient prospective payment system (IPPS) by adopting Medicare Severity Diagnosis-Related Groups, or the MS-DRGs, which would increase the total number of DRGs from 538 to 745. I understand that the CMS Office of the Actuary determined that such a significant expansion in the number of DRGs could lead hospitals to improve coding and documentation in order to have a case group assigned to a DRG with a higher payment. As discussed in the proposed rule, without an adjustment to the IPPS rates to account for this expected case mix growth, the change to these severity-based DRGs would not be budget neutral. Because the Social Security Act requires that CMS not increase or decrease payments when adopting a DRG system, the rule included a proposed budget neutrality adjustment. The necessary level of adjustment is supported by our internal analysis by the Office of the Actuary. CMS will revisit the adjustment in two years if projected and actual data are different, and we can make adjustments retrospectively as well as prospectively.

10)

Question:

Dr. McClellan was an advocate for preventing disease, and championed that goal through Medicare by instituting a "Welcome to Medicare" physical exam. Likewise, Secretary Leavitt initiated a 48 state bus tour to urge seniors to use Medicare's prevention services.

However, at the same time, CMS made cuts, some substantial, to reimbursement for technologies used to screen for osteoporosis and breast cancer. These are diseases whose incidence increases with age, and for which we have effective screening tools and proven interventions.

Lowering reimbursement for basic preventive services seems at odds with Medicare's commitment to disease prevention, particularly when screening rates are so low.

Fewer than 1/3 of Medicare beneficiaries receive annual mammograms, and CDC now tells us that mammography rates overall are declining. In addition, the number of women screened for bone density has never exceeded 15% in any year.

The promise of disease prevention rests on reasonably convenient access to services. If you are confirmed as Administrator, would you review these cuts and consider whether they might aggravate problems of access and drive utilization rates lower still? I would appreciate hearing from you within 30 days of your confirmation.

Answer:

Medicare beneficiary access to quality and efficient health care is a high priority for CMS, as well as for me. I have heard concerns raised about reductions in payment amounts for certain services under the Medicare physician fee schedule. It is my understanding that CMS will be monitoring access to these services closely.

My understanding is that these refinements to the payment amounts are not specifically targeted towards women's health. They are part of the comprehensive reviews of Medicare payment amounts for all physicians' services by expert physician panels that make recommendations to CMS to insure that Medicare pays appropriately for all services, including preventive services. Payments for physicians' services are based on the relative amount of physician work and the resources typically required in performing them. The reductions primarily occur as a result of the practice expense refinements. The data upon which these payments are based are the best data available and have been reviewed by the American Medical Association's Relative Value Update Committee.

I understand that CMS has taken some actions to help patients manage their care and achieve better outcomes by increasing payments for office visits so that physicians can spend more time with their patients. This includes critical services that can help to prevent or detect early the underlying conditions for the top causes of death in women such as heart disease, stroke, diabetes, and pulmonary disease. These increases in payments will allow physicians to spend more time with their patients to manage their care and achieve better outcomes.

11)

Question:

With respect to preventive benefits generally, do you believe Medicare and Medicaid offer the appropriate benefits? Are there financial or other impediments to the use of these benefits that ultimately end up costing money and lives?

Answer:

I believe prevention benefits are very important to the well-being of Medicare and Medicaid beneficiaries. They can save lives and avoid medical expenses for preventable complications associated with heart disease, diabetes, cancer, weak bones, high blood pressure, smoking, inactive lifestyles, and other illnesses and unhealthy behaviors.

As I am sure you aware, CMS has initiated public awareness campaigns such as the Prevention bus tour to promote using Medicare's preventive benefits. CMS also works with other agencies in the Department of Health and Human Services to promote preventive services.

Medicare preventive benefits are designed to provide seniors with better care and a higher quality of life. Medicare covers a broad range of services to prevent disease, detect disease early when it is most treatable and curable, and manage disease so that complications can be avoided. New Medicare beneficiaries have access to the "Welcome to Medicare" physical exam. Additional preventive benefits include screenings for cardiovascular disease, diabetes, heart disease, glaucoma, osteoporosis and cancers of the colon, breast, cervix, and prostate and ultrasound screening for Abdominal Aortic Aneurysm. In addition, immunizations for influenza, pneumococcal and hepatitis B are covered under Medicare. Medicare also covers smoking cessation visits to physicians and certain qualified practitioners for beneficiaries who are diagnosed with a smoking-related illness or are taking medicine that may be affected by tobacco. Medicare also provides diabetes self management training for certain people with Medicare who are at risk for complications from diabetes. Medicare coinsurance and/or deductibles are waived for a number of these preventive services.

The Medicaid program offers a full range of benefits, including many preventive services, which are mandated under Federal law. States also have the ability to cover additional benefits and have recently been provided the option to target benefit packages more appropriately to certain populations. For example, CMS has approved several State programs that include promotion of healthy lifestyle changes, including nutritional education and smoking cessation programs and incentives to seek out early detection and screening services. I assure you that, if confirmed, I will work with the States to determine what issues there are in providing preventive benefits.

12)

Question:

A new study by the Commonwealth Fund found that 25 percent of seniors joined Medicare with no prior coverage. Their health expenses are very high. This is the group that needs a Welcome to Medicare Visit but the take-up rate for this benefit is less than 3 percent. What would you do as CMS Administrator to improve the take-up rate?

Answer:

Prevention would be a primary focus of my efforts as CMS Administrator. I would build upon existing outreach campaigns that focus on beneficiaries and our partners, by also directly reaching out to the families and caregivers of beneficiaries. I have learned through personal experience with my parents that active caregiver and family engagement is crucial to helping Medicare beneficiaries take best advantage of the many benefits that Medicare offers. Reaching caregivers also serves double-duty, since many of these sons, daughters and other family-members are also future beneficiaries. Resources invested now in educating these folks about the value of preventive benefits like the Welcome to Medicare physical could help improve the health status for not just this generation of beneficiaries, but future beneficiaries as well.

13)

Question:

With CMS being the largest purchaser of healthcare in the country, what role will you play in moving the implementation of health information technology? How will CMS use its market force to bring others along in the Administration's goal of an electronic medical record by 2010?

The Administration has expressed its goal of a fully electronic medical record by 2010, putting the obligation on providers (both large and small) to invest enormous sums of money in technologies. Why has this process been so slow? How is CMS prepared to help providers pay for this?

Answer:

Health information technology can play a major role in reducing medical errors and improving the quality of health care. I have been personally involved in HHS' efforts to foster the adoption and implementation of health IT from the outset and I plan to continue supporting such efforts to the best of my ability as CMS Administrator. I fully support the Administration's goal of the majority of Americans having an electronic medical record by 2014.

CMS established the Physician Quality Reporting Initiative for 2007, which provides a financial incentive for eligible professionals to participate in a voluntary quality reporting program. CMS is currently working with physician specialty groups to develop the expanded set of PQRI measures for 2008, and to meet the statutory requirement of including structural measures, such as the use of electronic health records or electronic prescribing technology. CMS recently proposed the addition of structural measures in the proposed Medicare Physician Fee Schedule for Calendar Year 2008, and is also exploring the possibility of opening registry-based and EHR-based reporting for 2008.

CMS is also working towards the adoption and effective use of health information technology by physicians through the Doctor's Office Quality - Information Technology (DOQ-IT) project. The goal of DOQ-IT, which is managed by Medicare Quality Improvement Organizations (QIOs), is to improve the quality of care and safety for Medicare beneficiaries by promoting greater availability of high quality affordable health information technology (HIT) and by providing assistance to physician offices in adopting and using such technology. Under the 8th SOW, QIOs are required to implement DOQ-IT within each state. As part of the DOQ-IT requirements, QIOs are expected to recruit five percent of all primary care practice sites in the state and to provide assistance with HIT adoption and use to generate electronic clinical information, care management implementation and reporting of electronic clinical information.

In addition, the Medicare Care Management Performance (MCMP) demonstration is a 3-year pay-for-performance demonstration with physicians in small- and medium-sized physician practices. The goal of the demonstration is to promote the adoption and use of HIT to improve the quality of patient care for

chronically ill Medicare patients. Doctors who meet or exceed performance standards established by CMS in clinical delivery systems and patient outcomes will receive bonus payments for managing the care of eligible Medicare beneficiaries. Because the implementation of an electronic health record (EHR) and the ability to use it to facilitate the redesign of clinical practices can be critical to improving the quality of care, physicians in this demonstration will be eligible to receive additional incentive payments for implementing a CCHIT-certified EHR and reporting the clinical performance data electronically.

The President and the Department of Health and Human Services want hospitals to invest in expensive but necessary health information technology.

How can hospitals do this if their funding is not only not increased, but actually decreased as a result of the provision to reduce capital payments in the proposed inpatient prospective payment rule?

Answer:

Recent analysis of inpatient hospital Medicare capital margins (the difference between payments and costs, divided by payments) for FY 1998 through FY 2004 suggests high margins. Thus, several adjustments currently provided under the Medicare inpatient prospective payment system may be unnecessary. For instance, the high capital margins for urban hospitals suggest the large urban add-on may not be necessary. Accordingly, CMS proposed to eliminate this adjustment to the capital rate for large urban hospitals.

This is not to say that the Administration does not support adoption of health information technology. The hospital capital payments under the inpatient prospective payment system are one source of support for technology updates. We also think that investments in technology will save hospitals resources in the long run. If confirmed, I would be very interested in working with you to promote the adoption of health information technology not just in hospitals, but across the provider spectrum.

14)

Question:

The Medicaid EPSDT screening is supposed to identify children with weight issues and refer them for treatment, but this is not happening. What would you do as CMS Administrator to address this growing problem in the Medicaid and CHIP population?

Answer:

I certainly want to assure you that all individuals eligible for Medicaid and SCHIP are able to access the benefits that they should receive. Childhood obesity is a serious public health problem and its incidence is increasing. If children with weight issues are not receiving the care that they should be, I will work with the States to determine the extent of the problem and figure out how to best address it.

15)

Question:

What is CMS doing to ensure that all the products provided in the Negative Pressure Wound Treatment category will be clinically effective and clinically equivalent? What types of controls are being put in place to ensure that patient outcomes, and Part A solvency, are not adversely affected by this process?

Answer:

First and foremost, CMS is committed to protecting beneficiary access and quality of care. If confirmed, one of my first actions as CMS Administrator will be a top-to-bottom review of the DMS Competitive Bidding program. I will be assessing business process, beneficiary protection, and quality issues, and would be happy to further evaluate the concerns you raise with negative pressure wound therapy (NPWT). I have pledged in response to other questions and will reiterate here that if my review reveals

significant causes for concern – whether from a readiness, competitiveness or quality standpoint -- I will delay implementation of the program until those concerns can be adequately addressed.

CMS will be monitoring all aspects of the competitive bidding program as it is implemented. The program is designed to reduce beneficiary out-of-pocket costs, improve the accuracy of Medicare payments, and ensure beneficiary access to high quality medical equipment and supplies. CMS has designed a detailed supplier monitoring and evaluation process that will be used to ensure that beneficiaries are receiving the items and level of service they need and deserve.

In addition, CMS has made it mandatory that all contract suppliers be accredited and meet Medicare quality standards. Under the competitive bidding program, contract suppliers must also offer the same brands of items to Medicare patients that they offer to their other clients and they must furnish a particular brand to a beneficiary if the physician documents that use of the particular item would avoid an adverse medical outcome on the individual, work with the physician to find an appropriate substitute, or assist the beneficiary in locating another contract supplier that can furnish the particular brand. Therefore, contract suppliers must furnish quality items and services to any beneficiary in the competitive bidding area who requests their services.

16)

Question:

I am concerned about the fairness, timeliness, and impartiality of the CMS waiver process.

For example, my state and many others relied upon the Administration's "Health Insurance Flexibility and Accountability" initiative to cover more people through unused CHIP dollars. But a few years later, the Administration is now opposing those very same waivers it asked states to file and later approved!

In another example, CMS has been slow to approve family-planning waivers under Medicaid. A CMS-funded evaluation of state Medicaid family planning expansions found that all of the programs studied were not only cost-neutral, but yielded significant savings of \$15 million in a single year.

Currently, 26 states have applied for and obtained waivers to expand family planning services to women who need them, while at the same time generating significant cost savings for federal and state governments. However, CMS approval of a waiver involves a lengthy, burdensome, and costly process that takes an average of 24 months to complete.

What will you do as Administrator to ensure that waivers are reviewed fairly, impartially, and in a timely way?

Answer:

Waiver demonstration projects allow states flexibility in exploring innovative approaches in operating their Medicaid programs and I share your goal in ensuring that the waiver review process is conducted in a fair, timely, and impartial fashion. As part of these efforts, I am committed to strengthening transparency and intend to improve communication and collaboration with partners and will work to add a summary page of pending actions on waivers, including State and Federal contact information, to the CMS website within the next several months.

17)

Question:

My state has applied for a Medicaid waiver to cover at least an additional 500,000 people who currently do not have insurance. My understanding is that CMS has still not approved this waiver. Michigan had planned on financing this expansion by being credited for the significant savings it had saved the federal

government through the use of HMOs and effective drug purchasing. We had hoped to have an answer on this waiver by April. What is the current status, and when will the state receive an answer?

Answer:

Michigan has submitted a draft concept paper for the Michigan First Healthcare Plan (MFHP). MFHP would be a public and private partnership that seeks Medicaid waiver authority under Section 1115 of the Social Security Act for titles XIX and XXI to expand health care coverage subsidized by Medicaid to low-income individuals who represent one-half of the state's uninsured, and to reform Michigan's health insurance market by making affordable coverage more accessible and portable for Michigan's uninsured workers who are employed by small businesses. CMS has had several discussions with the State over the past several months regarding the financing of the MFHP concept. In the last 30 days, CMS staff has worked closely with the State to refine the financial projections and analysis. Michigan submitted responses to written questions on the financing of the proposal and requested a call with CMS staff to discuss the responses and additional issues relating to the financing. The call is scheduled for July 27, 2007. In addition the State is continuing to work on the benefits package and other parts of the proposal. CMS will continue to work closely with the State to provide technical assistance related to the development of a formal waiver application and an implementation timeline.

The Honorable Senator Cantwell:

1)

Question:

Mr. Weems, thank you for testifying. I appreciated the opportunity to meet with you last month. If you recall, we discussed a number of health care issues important to my state, including Medicare payment equity.

Washington state has a strong tradition of providing high-quality, low-cost care. However, we are routinely penalized under existing Medicare payment rules that reward inefficiency and pay more for more services rather than for better care. As a result, the areas of the country reporting higher volume s of services are paid more. This is troubling, since studies reveal that these variations in spending are unrelated to actual health outcomes.

How do you plan to address the regional variations in health care spending so that states like Washington are not penalized for providing efficient care?

Will you commit to a full-scale review of the academic research on regional variations in Medicare costs?

Answer:

This Administration has made a strong commitment to rural health issues, implementing many significant regulatory and departmental reforms to address the needs of rural America. I intend to continue those efforts, if confirmed, and I will commit to working with others in the Administration on a full-scale review of available academic research on regional variations.

The two main drivers of the relatively lower Medicare program payments that rural areas receive are different practice patterns and lower costs. Rural Medicare beneficiaries are, in general, less likely to be hospitalized and less likely to use physician's services. These two types of services account for three quarters of the program's costs. Rural beneficiaries who do receive such care tend to receive a lower volume of services with, for example, shorter lengths of stay and fewer visits. Finally, rural areas have lower input price structures for their health care delivery systems. At the same time, it is clear that high cost health care delivery does not necessarily reflect better care or better outcomes, it is simply an

indication of more care. For example, quality of care studies often identify rural states as having high quality care despite lower average Medicare expenditures.

As always, I welcome your comments and suggestions to improve the quality of America's health care programs. I remain committed to ensuring equal access to high-quality, up-to-date care for Medicare beneficiaries residing in rural areas.

2)

Question:

You are certainly aware of this committee's efforts to implement greater transparency in Medicare Part D. A significant federal investment has been made in these private plans, which in turn rely on Pharmacy Benefit Manufacturers to broker deals with drug manufacturers.

I'm concerned about this process. We don't know if PBMs are getting plans the best deals they can. We don't know if the rebates they negotiate are being passed onto the beneficiary as savings, or if they are simply being pocketed for financial gain.

We need to know that CMS is being a strong regulator and is effectively using its oversight authority to ensure that these deals are working for Medicare beneficiaries—not for private interests.

Recently, we've seen large employers push for more transparency in the practices of their PBMs. They have been able to reduce drug spending between 3 and 6 percent, at a time when drug spending is rising nationally.

Do you think that the federal government should expect the same accountability from private contractors under Part D plans as large employers?

As Administrator of CMS, what specific measures would take to establish greater transparency and oversight in the prescription drug program?

Answer:

I agree that the federal government should expect accountability and transparency from Part D plans. I believe that the program already demands a higher level of accountability and transparency from plans participating in Part D. For example, Part D provides an unprecedented degree of transparency for beneficiaries in terms of their ability to access estimated prices and costs under all Part D plans in their area. The plans are also required to provide extensive data reporting on prescription drug plan costs, along with rebates and other price concessions. However, if confirmed I would explore whether there are additional steps that could be taken in furtherance of these goals.

3)

Question:

My next question deals with an issue commonly referred to by the Social Security Administration as the Special T2 Disability Workload project. This issue is particularly concerning to my state because of its impact on our health care budget.

As you may know, the Social Security Administration has been working to correct a serious oversight that has impacted roughly 100,000 individuals on Supplemental Security Income (SSI). These individuals were eligible for Social Security Disability (SSDI) but were never notified by the Administration of their status.

SSDI status is important, as a beneficiary becomes eligible for Medicare after a 24-month period. If this person is also on Medicaid at the time they get shifted onto Medicare, their Part B premiums are paid for by the state under a "buy-in" agreement with CMS. Most people on Supplemental Security Income are also on Medicaid, since eligibility for the program is linked to SSI.

This is where the trouble for Washington and other states begins. CMS is billing states retroactively for Part B premiums that would have been paid if the Special Disability Workload cases had not been overlooked. Some of these retroactive payments date back as far as thirty years ago.

This is hardly fair. States have already been paying for these people through Medicaid. CMS is essentially asking that states pay for medical care twice—once through Medicaid, and again through Part B premiums.

I appreciate that CMS has been studying this complex issue. However, I am concerned by unrealistic proposals suggesting that states take Medicaid money back from providers and then have those providers file new Medicare claims. This approach is simply unworkable, as providers cannot be expected to return years' worth of payments.

Mr. Weems are you willing to examine this problem further at CMS?

Do you believe a solution can be worked out administratively in a manner that is fair to states?

Answer:

I am very familiar with this issue from my tenure as Chief Financial Officer at HHS. I fully appreciate that this is a critical issue for the States, and I will commit to examine it further at CMS if confirmed. I assure you that I will carefully examine whether an administrative solution can be worked out and look forward to continued dialogue with you and the States on this issue.

The Honorable Senator Ensign

1)

Question:

I believe we need to develop and encourage the use of best practices and clinical practice guidelines so that doctors and patients have the information they need to make appropriate clinical decisions. What can we do to better incorporate best practices into private health insurance programs and large government programs such as the Medicare and Medicaid programs? And, can you please provide me with an estimate in terms of savings that could be achieved as a result of the incorporation of best practices?

Answer:

The current Medicare payment systems often reward the volume of services provided, rather than the quality of the services provided to beneficiaries. This often has the effect of directing more resources to delivering care that is not of the highest quality (for example, duplicative tests and services, as well as hospital admissions or visits to treat potentially avoidable complications). Linking a portion of Medicare payments to valid measures of quality and the effective use of resources would give providers more direct incentives to utilize best practices and clinical practice guidelines. As Administrator, I would work to support provider payment reforms that reward quality and efficiency rather than quantity of services.

CMS has worked extensively to promote quality healthcare based on clinical best practices by developing a variety of programs that link Medicare payment to quality performance. For example, CMS is working to implement the Physician Quality Reporting Initiative (PQRI), which establishes a financial incentive for eligible professionals to participate in a voluntary quality reporting program. I expect that the PQRI

will help to promote adoption of best practices by physicians who treat Medicare patients, and will certainly impact practice patterns to the benefit of non-Medicare patients as well. CMS also is currently working with physician specialty groups to develop the expanded set of PQRI measures for 2008, and to meet the statutory requirement of including structural measures, such as the use of electronic health records or electronic prescribing technology.

In addition, the value-based purchasing (VBP) initiative, which is designed to link payment more directly to performance on quality measures, is a key policy mechanism that CMS is adopting to transform itself from being a passive payer to an active purchaser of care for millions of Medicare beneficiaries. CMS' hospital payment policy moving forward will focus on purchasing value for the Medicare program, so that hospitals will receive differential payments as a function of their performance by creating pay-for-performance programs that link quality of care with payment.

2)

Question:

A recent Harris Poll found that consumers can guess the price of a standard car within \$300. But when asked to estimate the cost of a four-day stay in the hospital, they were off by \$8,100. Clearly, patients typically do not know the cost of the medical services they receive. As we work to reduce Medicare and Medicaid spending, patients will need cost and quality information to make informed and prudent healthcare decisions. What policy and technological changes are needed to make such information more transparent and more routinely available?

Answer:

The Department of Health and Human Services has worked extensively through its Value-Driven Health Care Initiative to improve the transparency of health care quality and pricing information. Secretary Leavitt's cornerstones for building a value-driven healthcare system include measuring and making transparent quality information and price information.

CMS has supported this initiative, making dramatic strides towards the dissemination of quality and pricing data. CMS has a wide variety of programs in operation that create financial incentives for Medicare providers to report quality data on the care given to beneficiaries. In addition, CMS has worked extensively to publish quality data and disseminate information to healthcare consumers. This information will serve to empower consumers with the information necessary to make informed decisions regarding their healthcare, while giving providers additional incentives to identify and pursue better care protocols. For example, CMS recently published on the Hospital Compare Web site thirty-day mortality outcome measures for patients with hospital discharge diagnoses of acute myocardial infarction (AMI) or heart failure (HF). CMS also published the first annual update of pricing and volume information on certain elective hospital procedures. These are just a few examples of the Agency's ongoing activities to ensure the transparency of quality and pricing information. As Administrator, I would work hard to continue to expand on the demonstrated success of these efforts.

3)

Question:

The President's Budget contains several proposals to reduce the rate of growth in the Medicare program in an effort to improve the financial stability of the program. However, the President's Budget does not contain proposals for addressing the fatally flawed sustainable growth rate (SGR) formula, which cuts Medicare physician payment rates year after year. The Congressional Budget Office estimates that Medicare physician payment rates would be reduced by 10 percent in 2008 under current law. The 2007 Medicare Trustees report predicts cumulative reductions in Medicare physician payment rates of about 40 percent in the coming decade. These cuts, if allowed to occur, threaten to destabilize the Medicare program. What is your plan for addressing these pending cuts and replacing the SGR?

Answer:

For the past 5 years, Congress has intervened to prevent the implementation of the negative updates resulting from this formula. CMS will continue working with Congress as well as physician groups to identify payment methods that help improve the quality and efficiency of care in a way that does not increase costs for taxpayers or Medicare and its beneficiaries. The Medicare program needs to compensate physicians appropriately for the services they provide to people with Medicare. But how the program pays also matters. CMS thinks the early work on the Physician Quality Reporting Initiative program is one of those reforms that could help lead us to a point where we can promote better quality care and more efficient care.

4)

Question:

One of the most serious problems with the SGR is the inclusion of Part B drugs, whose rate of growth is beyond the control of physicians. In the past, large majorities of both the House and Senate have urged the Administration to remove Part B drugs from the formula, an action that will ultimately reduce the cost of permanently fixing the formula. Does the Administration have any plans to remove Part B drugs from the SGR formula in the short term, or plans to find a long-term fix for the physician payment formula?

Answer:

The Administration does not plan to remove Part B drugs from the SGR formula in the short term. For the past 5 years, Congress has intervened to prevent the implementation of the negative updates resulting from this formula. CMS will continue working with Congress as well as physician groups to identify payment methods that help improve the quality and efficiency of care in a way that does not increase costs for taxpayers or Medicare and its beneficiaries. The Medicare program needs to compensate physicians appropriately for the services they provide to people with Medicare. But how the program pays also matters. CMS thinks the early work on the Physician Quality Reporting Initiative program is one of those reforms that could help lead us to a point where we can promote better quality care and more efficient care.

5)

Question:

In my state, more than 30 percent of Medicare beneficiaries have chosen to receive their benefits through a Medicare Advantage plan. My state has also benefited by legislation that enhanced rural payments as far back as the Balanced Budget Act (BBA) in 1997. Some are now calling for eliminating those payment enhancements that we created back in the BBA by cutting Medicare Advantage rates. If Congress acts to cut Medicare Advantage payments, how would this impact premiums of the Medicare Advantage enrollees in my state? What would happen to the plan choices?

Answer:

It is difficult to know for sure how the payment cuts will specifically impact premiums and plan choices in the state of Nevada. Based on a preliminary estimate by the CMS actuaries, however, limiting Medicare Advantage payments to 100 percent of the fee-for-service rate would reduce payments on behalf of Medicare beneficiaries in Nevada by \$67 million over five years (2008-2012). In addition, CMS estimates that the cuts would affect 95 percent of Medicare Advantage enrollees, in 82 percent of Nevada counties.

**Senate Finance Committee
Nomination Hearing
July 25, 2007
Additional Questions for the Record for Mr. Weems**

Questions from Chairman Baucus

- 1) Federal law requires pharmaceutical manufacturers to pay rebates to the States to offset the price of pharmaceuticals billed to State Medicaid programs. Under the current system, States send pharmaceutical companies quarterly invoices stating the rebate amount which must be paid within 38 days or else interest accrues on the debt. CMS has provided guidance to states on the payment data that should be included in these invoices. Rebate invoices provided by the States to manufacturers are not provided in a consistent and sufficiently detailed manner for manufacturers to verify the amounts. This lack of uniformity and detail make it difficult for manufacturers to audit the rebate invoices so that they can notify the States of erroneous, duplicative or fraudulent drug payment claims. Some manufacturers have been able to discover fraudulent or erroneous payment claims, but the scope of these problems is unknowable. To facilitate accuracy, timeliness, and certainty, this rebate data should be submitted to manufacturers in a uniform electronic format (i.e., NCPDP format) to ensure that manufacturers can quickly verify claims and easily identify any questionable claims. Will CMS, under your leadership, take action to do this? If you do not have sufficient authority, will you in a timely manner inform this Committee of this so that Congress can take action?

Answer: Section 1927(b)(2)(A) of the Social Security Act requires States to provide information to manufacturers "in a form consistent with a standard reporting format established by the Secretary." The standard format established by CMS is the OMB-approved form, CMS-R-144. States may implement this requirement in various formats, so long as the thirteen data fields included on the CMS-R-144 are present for each drug. The CMS-R-144, also referred to as the State Rebate Invoice (invoice), is used for the current rebate quarter, as well as for adjustments to previous quarters. Further, the national rebate agreement provides manufacturers with an avenue to dispute the data provided on the invoice, and request additional documentation from states. However, if confirmed, I will look into this issue and see if additional steps should be taken. I will inform the Committee of this if we determine we do not have the authority.

Questions from Senator Hatch

- 1) Do you believe that physician administered drugs should be paid by Medicare consistent with section 1847A of the Social Security Act - the average sales price statute? If so, how is allowing carriers to continue the imposition of least costly alternative to a physician administered drug consistent with the ASP statute? Does CMS think it has authority to not follow 1847 with respect to these drugs? If so, please explain what that authority is?

Answer: CMS is aware that questions have been raised about the policy for applying LCA to drugs, and they take those issues seriously. At the same time, CMS also has concerns about whether it is good policy for CMS to pay for Lupron if other drugs can have the same beneficial effect at far lower cost. I am informed that CMS is looking at all of these issues carefully in light of all of the concerns raised, including the issues you raised, and that CMS has not made a final determination at this time.

- 2) Doesn't the imposition of least costly alternative unfairly impact lower income Medicare beneficiaries when they must bear the added cost of staying on a preferred therapy that is subject to such policy?

Answer: Payment at the least costly rate ensures that beneficiaries pay the lowest possible coinsurance and, in that sense, financially benefits the patient. That said, we are also concerned that patients have access to medically necessary drugs. Application of least costly alternative is a coverage determination under Medicare, which a beneficiary can appeal. Under BIPA, the BBRA, and the MMA, beneficiaries have expanded and expedited appeal rights when challenging a contractor's decision. If a beneficiary or his or her clinician believes that a contractor has inappropriately applied a least costly alternative policy, those enhanced appeal rights become available.

- 3) Why does Medicare require a prostate cancer patient that is on an effective therapy to choose between paying additional costs to stay on the therapy that they are using or having to switch to another therapy that has not been determined to be therapeutically equivalent or bioequivalent simply because it is the least costly drug?

Answer: CMS does not believe that contractors apply least costly alternative policy when there is no clinical basis to do so. As I stated in my previous response, LCA is a coverage determination under Medicare, which a beneficiary can appeal. Under BIPA, the BBRA, and the MMA, beneficiaries have expanded and expedited appeal rights when challenging a contractor's decision. If a beneficiary or his or her clinician believes that a contractor has inappropriately applied a least costly alternative policy, those enhanced appeal rights become available.

- 4) What suggestions or ideas would you have, with the full array of tools available to an Administrator at CMS at your disposal, to help assist rural hospitals that have experienced a natural disaster retain physicians?

Answer: In designated disaster areas, the Secretary of HHS can invoke waiver authority under Section 1135 of the Social Security Act, in appropriate circumstances. As you know, physician retention in disaster areas is a complex problem, often requiring a cross-agency approach and strong partnerships with State and local government. I would be happy to explore any specific situation with you in greater detail if confirmed.

- 5) CMS staff briefed the committee staff about the impact of the 2.4 percent reductions in the proposed rule. They said that if CMS "over-estimates" the magnitude of the reductions, the agency will return the money to hospitals in future years. Now, I don't

have to tell you that a lot of people out there—namely providers, the hospitals—don't have a lot of confidence that you folks are being truthful. What assurances can you give us that CMS will actually do that? Please answer for the record: will CMS pay back the money that CMS takes from hospitals when it's demonstrated that the agency over-estimated the effects of this rule?

Answer: In the final rule, CMS committed to re-examining documentation and coding behavior in the third year, when data from the first year of the transition to the new DRGs will be available. At that time, CMS will assess any over-estimates or under-estimates of the adjustment.

- 6) CMS published a rule entitled: Medicaid Program: Cost Limit for Providers Operated by units of Government and Provisions to Ensure the Integrity of Federal-State Financial Partnership that will go into effect in May of 2008 if Congress does not extend the existing one-year moratorium. This Rule will eliminate nearly \$4 billion over five years in Medicaid funding for safety net and teaching hospitals across the country. The dramatic decrease in funding targeted at safety net hospitals alone will have a ripple effect across all sectors of the health care system. In Utah, for example, the impact will be devastating. The University of Utah Hospitals and Clinics, the primary teaching and clinical arm of Utah's only academic medical center, will lose more than \$40 million in critical Medicaid support payments, effectively eliminating its margin. As a result, the University of Utah Hospital will be unable to support medical education, continue to provide a disproportionate amount of care to Medicaid and uninsured patients and its ability to be the source for specialized, unique, and referral services will be severely compromised. While I support CMS's efforts to improve the Medicaid program and ensure its financial viability, I am very concerned that CMS has singled out government providers and only government providers for a major base funding cut. Could CMS withdraw the Rule and propose a Rule that equitably distributes the \$3.9 billion cut across all providers?

Answer: In being a responsible steward for the Medicaid, Medicare and SCHIP programs, I believe it is important to promote transparency and accountability in financing and support efforts to maintain the integrity of the programs. I am happy that you share this viewpoint. There has been a great deal of success in the past few years in putting the questionable financing practices to an end. CMS has worked with 30 states to eliminate improper recycling provisions. CMS took further action by promulgating this Medicaid financing reform regulation to make changes permanently and prevent improper recycling activities from slipping back into practice in the future.

I appreciate that Medicaid is a vitally important program that serves very vulnerable populations. I am concerned by the perception that this Medicaid rule is intended to harm public providers; in fact, I understand it to protect health care providers. The rule will now assure governmentally-operated health care providers the opportunity to receive full cost reimbursement for serving Medicaid-eligible individuals, instead of being pressured to return some amount of their Medicaid payments to the State. And, non-governmentally operated health care providers, including many of the "public" safety net hospitals, are not affected by

the cost limit provision of the rule. I will work with you and the provider community to hear concerns about the rule that was published. If I find changes are needed, I will ensure that they occur.

Questions from Senator Salazar

- 1) In early June, I sent a letter with over 60 of my Senate colleagues, to the Centers for Medicare and Medicaid Services on two CMS provisions in the proposed Inpatient Prospective Payment System, which my colleagues and I are very concerned about. I have not received a response. As the Administrator of CMS do you have any plans to improve CMS's timelines in responding to members' concerns, especially when it comes to oversight issues such as this?

Answer: Senator, as I stated in my testimony before this Committee on July 25, 2007, I can assure you that improving responsiveness to Members of Congress is a high priority.

- 2) I am concerned about CMS' proposed Inpatient Prospective Payment System Rule that would cut approximately \$25 billion from the nation's hospitals over the next five years. If this regulation moves forward in its present form, my state of Colorado is estimated to lose \$21 million in FY08. The centerpiece of this rule is a behavioral offset that is flawed. CMS currently has the authority to recapture money lost by "behaviors" of hospitals, such as miscoding. CMS should be dealing with hospitals based on real evidence, not expectations that hospitals will change their behaviors. This rule takes action that is not needed and would have a harsh effect on many hospitals and limit access to care provided by them. I urge you to reconsider this rule. Mr. Weems, what is the status of this proposal and have you thought about its impact on rural hospitals?

Answer: Senator, I grew up in New Mexico and I fully appreciate the importance of rural hospitals to not just the Medicare beneficiaries they serve, but to the entire surrounding community. I share your commitment to preserving access to high-quality care for Rural America. The final inpatient hospital prospective payment system rule was released on August 1, 2007. Based on public comments received in response to the proposed rule, the new severity-adjusted DRGs will be phased in over two years, rather than one year, as detailed in April's proposed rule. The budget neutrality adjustment phase-in was also extended from two to three years. CMS has thought about the impact of this rule on rural facilities, however, the Medicare Actuary estimates that without an adjustment to account for changes in how hospitals document and code patient severity of illness, the new system would increase payments. Since we apply changes to DRGs on a budget-neutral basis, the offset was necessary to implement that policy. I understand that MedPAC sent a letter to Congress yesterday endorsing the approach that we took, and in fact, suggested that we could have even imposed a greater adjustment in the first year.

- 3) I was disappointed to see the final CMS rule regarding the Medicaid average manufacturing price, which continues to underpay pharmacies for the drugs they provide. I am particularly concerned because a recently released GAO Report and OIG Report indicates that reimbursing pharmacies based on AMP does not cover their actual

acquisition cost for the drugs. If rural pharmacies receive reimbursements that do not cover drug costs, they will be forced to close their doors, and the residents they serve will be left without a pharmacy. For many rural towns and communities, the pharmacies are the cornerstone of their fragile health care delivery system.

What steps is CMS taking to address the impact of this rule on rural pharmacies and the residents who rely on those pharmacies for medications?

Answer: CMS recognizes the critical role that pharmacists play in providing prescription drugs to beneficiaries on Medicaid. The Medicaid drug reimbursement changes in the Deficit Reduction Act of 2005 (DRA) were prompted by a series of 2004 reports by both the Government Accountability Office (GAO) and the HHS Office of the Inspector General (OIG) showing that Medicaid payments to pharmacies for generic drugs were much higher than what pharmacies were actually paying for those drugs. The GAO and OIG found that states were overpaying for drugs because they were using commercial drug pricing guides as the basis for setting state reimbursement levels. The investigation of these drug price "compendia" documented that these prices were artificially inflated, especially for generic drugs. One goal of the DRA was to encourage states to pay pharmacies more appropriately for the estimated acquisition costs of generic drugs.

CMS is required by the DRA to use 250 percent of AMP (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent as the formula for establishing a federal upper limit (FUL) for multi-source drug payments. This is an aggregate limit, so states may reimburse some multi-source drugs at higher than this amount and still receive federal matching payments. In addition, states retain the authority to set their own reimbursement levels and dispensing fees paid to pharmacists. Recognizing that the new FULs could result in some reduction in drug ingredient payments to pharmacies, CMS is actively encouraging states to evaluate whether the fees they pay pharmacies are adequate to compensate them for their costs in dispensing these prescriptions. Additionally, CMS is soliciting additional comments on two key areas of this rule: the so-called "outlier policy" that eliminates from AMP calculations any drug in an FUL that is priced significantly lower than other drugs in that category and the definition of AMP. This will allow CMS the benefit of further public comment as actual AMP numbers become available and the FULs are developed.

If confirmed as Administrator, I would work to ensure that the Medicaid drug pricing rule does not have the effect of limiting access to prescription drugs to our nation's most vulnerable citizens.

- 4) Mr. Weems, in early February, HHS announced a proposal of a new regulation for Medicaid rehabilitative services that would cut \$2.2 billion from that program over a five-year-period. You may be aware that both the disability and mental health communities have expressed deep concern to members of this Committee that these funding cuts would be met through reduced access to services like coaching and community skills training, which is now being provided to children with developmental disabilities and Medicaid recipients with serious mental illnesses. I have authored two proposals, which I entered in the Finance Committee's record at the SCHIP markup last week, to halt this proposed regulation, as well an amendment objecting to another CMS

proposal to limit Medicaid payments to school districts for students with disabilities. The president promised full access to Americans with disabilities in his “New Freedom Initiative.” But policies such as these limit services and opportunities for people with disabilities. Would you reconsider these proposals, especially since the services they limit provide needed services to prepare and help people with disabilities live productive and functional lives?

Answer: In being a responsible steward for the Medicaid, Medicare and SCHIP programs, I believe it is important to promote transparency and accountability in financing and support efforts to maintain the integrity of the programs. CMS has had longstanding concerns with claiming for Medicaid rehabilitation services and school-based services and both the HHS’ Office of the Inspector General and the Government Accountability Office have cited inappropriate activities in these areas. Claiming for rehabilitation services has often included Medicaid payment for services that are intrinsic to other programs or are not related to Medicaid. Claiming for Medicaid services in school settings is prone to abuse and overpayments, particularly administrative costs and transportation services. I believe it is critical to note that CMS will continue to reimburse States for appropriate rehabilitation and school-based Medicaid service costs in their approved State plan. In addition, if other programs pay the costs for services intrinsic to their programs, more funds will be available to State Medicaid programs to provide services for the elderly and the disabled.

I share your goal in making sure that Medicaid services are available for Medicaid eligible individuals and I believe that these two proposals will help guarantee that Medicaid dollars are being spent appropriately and preserve the program for those in need.

- 5) Mr. Weems, I am concerned about another issue with rehabilitative services under Medicaid, which has been implemented without Congressional guidance. We have heard a great deal of concern from states and disability groups about how CMS is handling administrative actions regarding both the Medicaid rehabilitative services and the targeted case management option. The specific concern is that CMS uses its administrative clout – through processes like waiver applications and plan amendments – to essentially force states into reducing access to community-based services for people with disabilities and individuals with mental illnesses. The services at issue are typically things like coaching and community-skills building to assist with daily living. If CMS has approved community-based services in prior state plans or waiver applications, do you feel bound by those prior determinations through the waiver? And should CMS change service definitions and place restrictions – and impose them on states – as the waiver is implemented? This seems unfair for states who have applied for such waivers.

Answer: I believe that every Medicaid beneficiary should get the services they need in the most appropriate setting, and in most instances, care in the community-based setting can be made available and is appropriate for people with disabilities. CMS has long been working to expand opportunities for people with disabilities to receive care in the community through waivers and initiatives such as the Real Choice Systems Change grants, the Money Follows the Person demonstration grants, the new DRA state plan option for home and community based services which supplement the need for waivers, and the new cash and counseling

option. If confirmed, I will continue to work to expand access to home and community based care, and will look carefully at waiver projects to ensure they preserve such access.

- 6) As you know, ESA is used to treat anemia caused by cancer chemotherapy treatments. I am concerned with CMS' proposed national coverage determination (NCD) of ESA services. CMS' NCD would significantly limit access to ESA therapy for the anemia of Americans suffering from cancer. Without ESA therapies, these individuals would have to manage their chemotherapy-related anemia through regular blood transfusions, which diminish both their quality of care and quality of life. Reduced access to ESA therapies could also adversely impact our national blood supply. With fewer cancer patients able to use ESA treatments under the rule there would be an increased need for blood transfusions for cancer patients. I urge you to reconsider this rule. What plans does CMS have to ensure that enough blood is available to allow for the management of chemotherapy-induced anemia through blood transfusions for Medicare beneficiaries with cancer in the absence of ESA therapies? Does CMS plan to create a special reserve of blood for Medicare beneficiaries? How does CMS recommend that physicians treat a cancer patient's anemia in the absence of ESA therapy and in the absence of available blood for a blood transfusion?

Answer: The safety of Medicare beneficiaries is paramount to this Administration. That is why CMS promptly opened this NCD, in response to the FDA Black Box warning, to assess whether there is sufficient evidence to conclude that ESA treatment is not reasonable and necessary for beneficiaries with certain clinical conditions, either because of a deleterious effect of the ESA on their underlying disease or because the underlying disease increases their risk of adverse effects related to ESA use.

CMS published its proposed NCD on May 14, 2007, which opened a 30-day public comment period. The initial decision proposed that Medicare coverage of ESA treatment in beneficiaries with cancer should be limited to circumstances in which the treatment is less likely to worsen the cancer and in cases where the beneficiary's anemia is responsive to the ESA. More than 2,600 public comments were received. After reviewing these public comments and additional evidence, CMS issued the final coverage decision on July 30, 2007.

CMS's goal was to maintain physician autonomy while ensuring the safety of Medicare beneficiaries in light of the FDA boxed warnings, and CMS does not expect it to generate need for additional blood transfusions. The final NCD is based on the best science to date. CMS looks forward to further reports from FDA and are prepared to make additional modifications to its policies to ensure that Medicare patients receive the best and most effective treatments.

STATEMENT OF WORK (SOW)
National Supplier Clearinghouse (NSC)

I. SCOPE

A. Background

The National Supplier Clearinghouse (NSC) is the single organizational entity responsible for issuing or revoking Medicare supplier billing privileges for suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and maintaining supplier files that contain information collected via the Medicare enrollment application (CMS – 855S).

The NSC was developed because of the unique and specialized requirements that distinguish DMEPOS supplier enrollment from that of other Medicare providers and suppliers. In particular this includes special licensing, insurance, inventory, etc. The unique standards that DMEPOS suppliers must meet are contained in 42 C.F.R. 424.57. The NSC assures that enrolled DMEPOS suppliers meet the standards through various means including site visits, and checks of submitted documents. The NSC also develops and investigates for potential non-compliance and fraud of DMEPOS suppliers. This activity has become increasingly important as fraudulent activity among DMEPOS suppliers has increased. The NSC conducts hearings and provides input for supplier appeals of revoked and denied suppliers. The NSC interacts with the DME MAC payment contractors which are the Durable Medical Equipment (DME) - Medicare Administrative Contractor(s), hereafter referred to as DME-MACs. The NSC also coordinates and supplies information to the Program Safeguard Contractor (PSC).

B. Purpose

The purpose of this Statement of Work is to contract with an entity to serve as the National Supplier Clearinghouse (NSC) who shall , properly issue and/or revoke Medicare supplier billing privileges for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) suppliers and to maintain supplier files that contain information collected via the Medicare enrollment application.

The NSC's primary responsibility is to ensure that DMEPOS suppliers meet and continue to meet all Federal and State requirements to bill the Medicare program. To this end, the NSC shall ensure that all DMEPOS suppliers who are enrolling or who are currently

enrolled in the Medicare program meet the supplier standards found in 42 CFR 424.57(c), Medicare provider enrollment requirements found at 42 CFR 424.500 – 424.545, and the provisions found in Publication 100-8, Chapter 10 of the Program Integrity Manual (PIM) and that enrollment decisions are documented and processed in an accurate manner.

Specifically, the NSC's primary responsibility is to:

Establish and maintain a fraud prevention and detection program

The NSC is also responsible for the following:

- Ensure that only qualified DMEPOS suppliers are enrolled or remain enrolled in the Medicare program including taking the necessary actions to revoke enrolled suppliers who no longer meet supplier standards;
- Processing DMEPOS supplier enrollment applications and appeals in a timely manner,
- Participate in the development, testing and transition/implementation/operation of the Provider Enrollment, Chain and Ownership System (PECOS) for DMEPOS suppliers; and
- Ensure that all DMEPOS suppliers are properly accredited.

II. REQUIREMENTS

1.0 Basic Requirements/Responsibilities

Independently and not as a agent of the Government, the contractor shall furnish all necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the requirements of this Statement of Work.

The NSC will use the information submitted on the Medicare enrollment application (CMS-855S), information obtained during the verification and validation process, and when applicable, accreditation and/or a site visit information to determine if a DMEPOS supplier meets or continues to meet the enrollment standards found in 42 CFR 424.57(c).

If a DMEPOS supplier does not meet the enrollment standards found in 42 CFR 424.57(c), the NSC shall deny a DMEPOS suppliers request for Medicare billing privileges. Moreover, if a supplier DMEPOS supplier's is found to no longer meet the standards in 42 CFR 424.57(c), the NSC shall revoke the DMEPOS supplier's billing privileges. A supplier's billing privileges that are revoked shall not be reinstated until the CMS is satisfied that all necessary recompense and/or remedial action have occurred and that the supplier will comply with the standards.

The NSC will use its consolidated supplier file to identify, qualify, and associate suppliers that serve multiple areas. The NSC creates an association by using the Employer Identification Number (EIN) and/or assigning a unique “base” number to a DMEPOS supplier having a single tax reporting or EIN with multiple locations. The base number will have modifiers identifying each of the branch offices or unique locations associated with that supplier from which items are provided to Medicare beneficiaries. The resultant Medicare NSC supplier number is supplied to the DME-MAC and PSC serving the four jurisdictions and is used by the DME-MAC contractors to establish supplier eligibility for claims payment. The NSC shall have open and reciprocating communication among various lines of business with each DME-MAC, PSC, and the Data Analysis Contractor (DAC) in order to accomplish its mission. shall maintain a national master file of all suppliers and shall electronically supply that information to the DME-MAC contractor. The NSC serves all four DME-MAC contractors equally in the conduct of its functions, and is not directly involved in the day-to-day conduct of DME contractor processing of claims or provider relations.

The NSC is subject to the CMS’s requirements for systems security, as stated in Pub 100-17, and privacy as stated in the Privacy Act of 1974, P.L. 93-579, and the corresponding regulations and general instructions.

1.1 Key Personnel Requirements

1.1.1 Director of the NSC

The Director of the NSC is required to direct or oversee all activities and requirements outlined in this Statement of Work, including all activities associated with implementation.

The Director shall possess ten or more years of professional experience with at least 3 years as a manager responsible for managing complex systems and work flow. This experience should include fraud prevention and investigation. In addition, the Director shall possess a bachelor’s degree from an accredited institution, plus a master’s degree from an accredited institution or substitution of 4 additional years of related work experience in lieu of the master’s degree.

1.1.2 Supplier Audit and Compliance Unit Manager

The NSC shall maintain a Supplier Audit and Compliance Unit (SACU) with the mission of preventing fraudulent and unqualified suppliers from enrolling in the Medicare program and revoking such suppliers billing number who are already enrolled. The manager of the SACU shall be a Certified Fraud Examiner (CFE) or Accredited Healthcare Fraud Investigator (AHFI) or have similar education qualifications. Team leaders in the SACU shall be encouraged to obtain CFE, AHFI, or education qualifications in fraud investigations. The SACU shall: educate suppliers about the Medicare enrollment process and the mandatory requirements to enroll in the Medicare

program; participate in Medicare and Contractor sponsored fraud conferences, meetings, and discussions; serve as a point of contact for organizations such as General Accounting Office (GAO), Office of Inspector General (OIG), Federal Bureau of Investigation (FBI) on NSC-related Medicare fraud issues; establish contacts among governmental fraud prevention agencies in areas of activity such as site visits; support the site visit process in general; and take whatever steps it deems reasonable, including appropriate travel, in compliance with existing regulations and laws to prevent fraudulent suppliers from gaining and keeping access to the Medicare program. The manager of the SACU shall also be responsible for overseeing the implementation and all activities associated with the implementation of the SACU. The SACU shall conform to the Internal Security Guidelines set forth in Pub 100-18.

1.1.3 Hearings and Appeals Manager

The NSC shall have a manager who has demonstrated experience in the requirements of Medicare hearings and appeals. The Hearings and Appeals Manager shall be familiar with all current policies and regulations concerning these matters. In particular, the Hearing and Appeals Manager should be familiar with 42CFR 498 and Section 19 of Chapter 10 of the PIM.

The manager shall have overall responsibility for: (1) the managing of the NSC hearings and appeals unit, and (2) assuring proper actions are taken concerning appeals of adverse hearing officer and Administrative Law Judge decisions. The Hearings and Appeals Manager can also function as the Director of the NSC or the SACU Manager.

The Hearings and Appeals Manager shall possess 2 or more years of professional experience with at least 2 years with the responsibility for making decisions involving determinations in accordance with legal principles and preparation of legal document files. In addition, the Hearings and Appeals Manager shall possess a bachelors degree from an accredited institution, however, the manager can substitute 5 or more years of related work experience in lieu of the bachelors degree.

1.2 Fraud and Abuse Control

The NSC through its SACU unit shall perform initiatives to control fraud and abuse for DMEPOS suppliers

1.2.1 Development and Use of Fraud Level Indicators

The NSC shall perform a fraud potential analysis of all DMEPOS applicants and current DMEPOS suppliers. The NSC shall develop a system where they assess and assign each DMEPOS supplier or applicant a fraud level indicator. The fraud level indicator shall represent the potential for fraud and/or abuse. Initially, the NSC shall use four fraud level indicator codes as follows:

- 1) Low Risk (e.g., National Drug Store Chains),
- 2) Limited Risk (e.g., Prosthetist in a low fraud area),
- 3) Medium Risk (e.g. midsize general medical supplier in a high fraud area), and
- 4) High Risk (e.g. very small space diabetic supplier with low inventory in a high fraud area whose owner has previously had a chapter 7 bankruptcy).

High fraud areas shall be determined by contractor analysis with concurrence of the NSC's Project Officer. In assessing a fraud level indicator, the NSC shall consider such factors as: (1) experience as a DMEPOS supplier with other payers, (2) prior Medicare experience, (3) the geographic area, (4) fraud potential of products and services listed, (5) site visit results (6) inventory observed and contracted, and (7) accreditation of the supplier.

For suppliers who appear to be high risk the assessment review shall include the use of criminal background checks and a review of related businesses. An independent verification service shall provide the criminal background checks and review of related businesses. CMS shall contract for these services independent of this contract. .

After a fraud level indicator is assigned and the DMEPOS supplier is enrolled, the NSC shall establish a DMEPOS Review Plan based on the fraud level assessment. The DMEPOS Review Plan would contain information regarding:

- 1) Frequency of unscheduled site visits,
- 2) Maximum billing amounts before recommendation for prepay medical review,
- 3) Maximum billing spike amounts before recommendation for payment suspensions/prepay medical review, etc.

The NSC shall advise the appropriate DME-MACs and PSCs of this information and the fraud level indicator assigned on a quarterly basis. The fraud level indicator shall be updated based upon information: (1) obtained through the Medicare enrollment process, such as reported changes of information, (2) obtained by the Office of Inspector General, (3) obtained from CMS, a PSC or CMS Satellite Office. In addition, the NSC should monitor and assess geographic trends which indicate or demonstrate that one geographic area has a higher potential for having fraudulent suppliers.

1.2.2 DMEPOS Site Visits to Detect and Deter Fraud in the Medicare Program

The NSC shall conduct an unannounced site visit for all newly enrolling DMEPOS suppliers with a fraud indicator of limited, medium or high prior to enrolling the DMEPOS supplier into the Medicare program.

The NSC shall conduct an unannounced site visit for all DMEPOS suppliers who are re-enrolling in the Medicare program when the DMEPOS supplier has fraud indicator of medium or high.

The NSC shall conduct a minimum of two unannounced site visits per year for DMEPOS suppliers who are assigned a fraud level indicator of high. In meeting this requirement, the NSC can consider a site visit associated with a re-enrollment as one of the two unannounced site visits.

The NSC shall conduct a minimum of one unannounced site visit per year for DMEPOS suppliers who are assigned a fraud level indicator of medium. In meeting this requirement, the NSC can consider a site visit associated with a re-enrollment as one of the two unannounced site visits.

In addition to the site visits required above, the NSC shall conduct at least 3,000 additional unannounced site visits not required for initial enrollment or reenrollment each calendar year.

1.2.3 Criminal Background Checks and Related Business Checks

The NSC shall review the results of criminal background checks and related business checks which shall be performed at least once for all high risk suppliers and medium risk suppliers in high risk geographic areas upon initial enrollment or reenrollment. For felonies uncovered by use of the criminal background checks the NSC shall take appropriate actions inclusive of revocation.

The criminal background checks shall be performed on all owners, partners, directors and managing employees. All applicants and suppliers who receive a criminal background check shall also receive a related business check, wherein the independent verification service advises of the other businesses associated with the individuals for whom the criminal background checks were made. CMS shall contract for these services independent of this contract.

1.2.4 Business Telephone Verifications

The NSC shall verify the existence of the business telephone for all "high" and "medium" risk suppliers every six months. The purpose of this verification process to ensure that the supplier has a business telephone which is answered by an owner or employee during posted business hours and that the owner or employee is able to respond to general DMEPOS issues, questions about products or services offered by the supplier and respond to beneficiary questions or concerns.

1.2.5 Monitoring of Changes of Ownership

Using information from an independent verification service provided by CMS, the NSC shall review the results of any changes of ownership for enrolled DMEPOS suppliers in geographic areas with high instance of fraud or for those DMEPOS supplier identified as high risk suppliers. The NSC shall take appropriate action based upon review of the results.

1.3 Systems and PECOS Development

1.3.1 Systems

The NSC shall maintain an on-line inquiry system for DME-MAC contractor personnel and CMS authorized personnel as directed by the Project Officer and/or designees. The system shall be available for 25 hours or more per week. (The hours will be established to satisfy the needs of the Contractors.) The NSC shall prepare, maintain, and provide a users' manual for all users of the NSC online inquiry system.

The NSC shall establish and maintain a system to collect, store and manipulate data collected from the Medicare enrollment application process. In addition, this system shall enable to the NSC to track case development, ensure timely follow-up for re-enrollments, allow the NSC to conduct data analysis, and generate standard reports. The NSC systems, files and all application programs shall be stand-alone modules, which will be portable to another Contractor. All programs shall be written in industry standard language, widely used, readily maintainable.

The NSC shall forward to CMS all Freedom of Information Act (FOIA) requests that the NSC cannot respond to. Simple requests that are within the NSC's day-to-day operating capability and do not violate the Privacy Act shall be answered directly by the NSC following CMS guidance. The NSC shall create a supplier file for use by the NSC to fill requests for data. The information shall be made available through a data cartridge, disk, or CD, as required by the user. Requests for this data shall be approved by the Project Officer and/or designees.

This file, of all suppliers, shall contain current information only, and shall be refreshed each month, and shall contain the following data elements, at a minimum:

- Supplier Number
- Supplier Company Name
- Supplier Individual Last Name
- Supplier Individual First Name
- Supplier Individual Middle Initial
- Supplier Individual Generation
- Supplier Individual Credential
- Supplier Street Address, City, State, Zip Code
- Supplier Telephone Number
- Supplier Mailing Address, City, State, Zip Code
- Supplier Participation Status
- Supplier Participation Date
- Supplier Specialty Code (up to 10)
- Supplier Status Code
- Supplier Status Date

The NSC shall maintain a link to the CMS website for the web-based version of the application form that suppliers may complete on-line, print, and mail to the NSC.

1.4 Accreditation

The NSC shall be familiar with the requirements for accreditation of DMEPOS suppliers, including implementation timeframes.

The NSC shall prepare to implement a CMS requirement to ensure that all enrolled DMEPOS suppliers are properly accredited for the products and services that the DMEPOS supplier has listed on the Medicare enrollment application (i.e., CMS-855S). This effort shall include sending letters to suppliers, advising suppliers of the requirements and taking revocation action when required. The NSC shall have an electronic record of the information provided by the accreditors concerning the date of accreditation and products and services accredited for the supplier. The NSC shall provide this information to site reviewers and use this information in developing supplier fraud level indicators.

1.4.1 Competitive Bidding

The NSC shall provide data and check supplier submitted data to support the operations of the Competitive Bidding Implementation Contractor (CBIC). The NSC shall also answer enrollment related inquiries and process supplier changes in support of the competitive bidding initiative. This includes expedited processing of specific, mutually agreed upon supplier changes required to support the competitive bidding process.

1.5 Customer Service

The NSC shall utilize an internal review process to continuously improve written and verbal communication. The NSC shall maintain a training plan for all staff based on surveys, trend analysis, and employee feedback. The NSC shall analyze supplier inquiries (both telephone and written inquiries) to identify specific areas of concern and use information gathered from such analysis to improve customer service through outreach and education activities. Written correspondence to suppliers shall contain sufficient information to allow suppliers to readily determine the actions the supplier shall take. The NSC shall work to install a system to monitor supplier telephone calls initiated by the suppliers and potential suppliers.

The NSC shall provide continuous inbound telephone customers service Monday through Friday, for 8 hours a day. Continuous inbound telephone customer service means that callers shall be able to speak to an NSC representative during the hours specified. During other times they should be informed to call back during regular business hours or told that the NSC shall call them back if they leave their phone number. It will, however, be acceptable for some calls to go to a voicemail box during peak call times provided follow-up is conducted within an agreed upon timeframe from receipt of the call. The NSC shall evaluate customer support service desk efficiency on an ongoing basis and

recommend appropriate changes to operating hours. The NSC shall ensure that the following customer service center performs at a minimum:

- Inbound calls must be answered no later than the 5th ring;
- Answers to inbound questions shall be answered within 24 hours, if more than 24 hours is necessary the NSC shall contact the requestor within 24 hours and provide an estimated date in which the answer will be provided.

The CMS Project Officer shall approve model language used in all routine correspondence to suppliers prior to use by the NSC. The NSC shall refer all beneficiary inquiries to the appropriate DME-MAC contractor.

The NSC shall respond to customized requests for data on participating suppliers. If the inquirer does not have website access capability, the NSC shall ascertain the nature and scope of each request and furnish the desired participation information via phone or letter. The NSC shall maintain liaison with the national and state supplier industry representative groups.

Allegations of fraud received by the NSC's telephone service unit shall be entered into a log and referred to the SACU for review, development and any further action. The complaint log shall list, at a minimum, the:

- Complaint and nature of the complaint;
- Supplier Name and Number
- Name of the NSC representative who received the complaint;
- Date the complaint was received,
- Date the complaint was referred to the SACU or resolved by the NSC; and disposition of the complaint.

If the NSC believes, after the SACU's review of a complaint, that fraud or potential fraud exists which should be investigated by the PSC, the NSC shall refer the complaint to the PSC.

1.6 Website Information

The NSC shall maintain a website that provides DMEPOS suppliers with the information needed to complete and submit an enrollment application or re-enrollment application, including, but not limited to, frequently asked questions, licensing requirements by product and/or State, insurance requirements, etc.

1.7 Deactivation

Consistent with manual instructions found in Section 13 of Chapter 10 of the PIM, the NSC shall deactivate DMEPOS supplier billing privileges. The NSC will receive from the ADMERC a quarterly electronic listing of suppliers who have not submitted claims

for four consecutive quarters within 45 days after then end of the quarter. Providers who have updated enrollment records or received their NSC number within the past 4 quarters are exempt from this requirement.

The NSC shall deactivate extra supplier privileges for the same location within 30 calendar days of discovery of the extra supplier numbers

1.8. Denials, Returns and Revocations

1.8.1. Denials

Consistent with manual instructions found in Section 6.2 of Chapter 10 of the PIM, the NSC shall deny a DMEPOS supplier request for billing privileges. In addition, the NSC shall deny any applicant who fails to meet the DMEPOS supplier standards found in 42 CFR 424.57(c). The NSC is not required to obtain prior project officer approval for denials based upon adverse legal actions.

1.8.2. Rejections and Returns

Consistent with manual instructions found in Section 3.1 of Chapter 10 of the PIM, the NSC shall reject or return a Medicare enrollment application submitted by a DMEPOS supplier. In rejecting or returning an enrollment application, the NSC shall provide a letter to the DMEPOS supplier stating what information is needed in order to process the enrollment application.

In addition, if a required site visit cannot be completed, the NSC shall notify the supplier that the NSC cannot verify the supplier's compliance with the 21 standards and shall advise the supplier that it may resubmit an application when a complete site inspection can be conducted. The NSC shall not deny the application.

1.8.3. Revocations

Consistent with manual instructions found in Section 13 of Chapter 10 of the PIM, the NSC shall revoke billing privileges. In addition to the manual instructions the NSC shall revoke a billing number if one or more of the following occurs:

- The supplier does not meet supplier standards in 42 CFR §424.57 as determined by the NSC;
- The entity, and/or its owner(s), and/or managing employee(s), are not eligible for participation in the Medicare program because they appear on the (Medicare Exclusion Database) MED or GSA Excluded Parties List found at <http://www.epls.gov/>;

For suppliers who appear to not meet the supplier standards the following methodology shall be followed.

- The NSC shall request verification of compliance from the supplier via a process that ensures proof of delivery. The notification shall request a response in 21 calendar days. If no response is received that verifies compliance with standards identified, the NSC shall recommend revocation to the Project Officer.
- In cases where the supplier is not present at their location, or where the lack of compliance of the supplier with the required supplier standards appears to be egregious (including loss of any required accreditation), the NSC can request revocation to the Project Officer without the 21 day notice. Upon approval from CMS, the NSC shall notify the entity of its revocation within 7 calendar days by the same process mentioned previously. The notice shall inform the entity of the reason for the revocation, its right to an appeal, and the instructions on how to submit a corrective action plan.

1.9. Appeals and Corrective Action Plans (CAPs)

The NSC shall provide an appeals process for suppliers in accordance with the manual instructions found in Section 19 of Chapter 10 of the PIM. This includes providing an adequate number of contractor hearing officers to conduct hearings within the required timeframes. Special processing directions in addition to the manual instructions are as follows:

The NSC shall provide for submittal of corrective action plans (CAPs) for revoked suppliers.

- For a revoked supplier - if the CAP submittal provides confirmatory evidence that the supplier was actually in compliance with the supplier standards at the time of revocation, then recommend reinstatement of the supplier effective as of the date of revocation.
- For a revoked supplier - If the supplier makes changes to be in compliance the following applies. If the problem corrected, or to be corrected, is minor and/or the amount of billed for out of compliance items is small, and this is the first time the supplier has been determined to be out of compliance, then the NSC should consider recommending reinstatement of the supplier. The proposed effective date shall be that date of actual compliance with the supplier standards.
- For a revoked supplier - If the circumstances described in the two preceding bullets do not apply, then the following applies. The CAP can be recommended for acceptance if the supplier makes changes to be in compliance and has a definitized repayment plan or has made financial restitution for any overpayments attributable to non-compliance. The NSC shall make a recommendation concerning the reinstatement date dependent upon the circumstances of the case. All of these cases should be discussed with the Project Officer prior to submission of any recommendation to reinstate. This CAP option applies only when the ownership has not changed and the supplier number will remain the same.
- For a revoked or denied supplier – If a CAP has been rejected, send a letter to the supplier advising them of this fact. The letter to the supplier should also advise the supplier of a) their rights concerning hearings/appeals, b) their right to reapply

and c) the fact that a CAP rejection cannot be appealed. The supplier should be advised that information submitted as part of the CAP submission will not be automatically applied to a reapplication and that they must make a formal reapplication.

The decision whether to request a carrier hearing and/or submit a corrective action plan is solely at the discretion of the supplier. The NSC shall be responsible for reviewing and appropriately acting upon information provided by revoked and denied suppliers. The NSC shall provide advise to all CMS and HHS components involved in the hearings and appeals process.

1.10 Participation Enrollment

The NSC shall conduct the annual participating physician/supplier (PAR) enrollment in accordance with Pub 100-04, with modifications to fit DMEPOS supplier needs (e.g., fee schedule information should not be provided).

The NSC shall submit Section 2 of the Participating Physician/Supplier Report in Contractor Reporting of Operational and Workload Data (CROWD).

The NSC shall maintain a link from the NSC website to the CMS Supplier Medicare Participating Physician/Supplier Directory (MEDPARD) website and shall supply CMS with a monthly file for this use.

1.11 Healthcare Integrity and Protection Data Bank (HIPDB)

The Secretary of the U.S. Department of Health and Human Services, acting through Office of the Inspector General (OIG), was directed by the Health Insurance Portability and Accountability Act of 1996 to create the Healthcare Integrity and Protection Data Bank (HIPDB) to combat fraud and abuse in health insurance and health care delivery. The HIPDB, developed by HRSA (Health Resources and Services Administration), is an alert tracking system that serves as a comprehensive review of practitioners, providers, and suppliers of adverse action.

The NSC is required to participate in the data transmission of adverse suppliers who have had their supplier numbers revoked. Revocation of a supplier number, for purposes of this instruction, is the result of the supplier location failing one or more of the supplier standards.

The Data Bank ID (DBID) will allow NSC the ability to query the HIPDB. As NSC utilizes the HIPDB for more querying initiatives, additional registration numbers may be requested. The NSC shall utilize the CMS DBID when submitting reports to the HIPDB on adverse actions against suppliers.

According to the Federal Register on October 26, 1999 the time frame for submitting reports to the HIPDB will be (1) within 120 calendar days from the date the final adverse

action was taken or the date when the reporting entity became aware of the final adverse action (the NSC will allow another 30 calendar days for appeal), or (2) by the close of the NCSA's next monthly reporting cycle, whichever is later. If an error or omission is discovered after the final adverse action is reported, then NSC shall send an addition or correction to the HIPDB within 60 calendar days of the discovery. NSC will utilize the CMS DBID for submitting reports to the HIPDB.

NSC will submit a separate HIPDB file for each adverse action being recognized by the HIPDB. For example, if a total of 120 suppliers are being reported to the HIPDB during a single data transmission, 120 separate files will be created by NSC and transmitted to HIPDB.

Only adverse findings on organizational entities will be transmitted to HIPDB. Therefore, all files submitted will be categorized as organizations.

Monthly update files may or may not include: 1) additional supplier numbers who have been revoked or 2) suppliers who had previously received an adverse action and have now submitted an appeal or 3) suppliers who have submitted an appeal and their supplier number has been re-instated.

1.12 Collaboration with Other Entities

The NSC shall:

- Share information with the OIG on suppliers related to sanctioned individuals or businesses;
- Release "alerts" for all associated businesses within 2 weeks of notification by aDME-MAC or PSC;
- Maintain daily (business days) file transmissions to the DME-MACs and PSCs of new and updated information;
- Support the Contractors in the "Do-Not-Forward" initiative for both checks and remittance advices, including controlling all materials received from all the Contractors in this effort, issuing appropriate and timely alert codes when required, developing the cases to determine whether the suppliers identified are still in compliance with supplier standards, and inactivating Medicare privileges where suppliers do not comply.
- Collaborate with independent accreditation organizations selected by CMS to implement the DMEPOS Quality Standards.

1.13 Quality Assurance Requirements

All work performed under this contract shall be ISO (International Standards Organization) compliant. The contractor shall be ISO 9001:2000 compliant. The Government shall monitor the contractor's performance under this contract by a) periodically reviewing contractor records to determine if they meet the requirements

shown in the Key Performance Standards Summary and b) reviewing required reports submitted to the CMS project officer.

1.14 Review Process

The NSC shall process all new supplier applications for billing numbers and update supplier information in accordance with this statement of work, the Medicare Program Integrity Manual Pub 100-08, Chapter 10, other Manual requirements and existing laws and regulations. Where the Manuals do not address requirements for completing the application from suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (i.e., the CMS 855S form), the NSC shall use instructions for the 855B, found in Chapter 10 of the PIM, where appropriate. This statement of work has precedence over any Manual requirements where there is a conflict. The CMS project officer shall advise the NSC of the correct policy to follow when new Manual requirements or joint signature memorandum do not appear to be compatible with efficient processing of NSC applications or NSC fraud and abuse prevention efforts.

The NSC shall have a completed supplier number application on the currently authorized Form CMS 855S before it processes the application. The supplier shall have an active billing number before it may receive payment. A billing number cannot be assigned and no payment can be made to a supplier without a complete disclosure of ownership and other business information. In general, the supplier billing number will be effective as of the date it is awarded by the NSC.

The NSC shall maintain the history of multiple occurrences of key data, have the capability to produce reports requested by the CMS on an ad hoc basis, and maintain all records until permitted to destroy them by the Project Officer. Hard copies of all materials shall be stored in a secure location and shall be readily retrievable.

The NSC shall maintain a control system to track suppliers' applications. The control system shall accommodate the tracking of applications received, status, and time-in-process from date of receipt to date of assignment/denial of a billing number.

The NSC's methodology for processing applications for enrollment includes:

- Ensuring that all applications are complete and information is consistent internally; developing applications for missing or ambiguous information in accordance with Provider Enrollment Manual Requirements;
- Maintaining on its master file the capability for tracking multiple instances of supplier effective dates and revocation/inactivation dates and reporting same to the Contractors Assigning/denying enrollment and
- Notifying the supplier of disposition of the applications.

Applicants who are adding a new location, as opposed to relocating an existing practice location, may complete only those data elements on Form CMS 855S that are being added, plus the basic information needed to identify the supplier plus the supplier's

NPI(s) if this has not already been furnished. The applicant should not complete the entire Form CMS 855S. If a current supplier is completing sections of the Form CMS 855S to open a new location or make another change and the NSC notices that data are missing from the supplier's existing record, the NSC may ask the applicant to complete any section that is missing from the record. Internal Revenue Service (IRS) documents are not required for additional location applications if one is already on file with the same legal business name. In addition, IRS documents and insurance documents are not required for large (i.e., 25 or more active locations) chains. Such documents are also not required for reenrollments and reactivations.

1.14.1 Exemptions from Manual Requirements

The NSC shall use overpayment data supplied monthly by the DME-MACs. The NSC shall collect and review initial electronic funds transfer (EFT) forms from all new applicants. The NSC shall check that the legal business name and signatures are correct and shall transfer this information to the appropriate DME-MAC contractors at least once a week. All other EFT agreements received that are not part of a new application shall be forwarded to the appropriate DME-MAC(s) weekly without further verification.

1.14.2 Verification

The NSC shall establish procedures in accordance with PIM Pub 100-8, Chapter 10 instructions to validate the information provided by applicants on the applications for Medicare billing numbers and additional documentation furnished. The NSC shall apply these procedures to all new applicants with the following exceptions for Medicare-enrolled entities: hospitals; skilled nursing facilities; home health agencies; physicians; ambulatory surgical centers; and requests for additional locations submitted by established, multi-location supplier chains with 25 or more active locations.

Additional validation procedures shall include, at a minimum, the following actions:

- Check the applicant name and address against post office finalist records. In particular applicants with an already used street address must have a separate post office suite number.
- Check that the applicant has a business phone number that is answered by an employee or owner of the applicant who can answer beneficiary questions. This shall be accomplished by calling the applicant. This is not required for additional locations of chain store suppliers with more than 25 locations. Verification of a correspondence phone number is not required.
- Querying all existing records in the supplier file to determine if common owners correlate to multiple tax identifications, and to determine if different companies are reporting common names and/or addresses;
- Matching all applicants against those previously denied and maintaining records of all denied applicants for the purpose of identifying other actions needed, (e.g., further validation);

- Conducting a site visit for those suppliers requiring a site visit according to 1.15. (Site Visits), and using the OMB-approved site visit questionnaire at the physical location for which a number is being requested;
- Checking against a NSC developed database of licensure requirements to ensure that appropriate licenses have been included. The database shall be correct and continuously updated;
- Checking the validity of required licenses submitted.
- For a Rehabilitation Agency the NSC shall obtain from the applicant a copy of the letter from the Regional Office which assigns the OSCAR number. No site visit is required for rehabilitation agencies.
- Ensuring that multiple numbers are not assigned to the same supplier for the same location;
- Verifying insurance policy with the insurance agent and ensuring that the NSC is a certificate holder.

In addition to the above procedures, the NSC shall use the CMS-approved on-line database service. This service shall be used to verify compliance with standards for new applicants suspected of non-compliance with standards. The NSC shall deny enrollment for new applicants and request revocation of any existing supplier who is found in non-compliance of supplier standards or for other reasons found in Chapter 10 of the PIM. Initial applications that do not include necessary information or documentation can be developed if the NSC believes that the omissions are not numerous and have a reasonable probability of being provided within the required application processing time guidelines. Pharmacies shall furnish only a copy of their State pharmacy license, and not local licenses. State pharmacy licenses and licenses missing information (e.g., issue date, expiration date) shall be verified with the issuing agency.

1.14.3 Edits and Matching Procedure

The NSC shall maintain the national supplier file and develop editing and matching procedures to identify and share with the Contractors supplier situations that might indicate fraudulent or abusive practices. The NSC shall have the capability to produce reports from their findings, at CMS's request, on an ad hoc basis. The following edits and matching procedures are required:

- Correlation of all ownership information, such as owners, managers and related businesses, to identify individuals or businesses that are common to multiple suppliers;
- Maintenance of multiple occurrences, for an audit trail or history, of key data fields in the supplier file; this history shall include the date the field was changed and the data field content;
- Matching the Medicare Exclusion Database (MED) listings of sanctioned individual and businesses and the GSA Excluded Parties List to any occurrences on the national file;
- Check all previous/current supplier numbers and all previous/current locations for those suppliers with revoked supplier numbers for fraudulent or abusive practices

and transmit the appropriate alert code to the DME-MACs and/or PSCs based on the results of this validation.

1.15 Site Visits

All suppliers are subject to unannounced site visits upon initial enrollment or reenrollment, except physicians and other licensed medical practitioners, certified Medicare providers, and suppliers with 25 or more active locations will not routinely be subject to site visits. Such suppliers shall be visited if the NSC has concerns about a supplier's compliance with the standards.

The purpose of the site visits will be to verify the supplier's compliance with the standards as outlined in 42 CFR Section 424.57(c). During the site visit, photographs of the supplier's business will be taken for inclusion in the supplier's file on an as needed basis to be used as proof of non-compliance with supplier standards. The on-site inspector shall write a report using the OMB-approved questionnaire, about the supplier visit for NSC action. If a site visit cannot be completed, the NSC shall notify the supplier that their compliance with all 21 standards cannot be determined and that they can re-apply.

For all site visits performed by NSC personnel (or those contracted by the NSC for the purpose of obtaining site visits), for fraud control efforts or required for reenrollment, the NSC shall provide the on-site inspector information from the suppliers' recent billing history before they conduct on-site inspections. This does not apply for special mass site visit initiatives approved by the CMS project officer. The on-site inspector shall compare this information with the suppliers' inventory and/or contracts for inventory and note inconsistencies on the OMB-approved questionnaire inventory section. For suppliers reporting inventory that is primarily maintained off-site or supplied through another company, an on-site inspection will be made to these separate location(s), except when this is impractical and the CMS project officer concurs.

The NSC shall maintain records of supplier site visits to assist in investigations and trend analysis. The on-site inspector shall forward copies of applicable records to the NSC to support NSC decisions for denial or revocation of a supplier's enrollment.

The NSC shall forward all cases of suspected fraud to the affected PSC and the OIG/Assistant United States Attorney (AUSA), as appropriate.

As resources permit, the NSC shall conduct random, out-of-cycle site visits to confirm compliance with supplier standards.

At a minimum, the NSC shall employ fifteen (15) full time equivalent (FTE) personnel whose function shall be to perform site visits and perform follow-up investigative activities related to the site visited applicants/suppliers. They shall be concentrated in high fraud and abuse areas.

1.16 Changes to Supplier Information

All requests for changes to supplier information—i.e., changes of address, changes of ownership, etc.—shall be submitted on the Medicare enrollment application (i.e., CMS-855S) and signed by an authorized individual. The NSC shall comply with PIM Pub 100-8, Chapter 10 requirements regarding timeliness of processing requests for changes. The NSC shall acknowledge, within 7 business days of the completed change, by letter, postcard, e-mail, or telephone, the completion of processing the change, and include the date the change was made. The NSC shall process termination requests submitted by letterhead if they are signed by an owner or other authorized official. The NSC can accept a change even if the applicant has incorrectly checked more than one box in section 1.B. of the CMS 855S.

A change of ownership, as defined by the Medicare enrollment application, of a supplier enrolled in the Medicare program through the NSC results in the issuance of a new billing number, unless the new owners assume all liabilities and the tax identification number of the existing supplier. Otherwise, the billing number may not continue to be used by the new owner.

Changes of ownership require the submission of a Medicare enrollment application by the new owners within 30 days of the change of ownership, along with a bill of sale, articles of incorporation filed with the State, and any other documents that show the exact nature of the transaction. The old supplier number shall be inactivated, and the new number will be effective with the date of the change of ownership, if all is in order including valid licenses, insurance and being established at the location. If the change of ownership is not reported within the required 30 days, the NSC shall take action to revoke the supplier. The supplier may then be reenrolled as a new supplier only after the appeal period has expired and the supplier meets all requirements.

1.17 Reenrollment of Suppliers

The NSC shall ensure that supplier information on the supplier master file is up-to-date:

- The NSC shall reenroll suppliers each year on a basis of 3 years after the initial enrollment or reenrollment. (Refer to 42 CFR §424.57) The reenrollment shall be performed monthly, with one-twelfth of the yearly total to be initiated each month. However, this schedule may be changed upon concurrence of the CMS project officer.
- The supplier number re-issuance/reenrollment process will consist of sending the supplier a printout of current supplier account information with instructions to the supplier to make any changes on the printout and sign the certification statement. Additionally the NSC shall obtain any new additional CMS-855S information (inclusive of an NPI) which is not on file for the supplier. The NSC shall instruct the supplier in the reenrollment letter how to recertify data elements that are not available from the supplier data file. The information shall be returned within 35

days or the supplier is subject to inactivation of its billing number. A reenrollment site visit to a supplier may be waived upon CMS project officer concurrence, if the NSC has conducted a site visit to the supplier within one year of the reenrollment.

- The NSC shall perform site visits on reenrolling suppliers according to 1.15. (Site Visits), using the OBM-approved questionnaire. Site visits shall not be conducted on suppliers with \$50,000 or less in allowed charges in the previous year; however, the NSC may conduct a site visit on any supplier if there is indication that the supplier may not be in compliance with the supplier standards.
- Non-responding suppliers shall be inactivated within 60 calendar days of mailing of the reenrollment package, with the exception of large chains, which shall be given 92 calendar days to respond. The NSC may grant one extension to a supplier or supplier chain of 60 calendar days for suppliers who are considered low or limited risk upon concurrence of the CMS project officer.
- The NSC shall work with suppliers with multiple locations to ensure an efficient process, such as all the locations scheduled for reenrollment in a year being scheduled together.
- The application for reenrollment may be signed by a delegated official.
- New location specific IRS documents and insurance documents are not required for large chains. An IRS document will not be required for any supplier if there is no EIN change.
- Suppliers shall be required to submit copies of licenses which shall be validated by the NSC.
- The NSC is not required to check reenrolling suppliers against the Fraud Investigation Database (FID).
- The NSC shall check suppliers against the MED and GSA Excluded Parties List.

1.18 Alert Codes

The NSC shall receive and maintain “alert indicators” from the DME-MACs and PSCs about, at a minimum:

<u>Alert Code</u>	<u>Definition</u>
A	possible fraudulent or abusive claims identified;
B	overpayments;
D	violations of disclosure of ownership requirements;
E	violations of participation agreements;
L	suspended by Contractor outside alert code process;
M	supplier is going through claims appeal process.

The NSC shall append the supplier file and transfer to the DME-MACs and PSCs the following alert codes in the following circumstances:

<u>Alert Code</u>	<u>Definition</u>
C	violations of supplier standards;
F	sanctioned by the Office of Inspector General or excluded by the GSA;
H	Meets supplier standards; however, the NSC recommends increased scrutiny by the Contractor (initiated by NSC only); and
N	Supplier being investigated under the "Do Not Forward" initiative (initiated by NSC <u>only</u>).

The NSC shall append an Alert Code "H" for any supplier that meets present supplier standards but appears suspect in one of the areas that are verified by the NSC. This alert code notifies the Contractors that a supplier may be inclined to submit a high percentage of questionable claims. Additional alert codes may be established for use in tracking and reporting Fraud Level Indicators.

The NSC shall share the above information with the Contractors by sending alerts within 7 calendar days after identification of a supplier having common ownership or business ties with a sanctioned or suspect supplier for their research and/or action. The NSC also shall forward alert codes submitted by the Contractors with the other Contractors within 7 calendar days after receipt.

1.19 Key Performance Standards Summary

In this SOW, CMS has identified meaningful, outcome-oriented “key” performance requirements and measures that speak to fundamental program purposes and to the CMS role as a steward of taxpayer dollars. The “Key Performance Standards Summary” are as follows:

1.19.1 Fraud Prevention and Detection

The NSC shall have documented evidence that they have, as a minimum, met the requirements shown below:

- Assign an appropriate fraud level indicator for at least 95 percent of all DMEPOS suppliers, upon initial or reenrollment. The fraud level indicator shall accurately reflect the risk the supplier poses to the Medicare program bases on pre-defined criteria.
- Assign an appropriate fraud level indicator for at least 95 percent of existing DMEPOS suppliers within six months of contract award.
- Update the DMEPOS fraud level indicator for each enrolled DMEPOS supplier on an annual basis.

1.19.2 Accuracy

The NSC shall have documented evidence that they have, as a minimum, met the requirements shown below:

- At least 95 percent of all names and businesses listed on applications shall have been checked against the MED and GSA Excluded Parties Lists.
- At least 95 percent of all new and re-enrollments shall have evidence that the contractor performed required checking of all applicable licenses, insurance and site visits.
- At least 95 percent of site visits were completed properly, including the completion of the site visit questionnaire, required photographs, and, when necessary, providing the site reviewer with billing information prior to the site visit.
- At least 95 percent of CAPs, hearings and appeals are processed in accordance with regulations, CMS’ manual instructions and contractor operating guidelines.

1.19.3 Timeliness

The NSC shall have documented evidence that they have, as a minimum, met the requirements shown below:

- Process 80 percent of CMS-855S applications, inclusive of reenrollment applications, within 60 calendar days of receipt, process 90 percent of CMS-855S applications within 120 calendar days of receipt and process 99 percent of CMS-855S applications within 180 days of receipt.
- Process 80 percent of CMS-855S change of information applications within 45 calendar days of receipt, process 90 percent of such applications within 60 calendar days of receipt and process 99 percent of such applications within 90 calendar days of receipt.

2.0 Reporting Requirements

2.1 Monthly Status Report

A Monthly Status Report shall be submitted electronically to the Project Officer on the 15th of each month. The CMS Project Officer shall agree upon the content and format of the Monthly Status Report if information is required other than described below:

- Prior month's activities by task and activity
- Issues of concern that require CMS action
- Any unresolved issues from the prior month
- Provide narrative regarding timeliness and production statistics; applications received, pending, processed, and returned; number of site visits conducted and outcome; number and type of denials or revocations of billing numbers

2.2 Cost Report

- The Cost Report shall be submitted monthly for the prior month's activities via the CMS Interim Expenditure Report (IER).

Appendices:

1. Program Integrity Manual (PIM)

2. Business Partners System Security Manual (BPSSM)

www.cms.hhs.gov/it/security

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C.1. Introduction

The Offeror shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work (SOW) beginning FY 2006. Hereinafter, the Offeror shall be called the Durable Medical Equipment Regional Carrier (DMERC).

C.1.1. Purpose of Contract

Under this contract, the contractor will perform numerous functions on behalf of Medicare beneficiaries and will establish relationships with providers of health care services, both institutional and professional, for a defined geographic area or "jurisdiction." The contractor will perform the requirements of this contract in accordance with applicable law, regulations, Medicare manuals and the Centers for Medicare & Medicaid Services' (CMS) requirements. The Medicare program's legal, policy and operating environment is complex, and the contractor will utilize or interact with certain CMS-required payment schedules, systems, equipment and/or operational capabilities in the performance of its functions. Further, the contractor will coordinate its activities not only with CMS, but also with a broad range of agencies (at the federal, state and local levels of government), other CMS partners and contractors, and a diverse range of stakeholders within the health care system of the United States.

It is CMS' mission to assure health care security for beneficiaries. This contract specifically applies to that mission by fostering excellence in the design and administration of CMS' programs.

C.1.2. Background

The Medicare program is an integral component of the federal government's commitment to the health and welfare of the American people, which includes the Social Security system, the Medicaid program (which is primarily administered by the states), and other programs. The Medicare program provides affordable health insurance to (1) individuals aged 65 and over; (2) certain individuals eligible for disability benefits under the Social Security system and their dependents; and (3) individuals with acute kidney failure (End Stage Renal Disease or ESRD). Approximately 42 million persons were enrolled for Medicare coverage in Fiscal Year (FY) 04.

Nearly all Medicare beneficiaries may access their insurance benefits through one of two health care delivery systems. First, in all areas of the country, a beneficiary may enroll in the "traditional" Medicare program (the Medicare Fee-For-Service (FFS) program) under which benefits are largely provided in keeping with an indemnity insurance model. That is, the beneficiary chooses his/her health care providers, the provider bills for its services to the appropriate Medicare claims administrator, and payment is made to the provider based on the Hospital Insurance (HI) and/or Supplementary Medical Insurance (SMI) program's eligibility, coverage and payment rules. The federal government bears all financial (underwriting) risk for the cost of program benefits under this program, and develops detailed administrative requirements and processes to support the claim administration process. As a national entitlement program, there is a strong imperative to provide a common level of benefits and

service in all areas of the country while maintaining adequate flexibility to account for local/regional medical practices.

Second, in many areas of the country, beneficiaries have the option to enroll in one or more privately sponsored Medicare plans under the “Medicare Advantage” (formerly Medicare+Choice) program. These private Medicare plans may organize themselves in keeping with one of several health care delivery and payment models (e.g., Health Maintenance Organizations, Preferred Provider Organizations, etc.). These private Medicare plans are required to cover the same basic benefits that the traditional Medicare program offers, but they are given fairly broad responsibility and latitude to set up their internal requirements and processes as they see fit. About 14% of Medicare beneficiaries are currently enrolled in Medicare Advantage.

More than 85 percent of all Medicare beneficiaries – or about 35.7 million – participate in the traditional Medicare program. The recently enacted MMA includes significant incentives to increase the participation in Medicare Advantage. However, for the next decade at least, a significant majority of all Medicare beneficiaries will likely remain enrolled in the traditional FFS Medicare program. FFS coverage in the Medicare Program consists of two distinct parts: (1) Hospital Insurance (HI), which also provides coverage for Medicare institutional benefits; and, (2) Supplementary Medical Insurance (SMI), which provides coverage for the professional medical services of physicians and certain other licensed practitioners, as well as coverage for a variety of other services and items (e.g., ambulance, durable medical equipment, etc.). In common usage, the HI program is known as “Medicare Part A,” although both the Part A and B trust funds are used to reimburse institutional claims, and the SMI program is known as “Medicare Part B,” and only the Medicare Part B trust fund is used to reimburse these claims.

In accordance with Section 1834 (a) (12) of the Act, the Centers for Medicare and Medicaid Services (CMS), in the Department of Health and Human Services, entered into contracts in 1992 with four Durable Medical Equipment Regional Carriers (DMERCs) to perform all of the DMERC duties associated with the processing of claims for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) under Part B of the Medicare program. This SOW proposes contracts for carrier operations associated with the processing for claims for DMEPOS items. These medical items are included in “medical and other health services” (§1832 (a)(1)(B)). Other carrier requirements are listed in 42 C.F.R 421.200-421.202. General claims processing guidelines may be found in the Internet Only Manual (IOM). Other more specific guidelines are found in this SOW.

The DMERCs process claims based on a Medicare beneficiary’s principal residence by State as follows:

- Region A: Connecticut, Delaware, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont
- Region B: District of Columbia, Illinois, Indiana, Maryland, Michigan, Minnesota, Ohio, Virginia, West Virginia, Wisconsin

- Region C: Alabama, Arkansas, Colorado, Florida, Georgia, Kentucky, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, Virgin Islands
- Region D: Alaska, Arizona, California, Guam, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, Mariana Islands, American Samoa

Payment will be made for most durable medical equipment and surgical dressings on the basis of local, i.e., state-wide, fee schedule amounts limited by the national median of state-wide fees for each item (ceiling) and 85% of the national median of state-wide fees for each item (floor). See §1834 (a) of the Social Security Act (the Act) for payment rules for durable medical equipment. The fee schedule amounts are increased annually by covered item updates. Per §1834(h)(1)(E) of the Act, these rules also apply to ostomy supplies, tracheostomy supplies, and urologicals. See §1834 (i) of the Social Security Act (the Act) for payment rules for surgical dressings.

Payment will be made for most prosthetic devices, orthotics and prosthetics, and therapeutic shoes and inserts on the basis of regional, i.e., per CMS Region, fee schedule amounts limited by 120% of the national average of the regional fees applied to each state (ceiling) and 90% of the national average of the regional fees applied to each state (floor). The fee schedule amounts are increased annually by covered item updates. See §1834 (h) of the Act for payment rules for prosthetic devices, orthotics and prosthetics, and therapeutic shoes and inserts.

Payment will be made for parenteral and enteral nutrients, equipment and supplies on the basis of national fee schedule amounts. Parenteral nutrition is the provision of nutritional requirements intravenously. Enteral nutrition is the provision of nutritional requirements through a tube into the stomach or small intestine. The fee schedule amounts are increased annually by covered item updates. See §1842 (s) of the Act for payment rules for parenteral and enteral nutrients, equipment and supplies.

Payment will be made for home dialysis supplies and equipment on a reasonable charge basis (§§1833 (a) and 1842 (b)(3) of the Act). Total monthly payments for home dialysis supplies and equipment are limited by a per patient cap (§1881 (b)(6) of the Act).

C.1.3. Special Standards of Eligibility

In order to qualify as a DMERC, the following three standards shall be satisfied:

- 1) The DMERC shall meet the statutory definition of a "DMERC" in section 1842 of the Social Security Act;
- 2) The DMERC shall utilize the VMS – VIPS Medicare System approved by CMS;
- 3) The DMERC shall have a full-time medical director and a full-time Program Integrity Coordinator (unless a Program Safeguard Contractor (PSC) has been established).

C.1.4. Roles and Responsibilities

The roles and responsibilities of the parties are outlined below.

C.1.4.1. The CMS

The Medicare program's authorizing statutes charge the Secretary of the Department of Health and Human Services with administrative responsibility for the Medicare program. In turn, the Secretary has delegated the program authority for Medicare (both the traditional fee-for-service program as well as Medicare Advantage) to the Administrator of the CMS, an operating division of the Department. Prior to mid-2001, the CMS was known as the Health Care Financing Administration (HCFA).

CMS administers the Medicare Program, including formulation and promulgation of Medicare Program policy and guidance, contract execution, operation and management, maintenance and review of utilization records, and general Medicare financing. CMS is the largest purchaser of health care in the United States and provides health care coverage to nearly one in four Americans. CMS' annual budget places it among the largest businesses in the world; our programs channel one out of every three dollars in the health care market and our policies influence the other two dollars. In 2004 CMS contractors processed over one billion Medicare claims.

As part of its responsibility to administer the Medicare program, CMS manages the work of the contractors engaged in its day-to-day operation. This management is accomplished through a variety of avenues, e.g. conferences held periodically on topics of general interest, targeted sessions with selected subsets of the contractors, issuance of manual updates describing changes in coverage, pricing, and eligibility, and evaluation of the performance of those contractors within the description of the work CMS engages them to do.

C.1.4.1.1. CMS Contracting Officer

The Contracting Officer is the only CMS official who can approve requests for additional funds under this contract. All contract changes shall have the prior approval of the Contracting Officer through a written contract modification.

C.1.5. Performance Measures

CMS may measure a DMEPOS regional carrier's administrative ability to manage the Medicare Program. CMS may evaluate the efficiency and effectiveness of its operations, its system of internal controls, and its compliance with directives and initiatives. CMS' evaluation of a DMEPOS regional carrier under this contract may include, but is not limited to:

- Systems Security;
- Disaster recovery plan/systems contingency plan;
- Internal controls establishment and use, including the degree to which the contractor cooperates with the Secretary in complying with the FMFIA.

C.1.6. Miscellaneous Instructions

DMERCs shall perform all Carrier functions specified in this Statement of Work and outlined in the Internet-Only Manuals (IOMs).

C.2. Applicable Documents

The following statutes, regulations, manuals, and documents are applicable to this requirement. The intent of this information is to provide information on either reference material or mandatory use.

C.2.1. Statutes

Contractors shall comply with all applicable laws. The major statute governing the Medicare program is the Social Security Act (Public Law 74-271) ("the Act"), as Amended. The Act and major amendments to the Act are outlined below. The identified amendments include legislation that made significant changes to the Medicare program, are in the process of being implemented, and/or significantly impact the scope of work.

C.2.1.1. Social Security Act (Public Law 74-271)

The act was enacted on August 14, 1935, with subsequent amendments. The Act consists of 20 titles, four of which have been repealed. The HI and SMI programs are authorized by Title XVIII of the Social Security Act. The vast bulk of traditional Medicare's program authorizing law is codified in Title XVIII of the Social Security Act, Parts A, B and E (Part C is primarily devoted to private Medicare plans, and the recently-enacted Part D governs the new Medicare prescription drug benefit. Other Medicare-related authorizing statutes may be found in Titles II and XI of the Social Security Act; other governing provisions may be found in the Internal Revenue Code and other statutes.

For purposes of this contract: Sections 1831 – 1848 (42 U.S.C. 1395j – 1395w-4), sections 1861 – 1892 (42 U.S. Code 1395x – 1395ccc). In particular, familiarity with sections 1832(a), and (h), 1842(a), 1862(n) and (s) and 1881(b) is suggested.

To the extent that there is no conflicting Medicare requirement, the administration of the traditional Medicare program is also governed by numerous statutes pertaining to the general administration of federal programs. General statutory authorities with broad implications for the traditional Medicare program and this contract include, but are not limited to,

- Appropriation and budget-related requirements (e.g., the Anti-Deficiency Act, etc.);
- Acquisition (e.g., the Competition in Contracting Act, etc.);
- Financial management and internal controls (e.g., the Federal Managers' Financial Integrity Act, the Chief Financial Officers' Act, etc.);
- Personnel and civil rights law (e.g., the Drug-Free Workplace Act, the Americans with Disability Act, etc.) and,

- Privacy and information technology requirements (e.g., the Privacy Act, the Information Technology Management Reform Act, etc.).

**C.2.1.2. Medicare Prescription Drug, Improvement and Modernization Act (MMA)
(Public Law 108-173)**

On December 8, 2003, the President signed into law the MMA. This statute makes the most sweeping changes in the structure of the Medicare program since its inception in 1966. The very significant changes made by this statute include:

- The establishment of a temporary Medicare prescription drug discount card program;
- The establishment of a permanent Medicare prescription drug program;
- The Medicare+Choice program is renamed Medicare Advantage, and significant new incentives are provided to facilitate the participation of private plans in Medicare;
- The provision of certain preventative benefits under both traditional Medicare and Medicare Advantage;
- The implementation of many changes in coverage and payment policy within traditional Medicare;
- The implementation of many administrative and regulatory reforms within traditional Medicare;
- Under section 911 of the MMA, the restructuring of the acquisition statutes that govern traditional Medicare, commonly known as Medicare contracting reform; and,
- Under section 927 of the MMA, the provision of provider education and technical assistance.

The MMA statute may be downloaded from www.thomas.loc.gov.

**C.2.1.3. The Health Insurance Portability and Accountability Act of 1996 (HIPAA)
(Public Law 104-191)**

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was enacted on August 21, 1996. Title II, Subtitle F, of HIPAA gives HHS the authority to mandate the use of standards for the electronic exchange of health care data; to specify what medical and administrative code sets should be used within those standards; to require the use of national identification systems for health care patients, providers, payers (or plans), and employers (or sponsors); and to specify the types of measures required to protect the security and privacy of personally identifiable healthcare information.

One of the major goals of HIPAA, under its Program Integrity provisions, is to “pay it right.”

C.2.1.4. The Tax Equity & Fiscal Responsibility Act of 1982 (TEFRA)

The Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) made Medicare the secondary payer for certain employees and dependents.

C.2.1.5. Benefit Improvement and Protection Act of 2000 (BIPA)

Section 521 of BIPA changes the Medicare appeals process to create a uniform procedure for handling all Medicare appeals (Parts A and B) and specified time frames for filing appeals and rendering decisions.

C.2.1.6. Other Key Statutes

- Federal Claims Collection Act of 1966.
- Privacy Act of 1974, Public Law 93-579, as amended (“Privacy Act”)
- The Debt Collection Improvement Act of 1996
- The Rehabilitation Act of 1998, Section 508 Accessibility Standards (“Section 508”)
- The Federal Information Security Management Act of 2002 (“FISMA”)

C.2.2. Regulations

Generally, Medicare regulations are located at Chapter 42 of the Code of Federal Regulations (42 CFR)

For purposes of this contract:

- 42 Code of Federal Regulations, sections 405 Subparts G and H, 410.1 – 410.175, 411.1 – 411.406, 420.1 – 420.304, 421.200 – 421.205 and 424.1 – 424.354.
- Final Rule with Comment Period – Medicare Program: Carrier Jurisdiction for Claims for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues Including Suppliers, and criteria and standards for Evaluating Regional DMEPOS Carriers; Federal Register: Volume 57, No. 118, June 18, 1992, pp. 27290-27309.
- Medicare Secondary Payer (MSP) Legislation and Regulations
 - The regulations implementing the MSP provisions are found at 42 C.F.R. 411., et seq. The only MSP references, which are not encoded there, are section 6202 of the OBRA 1989 and sections 4203 and 4204 of the OBRA 1990.

C.2.3. Implementing Instructions

C.2.3.1. Medicare Manuals

The Medicare Manuals contain CMS program instructions, day-to-day operating instructions, policies, and procedures that are based on statutes and regulations, guidelines, models, and directives. They are used by CMS program components, contractors, and State survey agencies to administer CMS programs. As CMS paper-based manuals are updated, the updated material is published in the Internet-only manuals (IOM) and eliminated from the outgoing old paper-based manuals. CMS will continue this phase-out/phase-in process until all manual instructions are included in the IOMs. IOMs can be found at <http://www.cms.hhs.gov>.

C.2.3.2. Other Manuals and Documents

There is a complete list of procedure codes and coverage information available on the CMS website. The link to access the NCD Coding Policy Manuals, Federal Register Final Rules, and related CMS Program Memoranda is as follows: <http://www.cms.hhs.gov/ncd/labindexlist.asp>.

For purposes of this contract, also refer to the following:

- IOM PUB. 100-8/Internet-Only Manual (IOM).
- Medicare Quality Assurance (QA) Handbook.
- Notice – Medicare Program: Establishing Procedures for Transmitting Information Between Medicare DMERCs and Medicare Supplemental Insurers; Federal Register: Volume 55, No. 225, November 21, 1990, pp. 48694-9.
- Audio Response Unit Beneficiary Applications System Manual.
- Audio Response Unit Supplier Applications System Manual.
- X12 Implementation Guides adopted as rational standards under HIPAA found at www.wpc-edi.com/HIPAA
- The National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard and Batch Standard as published by that organization
- IGS companion documents to those IG3 as posted by CMS at www.cms.hhs.gov/providers/edi/hipaadocs.asp.

C.3. Administrative Requirements

C.3.1. Internal Quality Control (Activity Code 11208)

DMERCs are to perform routine quality control techniques used by management to measure the competency and performance of claims processing personnel. Refer to IOM Pub 100-04, Pub 100-06, Pub 100-08, and Pub 100-16.

C.3.2. Systems Security (Activity Code 11206)

The contractor shall ensure that the security requirements defined in the CMS Business Partners Systems Security Manual (BPSSM), the CMS policy for Information Technology (IT) security and the CMS Information Security Handbook are maintained for all telecommunications, physical, and operational processes. All staff supporting the contract shall be trained on security procedures, as well as relevant aspects of the Privacy Act and the Freedom of Information Act (FOIA).

CMS' Core Security Requirements, as defined in the CMS Business Partners Systems Security Manual, including security standards adopted under the Health Insurance Reform regulations published pursuant to the Health Insurance Portability and Accountability Act (FR Volume 68, Number 34 of February 20, 2003), are applicable to this contract and to all subcontracts.

The contractor shall comply with the security requirements defined in the CMS Business Partners Systems Security Manual (BPSSM), the Core Security Requirements and its operational appendices (A, B, and C).

The contractor shall comply with the CMS Information Security Handbook and all CMS policies, standards and procedures contained within the handbook. Policies include, but are not limited to, all physical, operations, and management policies. Procedures include, but are not limited to, the CMS Systems Security Plan Methodology, the Information Security Risk Assessment Methodology, and the Information Security Incident Handling Procedures. Standards include, but are not limited to, the CMS Internet Architecture (including minimum platform security requirements), the CMS Enterprise Messaging Infrastructure (including architecture, standards, and implementation requirements), the CMS Web-Enabled Application Architecture, and the CMS Information Security Acceptable Risk Safeguards.

The contractor shall be in compliance with the CMS Business Partners Systems Security Manual and the Core Security Requirements (Appendix A) at the time the contract bid is presented.

The cost of initial and cyclical compliance with the CMS Business Partners Systems Security Manual and its operational Appendices (A, B, and C), and the CMS policies and handbooks for IT security, and all CMS requirements for IT security, shall be at the contractor's expense.

Each program managed requirement or each action step cycle shall comply at contractor's expense with the steps and timing as summarized and scheduled in the BPSSM Planning Table 3.1.

The contractor shall ensure that all of the contractor's subcontractors are also in compliance.

The contractor shall comply with and utilize standards and guidelines promulgated by the National Institute of Standards and Technology in its entity-wide information security program.

The CMS Business Partner Systems Security Manual (Publication 100-17) and related Program materials can be found on the Internet at: www.cms.hhs.gov/it/security

Note: The ten categories of the CMS Core Security Requirements are:

- Entity-wide Security Program Planning and Management Elements
- Access Control
- Systems Software
- Segregation of Duties
- Service Continuity
- Application Software Development and Change Control
- Application System Authorization Controls
- Application Completeness Controls
- Application System Accuracy Controls
- Networks

Any deficiencies or findings identified by audits, reviews, tests, such as Statement on Auditing Standards (SAS) -70, Inspector General, vulnerability assessments, etc., subsequent to the contract award shall be corrected in a timely manner at the contractor's expense, i.e., within 45 days of the final audit report, or sooner if the finding is a "high" vulnerability. Time is of the essence in correcting the deficiencies or in remediating the findings of the audit. Corrections shall be reported to CMS in accordance with the guidance provided by the CMS Business Partners Systems Security Manual (BPSSM).

The contractor shall allow the performance of periodic vulnerability testing/assessment of their facilities or the observance of any contractor conducted vulnerability tests/assessments by CMS staff or the government's independent vulnerability testing contractor.

The results of contractor annual compliance audits and vulnerability tests shall be made available to the Government for review upon request.

The contractor shall demonstrate the existence and functioning of an automated intrusion detection system. In addition, the contractor shall demonstrate the existence of incident handling procedures, and the recent training of personnel in the use of those procedures.

The contractor shall allow the presence of CMS reviewers, or reviewers contracted by CMS, on their premises for the performance or validation of any of the reviews or documentation listed above. The Government agrees to provide one-week notice to the contractor before any reviewers are scheduled to arrive at the contractor site.

The contractor shall adhere to all deadlines and formats outlined in the BPSSM and any other official CMS communications (e.g. joint signature memorandums, change requests) at the contractor's expense.

The contractor shall check the following CMS web site at least monthly for updates to the CMS BPSSM (Publication 100-17) and related program materials: www.cms.hhs.gov/it/security/.

The contractor shall participate in a variety of security and/or best practices conferences. Details are provided on the CMS Information Security homepage.

The contractor shall participate in certification and accreditation activities as a condition of contract award. The contractor shall examine the controls implemented for its systems and certify them as in compliance with CMS' policies and relevant business requirements.

C.3.3. Contractor Testing Requirements

Each DMERC shall participate in ongoing testing of software in support of regional DMEPOS processing.

1. As required whenever changes occur in the systems, the DMERC shall participate in the testing of new releases of software developed by VMS.

2. Each DMERC shall participate in testing of software developed by the CWF Maintenance contractor in support of DME processing as changes are required for DME processing.

NOTE: When CMS issues a Program Safeguard Contractor (PSC) task order for DMERC program integrity and medical review workloads, the DMERC affected shall coordinate with the chosen PSC, the Statistical Analysis DMERC (SADMERC) and the National Supplier Clearinghouse (NSC) to assure crosscutting information is communicated between the four. In addition, the DMERCs/SADMERC/NSC shall work with the PSC as needed.

During the transition of program integrity workload from a DMERC to a PSC, the PSC shall work with the DMERC to develop a Joint Operating Agreement (JOA). The JOA will be added to the specified DMERC's and the PSC's SOW/Contract, as an attachment, after all of the procedures in the JOA are agreed upon by the DMERC, the PSC and CMS. The JOA will ensure coordination and cooperation during the transition and thereafter.

DMERC Coordination with the PSC is imperative.

C.3.4. Quality Assurance (QA) Program Requirements

The DMERC shall comply with the instructions given in a memorandum from CMS dated October 30, 1996, entitled New Part B Quality Assurance Process (see attachment J.5A). This process encompasses the use of the Medicare QA Handbook and error subcategories as defined in sections 210.1 through 210.6 of the Handbook (see Attachment J.5).

The DMERC's QA program shall provide for the ongoing review of a sample of processed DMEPOS claims independent of the initial review. All DMEPOS claims, including PEN (Parenteral and Enteral Nutrition) claims, will constitute the claims universe. The DMERC's QA program shall include a statistically valid selection of a claims mix of adjudicated claims to comprise a random sample. The DMERC will review selected samples, analyze results for corrective actions, and submit (along with any required documentation) reports to the Regional Office in the method, manner, and time frame as agreed to by the Project Officer.

For QA evaluation and scoring purposes, a DMERC will be considered as a single entity for all states combined within each of the four designated regions. The definition of Random Sample is as follows -- In terms of statistical sampling it is a method used to ensure that a sample selection does not have a bias introduced in the selection of items from a sampling universe. In order for a sample to be randomly selected each item in the universe (one-day of claims, one month of correspondence, etc) has to have an equal chance of selection.

To accomplish a random selection, one should use a random digit generator or a random number table. Usually if a sample is being selected on a routine basis through a computer program a random number generator is used to ensure that all items in the universe have an equal chance of selection. If a one is doing the selecting one can use a random digit table and these are available in any Statistics textbook. One can also use a random number generator commonly available in software packages like Microsoft Excel or Lotus 123. For example, using Microsoft Excel one would use the Mathematical function RAND and determine the number of items in the universe and then enter an asterisk followed by that number next to the RAND (RAND()*100) function in

a cell and then press enter. A random number will appear in the cell. If more items are needed, one would copy that cell to the number of cells to the corresponding random numbers needed.

All of this assumes that one already has a sampling method (for example, simple random sample, systematic random sample, stratified simple random sample, etc.) and a sample plan designed and documented. The sample plan should show how one will array and identify each item in the universe so that once one begins using random numbers one will be able to identify a corresponding item in the universe.

C.4. Program Management (PM)

The DMERC shall maintain adequate staffing and training of employees. Each position shall be full time for the contract period.

Key personnel shall include:

- The Project Manager,
- A Claims Processing Manager, and
- A Systems Manager

DMERCs shall maintain staff sufficient to fulfill the SOW requirements, Program Management functions, and shall comply with IOM requirements.

- Claims Payment
- Hearings & Appeals
- Beneficiary Inquiries
- Supplier Inquiries
- PM Provider Communications

C.4.1. Claims Processing Ongoing (Activity Code 11205)

DMERCs shall be connected as satellites to the Common Working File (CWF) system for the submission of DMEPOS claims. Each DMERC shall be connected to a government-provided telecommunications network, using circuits sized according to their projected volume. The DMERC shall process DME claims using the VMS, and then submit DMEPOS claims via the telecommunications network to the CWF Host for payment or denial decisions.

DMERC responsibilities regarding the submission of claims to the CWF Host sites are provided in IOM Pub 100-04, Chapter 27. These instructions shall apply to the DMERCs as well. The DMERC shall process claims to the point of payment or denial in accordance with instructions specified throughout the IOM. At the point of payment or denial, the DMERC shall prepare and submit to the CWF Host a DMEPOS Claim Record (called an HUDC) and a Certificate of Medical Necessity (CMN) Maintenance Transaction Record (HUCM), if appropriate, for each claim processed.

The DMERC shall be directly connected to the CWF Hosts, which are in its region. Additionally, each DMERC shall be directly connected to the South CWF Sector Host for submission of Railroad Retirement Board (RRB) claims. CWF Hosts currently house all beneficiary information online for at least 24 months and have access to older information.

C.4.1.1. Receipt Conversion and Control (Activity Code 11202)

DMERCs shall continue to receive non-electronic claims (i.e., Hard Copy, Fax and Optical Character Recognition (OCR) claims). The process includes the following actions: receiving, opening and sorting mail; extracting claims; sorting claims by type; stamping control numbers; microfilming claims and attachments; copying microfilm; checking claims for missing data elements; batching, controlling, and data entry activities for claims/adjustments; scanning or imaging claims; and other activities as identified in the FY 2006 BPRs for activity code 11202.

C.4.1.2. Claims Adjustment Editing (Activity Code 11210)

DMERCs shall perform the following actions related to routing editing of claims and adjustment: returning claims failing front-end edits to the provider for correction and resubmission (Do not include edits performed for specialized purposes such as Medical Review (MR)/Utilization Review (UR) and Medicare Secondary Payer (MSP)). Refer to IOM Pub 100-04, Chapter 1.

C.4.1.3. Claims Resolution (Activity Code 11204)

DMERCs shall perform the following functions to complete claims adjudication:

- Deny, return or reject claims according to Central Office instructions—Most of these claims are returned and rejected; however, with those that are developed, include the cost of gathering missing, erroneous, or incomplete data, necessitating telephone or correspondence development with physicians, beneficiaries, suppliers, or providers to obtain information before further processing, and consultation with clinical staff if needed for claim determination.

C.4.1.4. Claims Processing (Activity Codes 11203 and 11204)

DMERCs shall coordinate with the VMS staff to define effective date, development specifications, and a schedule for installation and acceptance testing of a claims processing system that meets CMS Functional Standards and Part B Core System Requirements (as they pertain to DMEPOS Claims processing), and use software that is compatible with CMS systems that shall include:

- Data collection;
- Claims control; [Note: Date of receipt (DOR) is the date received by the DMERC, not by VMS. There is usually a 1-work day difference. The DOR shall be established by the DMERC.]
- Data validation;
- Claim adjudication;

- Claims payment;
- File and database maintenance;
- External interfaces.

DMERCs shall participate in the functional tag conference calls and the Change Control Board Process to assure that specifications meet CMS and DMERC requirements.

DMERCs shall investigate the alerts sent to them by CWF (**Except alert code B**).

The following are some examples of DMERC edits, which should assure necessary safeguards and, consistency edits shall include but not be limited to:

- Front-end return/reject edits to return claims to the supplier for correction and resubmission (IOM Pub 100-04, Chapter 1);
- All CWF Error codes and Disposition Codes (IOM Pub 100-04, Chapter 27);
- Ongoing exact and suspect duplicate services on claims processed at the individual DMERCs (IOM Pub 100-04, Chapter 1);
- Rental claims for the same or similar equipment billed by the same or different suppliers within the same rental month;
- Beneficiary residence/claim jurisdiction (i.e., detection of misrouted claims for beneficiaries who do not reside within the region serviced by the DMEPOS DMERC) (IOM Pub 100-04, Chapter 1);
- DME furnished to a beneficiary residing in an institution that does not qualify as a “home” for payment purposes;
- Fragmentation of billing, i.e., systems capability to identify and recombine component parts of items or kits to, prevent “unbundling” for payment purposes;
- DMEPOS rented or purchased beyond an established period of medical necessity (PUB. 100-8 Chapter 5);
- Contraindicated items of rented or purchased equipment or supplies;
- Billed DMEPOS rental months (i.e., rental month start dates) or purchase transactions that occur after a beneficiary’s date of death (PUB. 100-8 Chapter 5);
- DMEPOS rentals (i.e., rental months “start dates”) or purchases before Part B entitlement or after an end to Part B entitlement (IOM Pub 100-04, Chapter 20);
- Purchase claims for DMEPOS items that can only be paid for on a rental basis (IOM Pub 100-04, Chapter 20);

- Rentals for DMEPOS items that can only be paid for on a purchase basis (IOM Pub 100-04, Chapter 20);
- “Capped rental” and parenteral and enteral pump bills that exceed 15 continuous rental months (IOM Pub 100-04, Chapter 20);
- Fourth through fifteenth capped rental months subject to reduced payment limits (IOM Pub 100-04, Chapter 20);
- Capped rental items for which the beneficiary has chosen the purchase option and rentals have exceeded 13 months (IOM Pub 100-04, Chapter 20);
- Capped rental equipment and enteral pump maintenance and servicing claims (MS modifier cases) billed more often than every 6 months, and parenteral pump maintenance and servicing claims billed more often than every 3 months (IOM Pub 100-04, Chapter 20);
- Allowed amounts for rental of inexpensive and frequently purchased DMEPOS do not exceed the fee schedule allowance for purchase of the item (IOM Pub 100-04, Chapter 20);
- Inconsistent claims information (e.g., purchased liquid oxygen contents but the patient owns a gaseous oxygen delivery system or vice versa);
- Prior approval obtained, if required (PUB. 100-8 Chapter 5);
- Apply other payment rules and claims processing rules and instructions in IOM Pub 100-04, Chapters 1, 20, 23, and 27) and Change Requests as periodically transmitted by CMS, which are applicable to DMEPOS services. For example: suppress checks under \$1.00, operationalize the MSN;
- Process claims for all beneficiaries residing within their assigned geographic areas (this includes the pricing schedules for all localities in the region) (IOM Pub 100-04, Chapter 20);
- Process claims for beneficiaries according to CWF address and where applicable CMS written instructions (IOM Pub 100-04, Chapter 20 and Chapter 1);
- Comply with Claims Processing Timelines (CPT), payment floor and interest payment requirements. (The requirements for DMERCs shall be the same as those applicable for all other Part B carriers) (IOM Pub 100-04, Chapter 1);
- Utilize consistency and prepayment safeguard edits essential for accurate DMEPOS claim processing (IOM Pub 100-04, Chapter 1);

- Implement all other claims processing requirements described in this statement of work;
- Process claims based on date of service or date of receipt according to CO instructions (IOM Pub 100-04, Chapter 1).

DMERCs shall adhere to the following mandated standards:

- Not less than 95.0 percent of clean electronically submitted claims that comply with implementation guide requirements for those claim standards adopted under HIPAA are processed within statutorily specified time frames. Specifically, clean electronic claims can be paid as early as the 14th day (13 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt). CMS's expectation is that contractors will meet this percentage on a monthly basis.
- Not less than 95.0 percent of clean paper claims and clean electronic claims submitted in a non-HIPAA compliant format are processed within specified time frames. Specifically, clean paper claims and clean electronic claims submitted in a non-HIPAA compliant electronic format can be paid as early as the 27th day (26 days after the day of receipt) and must be paid by the 31st day (30 days after the date of receipt). CMS' expectation is that contractors will meet this percentage on a monthly basis.
- Properly generate 98.0 percent of Medicare Summary Notices (MSNs). CMS' expectation is that MSN messages are accurately reflecting the services provided.

C.4.1.4.1. DMERC Supplier File Maintenance

The NSC shall issue billing numbers and maintain a national supplier file. Only the NSC shall issue billing numbers to suppliers and collect ownership information. The NSC shall release information from the national supplier file to all DMERCs. Please refer to the statement of work for the NSC at Section C.6.

The DMERC shall:

- Update its supplier file based on NSC information;
- Maintain systems interfaces for the NSC-DMERC data exchange in accordance with specifications from the NSC;
- Send to the NSC via the telecommunications system "alert indicators" for
 - Suppliers with situations that may indicate fraudulent or abusive practices which are discovered in claims processing, post-payment reviews or complaints about a supplier, owner, or managing employee;
 - Suppliers in prepayment review status;
 - Suppliers in suspense status;

- Suppliers from which overpayments are being recovered; and
 - Do Not Forward suppliers;
- Supply a list to the lead Regional Office (RO) of alert codes submitted to the NSC for the period 10/1 – 6/30 each year. The list shall show the supplier number, alert code, and date submitted to the NSC;
 - Receive from the NSC, research and take appropriate action on “alert indicators” submitted by other DMERCs;
 - Receive NSC alerts of criminal and administrative sanctions, including exclusions from the Medicare program, and take appropriate action;
 - Enforce the participation selection made by the supplier and retained on the national supplier file by the NSC;
 - Inform suppliers via the newsletters (see Section C.3.1.(2)(8)) of the application process and the responsibilities of the NSC, its telephone number, and address;
 - Research/investigate beneficiary or other complaint that may indicate a supplier does not meet the supplier standards and forward results of the investigation with any recommendation for action to the NSC;
 - Otherwise cooperate with the NSC and other DMERCs to ensure that only suppliers that are eligible for Medicare payments are paid;
 - The DMERCs shall follow CO/RO instructions including periodic bulletin notices reminding suppliers of requirements to update addresses in compliance with the Do Not Forward initiative. The initiative began 2/1/97 and continues until further notice, including monthly reports to CO as required. NSC reports to CO quarterly; and
 - Maintain a master file capable of tracking at least 2 sets of supplier stop and start effective dates and revocation/inactivation dates.

C.4.1.5. Common Working File (CWF) (Activity Code 11205)

Each DMERC shall submit, on a daily basis (Monday through Friday, except all holidays), DMEPOS claims to each CWF Sector Hosts to which the DMERC is directly connected.

Each DMERC shall submit DMEPOS Claim Records (HUDCs) to the CWF Sector Host which houses, or based on ZIP code, is expected to house, the beneficiary history when directly connected to that CWF Host. Otherwise the DMERC shall submit the DMEPOS claim records to their Primary CWF Sector Host for Out of Service Area (OSA) processing.

Each DMERC shall establish and maintain a file, which identifies beneficiaries, and the Hosts at which their histories are housed.

Claims shall be forwarded to the CWF Host, which houses the beneficiary master record, if the DMERC is connected as a satellite to that CWF Host.

Claims for Beneficiaries whose master records are housed at a CWF Host to which the DMERC is not connected as a satellite shall be forwarded to their Primary CWF Sector Host for OSA processing.

Claims for beneficiaries never processed by the DMERC shall be forwarded to the CWF Host indicated by the zip code for the beneficiary's residence when directly connected to that CWF Host. Otherwise, the DMERC shall submit the DMEPOS Claim Records to their Primary CWF Sector Host for OSA processing.

Each DMERC shall update their beneficiary address file using the address from CWF, or other means, according to CMS written instructions.

DMERCs shall communicate with one another for the purpose of routing EMC submitted, out-of-DME-region claims to the correct DMERC.

DMERCs shall prepare and transmit to the CWF Hosts an HUDC for every DMEPOS claim prior to claims payment or denial.

The DMERCs shall send HUDCs to the Hosts daily for every claim, in place of the CWF Part B Claim Record (HUBC)

The HUDC shall be similar to the HUBC, a description of which can be found in current CWF systems documentation at <http://cms.csc.com/cwf/sys default table.htm>. The difference between the records is that the HUDC shall be specifically designed for the unique data needs of the DMEPOS claim, including certain medical review information.

DMERCs shall prepare and transmit to the CWF Hosts a HUCM for every DMEPOS claim requiring a CMN or other medical documentation. The HUCM shall be sent prior to, or with, the HUDC for said claim.

- The information from the HUCM shall aid in correct processing of DMEPOS claims utilization and verify the medical necessity of certain future claims.

Each DMERC shall receive HUDC Reply Records for each HUDC transmitted in place of the CWF Part B Basic Reply Record and take actions appropriate to each reply (e.g., pay the claim as submitted, pay the claim after making an adjustment, correct the claim and resubmit, wait and resubmit). The HUDC Reply Record shall be similar to the current CWF Part B Basic Reply Record, a description of which can be found in current CWF systems documentation at <http://cms.csc.com/cwf/sys default table.htm>.

Each DMERC shall receive HUCM Responses and take the actions appropriate to each response. The HUCM Response Record shall be similar to the current CWF Part B Basic Reply Record, a description of which can be found in current CWF systems documentation at <http://cms.csc.com/cwf/sys default table.htm>.

Each DMERC shall prepare and transmit adjustments to submitted HUDCs and HUCMs according to the instructions in IOM Pub. 100-04, Chapter 27.

Each DMERC shall receive and utilize other records and responses regarding DMEPOS claims, such as trailers containing CMN information. Such records are described in current CWF systems documentation at <http://cms.csc.com/cwf/sys default table.htm>.

Each DMERC shall be able to support the direct data entry eligibility screen supplied by CWF through their data center as specified in IOM Chapter 31 for access by authorized providers or vendors. Each DMERC shall meet the network service agreement requirements in IOM, Pub. 100-04, Chapter 24 to assure the security of electronic data when transferred among multiple parties.

CWF shall apply, at a minimum, basic consistency edits to both the HUDC and HUCM. Utilization and A/B Crossover edits shall also be applied.

C.4.1.6. Payment and Remittance

Medicare Summary Notice (MSN) and Supplier Remittance Advice (RA) – Perform all ongoing activities associated in support of the MSN and the supplier remittance advice (IOM Pub. 100-04, Chapter 22). These activities include but are not limited to ongoing supplier and beneficiary education efforts for the MSN and remittance advice, achieving maximum postage savings associated with mailing the MSN and remittance advice, and responding efficiently and effectively to all inquiries concerning the MSN and remittance advice.

Section 3 of the Administrative Simplification Compliance Act, Pub.L. 107-105 (ASCA), and the implementing regulation at 42 CFR 424.32 require that all initial claims for reimbursement under Medicare, except from small providers, be submitted electronically as of October 16, 2003, with limited exceptions. Refer to IOM Chapter 24, section 90.

C.4.1.7. Paper/Manual Data Interchange (Activity Code 11202)

DMERCs shall receive and enter data from HCFA-1500 and HCFA-1490 claim forms submitted by professional providers and beneficiaries, and conduct outreach with providers to inform them of changes in completion requirements for the HCFA-1500 as required by IOM Pub 100-04, Chapter 26.

C.4.1.8. Electronic Data Interchange (EDI) Support (Activity Codes 11201 and 11203)

CMS defines EDI as the fully automated transfer of data between a biller (provider or agent) and Medicare for billing, remittance advice, eligibility query/response, claims status query/response, claims development request/response, prior authorization, retail drug payments, and other purposes in lieu of an otherwise manual claims processing related activity, or between Medicare and a bank for electronic funds transfer or remittance advice or between Medicare and another payer for coordination of benefits. DMERCs shall adhere to the EDI requirements as defined in IOM Pub 100-04, Chapter 24 and in the EDI standard format implementation guides as issued by CMS and published on the CMS web page (<http://cms.hhs.gov/providers/edi/hipaadoc1.asp> and <http://cms.hhs.gov/providers/edi/hipaadoc2.asp>), or in implementation guides published at www.wpc-edi.com/HIPAA and as issued by the National Council for Prescription Drug Programs, which CMS directs its contractors to implement in compliance with HIPAA.

DMERCs shall establish and support EDI connections as required for Medicare. DMERCs shall conduct outreach activities with suppliers to educate them on and expand their use of the EDI transactions supported by Medicare. Outreach shall include training for supplier staff in submission of claims electronically using Medicare billing software (if selected by the supplier, provision of information on potential EDI vendors (through maintenance of an electronic billing Vendors Directory and distribution of copies of the directory on request), and information on and the advantages of use of each of the EDI standards supported by Medicare.

DMERCs shall acquire and maintain telecommunication protocols and lines, and software and hardware for the receipt and issuance of electronically transmitted batch transactions in a secure manner, and hardware for the processing of magnetic tapes delivered by trading partners. (NOTE: Reference to "lines" here does not refer to 800 lines at one time maintained for participating physicians and suppliers. As used here, "lines" refers to maintenance of adequate telephone lines so you have the capability to receive and send the quantity of EDI traffic resulting from your agreements with your electronic trading partners.)

DMERCs shall provide, maintain and distribute free or low cost Medicare electronic billing software (HIPAA versions).

DMERCs shall conduct system testing with electronic trading partners (suppliers, agents, clearinghouses, and other payers under COB) to assure compatibility between systems for successful exchange of data. Trading partner testing is mandatory for the HIPAA claim (837 and NCPDP), but is required only at the request of the submitter/receiver for other HIPAA transactions.

DMERCs shall obtain an EDI Enrollment Form from each supplier prior to electronic transfer of data and issuance of system passwords/billing numbers to protect the security of transferred data. DMERCs shall obtain Network Service Agreements from supplier agents, business associates, and subcontractors who transfer supplier EDI data electronically, as required in IOM Pub 100-04, Chapter 24.

DMERCs shall use the Medicare standard flat-file functional acknowledgement for confirmation of receipt of electronic National Standard Format (NSF) flat files. DMERCs shall use the X12 997 transaction to acknowledge receipt of X12 837 claims. DMERCs shall edit data received from trading partners for compliance with system requirements and format specifications.

DMERCs shall route edit and exception messages and remittance advices automatically to electronic trading partners via direct transmission or via deposit to an electronic mailbox for downloading by a trading partner.

DMERCs shall maintain the capability for submission of EDI transactions in batch and for batch correction of edits by electronic trading partners. "Batch" means the submission of data accumulated over a period of time, which is processed sequentially by the receiver in a subsequent computer system run with the results of processing relayed back to the submitter after completion of that run.

DMERCs shall continue to maintain direct data entry capability, where it existed pre-HIPAA, and shall make the data elements in those screens compliant with the data requirements of the corresponding HIPAA transaction implementation guides as specified in the HIPAA transaction implementation Program Memoranda.

DMERCs shall make skilled staff available to provide EDI support as needed to maintain connections with electronic trading partners.

DMERCs shall furnish providers and their clearinghouses/agents with at least 90 days advance notice of system changes that will impact the EDI transactions they send to or receive from Medicare. Depending on the extent of changes, DMERCs shall issue notices or provide educational programs to facilitate implementation of the changes or new standards by their trading partners.

DMERCs shall retain, or be able to recreate, all electronic transactions that were used to process or adjust claims, update claims or provider history files, to issue and be able to reissue if requested, remittance advices or electronic query responses, or to conduct any other transaction with a trading partner electronically in accordance with requirements in IOM Pub 100-04, Chapters 22, 24, 25, and 31.

DMERCs shall retain statistics on EDI performance to support workload reporting as specified in Contractor Reporting of Operational & Workload Data (CROWD) reporting requirements and in the HIPAA status reporting requirements issued by CMS.

DMERCs and their shared system maintainer shall make system changes as needed to update each of the current, CMS-supported standard electronic formats, including for COB, claims, remittance advices and claim status inquiries and responses once a year if so directed by CMS.

Key Shop and Optical Character Recognition (OCR)/Image Character Recognition (ICR) Output Mapping

DMERC key shop and OCR operations, that do not use either the HIPAA 837 or X12N-based flat file as output, shall create the output from paper claims in the X12N-based flat file format or the HIPAA 837, unless DMERCs allow keyshop/OCR operations to continue to create output from paper claims in the NSF file format. DMERCs that allow the output in the NSF format shall convert the format to the X12N-based flat file format prior to submission to their shared system. When the X12N-based flat file is the output the REF01 segment/element (found prior to the ST segment) shall contain a value of "+PR" and REF02 shall contain a value of "K" (key shop) or "O" (OCR/ICR). DMERCs who support telephone claim submission, the value in REF02 shall contain a "T" (teleclaim).

For outbound coordination of benefits (COB), these claims shall continue to be processed as "skinny" COBs and all necessary gap-fill measures shall be applied when the REF01 = "+PR" and REF 02 = "K", "O", or "T" on the X12N-based flat file. The outbound ANSI X12N 837 COB shall be built as a "minimum" data set. It shall contain all "required" ANSI X12N 837 COB segments and post-adjudicated Medicare data.

Health Insurance Portability and Accountability Act (HIPAA)

In order to implement the Health Insurance Portability and Accountability Act (HIPAA) administrative simplification provisions, the American National Standards Institute (ANSI) Accredited Standards Committee (ASC) version 4010A1 (referred to hereafter as HIPAA version) of the inbound X12N 837 Health Care Claim, outbound X12N 837 (Coordination of Benefits), X12N 835 Health Care Claim Payment/Advice, X12N 270/271 Health Care Claim Eligibility Inquiry/Response, and X12N 276/277 Health Care Claim Status Request/Response are the transaction standards being named under part 162 of title 45 of the Code of Federal Regulations. The NCPDP Telecommunications Standard Format Version 5.1 and equivalent NCPDP Batch Standard Version 1.1 are the transactions adopted for retail pharmacy drug claims. All other electronic formats for these transaction types will become obsolete as otherwise directed by CMS upon termination of the Medicare HIPAA contingency period.

ANSI ASC X12N (4010) Documentation

The HIPAA implementation guides for the ANSI ASC X12N transactions may be found at the following website: <http://www.wpc-edi.com/hipaa>

NCPDP Documentation

The HIPAA implementation guide for the NCPDP standards may be obtained from the following website: <http://www.ncdp.org>

Health Care Claims and Coordination of Benefits (COB)

ANSI X12N 837 Claim

DMERCs shall use the X12N-based flat file issued by CMS to map the incoming X12N 837 to the appropriate flat file data elements. This will allow a one to one correlation between the flat

file and the data received, eliminating omissions of data needed for building a compliant outbound X12N 837 coordination of benefits (COB) transaction.

The X12N-based flat file is in an Excel spread sheet format. It is available from the following website: <http://cms.hhs.gov/providers/edi/hipaadoe1.asp> The file name is P4010A1-3.zip.

EDI submitters may send an inbound X12N 837 transaction that contains all data possible, and DMERCs shall be capable of accepting it at their front end; however, DMERCs do not have to process non-Medicare information. DMERCs shall retain the original inbound X12N 837 data in order to transmit a fully HIPAA-compliant outbound X12N 837 COB to the DMERCs' COB trading partners. This data shall be stored in a repository file built by the DMERC standard system maintainer prior to entering the standard system's main processing system. The data in the repository file shall be retrieved at the back end, along with data required for Medicare, in order to build a HIPAA-compliant outbound X12N 837 COB transaction. The X12N flat file issued by CMS also accommodates COB data.

DMERCs shall continue their current practice for obtaining translation software unless directed otherwise by CMS. DMERC translators shall validate the syntax compliance of the inbound X12N 837 standard. DMERCs shall use the X12N 997 Functional Acknowledgment to report standard level errors detected by the DMERC translators. Implementation guide compliance validation of the translated X12N 837 is to be performed at the EDI second level edits, and include validation of required loops and segments, appropriate segments within a loop, valid calendar dates, qualifiers, etc.

Refer to Chapter 24 of the Internet-Only Manual for further information on the HIPAA X12N requirements.

ANSI X12N 837 COB

The outbound COB transaction is a post-adjudicative transaction. This transaction includes incoming claim data as well as COB data. Refer to Chapter 24 of the IOM. DMERCs shall be capable of receiving all possible data on the incoming X12N 837 although DMERCs do not have to process non-Medicare data. However, DMERCs shall store that data in a store-and-forward repository (SFR). This repository will be designed by the DMERC standard system. This data shall be reassociated with Medicare claim and payment data in order to create an outbound X12N 837 COB transaction. The DMERC standard system maintainer is to use post-adjudicated Medicare data (data used from history and reference files to adjudicate the claim) in COB transactions instead of data received on the claim when the post-adjudication data differs from the received data. DMERCs shall retain the data in the SFR for a minimum of 6 months.

The X12N-based flat file issued by CMS is the format to be used to reassociate all data required to map to the outbound X12N 837 (4010A1). DMERC translators will build compliant outbound X12N 837 COB from the X12N-based flat file. Also, refer to Chapter 24 of the Internet-Only Manual for further information on the HIPAA X12N requirements.

NCPDP Claim and COB

DMERCs shall implement the NCPDP Telecommunications Standard Format 5.1 and NCPDP Batch Standard 1.1 for retail pharmacy drug claims and COB. Refer to Chapter 24 of the Internet-Only Manual.

Free Billing Software

DMERCs shall upgrade their free billing software to support the submission of claims in the X12N 837 (HIPAA version) format. DMERCs shall make it available to requesting suppliers. The DMERC billing software shall be able to create an implementation guide (IG) compliant Medicare Part B claim. Refer to Chapter 24 of the Internet-Only Manual for further information on the free billing software requirements.

Remittance Advice

DMERCs shall continue to use a flat file for their internal system programming. DMERCs shall use the updated X12N 835 version 4010A1 remittance advice flat file issued by CMS. The file is available at the following website: <http://cms.hhs.gov/providers/edi/hipaadoc1.asp>. The document name is B835v4010&4010A1-5.zip. This document gets updated if and when needed, and the file name may change. The flat file maps each flat file field to the corresponding 835-version 4010A1 data element. DMERCs shall translate the 835 flat file data into a fully compliant 835 (HIPAA version) transaction prior to transmission to a supplier or a supplier's designated agent.

Refer to Chapter 22 of the Internet-Only Manual for further information on the remittance advice requirements.

Claim Status Inquiry and Response

DMERCs shall accept the X12N 276 (HIPAA version) at their front-end and shall translate that data to a flat file. DMERCs shall accept the claim status response flat file from the standard system and shall create a compliant outbound X12N 277. DMERCs shall use the flat file issued by CMS in order to map the incoming X12N 276 to the appropriate flat file data elements. This will allow a one to one correlation between the flat file and the data received.

The X12N-based flat file is in an Excel spread sheet format. It is available from the following website: <http://cms.hhs.gov/providers/edi/hipaadoc1.asp>. The file name is 276277b-a1mar03.

Refer to Chapter 31 of the Internet-Only Manual for further information on the claim status inquiry and response requirements.

Health Care Claim Eligibility Inquiry and Response

DMERCs will not be required to receive X12N 270 version 4010A1 eligibility queries or issue 271 responses. Pending further information from CMS concerning Medicare use of these

transactions, DMERCs shall continue to operate legacy formats to furnish providers and their authorized agents with beneficiary eligibility data.

Testing X12N HIPAA Transactions

DMERCs shall continue testing their EDI claim submitters on the HIPAA version of the X12N 837 Health Care Claim (4010A1) and the X12N 837 for coordination of benefits.

Refer to Chapter 24 of the Internet-Only Manual for further information on the Medicare requirements for provider and provider agent testing.

Testing NCPDP Transactions

DMERCs shall continue testing all EDI retail pharmacy claim submitters and COB trading partners on the NCPDP through the end of the Medicare HIPAA contingency period, and shall test new users of these transactions indefinitely. Refer to Chapter 24 of the Internet-Only Manual for further information on the NCPDP format requirements.

C.4.1.9. Claims Service (Activity Code 11210)

Maintain all original and hard copy claims processing information in accordance with the Department of Justice (DOJ) instructions, which includes:

- Filing, removing, updating, refiling and general maintenance of electronic and paper claim/adjustment files;
- Maintaining “Help desk” personnel as made available for all above tasks as necessary.

For further details regarding these activities, refer to IOM Pub 100-04, Chapter 1.

C.4.1.10. Coordination of Benefits (COB) (Activity Code 11207)

As provided in chapter 28, §70.6 of the Medicare Claims Processing Manual (Pub.100-04), DMERC contractors shall have ceased the marketing and execution of Trading Partner Agreements (TPAs) for the purpose of crossing Medicare paid claims data to other health care insurers effective April 1, 2005.

DMERC contractors shall receive notification from trading partners via an electronic e-mail notice, when these entities are ready to cancel their existing crossover TPAs with the DMERC contractors. This notification will occur no later than 15 business days prior to each trading partner’s scheduled production date. DMERC contractors shall operate under the assumption that all of their current eligibility file-based crossover trading partners will at least be in test mode with the COBC by September 30, 2005. Until crossover trading partners are transitioned to the COBC, DMERCs shall maintain existing Agreements and connectivity with these entities for purposes of crossing over Medicare paid claims data. DMERC contractors shall also continue to collect the associated crossover fees in accordance with CMS-issued instructions **until** they are notified that a trading partner has been transitioned to a national COBA. Once a

Common Working File (CWF) Beneficiary Other Insurance (BOI) reply trailer (29) is received, DMERC contractors shall follow the consolidated claims crossover process instructions set forth in chapter 28 §70.6 of the Medicare Claims Processing Manual with respect to transmission of processed claims to the COBC and to the trading partner as appropriate.

DMERCs will not be contacted by trading partners to terminate existing TPAs before December 2004. CMS plans to transition all existing eligibility file-based COB trading partners to the new COBA process by December 31, 2005.

Upon issuance of a CMS Program Transmittal, DMERC contractors shall coordinate with the COBC to ensure that COBA trading partner requests for retrospective claims or other recovery requests are processed timely.

Once all trading partners are transitioned to the COBA process, the COBC will assume complete responsibility for the collection, reconciliation, and distribution of claims crossover fees for those claims transmitted by the DMERC contractors to the COBC. DMERC contractors will continue to collect and reconcile crossover fees for any outstanding amounts owed as a result of claims crossed over to trading partners prior to completion of their transition to COBA.

Until a DMERC contractor receives confirmation, that a Title XIX State Medicaid Agency has signed a COBA, it shall continue to transmit Title XVIII crossover claims to Title XIX State Medicaid Agencies in compliance with instructions in Pub 100-06, Chapter 1, § 450 and Chapter 2, § 130.8 and the COB format specifications located at cms.hhs.gov/providers/edi/default.asp, http://www.wpc-edi.com/hipaa/HIPAA_40.asp and www.ncdpd.org. Other COB information in the ANSI X12N 837 COB information is located in C.4.1.8. To comply with the HIPAA requirements, all COB data shall be transferred via version 4010.A.1 of the X12N 837 implementation guide and/or the National Council for Prescription Drug Programs (NCPDP) Batch Standard Version 1.1 no later than the end of the CMS HIPAA contingency. DMERC contractors will be notified when the contingency is no longer in effect.

C.4.1.11. DMEPOS Fee Schedule (Activity Code 11204)

Fee schedules and reasonable charge screens (for items and services not under fee schedules) are the basis upon which payments are made for covered DMEPOS under Part B. In general, the following payment screens shall be required for payment of DMEPOS claims for services on or after January 1, 2005 (See IOM Pub 100-04, Chapter 20, § 30). The DMERC and SADMERC shall coordinate fee schedule updates:

- Durable medical equipment (DME) and surgical dressings -- Statewide fee schedules limited by the median of statewide fee schedule amounts for the item (ceiling) and by 85 percent of the median of statewide fee schedule amounts for the item (floor).
- Prosthetics and Orthotics (P & O) -- Regional fee schedules limited by 120 percent of the average of fee schedule amounts (ceiling) and by 90 percent of the average of fee schedule amounts (floor).

- Parenteral and enteral nutrients (PEN), equipment and supplies – National fee schedules.
- Home dialysis supplies and equipment -- Statewide prevailings, customaries, IICS, with per patient limits (IOM Pub 100-04, Chapter 8, § 90).
- Drugs (DME supplies) -- Average sales price (ASP) (IOM Pub 100-04, Chapter 17, § 10).
- Not otherwise classified items and services -- Payment for items included in the DMERCs workload which are not otherwise classified shall be based on local statewide fee schedule amounts, 95 percent of Average Wholesale Price (AWP) for drugs, or on an individual consideration basis for reasonable charge items.
- DMERCs shall update their system to include payment files transitioning from Reasonable Charge to Fee Schedule. This includes working with CMS to send requested information to CO.

C.4.1.11.1. Operational Activities (Activity Code 11204)

Pay claims for covered DMEPOS and oral anti-cancer drugs using current and prior year pricing files for each locality within the region.

- Limit payments for covered DMEPOS services to the lower of the billed charge or the applicable fee schedule or reasonable charge amount;
- Prorate payments of DME for partial months;
- Perform annual updates of local statewide fee schedules for DMEPOS paid on such basis;
- Install national fee schedule “floor” and “ceiling” payment limits furnished by the CMS for applicable fee schedule items;
- Install annual updates of reasonable charge screens (i.e., customary, prevailing, and IIC screens) for DMEPOS items and services not paid on the basis of fee schedules, including PEN therapy and immunosuppressive drugs;
- Apply gap-filling and inherent reasonableness pricing rules, as necessary, for DMEPOS items (IOM Pub 100-04, Chapter 23);
- Provide fee schedule data to appropriate entities per CMS instructions and also as requested.

C.4.2. Hearings and Appeals

The Medicare Appeals and Hearing function ensures that the due process rights of beneficiaries, physicians and other suppliers who are dissatisfied with initial claims determinations and

subsequent appeal decisions are protected under the Medicare program. The full requirements of the appeals process, which you shall follow, are found in the Internet Only Manual (IOM) Pub 100-04, Chapter 29, §§ 10ff, 20ff, 30ff, and 60ff as well as IOM Pub 100-04, Chapter 29, §70ff and §80ff and §90ff of Change Request (CR) 3127. Additional instructions found in IOM Pub 100-04, Chapter 29, §200 (currently under development, with CR numbers pending), §300 (see pending CRs 3939, 3942, 3943 and 3944), as well as 42 Code of Federal Regulations (CFR) §§ 405.900-1140 Interim Final Rule, dated March 8, 2005 shall be followed upon the transition of various workloads highlighted in the body of this document.

The Centers for Medicare and Medicaid Services (CMS) is currently implementing amendments to Section 1869 of the Social Security Act (SSA) required by Section 521 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) and Sections 933 and 940 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). Durable Medical Equipment Regional Carriers (DMERCs) are expected to comply with requirements as referenced in this document. CMS will issue additional instructions as other provisions of Section 521 of BIPA, and Sections 933 and 940 of MMA are implemented.

In accordance with IOM Pub 100-06, Chapter 7, DMERCs shall have a system of internal controls in place in the appeals unit to ensure policies and procedures are implemented as appropriate. In addition, standard operating procedures in the appeals unit shall be written to comply with CMS instructions, regulations and statutes found in SSA 1842 & 1869, 42 Code of Federal Regulations Sections 405.801-877 and the applicable IOM instructions referenced above.

DMERCs shall conduct some level of quality improvement and data analysis (QI/DA) activities in FY 2006 with the intent of eliminating unnecessary appeals. This shall be done as part of each specific level of appeals related activity and shall be comparable to the level of effort expended by the DMERC for QI/DA prior to the release of instructions outlined in IOM 100-04, Chapter 29, § 70. Separate tracking and reporting of QI/DA activities is not required for FY 2006.

The activities contained in this section follow those outlined in the FY 2006 Budget and Performance Requirements (BPRs) for Hearings and Appeals. Though developed for budgetary purposes only, referencing the contents of the BPRs can assist DMERCs to plan workloads for FY 2006. The BPRs are designed to provide continued support and guidance to the Medicare contractors as they focus efforts on efficiently and effectively administering all levels of the Part B appeals process. The FY 2006 BPR activities for the appeals area are outlined below.

C.4.2.1 Part B Telephone Redeterminations (Activity Code 12141) (IOM Pub 100-04, Chapter 29, §§ 60.12 and 60.11)

The DMERCs shall process telephone redeterminations for initial determinations made before January 1, 2006. Telephone redeterminations will not be conducted for initial determinations made on or after January 1, 2006. In accordance with statutory requirements, DMERCs are expected to process and mail all redetermination decisions within 60 days of receipt of the redetermination request. Timely processing of telephone redeterminations is a statutorily mandated requirement.

Telephone redeterminations are those redeterminations that are requested by telephone and subsequently completed over the phone. For timeliness purposes, the date of filing for telephone requests for redetermination is identified as the date the telephone call is received. The date the telephone redetermination is completed is defined as when the final determination is printed and released.

Follow instructions contained in IOM Pub 100-04, Chapter 29, § 60.12, (and IOM Pub 100-04, Chapter 29, § 60.11, as referenced in IOM Pub 100-04, Chapter 29, § 60.12) when conducting telephone redeterminations. These instructions address such issues, for example, as documenting the telephone call, types of issues that can be handled over the telephone, transferring of requests to the written redetermination unit, as appropriate, and completion of the redetermination.

Various tasks generally associated with performing this activity are highlighted in the Appeals Carrier Activity Dictionary, Activity Code 12141. Information on capturing workload in the Contractor Reporting of Operational and Workload Data (CROWD) system is also provided.

C.4.2.2. Part B Written Redeterminations (Activity Code 12142) (§1842(b)(2)(B) of the Social Security Act 42 CFR 405.807-405.812; IOM Pub 100-04, Chapter 29, § 60.11; IOM Pub 100-04, Chapter 29, § 80 of CR 3127; Section 521 of the Benefits Improvement and Protection Act of 2000; Sections 933 and 940 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003; pending CRs 3939, 3942, 3944; CR 2620, 3635)

In accordance with statutory requirements, DMERCs are expected to process and mail all redetermination decisions within 60 days of receipt of the request, unless additional documentation pertinent to the request is received. If additional documentation is received, DMERCs will have up to 74 days to process and mail the redetermination notice. Timely processing of redeterminations is a statutorily mandated requirement.

For timeliness purposes, date of receipt is defined as the date the request for redetermination is received in the corporate mailroom. Completion is defined as when the final determination (or a brief notification thereof, for fully favorable decisions) is mailed, or upon notification of withdrawal by the appellant.

In accordance with MMA § 933, DMERCs shall prepare written notice of the right to appeal the redetermination, and include instructions on how to initiate such an appeal. The notice must be written in a manner calculated to be understood by the individual enrolled under Part B. This is a mandated requirement.

Follow instructions contained in IOM Pub 100-04, Chapter 29, § 60.11ff, in addition to instructions highlighted in the above references for handling written redeterminations. These instructions address such issues, for example, as timely processing requirements, what constitutes a request for redetermination, conducting the redetermination, contents of the redetermination letter.

Various tasks generally associated with performing this activity are highlighted in the Appeals Carrier Activity Dictionary, Activity Code 12142. Information on capturing workload in CROWD is also provided.

**C.4.2.3. Part B Incomplete Review/Redetermination Requests (Activity Code 12143)
(IOM Pub 100-04, Chapter 29, § 60.11; pending CR 3939; CR 2620, 3635)**

Follow instructions in IOM Pub. 100-04, Chapter 29, § 60.11.1 regarding what constitutes a complete redetermination request, as well as handling of requests for which required information is missing. For redetermination requests received on or after January 1, 2006, the DMERC shall handle incomplete redetermination requests as dismissals.

Various tasks generally associated with performing this activity have been highlighted in the Appeals Carrier Activity Dictionary, Activity Code 12143. Information on capturing workload is also provided.

C.4.2.4. Part B Hearing Officer (HO) Hearings (Activity Code 12150) (§ 1869 and §1842 (b)2(B)(ii) of the Social Security Act; 42 CFR 405.821-405.836; IOM Pub 100-04, Chapter 29, §§ 60.13-60.18; IOM Pub 100-04, Chapter 29, § 60 of CR 3127; pending CR 3939)

The DMERCs shall continue to process Part B HO hearings for all redeterminations issued prior to January 1, 2006. For all redetermination decisions issued on or after January 1, 2006, the second level of appeal, known as a reconsideration, will be performed by a QIC. DMERCs shall also follow instructions contained in pending CR 3939 following the transition of the workloads. DMERCs shall continue to process HO hearing requests in accordance with current IOM instructions until implementation of the QIC process occurs.

DMERCs shall issue 90% of all HO hearing decisions within 120 days of receipt of the request for HO hearing. For timeliness purposes, the 120 days starts on the date of receipt of the request in the corporate mailroom. Timely processing of HO hearings is a statutorily mandated requirement.

Follow instructions in IOM Pub. 100-04, Chapter 29, §§ 60.13--60.18 when handling HO hearings. These instructions address, for example, such issues as case file development and preparation, types of HO hearings, authority and responsibilities of the HO, procedures associated with the HO hearing and effectuation of the HO decision, etc.

DMERCs shall pay specific attention to HO case file preparation requirements. Refer to IOM Pub 100-04, Chapter 29, § 60.14.6.

DMERCs often find it necessary to transfer cases to another DMERC. Instructions related to the transfer of cases are contained in IOM Pub 100-04, Chapter 29, §60.14.3 of CR 3127.

Various tasks generally associated with performing this activity are highlighted in the Appeals Carrier Activity Dictionary, Activity Code 12150. Information on capturing workload in CROWD is also provided.

**C.4.2.5. Part B Administrative Law Judge (ALJ) Hearings (Activity Code 12160)
IOM Pub 100-04, Chapter 29, §§ 60.19-60.22; IOM Pub 100-04, Chapter 29,
§ 80 of CR 3127**

The DMERCs shall be responsible for processing all Part B ALJ hearing requests for redeterminations issued before January 1, 2006. The QICs will be responsible for forwarding case files to the ALJ for all redeterminations issued on or after January 1, 2006. The DMERCs shall remain responsible for effectuating ALJ and Departmental Appeals Board (DAB) decisions. The DMERCs shall follow all relevant IOM instructions.

DMERCs shall control receipt of ALJ hearing requests based on the date of receipt in the corporate mailroom. Follow instructions in IOM Pub 100-04, Chapter 29, §§ 60.19 -- 60.22 when handling ALJ hearings and DAB activities. These instructions address, for example, such issues as requests for review, case file preparation, numerous timeframe requirements, processing of DAB referrals and effectuation of the decision.

DMERCs shall closely follow instructions related to case file assembly and forwarding. For specific instructions, refer to IOM Pub 100-04, Chapter 29, § 60.19ff.

Various tasks generally associated with performing this activity are highlighted in the Appeals Carrier Activity Dictionary, Activity Code 12160. Information on capturing workload in CROWD is also provided.

**C.4.2.6. Part B Courier Service Fee (Miscellaneous Activity Code 12160-01) (IOM Pub
100-04, Chapter 29, § 60.19.4; § 80 of CR 3127)**

DMERCs shall properly prepare and forward case files to the ALJ for all redeterminations used before January 1, 2006. QICs will be responsible for forwarding case files to the ALJ for redeterminations issued on or after January 1, 2006. Use of the courier service for forwarding of the case file to the ALJ is addressed in IOM Pub 100-04, Chapter 29, § 60.19.4. Information on such things as package preparation and mailing is also addressed in IOM Pub 100-04, Chapter 29, § 60.19.

**C.4.2.7. Qualified Independent Contractors Support Services (Activity Code 12180)
(IOM Pub 100-4, Chapter 29, Section 320 of pending CR 3939)**

DMERCs shall follow instructions contained in IOM Pub 100-04, Chapter 29, § 320 of pending CR 3939 related to the support, preparation and forwarding of case files to the QICs. DMERCs shall send or transmit the case file within 7 calendar days of the date of the QICs request. Misrouted requests received by the DMERC shall be sent to the QIC within 14 days of receipt in the contractor mailroom.

C.4.2.8. Clerical Error Reopenings (Activity Code 12190)

Section 937 of the MMA allows providers, physicians and other suppliers the opportunity to correct minor errors and omissions without the need for an appeal. Consistent with MMA, the DMERCs shall process clerical errors and omissions as a reopening rather than a redetermination. Such reopenings shall be handled over the telephone or in writing. Refer to IOM, Pub 100-04, Chapter 29, Section 90ff as well as 42 Code of Federal Regulations (CFR) 405.980-405.986. Interim Final Rule, (dated March 8, 2005) for instructions. Manual instructions are being developed. CMS will issue a modification to the SOW when the instructions have been released, if necessary.

Managing Workload

CMS recognizes that DMERCs encounter circumstances, which often require prioritization of workloads. Refer to IOM Pub 100-04, Chapter 29, § 80 of CR 3127 and pending CR 3943 as appropriate upon implementation, for guidance on prioritization instructions.

C.4.3. Financial Management of Trust Fund Dollars

CMS may review the DMEPOS regional carriers' efforts to establish and maintain appropriate financial and budgetary internal controls over benefit payments and administrative costs. Proper internal controls must be in place to ensure that contractors comply with Chapter 7 (Internal Control Requirements) of the Medicare Financial Management (Publication 100-6). Additional functions that may be reviewed under this criterion include:

- Compliance with financial reporting requirements;
- Adherence to approved Program Management and MIP budgets and
- Control of administrative cost and benefit payments.

C.4.3.1. Chief Financial Officer (CFO) Substantive Testing Review Activities

If the DMERC is participating in the CFO Audit for FY 2006, it shall:

- Report on the applicable personnel dedicated to the CFO Audit, in terms of Full Time Equivalents (FTE) by staff position (e.g., nurse, clerical, etc.);
- Recover all improper payments identified in the audit. From the improper payments identified in the audit, the DMERC shall also report to CMS the overpayments recovered, overpayments appealed and any associated appeal affirmations or reversals. The DMERC shall report this information to CMS on a quarterly basis. A standard reporting format shall be provided;
- Develop a "Lessons Learned" document. This document should provide information that will help to improve the CFO Audit in future years. It may include items discovered in the CFO Audit that the DMERC could have performed more efficiently, with less time, less/different resources, problems encountered, etc.

CMS will provide the Activity Code for reporting all costs associated with the CFO Audit to the DMERCs that participate in the Audit.

C.4.3.2. Overpayments

General

Overpayments as defined by the Medicare Financial Management Manual, Chapters 3 & 4 (MFMM) are Medicare funds a supplier has received in excess of amounts due and payable under the Medicare statute and regulations. Once a determination of overpayment has been made, the amount so determined is a debt owed to the United States Government.

The DMERC shall comply with the instructions in the MFMM and all CMS written instructions when identifying, collecting, reporting, and referring an overpayment case.

These requirements and the CMS instructions cited are for Non-MSP Overpayments. For MSP overpayments the DMERC shall refer to current MSP Overpayment instructions.

The costs incurred in the recovery of all Part B overpayments by DMERCs in accordance with applicable laws and regulations shall be notated under the activity name Non-MSP Carrier Debt Collection/Referral (Activity Code 11211). In addition to the current debt collection procedures this activity name also includes the following tasks:

- Initiate the prompt recoupment of payments to suppliers to assure proper recovery of program overpayment and reduce the risk of uncollectible accounts
- Verify bankruptcy information for accuracy and timeliness
- Coordinate with CMS/Office of General Council (OGC)
- Update the PSOR to ensure proper treatment and collection of overpayments
- Refer eligible debt to Treasury
- Review all extended repayment plan requests (ERPs)
- Coordinate with CMS on ERPs when necessary

Aggressive Collection of Debt

The DMERC shall maintain timely collection of overpayments. The DMERC shall aggressively recoup debts from all suppliers in order to protect the integrity of the Medicare Trust Fund. Aggressive recoupment efforts include, but are not limited to, demanding repayment, recouping from amounts owed the debtor, establishing repayment plans, and efforts to locate the debtor when demand letters are returned "undeliverable". If the supplier does not respond to the demand letters, the DMERC shall attempt to contact the supplier by telephone. If the DMERC cannot reach the physician/supplier by telephone or the DMERC receives any demand letter back as undeliverable the DMERC shall attempt to locate the physician/supplier through other means. Some examples of other sources include state and local medical societies, the American Medical Association, telephone directories, driver's license records, state insurance boards, Secretaries of State and the DMERC's own Medicare beneficiary records. Overpayment departments shall

refer to physician/supplier enrollment applications, Medical Review staff, and Fraud and Abuse staff for further ideas concerning the debtor's whereabouts. Overpayment departments shall attempt to find out if the physician/supplier is bankrupt and the names of the owner, partners, or the corporation officers. If the DMERC has access to an Internet search site, such as Lexis-Nexis® or a similar program, in the Overpayment department or another department this shall also be utilized. If the DMERC does not have access to a search program the servicing regional office shall be contacted to see if they could be of assistance. All attempts to find the physician/supplier shall be documented in the case file. Aggressive recoupment efforts shall continue until the debt is referred to the Department of the Treasury or the debt is approved by CMS for termination of collection activity and write-off closed.

If the DMERC's volume of debt precludes the DMERC from meeting the requirement to call suppliers with delinquent debt weekly (See MFMM, Chapter 4 §80.2), the DMERC shall submit a debt collection plan to their servicing regional office. This debt collection plan shall include an alternative plan for calling suppliers with delinquent debt specific to the DMERC's volume of debt. The servicing regional office and/or Central Office will review this debt collection plan and the DMERC will be notified of its approval. Once notified this debt collection plan shall be placed in the DMERC's standard operating procedures and will be effective for the current fiscal year unless CMS or the DMERC decide to revisit the approved debt collection plan. Absent an approved debt collection plan the requirements in MFMM, Chapter 4, §80.2 shall apply to the DMERC.

Referral of Delinquent Debt to the Department of Treasury

The Debt Collection Improvement Act (DCIA) of 1996 requires that CMS refer delinquent debt over 180 days old, unless specifically exempted, to Treasury for collection. Exemptions include debts in bankruptcy, debts in appeal, debts already at the Department of Justice, and debts under a repayment plan. Prior to referring delinquent Debt to Treasury, the Medicare DMERC shall certify that the debts selected for referral are valid. This certification process requires the DMERC to validate the amount and status of the debt, accrue interest up to the specified date, and provide notice to the debtor regarding specific information and rights regarding DCIA referral. This notice, in the form of an intent to refer letter allows the debtor 60 days to respond. After 60 days, if the debtor has not responded or repaid the debt in full, the Medicare DMERC will enter the debt information to the Debt Collection System (DCS) database. This database, developed by CMS, allows the electronic transfer of debtor information to Treasury for cross servicing. Medicare DMERCs cease all active collection efforts on the debt, once it is transferred to Treasury. However, the debt is still eligible for internal offset through the Medicare program and shall continue to accrue interest in the DMERC system for this purpose. To maintain consistency in the reporting of referred debts, any changes to the status, amount due, or other pertinent debtor information shall be communicated to CMS Central Office, Office of Financial Management, Accounting Management Group, Division of Debt Referral and Oversight.

Physician/Supplier Overpayment Reporting System

Overpayments shall be input into the Physician/Supplier Overpayment Report (PSOR) on a timely basis. The new overpayment and any updates shall be entered into the PSOR within 10 calendar days. Because this system is a real time system, it is imperative that timely and accurate information be maintained so CMS can manage and account for all overpayments. Failure to comply with these reporting requirements compromises the integrity of the overpayment reporting process and constitutes noncompliance with the internal control expectations noted in the Federal Manager's Financial Integrity Act of 1982 (FMFIA). (For PSOR requirements see the MFMM, Chapter 3, §150 Exhibit 2.)

Demand Letter Requirements

DMERCs shall include language in demand letters explaining why the supplier is liable for the overpayment. For medical necessity determinations the DMERC shall make a determination based on section 1879 of the Social Security Act. For without fault determinations the DMERC shall make a determination based on section 1870(b) of the Social Security Act. If the overpayment determination involves multiple claims, it is necessary to make specific findings under 1879 and/or 1870(b) for each claim at issue.

Deposits

All supplier checks shall be deposited within 24 hours of receipt in accordance with the MFMM, Chapter 5, §100.3. Upon deposit, apply monies against any established account(s) receivable. Make appropriate adjustments to the claims and/or the claim history file for the identified claims as you would normally do.

Overpayments Identified with a Principal Balance less than \$10.00

The DMERC's standard system generates an Under Tolerance Report on the close of business on the last business day of the month. This Under Tolerance Report includes all overpayments identified during the month that have an original balance less than \$10.00 and have not been demanded. The DMERC shall review the Under Tolerance Report and attempt to manually aggregate the physician/supplier debts. If a physician/supplier's debts on the Under Tolerance Report total \$10.00 or more the DMERC shall generate a demand letter and create an accounts receivable. If a physician/supplier's debts on the Under Tolerance Report do not total \$10.00 or more the DMERC is not required to pursue collection. The DMERC shall perform any necessary manual aggregation by the 20th day of the following month. When generating the demand letter the determination date shall be the date the demand letter is generated and the interest rate shall be the rate in effect on the determination date.

The DMERC's standard system shall continue to systematically aggregate within the batch cycle. The DMERC shall retain the Under Tolerance Report in accordance with CMS retention policies. An appropriate audit trail with supporting documentation shall be retained for all aggregation and abandonment cases.

Analysis of Extended Repayment Plans (ERP)

ERP applications sent into the DMERC by providers shall be complete and shall be reviewed by the DMERC. The DMERC may approve an ERP application up to 12 months in length. ERP applications greater than 12 months, where the DMERC recommends approval, shall be forwarded to the Regional Office for approval. All ERP applications, regardless of approval or denial, shall contain a supervisory review and documented financial analysis. This analysis may include quick and current ratios, a review of the balance sheet or income statement, an analysis of claims history, a review of the provider's payment history, or any another financial analysis deemed appropriate by the DMERC to make a decision concerning approval. Upon review, an auditor shall be able to determine why the ERP application was approved or disapproved. While the actual decision will not be audited the process to reach the decision may be subject to review.

Recovery Audit Contractors (RAC)

The DMERC shall interact with all RAC(s) under contract with CMS to identify Medicare overpayments and underpayments and recover Medicare overpayments in the DMERC's jurisdiction. This includes Non-MSP and MSP overpayments. This interaction shall include, but not be limited to, communication regarding requests for medical records, electronic and/or manual updates to a database housing potential and demanded overpayments, communication regarding appeal requests, fraud cases and payment collections and assisting CMS and the RAC with provider education. Requirements for the DMERC interaction with RACs can be found in CMS Publication 100-6, Chapter 4, section 100 for Non-MSP instructions and CMS Publication 100-8, Chapter 8 for MSP instructions. MSP, Chapter 8.

C.4.3.3. Management Reporting

Monthly and quarterly workload reporting shall be required per the instructions in the IOM Pub 100-06, Chapter 6, § 210.

The DMERC shall follow the Medicare Financial Management Manual, IOM Pub 100-06, Chapter 6 – Workload Reporting, Section 450 Medicare Contractor Transaction Reporting (Form CMS-5). The DMERC shall follow CR 3257 (subsequent changes to Form CMS-5).

C.4.4. Customer Service

DMERCs shall assure that suppliers are fully knowledgeable about Medicare provisions impacting them and of the proper claims submission requirements.

DMERCs shall inform suppliers in writing of changes in policy and claims submission requirements and the effective dates of these changes with adequate lead time, when possible, not less than thirty days before changes are put into effect, so that suppliers have time to adjust;

From NSC information identifying new suppliers, develop and conduct intensive training of new suppliers. Continue to provide, at least once a year, refresher training for existing suppliers throughout geographic area of responsibility.

DMERCs shall coordinate their professional relations efforts with those of other DMERCs, local intermediaries and carriers, specifically to inform physicians, discharge planners, etc., about coverage and medical necessity documentation requirements for DMEPOS. Prepare notices for use by DMERCs in bulletins to train suppliers on the basics of DME. **NOTE:** Since Medical Review findings will drive the DMERCs Local Provider Education and Training (LPET) educational efforts, the Region A DMERC will not be responsible for LPET. The Region A DMERC PSC will be responsible for LPET.

C.4.4.1. Operational

The DMERC Professional Relations staff shall:

- Ensure that all suppliers have access to Ombudsmen. The DMERC may use its discretion regarding the location of its Ombudsmen to best serve the needs of the supplier community.

NOTE: The roles and responsibilities of the Ombudsmen may vary among contractors. However, DMERCs should proportionally charge their Ombudsmen budgetary costs to the appropriate Contractor Administrative, Budget and Financial Management (CAF) activity codes.

For the Region A DMERC: Any Local Provider Education and Training (LPET) educational activity being conducted by the Ombudsmen shall be done under the direction of a clinician from the Region A DMERC MR PSC.

- Identify suppliers, which habitually submit erroneous or incomplete claims, which create processing problems, including costly delays for additional development. They shall target these suppliers for special training to bring their billing/claims submission practices up to standard and/or referral to the fraud unit. Note: Since Medical Review findings will drive the DMERCs LPET educational efforts, the Region A DMERC will not be responsible for LPET. The Region A DMERC PSC will be responsible for LPET.
- Prepare and distribute a supplier manual to each supplier within its region. The manual shall present information to facilitate understanding of the Medicare payment and appeals process and shall aid the supplier in preparing and submitting DMEPOS claims. The DMERC shall provide a free copy of the manual only to new suppliers. Any supplier, supplier association, billing agent or other interested party requesting copies of the manual shall be provided them at cost. The manual shall include, at a minimum, the following sections:
 - Remittance advice
 - Electronic funds transfer
 - Pricing
 - Appeals
 - HCPCS Codes and Definitions
 - Systems Outputs (remittances, letters, etc.)

- Information Contacts' Telephones and Addresses
- Region-wide Medical Review Policy, including documentation requirements

DMERCs shall provide an initial copy of the supplier manual in a CD-ROM, unless the supplier requests a hardcopy at which time, the DMERC will provide. Additional copies may be provided electronically.

- Periodic supplier and physician training/seminars shall be conducted within the region. On an ongoing basis DMERCs shall train all suppliers on changes in the DMEPOS program, including the submission of claims, determining covered and non-covered services and the desirability of submitting bills via Electronic Media Claim (EMC) Training sessions shall be scheduled to allow all suppliers to participate. Individual meetings shall be at a site centrally located and as convenient as possible for those attending. Meetings shall address significant changes in the DMEPOS program and respond to concerns of participants. DMERCs shall construct a formal training plan detailing the gamut of training activities scheduled during the current contract year. The key features of this plan include the detailing of the targeted audiences, the mode and the scheduling of training.
- The DMERC shall send its DMERC newsletter and its supplier manual (and all updates) to each key CMS component, as shown below:
 - DMERC Contracting Officer Technical Representative (COTR) – 1 copy
 - Director, Center for Medicare Management/Provider Billing Group/Division of Supplier Claims processing – 1 copy
 - Director, Program Integrity Group – 1 copy
 - Director, Office of Clinical Standards and Quality, Coverage and Analysis Group – 3 copies
 - Director, Center for Medicare Management/Chronic Care Policy Group – 2 copies
 - Director, Center for Medicare Management/Provider Communications Group – 2 copies
 - Director, Center for Medicare Management/Medicare Contractor Management Group – 2 copies

C.4.4.2. Beneficiary Inquiries

The DMERC shall meet the standards for beneficiary services described in the IOM Pub 100-09, Chapter 2, § 20, Beneficiary Customer Services. The DMERC shall provide telephone, written, and visitor customer services. The DMERC shall utilize an internal review process to continuously improve written and verbal communication. The DMERC shall maintain a training plan for all staff based on surveys, trend analysis and employee feedback. The DMERC shall coordinate its activities with beneficiary counseling group, the SHIPs, and participate in meetings. The DMERC shall analyze beneficiary inquiries (both telephone and written inquiries) to identify specific areas of concern and use the information gathered from such analysis to improve customer service.

If a caller indicates an item or service was not received, or that the provider is involved in some potential fraudulent activity, the complaint shall be screened for billing errors or abuse before being sent to the benefit integrity unit. After screening has been performed, if abuse is suspected, the complaint shall be forwarded to the benefit integrity unit and the caller shall be told the benefit integrity unit will contact him/her about the complaint. The DMERC staff shall assure the caller that the complaint will be investigated and shall prepare the caller for requests for additional information from the BI unit.

1-800-MEDICARE shall be printed in the Customer Service Information box on all Medicare Summary Notices (MSNs), as well as all other beneficiary correspondence.

1-800-MEDICARE (1-800-633-4227) is the single number beneficiaries call for all questions related to Medicare claims and services, including questions regarding the MSN.

All beneficiary telephone inquiries shall be processed in accordance with the guidelines shown below and shall be reported using Activity Code 13005. All tasks related to this activity are mandatory and shall be reported to CMS's web-based Customer Service Assessment and Management System (CSAMS) as required.

CMS expects that each DMERC shall continue to prioritize its inquiry workloads in the following manner:

1. Telephone Inquiries (including Quality Call Monitoring and Next Generation Desktop),
2. Screening of Complaints Alleging Fraud and Abuse (IOM Pub 100-08 , 4.6-4.6.3)
3. Written Inquiries,
4. Beneficiary Outreach to improve Medicare customer service.

C.4.4.2.1. Beneficiary Written Inquiries (Activity Code 13002)

All written inquiries shall be processed in accordance with the guidelines shown below and are provided in the IOM Pub 100-09, Chapter 2, § 20, Beneficiary Customer Services. Also refer to the Activity Dictionary (Attachment J. 14) or the lists of tasks for this activity.

All beneficiary written inquiries must be answered via telephone with a few exceptions. Contractors shall respond to all beneficiary written inquiries within 45 business days. This action is being taken to reduce the costs of responding to beneficiary inquiries. Exceptions will be allowed in the following circumstances if documented in the file.

- a. After reasonable effort (e.g., directory assistance, telephone book white pages, Internet, MCS/FISS system information), the contractor is unable to obtain a telephone number for the correspondent, or
- b. After at least two attempts to contact the correspondent during regular operating hours, on the same or consecutive business days, the contractor is unable to speak with the correspondent.
- c. Congressional written inquiries will continue to be answered in writing.

The majority of Medicare contractors currently retain all written inquiries on site. Some DMERCs may house files at a remote location during the year due to cost and space constraints. Those DMERCs housing written inquiries off site shall notify CMS within 6 weeks of the issuance of this SOW of the exact address/location of their off site written inquiries. This information should be sent electronically to Glenn Keidel (Gkeidel@cms.hhs.gov) and to the servicing RO Beneficiary Branch Chief. This notification is necessary in the event an onsite CPE review is conducted. DMERCs shall allow CMS access to all written inquiries stored off site within one day of notification to the DMERC so that cases can be retrieved timely.

All written inquiries, whether maintained on site or off site, shall be clearly identified and filed in a manner that will allow for easy selection for the CPE review. Identification data shall be kept that will allow electronic production of a sequential listing of the universe of written inquiries.

DMERCs shall date-stamp the cover page of the incoming letter and the top page of each attachment. Date stamping the envelope is optional for the DMERCs.

In an effort to provide consistency to the fogging process, all DMERCs shall use the Gunning Fogging Method. This is the same tool that CMS uses in contractor performance reviews. Please see Attachment J.14A for a copy of the fogging calculation worksheet. DMERCs using standardized paragraphs provided by the Next Generation Desktop (NGD) are not required to fog those paragraphs. When fogging a piece of written correspondence, if the 8th grade reading level was excluded, documentation shall be in the file that explains why.

C.4.4.2.2. Beneficiary Walk-In Inquiries

CMS expects DMERCs to be courteous and responsive to any visitors coming to the contractor's facility. Costs incurred and workload involved with servicing visitors should generally be reported under code 13002-Written Inquiries. If the visitor inquiry is not general in nature, but rather more specific to another functional area (e.g., MSP, Appeals), the costs and workload should be reported to the specific functional line item.

C.4.4.2.3. Beneficiary Customer Service Plan (CSP) (Activity Code 13004)

In FY 2006, all DMERCs may continue to provide Customer Service Plan activities. Refer to the Activity Dictionary (Attachment J.14) for the lists of tasks for this activity.

CSP funding nationally has been reduced in FY 2006 by 10% from the FY 2005 funding levels. DMERCs who wish to continue CSP activities should submit an annual CSP to their Associate Regional Administrators for Beneficiary Services. There is no national format for the CSPs and copies of the CSP should not be sent to CMS headquarters. Plans should be as innovative as possible and propose only the most effective education and outreach activities within the limited budget constraints. Each regional office shall decide the CSP funding level for their contractors. Given the CSP funding level nationally, it is possible that all DMERCs shall not receive CSP funding in FY2006.

C.4.4.2.4. Beneficiary Telephone Inquiries (Activity Code 13005)

All tasks related to this activity are mandatory and shall be reported to CMS's web-based Customer Service Assessment and Management System (CSAMS) as required. All Beneficiary telephone inquiries shall be processed in accordance with the guidelines provided in the IOM Pub 100-09, Chapter 2, § 20, Beneficiary Customer Services. Also refer to the Activity Dictionary (Attachment J.14) for the lists of tasks for this activity.

The DMERC shall provide toll free telephone service to respond to beneficiaries' telephone inquiries in a manner that meets or exceeds the following performance standards (The instructions for beneficiary telephone inquiries are described in the IOM Pub 100-09, Chapter 2, § 20, Beneficiary Customer Services. Definitions, calculations and additional information for each of the required telephone customer service data elements as well as any associated standards are posted on the CSAMS Web site at <https://bizapps.cms.hhs.gov/csams>).

Due to funding reductions in FY 06 as well as planning for the transition of the beneficiary inquiry workload under Medicare Contractor Reform, DMERCs must not backfill permanent beneficiary CSR positions that are vacated beginning January 1, 2006. As attrition occurs, DMERCs may request that CSR positions are filled with temporary employees. Requests to backfill must be sent in advance to CMS for approval.

AVAILABILITY OF TELEPHONE SERVICE

- Make live telephone service available to callers continuously during normal business hours. While there are no required standard hours of operations for beneficiary call centers, the preferred normal business hours for telephone service continues to be 8:00 a.m. through 4:30 p.m. for all time zones of the geographical area serviced, Monday through Friday. Contractors shall respond to all beneficiary telephone calls routed to them up to the end of their business day. Contractors shall not stop taking calls prior to the end of the business day in order to eliminate calls waiting in queue.
- At the beginning of each fiscal year, DMERCs shall send their list of call center holiday closures for the entire fiscal year to the Beneficiary Network Services (BNS) at bnsadmin@bah.com and also to the servicing CMS regional office.
- In any situation where CSRs are not available to service callers or the call center is experiencing reduced beneficiary customer service due to diminished answering capacity, CMS plans to re-route call traffic within the national network to ensure that callers receive the best possible service. These situations include, for example, emergency and weather-related closings, training closings, and other deviations from their normal hours of operation.
- The contractor shall follow standard operating procedures (SOP) to identify and address situations that shall require action by the contractor to notify CMS to re-route beneficiary calls. The SOP shall include the various procedures call centers will follow including who to contact, when to contact, etc.

- When a determination is made whether to close a beneficiary call center due to emergency or weather-related circumstances, the contractor shall consider whether it is also closing other co-located Medicare operations (e.g., medical reviews, claims processing, provider operations, appeals, MSP, etc.). As a general rule, if other co-located Medicare operations are open, the beneficiary call center should be open.
- Under no circumstances shall a beneficiary call center close to avoid a negative impact on call center performance statistics or to staff provider call center operations.

Medicare Fee-for-Service (FFS) beneficiary call centers are part of a larger network, and other FFS contractors, as well as General Medicare, need to transfer calls to these centers. This notification needs to be sent to the BNS in advance. Therefore, it is imperative that CMS is made aware of any days or partial days when beneficiary call centers are closed in order to properly notify other sites, so they can anticipate call volume. This will ensure that beneficiary callers are not unnecessarily inconvenienced and that CMS has adequate time to arrange the re-routing of calls.

Call center staffing should be based on the pattern of incoming calls per hour and day of the week, ensuring that adequate coverage of incoming calls throughout each workday is maintained.

Contractors shall notify CMS via the Beneficiary Network Service (BNS) at the start of the fiscal year of their normal hours of operation for CSR service as well as for any planned call center closures. On Federal holidays, in lieu of answering telephone inquiries, contractors may choose to perform other appropriate call center work, e.g., provide CSR training. Contractors exercising this option should include these "in lieu of" days when notifying CMS of their planned closures. Changes to the schedule should be reported to the BNS no later than 60 days in advance. Contractor call centers will be open and providing telephone customer service based on the schedule provided to CMS. The only acceptable deviations from this schedule will be for emergency closings and those closings approved by Division of Call Center Operations (DCCO), Beneficiary Information Services Group (BISG), Centers for Medicare and Medicaid Services (CMS).

Since a call center's primary purpose is to respond to telephone inquiries, contractors shall make every effort to avoid closing their call center for meetings, training sessions, etc. However, in addition to emergency closings, there may be certain unforeseen times when it is necessary to request CMS approval to close your office. In these situations, the contractor shall follow these instructions:

- The contractor shall send an e-mail request to the **Beneficiary Network Service (BNS)** at **bnsadmin@bah.com** and include the following information:
 - Name and Location of call center
 - Date and Time of proposed closing

- Detailed explanation which provides the rationale and necessity for the proposed closing
- Typical workload (number of calls your call center receives) for the requested closing time

Requests shall be reported to the BNS as soon as possible, but no later than 5 work days in advance of the proposed closure date.

- After the request is received, the BNS will open a trouble ticket and log the request.
- Premise-based equipment shall not be programmed to allow for the recording of voice messages by callers at any time.

CSR TRAINING

- DMERCs shall implement standardized CSR training materials, including job aids and frequently asked questions (FAQ) for all CSRs upon receipt from CMS. The development of the training materials shall be done by CMS and it is not expected that there will be any costs to the DMERCs to use these training materials. Standardized training materials and FAQs will be available through links found on the Call Center home page at the following website: <http://www.cms.hhs.gov/callcenters/>. DMERCs shall check this website monthly for updated training information.
- To facilitate consistency in training and ability to share training materials across call centers CMS is developing guidelines for standard print and web-based training materials. DMERCs are encouraged to use these guidelines in developing their local training materials when the guidelines are finalized.
- Call center managers should subscribe to the call center Listserv by going to <http://list.nih.gov/archives/cam-callcenters.html>. The Listserv subscribers will be notified directly through E-mail regarding new and updated training, scripting, and/or frequently asked questions and answers regarding the Medicare Modernization Act.

PUBLICATION REQUESTS

- If a CSR has Internet access, then all requests for CMS beneficiary – related Medicare publications and alternative CMS products should be ordered at on-line www.medicare.gov for callers. If a CSR does not have Internet access, then callers with such requests should be referred to www.medicare.gov for on-line ordering or to the 1-800 MEDICARE Helpline. Contractors using the NGD should order publications using desktop functionality. NGD operation's procedures for publication ordering can be found at the Medicare Beneficiary Telephone Customer Service web site, <http://www.cms.hhs.gov/callcenters/>. (Note: Procedures are in development and will be posted at this site when completed). DMERCs should retain a minimum number of CMS publications for outreach/education efforts or for unique or extenuating circumstances. DMERCs shall maintain their in-house developed materials and products.

MEDPARD

- DMERCs shall provide callers with supplier directory Medicare Participating Physician Supplier Directory (MEDPARD) information upon request. MEDPARD information shall be provided to callers verbally. Written or printout forms shall be provided when requested or if the list of suppliers would significantly lengthen the call. Contractors using the NGD should order the MEDPARD information using desktop functionality. NGD operational procedures for ordering the MEDPARD directory can be found at the Medicare Beneficiary Telephone Customer Service web site, <http://www.cms.hhs.gov/callcenters/>. (Note: Procedures are in development and will be posted at this site when completed.)

QUALITY CALL MONITORING (QCM) PROCESS

- Monitor, measure and report the quality of service continuously by employing the CMS-developed Quality Call Monitoring (QCM) Process. Record all monitored calls on the standard scorecard, using the QCM chart as a guideline. Copies of the official QCM scorecard and chart may be obtained at the telephone customer service Web site <https://www.qcmscores.com>. Use only the official version of the scorecard and chart posted at the Web site. The QCM reporting tools and format, also posted on the Web site, shall be used to collect monitoring results which shall be reported monthly in CSAMS.
- Monitor the calls in any one or more of the following ways: live remote, live side-by-side (shadow), or taped.
- Complete the scorecard in its entirety and give feedback to the CSR within two working days of the call for calls monitored live or seven working days for taped calls. Coach and assist the CSR to improve in areas detected during monitoring or compliment on good performance, as appropriate.
- Monitor all CSRs throughout the month, using a sampling routine. The sampling routine shall ensure that all CSRs are monitored at the beginning, middle and end of each month (ensuring that assessments are distributed throughout the week) and during morning and afternoon hours.
- Participate in all national and regional calibration sessions organized by CMS. Calibration is a process to help maintain fairness, objectivity and consistency in scoring calls by staff within one or more call centers or throughout CMS. Instructions on how to conduct calibration are posted at the telephone customer service Web site at <http://www.cms.hhs.gov/calcenters/qcm.asp>. National sessions are held on the first Wednesday of February, May, August and November at 1:30 Eastern Standard Time.
- Conduct regular calibration sessions within the call center or between multiple call centers. Monthly calibration sessions within the call centers are recommended.

Contractor call centers with more than one Quality Assurance Analyst should conduct regular monthly calibration sessions.

- If there is more than one auditor, rotate CMS monitoring assignments regularly among the auditors. Analyze individual CSR data regularly, identify areas needing improvement or best practices. Implement and document corrective action plans. Analyze QCM data routinely to determine where training is indicated, whether at the individual, team, or call center level.
- Report QCM results monthly in CSAMS.
- Train every CSR and auditor on the scorecard and chart and ensure that each person has a copy of the chart available for reference.
- DMERCs are encouraged to heavily monitor CSR trainees that have just completed classroom instruction before they begin to handle calls without assistance of a “mentor.” Scores for these trainees shall be excluded from CSAMS reporting for 30 days following the end of formal classroom training. The calculation will be done automatically when the CSR trainees are entered into the QCM database with the appropriate indicator and the date that formal training ended.
- CMS standards for quality performance:
 - Of all calls monitored for CSRs each month, the percent of calls scoring as “Pass” for Adherence to Privacy Act shall be no less than 90 percent.
 - Of all calls monitored for CSRs each month, the percent of calls scoring as “Achieves Expectation” or higher shall be no less than 90 percent for Customer Service Skills Assessment.
 - Of all calls monitored for CSRs each month, the percent of calls scoring as “Meets Expectation” or higher shall be no less than 90 percent for Knowledge Skills Assessment.
- DMERCs that tape calls for QCM purposes shall be required to maintain such tapes for an ongoing 90-day period during the year. All tapes shall be clearly identified by date and filed in a manner that will allow for easy selection of tapes for review.
- DMERCs shall monitor a minimum of three calls per month per CSR. Any deviation from this requirement shall be requested and justified to the CMS regional office in order to determine if a waiver is warranted.
- In order to perform remote call monitoring, the DMERC shall provide remote access to CMS personnel to one of the following: agent split/group, DNIS, trunk, or application. This will allow CMS personnel to hear live calls as they are occurring. CMS will take reasonable measures to ensure the security of this access, (e.g., passwords will be controlled by one person, no passwords shall be sent via E-mail, no one outside of CMS service shall have access to the passwords, etc.).

- The MCSC-NGD does not change the QCM process or tools. Quality call monitors should attend NGD CSR training so they are aware of MCSC-NGD functionality and how CSRs will be using MCSC-NGD in responding to inquiries.

AUTOMATED SERVICES - INTERACTIVE VOICE RESPONSE (IVRs)

- All beneficiary premise-based IVR services provided by the contractor shall be discontinued at the time the contractor migrates to 1-800-Medicare. This also includes features such as “auto attendant” or “vectoring” where callers can opt to make a selection to listen to an announcement (such as a message concerning a list Medicare Card) to have their question answered. All calls routed to beneficiary call centers shall be handled directly by a Customer Service Representative (CSR).

CUSTOMER SERVICE ASSESSMENT AND MANAGEMENT SYSTEM (CSAMS)

- Reporting Requirements – CSAMS is an interactive web-based software tool used by CMS to collect and display Call Center Telephone Performance data. Each call center site shall enter required telephone customer service data elements into CSAMS between the 1st and the 10th of each month for the prior month. To correct or change data after the 10th of the month, users shall inform CMS central office via e-mail at csams@cms.hhs.gov. In those rare situations where one or more data elements are not available by the 10th of the month, the missing data shall not prevent the call center from entering all other available data into CSAMS timely. The call center shall supply the missing data to CMS within two workdays after it becomes available to the contractor.
- Definitions, calculations and additional information for each of the required telephone customer service data elements as well as any associated standards are posted on the CMS’s telephone customer service website at <http://www.cms.hhs.gov/callcenters>.

Note: Implementation by CMS of various services and technologies (e.g., single 800 number, network IVRs, network call routing) may result in changes to some of the data element definitions currently being reported as well as the potential elimination of others. As this transition occurs, every effort will be made by CMS to accommodate those call centers that have converted to the latest technology and those who have not converted. While the sources of the data may change, CMS will attempt to maintain the current definitions to the fullest extent possible

- All DMERCs shall ensure that monthly CSAMS data are being reported by individual call centers and that the data are not being consolidated. CMS wants telephone performance data grouped at the lowest possible physical location in order to address performance concerns. A call center is defined as a location where a group of CSRs are answering similar type calls (A, B, DMERC, A&B, MCSC, or some breakout/consolidation of these calls). The physical location could be in the same room, building, or complex but not in a separate geographic location, city, state, etc.

- Establish and follow a standard CSR sign-in policy in order for CMS to ensure data collected for telephone performance measurement is consistent for DMERCs. Other support staff assigned beneficiary telephone workload should follow the same sign-in policy as CSRs to ensure data consistency. That policy shall include the following:
 - CSRs available to answer telephone inquiries shall sign-in to the telephone system to begin data collection;
 - CSRs should sign-off the telephone system for breaks, lunches, training, and when performing any other non-telephone inquiry workload. (Note: If the telephone system supports an additional CSR work-state or category that accumulates this non-telephone inquiry performance data so that it can be separated and not have any impact on the measurements CMS wants to collect, this work-state or category may be utilized in lieu of CSRs signing-off the system); and
 - CSRs should sign-off the telephone system at the end of their workday.

DMERCs shall capture and report the following data each month:

- **Number of Attempts.** This is the total number of calls offered to the beneficiary call center via the FTS Toll-Free service provider during the month. This should be taken from reports produced by FTS Toll-Free service provider. The current provider is MCI and the reports are available at their web site, <https://customercenter.mci.com/>.
- **Number of Failed Attempts.** This represents the number of calls unable to access the call center via the toll-free line. This data should also be taken from reports produced by FTS Toll-Free service provider.
- **Calls in CSR Queue.** This is the total # of calls delivered to the CSR queue.
- **Calls Answered by CSRs.** Total # of calls answered by All CSRs.
- **Calls Answered <= 120 seconds.** Total # of calls answered by All CSRs within 60 seconds in the CSR queue.
- **Calls Abandoned <= 120 seconds.** Total # of calls abandoned before or at 60 seconds in the CSR queue.
- **Average speed of answer.** This is the amount of time that all calls waited in queue before being connected to a CSR. It includes ringing, delay recorder(s), and music. This time begins when the caller enters the CSR queue and includes both calls delayed and those answered immediately.
- **Total Sign-In Time (TSIT).** This is the amount of time that CSRs were available to answer telephone inquiries. This time includes the time that CSRs were plugged-in,

logged-in, handling calls, making outgoing calls, in the after call work state or in an available state.

- **Number of Workdays.** This is the number of calendar days for the month that the call center is open and answering telephone inquiries. For reporting purposes, a call center is considered open for the entire day even if the call center was closed for a portion of the day and/or not able to answer telephone inquiries for a portion of the day.
- **Talk Time.** This is the total amount of time that all CSRs were connected to callers and includes any time the caller is placed on hold by the CSR during the conversation.
- **Available time.** Available time is the amount of time that CSRs were signed-in on the telephone system waiting for a call to be delivered (i.e., the CSR is not handling calls, making outgoing calls, or in the After Call Work (ACW) state).
- **After Call Work Time.** This includes the time that CSRs need to complete any administrative work associated with a call after the customer disconnects.
- **Number of callbacks required.** This number is based on calls received for the calendar month and represents the number requiring a callback as of the last workday of the month.
- **Number of callbacks closed within 5 workdays.** This number is based on calls received for the calendar month and represents the number closed within five workdays even if a callback is closed within the first five workdays of the following month. For Call Centers that have transitioned to the NGD, the collection of this data point shall be automated and shall be based on seven calendar days rather than five workdays.
- **QCM-Number of CSRs available for monitoring.** This is the number of non-trainee CSRs (not FTEs) that take calls on a regular basis, both full-time and part-time CSRs. This number is obtained from the QCM database.
- **QCM-Number of completed scorecards.** This represents the number of call monitored. This number is obtained from the QCM Database.
- **QCM-Customer Skills Assessment.** This is the percent of calls monitored that scored greater than or equal to Meets Expectations. This number is obtained from the QCM Database.
- **QCM-Knowledge Skills Assessment.** This is the percent of calls monitored that scored greater than or equal to Meets Expectations. This number is obtained from the QCM Database.
- **QCM-Privacy Act.** This is the percentage of calls that scored as Pass. This number is obtained from the QCM Database.

CALL CENTER USER GROUP (CCUG)

- Call centers shall participate in the monthly CCUG calls. The CCUG is held the third Wednesday of each month at 2:00 Eastern Time.

CALL HANDLING REQUIREMENTS

- Contractors handle no less than 90 percent of the calls to completion during the initial contact with a CSR. A call is considered resolved during the initial contact if it does not require a return call by a CSR.
- Each month, contractors answer no less than 85 percent of all callers who choose to speak with a CSR within the first 120 seconds of their delivery to the queuing system.
- CMS does not intend to cite the contractor for performance issues due to attrition of CSRs. If a contractor cannot meet the ATB level (20%) or the service level in FY 06 (85% in 120 seconds), CMS will review the CSR productivity level at the contractor. CMS's productivity level will be 500 calls per month per CSR.

If a contractor fails to meet the ATB, service level and CSR productivity requirements, the contractor will not be in compliance with CMS standards. The contractor may elect to submit a waiver request if the CSR attrition rates or other factors have caused this situation. CMS will address each waiver request on a case by case basis and notify the contractor with in a timely fashion.

- The All Trunks Busy (ATB) External Rate (also known as the monthly Incompletion Rate) shall not exceed 20 percent for any Beneficiary call center. This includes all of the call center's voice lines as well as any "hidden" toll-free lines terminating at the call center. Any situation that disturbs the usual operation of the call center, and results in extreme variances in the call center's performance level will be considered as an exceptional event by CMS and reviewed on a case-by-case basis.
- Implementation by CMS of various services and technologies (e.g., single 800 number, network IVRs, network call routing) may result in modifications to some call handling requirements. For example, queue messages may be delivered in the network rather than by the premise-based equipment. As these transitions occur and changes are necessary to these requirements, CMS will provide instructions to those contractors impacted at the appropriate time.
- Standardized business procedures and training for the Single 1-800-Medicare initiative will be posted on the Medicare Beneficiary Telephone Customer.
- Service web site, <http://www.cms.hhs.gov/callcenters/>. Contractors should access this site monthly for updates.

C.4.4.2.5. MCSC Next Generation Medicare Desktop Application (Activity Code 13005)

CMS is developing a new MCSC NGD application to be deployed at Medicare contractor sites. The new desktop will allow Customer Service Representatives (CSRs) to answer telephone and written inquiries from beneficiaries. The NGD application will enable CSRs to address, at a minimum, the same general Medicare and claims inquiries currently handled, but in a more user-friendly and efficient manner. The NGD is being developed on requirements gathered from call center personnel currently handling telephone and written inquiries. Although NGD may be found useful by other components interacting with the telephone and written inquiries areas, specific requirements are not being identified for those areas.

The initial rollout of NGD will provide contractors with access to information from the VIPS Medicare System (VMS), Fiscal Intermediary Standard System (FISS), and Multi Carrier System (MCS) claims processing systems used today. Initially contractors will only access information to perform the functions required within their existing workload. However, the technology being built into the NGD will ultimately allow contractors to access claim information outside their service areas and to access additional CMS databases once those business processes have been defined. This increased access will enable contractors to support each other in times of heavy call volumes, disaster situations, emergency closings, and any other downtime as well as to handle more of the calls currently being blocked in the network. As NGD is rolled out, those contractors utilizing NGD will have call history information displayed for beneficiaries who have previously contacted other sites using NGD. For example, call history in Ohio will be visible to both the Carrier and the Intermediary Call Centers for Ohio after both Call Centers begin utilizing NGD. The call history information does not contain claim information, only a record of and reason for the call.

C.4.4.2.5.1. Implementation Approach and Schedule

Those contractors who will be deploying NGD in FY 2006 must include NGD implementation costs in their FY 2006 budget requests. These costs shall be reported in Miscellaneous Code 13005/01 and need to be **identified separately** as NGD implementation costs in the contractor's budget request.

All contractors are required to provide back-end connectivity to their systems for the NGD. CMS will schedule future NGD deployments based on many factors including the MAC and BCC award schedule. With this in mind, contractors are instructed to budget for all NGD activities as outlined in these requirements but they must receive written approval from CMS (Director, Division of Call Center Operations, CBC) prior to spending any funds on activities that are not directly related to back-end system connectivity to the NGD.

Call centers will be notified at a minimum of six months in advance of beginning deployment discussions. Call centers will be implemented with consideration to business impact to the Medicare program as a whole. Input from contractors regarding the desired timing of implementation will be considered, as well as, other implementation activity and specific circumstances of each call center.

Centers Using Non-Standard Claims Processing Systems

Currently, plans provide for the NGD to support FISS, MCS, and VMS (Part B and DMERC) claims processing systems. Centers using other systems will not implement the NGD until they have converted to one of these standard systems.

C.4.4.2.5.2. Technical Considerations

Hardware

The hardware necessary to implement the NGD application includes Siebel Systems' eHealthcare product, centrally-located servers, and personal computers (PCs).

Siebel

The NGD is being built using Siebel Systems' eHealthcare product. This product employs a "zero footprint" Web-based client, which means that no specialized hardware or software is required on the agents' desks other than a typical Personal Computer (PC) and a Web browser. PCs that will be used to generate correspondence will also require Microsoft Word 2000 Service Pack 2 or a higher version of Word, which will be the responsibility of the Medicare contractor to procure. CMS is purchasing the necessary Siebel software licenses and ongoing Siebel software maintenance contracts.

Servers

All servers needed to run the NGD application will be centrally-located (initially at the AdminaStar Federal data center in Shelbyville, KY). Each call center site will access the servers via the Medicare Data Communications Network (MDCN); CMS currently uses AT&T Global Network Services (AGNS) to provide service to the MDCN. Prior to implementation, each call center's network configuration will be evaluated to ensure that sufficient network bandwidth will be available.

Firewalls

All Internet Protocol (IP) access to the MDCN/AGNS network will be firewall protected. Each call center will be responsible for the installation and configuration of a firewall solution between themselves and the MDCN/AGNS network. Call centers will access the NGD system via IP. The NGD will provide access to the mainframe processing systems at the data centers via IBM's System Network Architecture (SNA). SNA connectivity will not require firewall protection. Future plans may include access to the mainframe processing systems via IP; however, CMS will work closely with the data centers if and when this option becomes available. The contractors are only responsible for having the firewall(s) implemented at their call centers and/or data centers.

Personal Computers

NGD Personal Computer (PC) Requirements – Following are updated PC software requirements for MCSC-NGD. These requirements supersede all previous guidance on personal computers needed for NGD. The only additional software requirements for FY 2005 are the Microsoft Word and Adobe Acrobat viewers which can be downloaded free of charge.

Consideration will be required for coexisting software applications in addition to NGD.

The system requirements may increase based on these additional applications. Please consult the software vendor for this information and make appropriate modifications to these requirements on the basis of that information.

Requirements for an NGD Personal Computer	
Processor:	500MHz Pentium III or comparable AMD 800MHz Celeron or comparable AMD
Disk Space:	100MB available
Memory:	224MB for Windows 2000 288 MB for Windows XP
Operating System:	Windows 2000 Service Pack 2 OR Windows XP Service Pack 1 or Service Pack 2
Browser:	Internet Explorer 5.5 Service Pack 2 with the latest cumulative patch for Internet Explorer from Microsoft that includes patch Q832894 OR Internet Explorer 6 Service Pack 1 or Service Pack 2 with the latest cumulative patch for Internet Explorer from Microsoft that includes patches Q832894 and Q831167. As of 1/10/2005, the latest appropriate cumulative patch is Q889293/
Monitor:	21"
Pointing Device:	Mouse with scroll (optical mouse recommended)
Network Interface:	Network Interface Card compatible with the call center LAN, which will ultimately allow workstation access to MDCN
Word Processor:	Microsoft Word 2000 SP2 (or higher version) – Required only for generation of correspondence.
Viewers:	Microsoft Word Viewer (provided free by Microsoft) and Adobe Acrobat Reader (v4.05 or v5.0 free from Adobe) shall view correspondence and some reference materials available in NGD.

Integration Methods

Standard Systems

Integration between the NGD and VMS, CWF, MCS, and FISS will be accomplished using Jacada's Integrator software product. Jacada uses TN3270 sessions to work with these systems. This allows NGD to be implemented without any changes to the standard systems. Access to CWF will be through the claims systems. The NGD Integration Layer will log and time-stamp all interactions, recording the NGD user, the back-end system user, and the transaction being performed along with the transaction's data. Integration with CMS Enrollment Database (EDB) and Master Beneficiary Record (MBR) will be done using IBM CICS Transaction Client Application Program Interface (API). Access to these systems will be via the CMS Traffic Cop application.

Computer Telephony

CTI is not currently in the scope of the NGD development for Releases One and Two. CTI may be integrated in a future release.

C.4.4.2.5.3. Impact on Contractor Resources

Although implementing the NGD will improve the overall efficiency of the call center operations, there will be some short-term impact on resources during the initial implementation. Resources potentially affected include CSRs, trainers, information services and technology staff. A reduction in CSR efficiency is expected during the learning curve of first using the new system. As CSRs become proficient with the new environment, efficiency should improve.

Early in the deployment process, CMS and the NGD team will review with each site the expected staffing levels that will be in place when NGD is implemented. Performance measures available from previously deployed locations will be shared to assist in determining potential impact and needed support.

A Deployment Assistance Center (DAC) has been established to support call centers during NGD implementation. The DAC is staffed with CSRs trained to handle Medicare inquiries from all lines of business. Certain functions may need to be transferred back to the site, however, it is expected that based on DAC availability, the sites deploying NGD will utilize the services provided by the DAC prior to requesting any performance waivers. During the period of implementation, CMS will work with the contractor to determine the support needed from the DAC and relax performance standards where it is still deemed appropriate.

Call Center CSRs

It is expected that CSRs already trained to handle Medicare inquiries shall attend three-four days of training on the new system. Contractors will continue to provide new CSRs with Medicare program training and any changes to local procedures resulting from NGD. Generally, CSRs will continue to answer the same types of inquiries they currently answer today, so the primary focus of the initial NGD training will be on how to access the same information within the new desktop. Additionally, NGD will offer some enhanced features and functionality, which will deliver improved service to CMS customers. Training materials will be provided for any new functionality in NGD. Although contractors can choose to phase in the implementation of any new NGD features, it is expected that CSRs shall fully utilize the functionality built within NGD.

Below is a sample of identified changes to pre-NGD procedures:

National Standardized Business Processes – CMS is standardizing some of the business processes for the users of NGD to facilitate consistent customer service performance, reporting and training. Standardized NGD business procedures will be posted on the Medicare Beneficiary Telephone Customer Service website, <http://www.cms.hhs.gov/callcenters/>. Contractors using NGD shall train and use these procedures within 30 days of posting. Contractors should access the website monthly for updates. Training for the standard procedures is being developed by

CMS and will be distributed to the contractors as developed. The training will be incorporated into the CMS NGD training package on a quarterly basis.

NGD Overview/Business Process Training – Contractors in the process of deploying NGD shall plan for five additional days of NGD training/workshop to be held at central location for the purpose of identifying any business process changes that need to be implemented.

Publication Requests and General Information – Contractors using the NGD should order publications using desktop functionality. NGD operational procedures for publication ordering can be found at the Medicare Beneficiary Telephone Customer Service web site, <http://www.cms.hhs.gov/callcenters/>. (Note: Procedures are in development and will be posted at this site when completed.)

Medicare Participating Physicians and Suppliers Directory (MEDPARD) – Contractors using the NGD should order the MEDPARD information using desktop functionality. NGD operational procedures for ordering the MEDPARD directory can be found at the Medicare Beneficiary Telephone Customer Service web site, <http://www.cms.hhs.gov/callcenters/>. (Note: Procedures are in development and will be posted at this site when completed.)

Scripted Responses - The NGD will include standard CMS-approved scripted language for some Medicare topics to be used by CSRs when responding to inquiries. The purpose of scripted language is to ensure accuracy and consistency of the information conveyed by the call centers.

Callbacks Closed - The counting for this CSAMS metric will change for those call centers using MCSC-NGD. Currently this number is based on calls received for the calendar month and represents the number closed within five workdays even if a callback is closed within the first five workdays of the following month. For MCSC-NGD call centers, the desktop will provide a report based on seven calendar days, which will be used to satisfy this requirement. The callback report will be provided to NGD sites after the 8th day of the month.

Logging Issues – NGD provides the functionality to log multiple issues on one call. Once NGD Release Two is implemented, many of the high frequency topics or activities worked on a call are automatically logged. There is a need for some manual logging by CSRs. Those conducting quality call monitoring should ensure that CSRs are making use of this additional functionality to log multiple issues. This will provide the call centers and CMS with more accurate and thorough reporting. For quality call monitoring (QCM) purposes, all logging and coding including the logging of multiple issues is to be recorded under the Call Action portion of the Knowledge Skills Assessment section of the QCM scorecard. Correct logging of calls falls under the performance criteria of “completes call activities”.

Ordering a Replacement Medicare Card – The NGD has built in the functionality to allow for a CSR to order a replacement Medicare card. NGD will perform the edit checks for the CSR, which will minimize the training needed for this function. This functionality may be implemented at some or all NGD locations.

Trainers

This project will use a “Train the Trainer” approach. This approach requires each contractor to provide trainers and training facilities to instruct CSRs, supervisors, quality assurance personnel, and other support staff on how to use the system. Training materials will be provided by CMS. The initial “Train the Trainer” classes (covering each contractor’s primary line of business) will be five days of instruction. An additional two days are required for any added line of business (Part A, Part B, DME). “Train the Trainer” classes will be held in a central location or at contractor locations, if warranted by the number of trainees.

The local call center trainers shall train all CSRs on the NGD. For example, the training may take a phased approach in which some CSRs are trained while others continue to take calls in the current manner. At some point in time an individual call center may have some CSRs utilizing the current methods, some in training, and others using the NGD if a phased approach is followed. Regardless of the approach followed during the period of implementation, CMS will work with each contractor to define the extent of the impact during the transition, schedule support, as available, from the Deployment Assistance Center and relax performance standards where it is deemed appropriate.

The NGD will have the ability to facilitate national web-based training. Contractors who wish to have their locally-developed web-based training accessible directly from the NGD are encouraged to comply with CMS standards. The CMS standards for both print and web-based training design can be found on the Medicare Beneficiary Telephone Customer Service home page @ <http://cms.hhs.gov/callcenters/>. In addition to the PC requirements outlined previously, in order to fully utilize the national web-based training modules, contractors will also need to have an audio player capable of playing .wma files (generally Windows Media Player); sound card and speakers (headphones are suggested); and Microsoft Word 2000 or higher.

Local Site Administration

Several administrative functions shall be performed at the call center level by contractor personnel. Two-three days of mandatory training on these functions will be provided by NGD trainers at a central location. These functions include:

- Creating and Maintaining User Profiles
- Adding User Accounts (includes identifying each user’s zip code, state, and time zone)
- Disabling User Accounts
- Adding and Maintaining Personal Information
- Adding, Maintaining and Resetting User Passwords
- Defining and Maintaining User Responsibilities
- Defining and Maintaining User Positions
- Defining the Local Organizational Structure
- Creating and Maintaining System User Alerts and Broadcast Messages

Helpdesk

Each contractor shall operate a local help desk (Tier One) for NGD. The NGD trainers will provide a two-day training course for helpdesk personnel at a central location. The Tier One

Help Desk Analysts are responsible for supporting the call center personnel in resolving issues they experience within the NGD application. This may be incorporated within the contractor's existing helpdesk or defined independently. The local help desk will be expected to triage NGD-related issues to determine if resolution can occur in house and those issues that need to be documented and submitted to the NGD Help Desk (Tier Two).

Local Tier One application support will likely be comparable to existing MCSC-Forte and CustomView sites. Support levels for those locations currently using mainframe applications only will probably increase. The call centers will need to provide Tier One help desk support. Tier One help desk support will be a focal area for each call center and will begin the resolution process. They will help identify if the issue resides at the call center or if it is an issue that shall be resolved outside of the call center. If the issue can be resolved locally, then the normal call center process will be followed. If the issue cannot be handled locally, the local help desk will contact the NGD Tier Two Help Desk. The NGD help desk will work to resolve the issue within forthcoming Service Level Agreement standards. If the issue cannot be resolved by the NGD help desk, the NGD helpdesk will contact the appropriate NGD resources (Tier Three), including Siebel and AT&T for MDCN/AGNS issues. Once resolved, the NGD help desk will contact the local help desk so any log entries opened there can be closed.

At a minimum, the local help desk shall handle:

- Determining if the reported issue is a training issue
- Determining if the reported issue is a business process issue
- Determining if the reported issue is a result of the contractor's mainframe or CWF being unavailable
- Establishing local workstations and verifying correct configuration
- PC and PC software configurations – Tier Two can assist Tier One or provide guidance in correcting the problem, but ultimately it is the responsibility of Tier One to resolve PC configuration/setup issues. The settings shall follow NGD and CMS guidelines.
- Providing technical "floor support" during First Live Calls
- Resolving Internet browser issues
- Resetting passwords
- Reporting Local Area Networks (LAN) & AGNS line outages and mainframe system outages affecting the NGD to the Tier II NGD Help Desk. Contacting AT&T for any AGNS issues related to the sites connectivity.

The help desk training provided by the NGD trainers will provide more details on what is expected of the local help desk.

Information Technology

For those sites that currently have PCs on the CSRs' desktops, little, if any, change in demand for infrastructure support is expected. Connectivity between the NGD servers in Shelbyville, KY and contractor mainframe claims processing systems (i.e. data center) is planned to be via MDCN/AGNS using SNA. Contractor PCs at Call Centers using the NGD will access the NGD servers in Shelbyville using MDCN/AGNS via IP.

Existing call monitoring applications, such as e-Talk Recorder and Witness eQuality Balance, that are integrated with a call center's Automatic Call Distribution (ACD) system should continue to function with no change.

C.4.4.2.5.4. Impact on Data Center Resources

Contractors shall work with their respective data centers to ensure Data Center staff performs the following tasks in support of the NGD implementation. These tasks include, but are not limited to:

- Provide a Data Center Point of Contact (POC) to coordinate NGD testing and deployment activities
- Assist in planning for adequate MDCN/AGNS bandwidth and routing changes
- Create and assign standard system mainframe User IDs per CMS/NGD requirements
- Provide TN3270, TCP/Internet Protocol (IP), or System Network Architecture (SNA) connectivity information and create any required SNA Logical Units (LUs) to establish the necessary sessions
- Ensure that claims systems test regions and test data are available as required for system testing

After initial testing the following support is required:

- Test regions need to be available during normal business hours beginning when system testing starts and continuing through the deployment of the desktop at all call centers. Availability of test regions will also be required for subsequent quarterly releases.
- Ensure system production regions are available by contractor Go Live date(s)
- Ensure system production regions are available during Call Center hours of operation

C.4.4.2.5.5. NGD Access for Other Departments

It may be desirable for other departments (Correspondence, Benefits Integrity, Medical Review, and so on) to have limited access to the new system. If so, some minimal training for the users from these departments will be required. Using the NGD in other departments will be considered on a case-by-case basis. Other departments will be expected to acquire the necessary NGD Siebel desktop licenses and appropriate PCs within their own budgets.

C.4.4.2.5.6. Security and Connectivity Issues

Technical Kick-off Meeting

Contractors deploying NGD may be required to send technical representation to a two-day technical kick-off meeting conducted by NGD infrastructure personnel in a central location. This meeting will take place prior to beginning the project plan to deploy NGD. Once all needed connectivity is obtained, an official deployment kickoff meeting will take place to begin the rollout of NGD to the contractor location(s).

Mercury Topaz

Mercury Topaz will be installed on one Personal Computer (PC) at each call center location prior to the rollout of NGD. Mercury Topaz is a service that measures call center transaction response times. This tool is useful to CMS to measure the true response time of a CSR at a call center. One PC per call center with the minimum requirements of an NGD Personal Computer shall be available at each call center to run simulated transactions. CMS will work closely with each call center on the initial set up of the PC beyond that of normal NGD PC. The NGD team will provide further guidance on the overall process once Topaz is installed.

Call and Data Center

NGD retrieves data from systems, such as the CMS Enrollment Database (EDB) and the SSA Master Beneficiary Record (MBR). These systems are Privacy Act protected and require high levels of security. Data and Call Centers shall follow strict security controls in their data center implementation to segregate CMS data from other business data and to safeguard the confidentiality, integrity and availability of such data.

NGD Network Traffic and Overview

For MCSC NGD implementation, connectivity shall be established between Siebel NGD and SNA (System Network Architecture) servers, the Medicare Data Communications Network (MDCN) and the Medicare Call Center's servicing data center. Currently, the Siebel NGD and SNA gateway servers reside at the AdminaStar Federal Data Center in Shelbyville, Kentucky.

A Customer Service Representative (CSR), as a NGD user located at the Medicare Call Center, uses a browser-based, thin client with zero footprint to access the Siebel NGD servers. All communications between client and server travel via the MDCN, provided by AT&T Global Network Services (AGNS). This configuration establishes Private Virtual Connection's (PVC) from each Call Center to the NGD Data Center, and between the NGD Data Center and all Medicare Data Centers. Call Centers are directly connected to Shelbyville NGD via AGNS. Louisville NGD is connected to all host Medicare Data Centers. The Shelbyville DC queries the host for the information. After Shelbyville DC gets the information from the host data center, paints the screen and sends the data back to the call center's CSR desktop.

When the Siebel NGD application requests Medicare shared claims processing systems information for an NGD user, the NGD systems' Integration Server acts on behalf of the NGD user and utilizes a CICS transaction-based approach to retrieve the requested information. This SNA connection communicates directly with the Medicare shared claims processing systems (MCS, VMS, FISS) via the MDCN, to process the NGD users' information request.

NGD update requests to Medicare shared claims processing systems are limited to users within the local call center, as controlled by their specific Local System Administrator and their local NGD security profile. Therefore, updates are allowed only to native users. **Non-native call center NGD users (e.g. other Medicare Call Centers) will have read-only access to the specific data center's Medicare systems as described in the Mainframe ID's paragraph below.** Memorandums of understanding between the data center and call center contractors will be needed prior to NGD's authorization (or capability) to update Medicare shared claims processing systems that are not native to the NGD user. If this non-native update capability

becomes necessary, CMS will work with call center contractors to establish these memorandums of understanding.

Mainframe IDs

The Siebel application identifies the information's requester and determines the source required to fulfill the information request. This information is passed to the Integration Server, which establishes a session between NGD Data Center and the source Data Center. The Integration Server uses an established Logical Unit (LU) connection from available LU session pools. Each Data Center will be assigned a specific number of LU session IDs, which will be assigned and controlled by AGNS.

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The session pool concept is referred to as Master ID since only a limited number of sessions are available for a larger number of users sessions. Master IDs are used by NGD Integration Servers, which acts in behalf of NGD users, to access the source Data Center's mainframe. Master IDs have been successfully implemented within other CMS applications with similar large user base and technical requirements. It is important to note that allowing NGD users read-only access to other Medicare contractors databases is not a new idea, and in theory the NGD read-only access is not too different than the shared access that all Medicare contractors have to the Common Working File (CWF).

The Data Center's System Administrators restricts and controls access to the shared claims processing systems housed at their data center, thus protecting the Government's Medicare claims information that they have been entrusted to maintain. It is the Data and Call Centers System Administrators' responsibility to establish, add, and maintain the NGD-provided LU sessions and Master IDs on the mainframe's security software for NGD access as needed for development, validation, training, and production. The benefit of establishing and maintaining a limited number of LU IDs and Master IDs for each Call Center, versus establishing individual accounts for each NGD user, results in reduced administrative tasks and costs.

NGD Security Responsibilities

The NGD Contractor (currently AdminaStar Federal) is responsible for the security controls within NGD. It is National NGD Security Administrators' responsibility to establish, add maintain, and track the AGNS-provided LU sessions and Master IDs for all Medicare contractors on the applicable NGD software, (e.g., Siebel server, Jacada server, etc.). The NGD software is developed to enable each Call Center to grant security access to its files, and will only retrieve/display data defined within the security access granted. Security tests have been developed to ensure access controls mechanisms are in place and operating as intended.

Stringent controls and monitoring processes will be in place to ensure that only assigned personnel gain access to the range of IDs assigned to their Center. Those transactions will be performed in NGD's authentication servers within a secured environment.

The NGD system generates transaction logs with information to fulfill user traceability requirements. The Siebel server, Integration server, and CICS/SNA gateway logs will document the transactions being performed, who performed them, when they were performed, what User ID and what LU session, host, and system were used to perform the transaction. This logging

supports the use of Master IDs within the NGD, providing individual accountability for NGD users. Auditing will be performed within the NGD network and will provide a trace mechanism for the Medicare shared claims processing systems to validate users.

Security Oversight

Oversight and separation of duties for NGD security will be accomplished by:

- Establishing System Administrators for Call and Data Centers, when applicable, with access only to the range of IDs designated for their Center;
- Establishing a National NGD Security Administrator responsible for establishing user IDs and granting security access to Call and Data Center's System Administrators; and
- Designating a third-party to audit security functions and logs, including the National NGD Security Administrator.

C.4.4.2.5.7. Shared/Standard System Issues

The Next Generation Desktop (NGD) relies on extensive interfaces with many standard Medicare systems, operated by CMS as well as contractors. In order to make each contractor's deployment to the NGD as problem-free as possible, it would be helpful if each contractor provided systems documentation for any changes or customizations that they have made to the standard system. By providing this documentation during the discovery period, it will allow the NGD developers to make any necessary adaptations before deployment. Once a site has implemented NGD, the NGD team will need to be made aware of any local planned changes to these shared systems well in advance. This will allow time to make sure that the interfaces with the shared systems continue to perform correctly.

NGD updates will occur quarterly and will follow the release schedule used for the shared system updates. Once the NGD is implemented, contractors are requested to inform the NGD team of any notifications of changes being planned to the standard systems currently accessed. This will serve as a backup to the current process CMS has in place for notification of systems changes. It is important that the NGD sites work closely with the NGD team to coordinate any additional testing needed specific to NGD in conjunction with testing for the shared system quarterly releases.

For further information regarding NGD testing requirements, refer to Pub. 100-01 Medicare General Information, Eligibility, and Entitlement/Chapter 7/Section 40-Shared System Maintainer and Medicare Contractor Responsibilities for System Releases, Subsection 40.3, Shared System Testing Requirements for Maintainers, Beta Testers, and Contractors, with NGD Specific information in Section 40.3.11 – "Next Generation Desktop (NGD) Maintainer Requirements."

C.4.4.2.5.8. Implementation Planning and Support

Implementation of the NGD will represent significant change for many call centers. Managers and staff will need to be available for pre-implementation meetings (e.g., conference calls, in-house meetings, completion of surveys, etc.), to provide information about the site in general, the

technology used, and to plan for the rollout of the NGD. To minimize the impact of this change, at a minimum, the call centers will be provided with the following assistance:

- Planning for functional, technical and business process change;
- Deployment Notebook detailing key aspects of the deployment process;
- Deployment Checklist/Project Plan and updates to the project plan;
- Regularly scheduled NGD specific conference calls;
- Training assistance as described above; and
- 24 X 7 post-implementation support (on site, if required).

C.4.4.2.5.9. Future Changes to the NGD

The CMS will implement an NGD Change Control Board that will include representation from the contractor community. Change requests can be submitted in a variety of ways: feedback forms within the NGD system, change requests submitted to the NGD helpdesk and participation in user acceptance testing and functional workgroup meetings. The change control procedures will be provided in the call center deployment notebook for further reference. New releases of the NGD are expected to follow the current standard mainframe system quarterly release schedule.

Contractors using NGD shall be required to participate in monthly NGD User Group calls for NGD updates and/or to provide input on suggested changes.

C.4.4.2.5.10. Retirement of Redundant Systems

After implementation of the NGD, several existing systems will become redundant. For beneficiary call centers, these include the current MCSC Forte application, the 1-800 GT-X application and some of the CustomView implementations. There may be other contractor or call center specific applications that will also become redundant. Retirement of these redundant applications may involve archival of data and disposition of any surplus hardware. The CMS and the affected contractors will determine the specific tasks required.

C.4.4.2.6. Screening Complaints Alleging Fraud and Abuse

Initial screening activities shall be charged to Activity Code 13002 (Beneficiary and Provider Written Inquiries), Activity Code 13005 (Beneficiary Telephone Inquiries), or Activity Code 33001 (Provider Telephone Inquiries), whichever is the most applicable. In fiscal year 2004, there is a separate Activity Code for Provider Written Inquiries (33002) and Provider Walk-in Inquiries (33003). The current Beneficiary Inquiries Manual Instructions and the BPR reflect the following Performance Priorities: 1) Telephones, 2) Second Level Screening, 3) Written, and 4) Customer Service Plan Activities.

The AC and Medicare contractor shall report all cost associated with second-level screening of inquiries for both beneficiaries and providers in Activity Code 13201. Report the total number of second-level screening of beneficiary inquiries that were closed in workload column 1; report the total number of medical records ordered for beneficiary inquiries that were closed in

workload column 2; and report the total number of potential fraud and abuse beneficiary complaints identified and referred to the PSC or Medicare contractor BI unit in workload column 3.

Refer to IOM Pub. 100-8, Chapter 4, §4.6.2.

C.4.4.3. Supplier Inquiries

In keeping with our FY 2003 efforts, we are maintaining our pursuit of providing improved service to all Medicare Providers. The Provider Inquiries instructions in IOM Pub 100-09, Chapter 3, together with this SOW, identify the work to be performed in FY 2006. In FY 2006 the Provider Inquiries section of the SOW will again incorporate Activity Based Costing (ABC) in the budget process. ABC identifies the all inclusive business process for each activity so that the total costs of the activity are fully visible. Business processes are defined for each Provider Inquiries Activity Code and are included in the Activity Dictionary. Call Center managers should identify only those costs associated with Activity Code definition to ensure the integrity of the ABC process.

CMS expects that each DMERC prioritize its workload in such a manner to ensure high quality service to all providers. CMS expects that each DMERC will continue to prioritize its provider inquiry workloads in the following sequential manner:

Supplier Telephone Inquiries
Supplier Written Inquiries,
Supplier Walk-In Inquiries

NOTE: When CMS issues a Program Safeguard Contractor (PSC) task order for DMERC program integrity and medical review workloads, the DMERC affected shall coordinate with the chosen PSC, the Statistical Analysis DMERC (SADMERC) and the National Supplier Clearinghouse (NSC) to assure cross-cutting information is communicated between the four. In addition, the DMERCs/SADMERC/NSC shall work with the PSC as needed.

During the transition of program integrity workload from a DMERC to a PSC, the PSC shall work with the DMERC to develop a joint operating agreement (JOA). The JOA will be added to the specified DMERC's and the PSC's SOW/Contract, as an attachment, after all of the procedures in the JOA are agreed upon by the DMERC, the PSC and CMS. The JOA will ensure coordination and cooperation during the transition and thereafter.

C.4.4.3.1. Supplier Written Inquiries (Activity Code 33002)

In addition to the requirements listed below, all written inquiries are to be processed in accordance with the guidelines provided in the IOM Pub 100-09, Chapter 3 §20.2

- Contractors shall send a final response to all provider written correspondence with 45 business days.
- Contractors shall date-stamp the cover page of the incoming letter and the top page of each attachment.
- Contractors shall not be required to keep the incoming envelope. However, if it is a contractor's normal operating procedure to keep envelopes with the incoming correspondence, the envelope, incoming letter and any attachments shall be date-stamped in the corporate mailroom.
- Contractors shall not use the "Dear Provider" in the salutation of the outgoing letter. They shall use the name on the incoming or the name in the contractors' systems.

CMS has modified the workloads associated with this activity code. Workload 1 reflects the number of general written inquiries received by the contractor. Written inquiries include letters, e-mails, and faxes. Workload 2 is the number of inquiries handled by the Provider Relations Research Specialists, for those contractors funded for CR 3376. Workload 3 will be the cumulative provider walk-in inquiries.

C.4.4.3.2. Supplier Walk-In Inquiries (Activity Code 33002)

All walk-in inquiries are to be processed in accordance with the guidelines provided in the IOM Pub 100-09, Chapter 3 §20.3. Contractors should not actively publicize the walk-in function. However, the DMERC shall give individuals making personal visits to you the same high level of service that is expected through a phone contact.

C.4.4.3.3. Quality Written Correspondence Monitoring (QWCM) Performance Measures (Activity Code 33014)

Beginning in FY06, all DMERCs shall be required to use the Quality Written Correspondence Monitoring tool. All DMERCs shall monitor at least 5 pieces of correspondence per correspondent or the entire universe of correspondence, whichever is less. All DMERCs shall meet the following QWCM performance requirements:

Of all written responses monitored for the quarter, the number of correspondents scoring as "Pass" for Adherence to Privacy Act shall be no less than 93 percent. During the quarter, no month shall fall below 85%. This standard will be measured quarterly and will be cumulative for the quarter.

Of all written responses monitored for the quarter, the number of correspondents scoring as "Achieves Expectations" or higher for Knowledge Skills shall be no less than 93 percent. During the quarter, no month shall fall below 85 percent. This standard will be measured quarterly and will be cumulative for the quarter.

Of all written responses monitored for the quarter, the number of correspondents scoring as "Achieves Expectations" or higher for Customer Skills Assessment shall be no less than 93 percent. During the quarter, no month shall fall below 85 percent. This standard will be measured quarterly and will be cumulative for the quarter.

C.4.4.3.4. Supplier Telephone Inquiries (Activity Code 33001)

All provider telephone inquiries are to be processed in accordance with the guidelines provided in the IOM Pub 100-09, Chapter 3 §20.1.

In FY 2006, Inquiries will incorporate Activity Based Costing (ABC) in the budget process. ABC is a management reporting system that focuses on the costs of the work activities instead of concentrating on the standard cost centers associated with the traditional cost accounting structure. ABC identifies the all inclusive business process for each activity so that the total costs of the activity are fully visible to the Inquiries manager.

C.4.4.3.4.1. General Instructions

Answering Provider Telephone Inquiries (Activity Code 33001)

In addition to the new requirements listed below, all contractors shall meet existing requirements outlined in IOM Pub 100-9 Chapter 3 §20.1.

NOTE: All Equipment and Maintenance costs shall continue to be reported under Code 33001. Costs of purchasing and maintaining an IVR shall be reported under 33001/02.

1. The definition for CSR productivity will be changed to read "CSR Productivity is the average number of calls handled by each CSR (calculated FTE) per month."
2. Those call centers having separate CSR and IVR lines shall track and report the following information:
 - Number of Attempts for the IVR only line
 - Number of Failed Attempts for the IVR only line

These data points will be used to determine the completion rate for the IVR only lines.
3. In FY 2003, CMS mandated that all contractors shall provide CMS the capability to remotely monitor provider calls. The following requirements clarify how the remote monitoring system shall be set up. CMS monitoring personnel shall have the capability to monitor provider Medicare calls by:
 - Specific workstation (CSR)
 - Next call from the network or next call in the CSR queue
 - By specific business line (Carrier, Fiscal Intermediary, or DMERC).

4. In accordance with Section 508 of the Rehabilitation Act of 1973 and the Workforce Investment Act of 1998, all call centers shall provide the ability for deaf, hard of hearing or speech-impaired providers to communicate via TeleTYpewriter (TTY) equipment. A TTY is a special device permitting hard of hearing or speech-impaired individuals to use the telephone, by allowing them to type messages back and forth to one another instead of talking and listening. (A TTY is required at both ends of the conversation in order to communicate.) Call centers currently having the ability to provide this service for beneficiary callers may use the same equipment; however, they may not use the same inbound lines. Contractors shall follow the process outlined in IOM Pub 100-9 Chapter 3 §20.1.1.B to request additional lines to handle this requirement. Contractors shall publicize the TTY line on their websites.
5. For claims status inquiries handled in the IVR, all call centers shall authenticate the caller using at least the following information:
 - Provider number
 - Health Insurance Claim (HIC) number
 - Date of service
6. Call centers may limit the number of issues discussed during one phone call, but all call centers shall respond to at least three issues before asking the provider to call back.
7. All contractors' IVRs shall provide definitions for the 100 most frequently used Remittance Codes as determined by each contractor. Contractors are not limited to 100 definitions and may add more if their system has the capability to handle the information.
8. All call centers with separate IVR only lines shall complete at least 95% of calls on these lines.
9. When a call center routes calls to another site, CMS needs to make sure that the contractor handling the calls gets credit for the work. If a call is forwarded over a contractor's system there is no way for CMS to determine the final termination point of the call. Therefore, prior to transferring calls to another center, contractors shall notify CMS through the Service Reports mailbox at servicereports@cms.hhs.gov. Contractors shall also notify the appropriate Regional Office.
10. Contractors with blended call centers (that is, CSRs answer both beneficiary and provider calls) shall answer no less than 85 percent of callers who choose to speak to a customer service representative within the first 120 seconds of their delivery to the queuing system. This standard will be measured quarterly and will be cumulative for the quarter.

11. Contractors with provider-only call centers shall meet an average speed of answer standard rather than a service level indicator standard. The new standard shall be that:

- “Of all calls answered by the contractor by a customer service representative (CSR) during a quarter, the contractor shall maintain an average speed of answer of 40 seconds. During the quarter, no month shall have an average speed of answer greater than 60 seconds. This standard shall be measured quarterly and will be cumulative for the quarter.”

The definition of average speed of answer (ASA) remains unchanged. ASA is “the amount of time that all calls waited in queue before being connected to a CSR. It includes ringing, delay recorder(s), and music. This time begins when the caller enters the CSR queue and includes both calls delayed and those answered immediately.”

12. Each CSR line shall have a completed rate of no less than 80 percent. This standard will be measured quarterly and will be cumulative for the quarter.

13. Contractors shall handle no less than 90 percent of calls to completion during the initial contact with the CSR. This standard will be measured quarterly and will be cumulative for the quarter.

C.4.4.3.4.2. Quality Call Monitoring (QCM) Performance Measures (Activity Code 33014)

In addition to the new requirements listed below, all contractors shall meet existing requirements outlined in IOM Pub 100-9 Chapter 3 §20.1.7.

Of all calls monitored for the quarter, the number of CSRs scoring as “Pass” for Adherence to Privacy Act shall be no less than 93 percent. During the quarter, no month shall fall below 85%. This standard will be measured quarterly and will be cumulative for the quarter.

Of all calls monitored for the quarter, the number of CSRs scoring as “Achieves Expectations” or higher for Knowledge Skills shall be no less than 93 percent. During the quarter, no month shall fall below 85 percent. This standard will be measured quarterly and will be cumulative for the quarter.

Of all calls monitored for the quarter, the number of CSRs scoring as “Achieves Expectations” or higher for Customer Skills Assessment shall be no less than 93 percent. During the quarter, no month shall fall below 85 percent. This standard will be measured quarterly and will be cumulative for the quarter.

C.4.4.3.4.3. Staff Development and Training (Activity Code 33020)

Contractors shall meet all requirements outlined in IOM Pub 100-9 Chapter 3 §20.1.6, including being allowed to close for up to 8 hours per month for CSR training.

C.4.4.3.5. Second Level Screening of Provider Inquiries (Activity Code 13201/01)

The Medicare fee-for-service contractor shall keep a record of the cost and workload associated for all provider inquiries by current or former provider employees of potential fraud and abuse that are referred to the PSC or Medicare fee-for-service contractor Benefit Integrity Unit (BIU) in Activity Code 13201/01.

Workload

Provider Telephone Inquires workload (Workload 1 in CAFMII) is the cumulative inquiries as reported on the HCFA-1566, Line 35, Provider Column.

C.5. Medicare Integrity Program (MIP)

Program Integrity's primary principle is to protect the Trust Fund. In order to meet this goal, DMERCs shall ensure that they pay the right amount, in the appropriate frequency for covered durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) rendered to eligible beneficiaries by legitimate suppliers. The DMERCs shall prevent inappropriate payments by: detecting program vulnerabilities through on-going data analysis and other referral sources; by coordinating and communicating with CMS partners; and by implementing fair and firm enforcement policies in accordance with the principles of Progressive Corrective Action (PCA) (IOM Pub. 100-8 3.2).

This section relates to the following Medicare DMERC operational functions:

- Medical Review (MR)
- Medicare Secondary Payer (MSP)
- Benefit Integrity (BI)
- Local Provider Education and Training (LPET)
- MIP Provider Communications (MIP PCOM)

The DMERC shall maintain adequate staffing and training of employees. Each position shall be full time for the contract period.

Key personnel shall include:

- A Medical Director *
- A Program Integrity Coordinator,
- A Medical Review Manager

DMERCs shall maintain staff sufficient to fulfill the SOW requirements, Medicare Integrity Program functions, and shall comply with IOM Pub. 100-8 requirements. The DMEPOS regional carriers shall undertake actions to promote an effective program administration with respect to DMEPOS regional carrier claims.

NOTE: The Medicare Integrity Program (MIP), which was created under the Health Insurance Portability and Accountability Act of 1996, authorized CMS to contract with Program Safeguard Contractors (PSC) to perform specific program safeguard functions. PSCs may be contracted to perform specific specialized functions or assume full MIP responsibilities.

* Should a PSC be implemented for a DMERC's jurisdiction, CMS will alter this requirement to best suit the activities that will remain at the DMERC and those that will transfer to the PSC. This may include, but is not limited to, reducing the Medical Director to part time status or waiving the requirement for a Medical Director altogether. CMS will work jointly with the PSC and DMERC during the transition period to determine the timing of such an alteration.

C.5.1. Medical Review (MR)

***Disclaimer:** The following sections, C.5.1 – C.5.1.4, of this Statement of Work applies only to those Durable Medical Equipment Regional Carriers (DMERCs) who remain unaffiliated with a Program Safeguard Contractor and the "full-PSC" DMERC. This document refers to both parties as "DMERC". Further, this document refers to Contractors affiliated with Program Safeguard Contractors as affiliated contractors (AC). The CMS will provide the "full-PSC" DMERC with additional instructions regarding their responsibilities regarding interacting with the AC.*

Section 1862(a)(1)(A) of the Social Security Act requires carriers to make no payment for items or services which "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Section 1842(a)(2)(B) requires that Part B contractors apply safeguards against the unnecessary utilization of items and services furnished by suppliers.

The DMERC MR program shall follow the instructions and definitions set forth in CMS's IOM Pub. 100-8 (Program Integrity Manual (PIM)) relevant to DME MR activities and other CMS instructions (e.g., Budget Performance and Requirements (BPR) for FY 2006, etc.) When differences or conflicts occur, this SOW will take precedence over the IOM Pub. 100-8, and/or BPR. The DMERC shall contact their Lead Regional Office (LRO) if budgetary concerns occur because of this conflict. The DMERC PSC shall contact their MR GTL.

Medial Review is a national CMS initiative implemented by the Medicare fee-for-service contractors and some PSCs to ensure the fiscal integrity of CMS programs and accountable stewardship of public funds. This initiative fosters healthcare security for our nation's 40 million Medicare beneficiaries. The MR program is a structured approach to interpretation and implementation of Medicare policy, most often requiring the evaluation of medical records to determine medical necessity of Medicare claims. MR's primary mission is to reduce the claims payment error rate by evaluating claims data to identify Medicare program areas most

susceptible to billing errors, over-utilization and/or suppliers that deviate from the expected norm. The MR and LPET programs are dependant on an effective program strategy developed and implemented by contractor management. The MR staff may utilize a variety of interventions to achieve the desired outcome as specified in their strategy. Primarily, MR reduces the error rate by identifying patterns of inappropriate billing, educating providers on medical review findings, and by performing medical review of claims.

DMERCs shall name a MR point of contact that will act as the primary contact between the DMERC and CMS concerning the DMERC's entire MR program. Although DMERCs have the discretion to title the position however they choose, this document refers to this individual as the "MR Manager."

C.5.1.1. Progressive Corrective Action (PCA)

PCA is a process for structuring the MR program to effectively and efficiently target MR resources toward rectifying the most egregious program vulnerabilities (here in referred to as problems). The process utilizes data to identify and prioritizing potential problems, validating the problems, and using education and claims review as tools to rectify provider aberrant behavior. Under PCA, DMERCs shall always employ education as the primary tool in correcting aberrant billing behavior. DMERCs shall use a variety of interventions to effectively address the local Medicare suppliers/providers educational needs based on the extent of the supplier's/provider's individual error rate. The DMERCs shall include in their MR/LPET Strategy achievable goals and evaluation methods that test the effectiveness and efficiency of educational activities designed to resolve targeted MR problems. PCA assists DMERCs in making the most efficient use of MR resources, in identifying and prioritizing areas of vulnerability, ensuring that medical review is objectively based, and in reducing undue burden on suppliers, providers and beneficiaries.

DMERCs shall design a MR/LPET Strategy document that will satisfy the MR/LPET program requirements in accordance with IOM Pub. 100-8, Ch. 1. The PCA process shall be used when developing and updating the MR/LPET Strategy and Quarterly Strategy Analysis (QSA). The DMERC shall identify targeted problems and the interventions that will be used correct them in the strategy and QSA. The DMERC shall refer to IOM Pub. 100-8, Ch.1 & 7 for individual elements to be included in the strategy and QSA. Interventions to be used in the PCA process include Local Provider Education and Training (LPET), medical review of claims, and Local Coverage Determination (LCD) development.

(References: IOM Pub. 100-8, Ch. 3)

C.5.1.1.1. Local Provider Education and Training (LPET)

The LPET program is designed to support MR by educating those providers who demonstrate erroneous claims-submission behaviors. All LPET activity supports the MR program. As such, all LPET activity is a response to problems identified through the analysis of the Comprehensive Error Rate Testing (CERT), MR findings, information from various operational areas of the DMERC, as well as data from other sources. The ultimate goal of the LPET program is the continual reduction in the national claims payment error rate. DMERCs shall evaluate the data,

develop and prioritize identified problems, and design educational interventions that effectively address the identified problems.

LPET education is always a response to the individual provider's claim submission patterns and information needs. To meet this goal, DMERCs shall use various methods such as print, Internet, telephone, and face-to-face contacts. Simply sending a letter in response to the review of claims is not always the most effective mechanism with which to educate providers on coverage, coding and billing errors identified by medical review.

The DMERCs shall develop multiple tools to effectively address the local Medicare providers' wide-ranging educational needs. Educational activities to address problems on the problem list shall be conducted throughout the year. The DMERC shall include in their MR/LPET Strategy achievable goals and evaluation methods that test the effectiveness and efficiency of educational activities designed to resolve targeted MR problems. In doing such, the DMERC shall utilize a provider tracking system (PTS) that documents educational contacts, issues addressed and types of intervention used. As problems are addressed, the DMERC shall incorporate processes for follow-up that ensure appropriate resolution of the issue. If aberrancies continue the DMERCs shall use the information contained in the PTS to determine a more progressive course of action. As issues are successfully resolved, the DMERCs shall continue to address other program vulnerabilities identified on the problem list. CMS does not prescribe any type of mandatory configuration or format for the PTS, so long as it is capable of efficiently carrying out required functions as outlined in IOM Pub. 100-8, Ch. 3 § 1.1.

Clinical expertise is required to educate providers concerning coverage, coding, and billing issues related to medical review. Educational interventions shall be performed at the direction of the MR Manager, clinicians, and by specially trained non-clinical staff working under the direction of the clinicians.

The DMERCs will base their MR/LPET strategy and budget request on the requirements set forth in the FY 2006 BPR. Each DMERC will be given a specified maximum budget for LPET activities. DMERCs shall identify the appropriate budget and workload, for each activity code within the constraints of their budgets.

DMERCs shall NOT use a record of attendance at (or failure to attend) educational activities or other information gathered during an educational program conducted to select or track providers of services or suppliers for the purpose of conducting any type of audit or prepayment review.

Since MR data analysis and review findings will drive the DMERC's LPET educational efforts, the Region A DMERC will not be responsible for LPET. The Region A DMERC PSC will be responsible for LPET.

(References: IOM Pub. 100-8, Ch. 1)

C.5.1.1.2. Medical Review of Claims

Prepayment MR of claims requires that a benefit category review, statutory exclusion review, reasonable and necessary review, and/or coding review be made BEFORE claim payment.

Prepayment MR of claims always results in an “initial determination.” See 42 CFR 405.802 and 42 CFR 405.702 for a complete definition of “initial determination.”

Postpayment MR of claims requires that a benefit category review, statutory exclusion review, reasonable and necessary review, and/or coding review be made AFTER claim payment. These types of review allow the DMERC the opportunity to make a determination to pay a claim (in full or in part), deny payment or assess an overpayment. Postpayment MR of claims may result in no change to the initial determination or may result in a “revised determination.” See 42 CFR 405.841 and 42 CFR 405.750 for a complete definition of “revised determination.”

When initiating prepay or postpay review (provider specific or service-specific), DMERCs shall notify providers of the following:

- That the provider/supplier has been selected for review and the specific reason for such selection. If the basis for selection is comparative data, DMERCs and DMERC PSCs shall provide comparative data on how the provider/supplier varies significantly from other providers/supplier in the same specialty payment area or locality. Graphic presentations may help to communicate the perceived problem more clearly;
- Whether the review will occur on a prepayment or postpayment basis; and
- If postpayment, the list of claims that require medical records.

This notice must be in writing and may be issued separately or in the same letter that lists the additional documentation that is being requested. DMERCs may (but are not required to) make this notification via certified letter with return receipt requested. In addition, the DMERC may include information on its Web site explaining that service-specific review will be occurring and the rationale for conducting such review.

(References: IOM Pub. 100-8, Ch. 3)

C.5.1.1.2.1. Types of Claims Review

Claim review activities are divided into three distinct types of review:

Automated Prepayment Review

When prepayment review is automated, decisions are made at the system level, using available electronic information, without the intervention of contractor personnel. The DMERC shall make every effort to revise edits for automated review. See IOM Pub. 100-8, Ch.3, Section 3.5.1 for further discussion of automated prepayment review.

Routine Prepayment/Postpayment Review

Routine prepayment review is limited to rule-based determinations performed by specially trained non-clinical MR staff. An intervention can occur at any point in the review process. For

example, a claim may be suspended for routine review because an MR determination cannot be automated.

Routine review requires hands-on review of the claim, and/or claims history file and/or internal MR guidelines but does not require the application of clinical judgment by a licensed medical professional.

Complex Prepayment/Postpayment Review

Complex medical review involves the application of clinical judgment by a licensed medical professional in order to evaluate medical records. Medical records include any medical documentation, other than what is included on the face of the claim that supports the service that is billed. For items of durable medical equipment that require a Certificate of Medical Necessity (CMN), the CMN is considered part of the face of the claim. Complex medical review determinations require a licensed medical professional to make a clinical judgment about whether a service is covered, and is reasonable and necessary.

Complex review for the purpose of making coverage determinations must be performed by nurses (RN/LPN) or physicians, unless this task is delegated to other licensed health care professionals. DMERCs shall ensure that services reviewed by other licensed health care professionals are within their scope of practice and that their MR/LPET Strategy supports the need for their specialized expertise in the adjudication of particular claim type (i.e. speech therapy claim, physical therapy claim).

Complex medical review performed by MR staff for purposes other than MR (for example, appeals or claims processing) as identified in the MR/LPET Strategy should be charged for expenditure reporting purposes to the area requiring MR services.

(References: IOM Pub. 100-8, Ch. 1)

C.5.1.1.2.2. Medical Review Edit Effectiveness

Chapter 3 of the IOM Pub. 100-8 states that prepayment review occurs only when claims system edits specified by the DMERC identify and/or suspend services for closer scrutiny. The edits should be specific enough to identify only those claims that the DMERC determines to be questionable. DMERCs should base the development or retention of edits on data analysis, identification, and prioritization of identified problems as identified in the MR/LPET strategy.

Automated edits shall be evaluated annually and all edits that suspend claims for routine or complex review shall be evaluated quarterly. These evaluations are to determine the edit's effectiveness and contribution to workload. DMERCs shall consider an edit to be effective when an edit has a reasonable rate of denial relative to suspensions and a reasonable dollar return on cost of operation or potential to avoid significant risk to beneficiaries. Edits that are determined to not be effective shall either be retired or revised to be more effective. Edits may be ineffective when payments or claims denied are very small in proportion to the volume of claims suspended for review. It may be appropriate to leave edits in place if sufficient data is not available to

evaluate effectiveness, for example if a measurable impact is expected, or if a quarter is too brief a time to observe a change. DMERCs should analyze prepayment edits in conjunction with data analysis to confirm or re-establish priorities. DMERCs should replace, if appropriate, existing effective edits to address problems that are potentially more costly. All MR edits that suspend claims for review shall be included in the MR/LPET Strategy and with specific interventions using the PCA process. If the DMERC's PCA process is effective, edits will not need to be in place for extended periods of time. To the extent that the DMERCs operate the same or similar edits, their MR staffs shall work together to ensure that consistent claims payment is made across DMERCs (i.e., identical situations shall produce identical types of denials). DMERCs shall report such denials consistently.

(References: IOM Pub. 100-8, Ch. 3)

C.5.1.1.3. Local Coverage Determinations

Section 522 of BIPA amends section 1869(f)(2)(B) of the Act, to define Local Coverage Determinations (LCD) as

“a determination by a fiscal intermediary or a carrier under part A or Part B as applicable, respecting whether or not a particular item or service is covered on an intermediary-or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A).”

Section 1869(f)(2)(B) of the Act limits an LCD as a determination only under section 1862(a)(1)(A) of the Act's “reasonable and necessary provision.”

DMERCs shall create all new policies as LCD restricting the content of these policies to only those 1862(a)(1)(a) determinations. Non 1862 (a)(1)(a) instructions shall be published in the form of an educational article. Costs associated with the activity shall be reported in CAFM II Activity Code 24118.

DMERCs shall convert all existing LMRP to the LCD format no later than December 31, 2005. CMS has developed an application within the Medicare coverage database backend that will facilitate this conversion. The DMERC shall convert the pertinent LMRP information into an LCD and place the remaining information (benefit category, statutory exclusion, and coding provisions) in an article or delete it.

Because both LMRPs and LCDs will exist until December 31, 2005, the term LCD, for purposes of a 522 challenge, will refer to both of the following:

Separate, stand-alone documents entitled “LCDs” that contain only reasonable and necessary language; and the reasonable and necessary provisions of an LMRP/LCD.

(References: IOM Pub. 100-8, Ch. 13)

C.5.1.1.3.1. Role of the “Lead” DMD in Developing LCD

For each LCD proposed, the DMERCs shall select a “Lead” DMD. The DMERCs shall rotate the lead role among the DMDs. The lead shall:

Coordinate the development of a uniform list of appropriate national organizations from which the lead DMERC shall solicit comments. The list will include manufacturer, supplier, beneficiary, physician, and other clinician organizations concerned with the issues related to the LCD, the elderly and people with disabilities.

Coordinate development of the LCD and make changes as a result of discussions with the team members.

Lead discussions of uniform draft LCDs or questions/issues on the LCD conference calls between the DMERCs and CMS and make changes as appropriate.

(References: IOM Pub. 100-8, Ch. 13)

C.5.1.2. MR Workload, Cost and Savings Allocation

DMERCs, except the DMERC PSC shall report costs and workload by the following activity codes.

C.5.1.2.1. Automated (Activity Code 21001)

This review requires no human intervention. It occurs when a claim/line passes through the DMERCs’ MR system edits or any adjunct system containing MR edits AND is denied in whole or in part because the item (s)/service(s) is non-covered (including not reasonable and necessary). Automated review shall have clear policy that serves as the basis for denial, be based on medical unbelievable services or occur when no timely response is received to an additional documentation request (ADR) letter.

DMERCs shall maximize automated review. When items and/or services are specifically non-covered or never reasonable and necessary (per statute, national coverage policy, or LMRP/LCD), DMERCs shall develop edits to automatically deny these items/services.

Report the costs associated with automated review including personnel to install and activate supplemental edit software in Activity Code 21001. In the workload section of CAFM II, Activity Code 21001, DMERCs should report the number of claims denied in whole or in part in Workload 1. To the extent the DMERCs can report claims subjected to MR automated review, record this number in Workload 2.

(References: IOM Pub. 100-8 Ch. 3, IOM Pub. 100-8, Ch. 11)

C.5.1.2.2. Routine Review (Activity Code 21002)

Routine review is limited to rule-based determinations performed by specially trained non-clinical MR staff. An intervention can occur at any point in the review process. For example, a claim may be suspended for routine review because a MR determination cannot be automated.

Routine review requires hands-on review of the claim and/or any attachment submitted by the provider, but does not require the application of clinical judgment by a licensed medical professional. Only in those instances where DMERCs cannot automate these reviews and no clinician review is indicated shall the DMERC conduct routine reviews. DMERCs shall make every effort to automate reviews. However, routine reviews that are not automated shall be addressed in the MR/LPET Strategy with the reason for why they cannot be automated.

For claims that suspend for routine review, DMERCs shall review the claims using the DMERCs' internal review guidelines. These reviews shall focus on those areas identified as program vulnerabilities. CMS, or the DMERCs can identify program vulnerabilities.

Report all costs associated with routine reviews in Activity Code 21002. In the workload section of CAFM II, Activity Code 21002, report the number of claims subject to review in Workload 1. DMERCs shall report the number of claims denied in whole or in part in Workload 2. Report the number of suppliers/providers subjected to routine review in Workload 3.

(References: IOM Pub. 100-8, Ch. 3 IOM Pub. 100-8, Ch. 11)

C.5.1.2.3. Data Analysis (Activity Code 21007)

Each DMERC shall perform ongoing data analysis to identify potential errors. The DMERC shall carry out data analysis activities as described in IOM Pub. 100-8, Ch. 1, 2 and 3.

In addition to the activities described in the IOM Pub.100-8, the DMERC shall perform the following data analysis activities:

- Analyze data continuously through out the year to discover emerging patterns of aberrant billing behaviors
- Utilize innovative data analysis approaches, methods and software to improve the identification of program vulnerabilities (problems).
- Determine metrics that will be utilized to determine problem prioritization.
- Maintain an on-going prioritized problem list that is updated based on emerging trends and prioritization criteria.
- Consider reviewing data based upon services in addition to the ordering or the referring provider.

- Use data analysis to determine the need for policy development and system edits.
- Use data analysis after medical review interventions (education, medical review) to validate the effectiveness of the selected intervention on billing behaviors.

Report all costs associated with data analysis activities performed for MR and LPET purposes in CAFM II Activity Code 21007.

(References: IOM Pub. 100-8, Ch. 1, IOM Pub. 100-8, Ch. 2, IOM Pub. 100-8, Ch. 3, IOM Pub. 100-8, Ch. 11)

C.5.1.2.4. Policy Development Activities (Activity Codes 21208 and 21206)

Report all costs associated with new Local Coverage Determinations (LCD) development activity in CAFM II Activity Code 21208. In the workload section of CAFM II, Activity 21208, report the number of new policies that were presented for notice and comment in Workload 1. Report the number of policies that became effective in Workload 2. Report the number of IDE requests developed in Workload 3.

Report all costs associated with reconsiderations and revisions to Local Medical Review Policies or LCDs in Activity Code 21206. Include reconsideration requests made as a result of IOM Pub. 100-8, Ch. 13, Section 11. In the workload section of CAFM II, Activity Code 21206, report the total number of policies/coverage determinations revised in Workload 1. Report the number of policies/coverage determinations revised that required notice and comment in Workload 2. Report the number of policies/coverage determinations revised due to an outside request (e.g., beneficiary or supplier request) in Workload 3.

(References: IOM Pub. 100-8, Ch. 11, IOM Pub. 100-8, Ch. 13)

C.5.1.2.5. MR Program Management (Activity Code 21207)

MR program management encompasses managerial responsibilities inherent in managing MR and LPET, including: development modification and periodic reporting of MR/LPET strategy and quality assurance activities; planning, monitoring and adjusting workload performance; budget-related monitoring and reporting; and implementation of CMS instructions. See FY 2006 BPRs for inclusive list of tasks to include in activity code 21207.

Report all costs associated with MR program management including developing and modifying MR/LPET strategy, developing and modifying quality assurance activities, including special studies, inter-reviewer reliability testing, committee meetings, and periodic reports; evaluating edit effectiveness; planning, monitoring and overseeing budget, including interactions with contractor budget staff and RO budget and MR program staff; managing workload, including monitoring of monthly workload reports, reallocation of staff resources and shifting workload focus when necessary; implementing MR instruction from CMS; and educating staff on MR issues, new instructions, and QA findings in CAFM II Activity Code 21207. There is no workload reported for this activity.

(Reference: IOM Pub. 100-8, Ch. 11)

C.5.1.2.6. Complex Probe Review (Activity Code 21220)

DMERCs shall perform limited size probe reviews to verify potential program vulnerabilities discovered during data analysis. Probe reviews may be conducted pre- or post-payment and may be provider- or service-specific.

Report all costs associated with prepay and postpay complex probe review in Activity Code 21220. In the workload section of CAFM II, Activity Code 21220, report the number of claims reviewed in Workload 1. Report the number of claims denied in whole or part in Workload 2. Report the number of suppliers/providers subjected to probe review in Workload 3.

(References: IOM Pub. 100-8, Ch.3, IOM Pub. 100-8, Ch.11)

C.5.1.2.7. Prepay Complex Review (Activity Code 21221)

Complex review goes beyond the routine review to include the evaluation of medial records or other medical documentation. Complex medical review involves the application of clinical judgment by a licensed medical professional in order to evaluate medical records. Medical records include any medical documentation, other than what is included on the face of the claim that supports the service that is billed. For items of durable medical equipment that require a Certificate of Medical Necessity (CMN), the CMN is considered part of the face of the claim. Complex medical review determinations require a licensed medical professional to make a clinical judgment about whether a service is covered, and is reasonable and necessary. DMERCs are not required to develop unassigned claims before making coverage and payment decisions. DMERCs shall use nurses (at least LPN) or physicians to perform complex reviews.

The purpose of complex manual review is to determine if the underlying medical documentation supports the services billed. DMERCs utilize data analysis techniques to identify areas of the greatest program vulnerabilities. DMERCs shall perform complex reviews only in areas of potential program vulnerabilities based on data analysis that are identified in the MR/LPET Strategy.

DMERCs should consider complex reviews a part of the normal prepayment review process and workload. DMERCs should take steps to increase the receipt of requested documentation. Complex medical review performed by MR staff for purposes other than MR (for example, for appeal or claims processing) should be charged for expenditure reporting purposes to the area requiring clinical consultation.

Report all costs associated with prepay complex manual reviews in Activity Code 21221. In the workload section of CAFM II, Activity Code 21221, report the number of claims reviewed in Workload 1. Report the number of claims denied in whole or in part in Workload 2. Report the number of suppliers/providers subjected to complex review in Workload 3.

(References: IOM Pub. 100-8, Ch. 3, IOM Pub. 100-8, Ch. 11)

C.5.1.2.8. Advance Determination of Medical Coverage (ADMC) (Activity Code 21221/01)

DMERCs' budgets should include funds for activities associated with providing advance determinations of Medicare coverage for certain customized items of DME. The funds should cover the operational (e.g., accepting and processing requests) and administrative (e.g., tracking and reporting) activities associated with this program.

DMERCs are to report all costs associated with performing ADMCs in Miscellaneous Code 21221/01. DMERCs are to report the number of ADMC requests accepted in workload 1. DMERCs do not report any other workload in the CAFMII system for this miscellaneous code.

(References: IOM Pub. 100-8, Ch. 5, IOM Pub. 100-8, Ch. 11)

C.5.1.2.9. Postpay Complex Review (Activity Code 21222)

Complex medical review involves evaluating medical records or any other documentation by a licensed medical professional. Complex medical review determinations require the reviewer to make a judgment about whether a service is covered and is reasonable and necessary. DMERCs shall use nurses (at least LPN) or physicians to perform complex reviews.

Report all costs associated with postpay complex review in Activity Code 21222. In the workload section of CAFM II, Activity Code 21222, report the total number of claims reviewed on a postpayment basis in Workload 1. Report the number of claims denied in whole or in part in Workload 2. Report the number of suppliers/providers subjected to postpayment review in Workload 3.

(References: IOM Pub. 100-8, Ch. 3, IOM Pub. 100-8, Ch. 11)

C.5.1.2.10. Medical Review Re-openings (Activity Code 21210)

When conducting complex medical review on a claim, it is often necessary for contractors to send to physicians, providers or suppliers additional documentation requests (ADRs). Generally, an ADR is made to assist the contractor in determining if payment of the claim is reasonable and necessary. Physicians, providers or suppliers are given 45 days to respond to ADRs. If the ADR is not responded to in a timely manner, contractors must determine if the claim is reasonable and necessary based on the existing information. Since ADRs are generally sent only when the record contains little or no evidence to support paying the claim, failure to respond to an ADR usually results in a claim denial. These denials are issued with Remittance Advice Code N102/56900 ("Denied due to failure to submit necessary medical documentation.")

When a N102/569000 claim denial is appealed and the documentation requested is received after the 45-day deadline, or is received with the appeal request, the MR Unit shall review the requested documentation as opposed to the Appeals Unit. The Appeals Unit will forward the file

based on which unit issued the N102/56900 denial (i.e., MR issued the denial, MR shall receive the forwarded file and conduct the review).

Report all costs associated with this medical reopening reviews in Activity Code 21210. In the workload section of CAFM II, Activity Code 21210, report the number of reopening requests received in Workload 1. Report the number of reopening requests resulting in payment in Workload 2. Report the number of providers/suppliers requesting a reopening in Workload 3.

C.5.1.3. LPET Workload, Cost and Savings

DMERCs shall perform the following activities in support of LPET.

C.5.1.3.1. One-on-One Provider Education (Activity Code 24116)

DMERCs shall develop One-on-One Provider Education in response to MR related coverage, coding, and billing problems verified and prioritized through the review of claims and/or the analysis of information. As these contacts are directly with the provider/supplier, clinical expertise is required to conduct this activity. One-on-One Provider Education includes face-to-face meetings, telephone conferences, videoconferences, letters, and electronic communications (e-mail) directed to a single provider in response to specific medical review findings. Include in this activity code the cost and workload for responding to provider/supplier questions concerning their specific medical review activities, or new or revised local policies.

DMERCs choose the type of one-on-one educational activity based on the level of MR related coverage, coding, and billing errors identified. For a moderate problem, the DMERC may choose to educate a provider/supplier via telephone conference. For more severe problems, or a problem that was not resolved through a telephone conference, a face-to-face meeting may be more appropriate. All one-on-one contacts shall be reported in the provider tracking system (PTS). The information to include in the PTS should be an explanation of the problem, the type of educational intervention performed, and the directions given to correct the errors. Written explanation of the problem and directions on how to correct the error might be appropriate for more severe problems, or upon provider request. While one-on-one provider/supplier education is likely to correct most MR coverage, coding and billing errors, it may be necessary for DMERCs to provide additional remedial education if the provider's/supplier's billing pattern continues to demonstrate aberrancies.

Report the costs associated with One-on-One Provider Education in Activity Code 24116. Include the cost of developing the written material used in provider/supplier specific educational activities. Written materials, or electronic communications to providers/suppliers during a One-on-One Provider Education, should **not** be reported in Education Delivered via Electronic or Paper Media, Activity Code 24118. Activity Code 24116, One-on-One Provider Education, shall capture the one-on-one contact between the DMERC and provider/supplier, and the written materials or electronic communication used to facilitate the one-on-one education. Included in this activity code would be letters sent to a provider/supplier that specifically addresses the MR findings and instructions to correct the errors. Any contacts to providers/suppliers made solely

by paper or computer, without specifically addressing an individual provider/supplier, should not be reported here.

Report all costs associated with one-on-one provider education in Activity Code 24116. In the workload section of CAFM II, Activity Code 24116, report the number of educational contacts in Workload 1. Report the number of providers/suppliers educated in Workload 2. If a provider/supplier sends a representative(s) on his behalf to a one-on-one educational contact, count the number of provider(s)/supplier(s) not representative(s) to whom the educational activity was directed.

(References: IOM Pub. 100-8, Ch. 1, IOM Pub. 100-8, Ch. 11)

C.5.1.3.2. Education Delivered to a Group of Providers (Activity Code 24117)

To remedy wide spread service-specific aberrancies, DMERCs may elect to educate a group of providers/suppliers, rather than provide one-on-one contacts. Subjects more appropriately addressed in a group setting include, but are not limited to, proactive seminars regarding medical review topics, educational interventions related to a group of services that combine for a comprehensive benefit (e.g., psychotherapy services) and local provider educational needs presented by new coverage policies. This activity is not to be used to educate providers/suppliers on issues of national scope. Activity Code 24117, Education Delivered to a Group of Providers, is designed to educate groups of local providers only.

Education Delivered to a Group of Providers may include seminars, workshops, and teleconferences. A differentiating factor between Education Delivered to a Group of Providers and Education Delivered via Electronic or Paper Media is live interaction between educator and providers/suppliers. For example, a computer module with the capacity to educate many providers/suppliers simultaneously would not be captured here, but would be captured under Education Delivered via Electronic or Paper Media. The determining factor is that there is not spontaneous, live interaction, between educator and providers/suppliers, with the computer module.

Report all costs associated with Education Delivered to a Group of Providers in Activity Code 24117. In the workload section of CAFM II, Activity Code 24117, report the number of group educational activities in Workload 1. Report the number of providers/supplier educated in Workload 2. If a provider sends a representative(s) on his behalf to a group education activity, count the number of provider(s)/supplier(s) not representative(s) to whom the educational activity was directed.

(References: IOM Pub. 100-8, Ch. 1, IOM Pub. 100-8, Ch. 11)

C.5.1.3.3. Education Delivered via Electronic or Paper Media (Activity Code 24118)

DMERCs may elect to provide education via electronic or paper media. Do not report here an electronic tool or a paper document developed and utilized as an adjunct to One-on-One Provider Education (Activity Code 24116), or Education Delivered to a Group of Providers (Activity

Code 24117). Instead, report education delivered solely by electronic or paper media that does not involve the facilitation or interpretation of a live educator. A comparative billing report issued to an individual provider/supplier during a one-on-one educational activity that included instructions on curing aberrant practices is an example of a paper tool used by the educator, and therefore would not be captured here. It would be included in the One-on-One Provider Education (Activity Code 24116) because it was an adjunct paper tool. A written letter composed by an educator containing specific instructions to an individual provider would also be considered One-on-One Provider Education. However, comparative billing reports issued to specialty groups upon request, or posted on the Web as a means to illustrate patterns, would be captured here.

DMERCs shall maintain a Web site. Included in this category are developing and disseminating medical review bulletin articles. In addition, DMERCs shall submit to CMS those articles/advisories/bulletins that address local coverage/coding and MR related billing issues (IOM Pub. 100-8 Ch. 1, §5). Frequently asked questions (FAQs) are part of Education Delivered via Electronic or Paper Media as well. DMERCs shall update them quarterly and post them to their Web sites. DMERCs are encouraged to develop FAQ systems that allow providers to search FAQ archives and subscribe to FAQ updates. CMS requires DMERCs to forward all articles and FAQs to CMS per the instructions in IOM Pub. 100-8 Ch. 1, §5. Another example of Education Delivered via Electronic or Paper Media, includes, but is not limited to, scripted response documents to LCDs and coverage review questions to be utilized by the customer service staff.

Report the costs associated with Education Delivered via Electronic or Paper Media in Activity Code 24118. In the workload section of CAFM II, Activity Code 24118, report the total number of educational documents developed for use in non-interactive educational documents in Workload 1. Report the number of CBRs developed in Workload 2 (do not include CBRs developed for Activities in 24116 and 24117). Report the number of articles/advisories/bulletins developed in Workload 3. Workloads 2 and 3 are subsets of workload 1.

(References: IOM Pub. 100-8, Ch. 1, IOM Pub. 100-8, Ch.3)

.C.5.1.4. MR and LPET Deliverables

The initial strategy submitted at the beginning of the fiscal year shall be based on the strategy from the current fiscal year, updated and expanded upon as necessary. The MR/LPET Strategy shall be submitted to the RO BFE with the Budget Request (BR). The DMERC shall negotiate their MR/LPET Strategy with the Regional Office. Negotiations with the RO budget and MR staff will center on the strategy and the individual elements of the strategy. RO budget and MR staff retain the authority to restrict DMERCs' funding amounts for MR strategies that are not approved based on lack of detail in methodology, inappropriate use of resources, or inappropriate selection of activities for reducing the claims payment error rate. The DMERC shall submit the final approved MR/LPET Strategy to the Regional Office and the CMS Central Office mailbox at MRSTRATEGIES@cms.hhs.gov prior to the submission of the RO budget recommendation to CO.

- DMERCs shall submit a QSA that assesses the accomplishments of individual elements of the MR/LPET Strategy, as well as other components of the MR/LPET process in accordance with IOM Pub. 100-8, Ch. 7 § 7.8. For FY 2006, this report shall be submitted electronically to the Regional Office and to Central Office at MRSTRATEGIES@CMS.HHS.GOV forty-five calendar days after the close of the quarter (IOM Pub. 100-8, Ch. 7 §7.11).
- Quarterly, the DMERC shall submit its medical review information according to instructions provided by CMS for the Program Information Management Reporting System.

C.5.2. Coordination with Program Safeguard Contractors (PSCs)

C.5.2.1. Full (Medical Review and Benefit Integrity) PSC

The DMERC shall work with the PSC to develop a joint operating agreement (JOA). The JOA will be added to the specified DMERC's and the PSC's SOW/Contract, as an attachment, after all of the procedures in the JOA are agreed upon by the DMERC, the PSC and CMS. The JOA will ensure coordination and cooperation during the transition and thereafter.

From time to time, CMS may direct work to be performed by a PSC and one or more of the DMERCs. This work may be ad hoc in nature (outside the realm of normal PSC/DMERC cooperative efforts) and may be minimal from a cost perspective, or it may require significant effort by the DMERC. CMS will issue a task order to the PSC, and in all cases, the PSC will communicate in writing directly with the regional Contracting Officer's Technical Representative (COTR). The COTR will coordinate with DMERC management concerning (1) the implementation of the required effort, (2) the priority, and (3) the preparation of a cost proposal, if necessary. The PSC will provide CMS's DMERC Contracting Officer with a copy of the correspondence to the COTR.

C.5.3. Comprehensive Error Rate Testing Program (CERT)

To support the CERT PSC in its efforts, DMERCs are required to:

- Coordinate with the CERT contractor to provide the requested information for claims identified in the sample in an electronic format (Note: These are changes to the standard system -- The sampling module will reside on a server in the CMS Data Center. Use of the sampling module will be under the supervision of the CERT operations center).
- Submit a file daily to the CERT contractor (via CONNECT: Direct) containing information on claims entered during the day.
- Provide the CERT contractor with all applicable materials (e.g., medical records) used to deny (in-part or total) or approve a sampled claim for medical review reasons or deny a sampled claim due to claims processing procedures. (CMS expects the volume of such materials to be very low. The anticipated CERT sample is not expected to exceed 200

claims per month (or 2,000 per year) from each contractor. Generally, contractors will have to supply additional materials on 10% or less of those claims).

- Receive overpayment (or underpayment) referrals and undertake appropriate collection action on cases in which the CERT contractor has determined an error has occurred.
- Provide the CERT contractor with the status and amounts of overpayments that have been collected (or underpayments that have been made) within 10 working days of a CERT request.
- Provide the CERT contractor with the requested feedback for those claims identified on the monthly CERT review report within five days of a CERT request.
- Process appeals stemming from the CERT project, e.g., CERT decisions appealed by providers or beneficiaries.
- Provide the CERT contractor with the status of appeals and final decisions on appeals within 10 working days of a CERT contractor request.
- Provide answers to the CERT contractor on the status of claims that were identified in the sample, but for which, there is no indication that the claim has been adjudicated. Provide clarification/coordination with the CERT contractor on issues arising as part of the CERT project.
- Assist the CERT contractor by disseminating information concerning CERT to affected providers.

C.5.3.1. MIP Comprehensive Error Rate Testing (CERT) Support

For FY 2006, CMS will provide funding earmarked for the AC to support the CERT contractor. This funding will be a “reverse auction” funding system as is found in the prior portions of the MR BPR. The MIP CERT Support funding is over-and-above the level of funding provided to perform the MR activities listed earlier in this BPR. DMERCs are not required to develop a CERT Support strategy. DMERCs shall not include MIP CERT Support work in their MR strategies. DMERCs shall not shift additional funds from MR/LPET activities to this line.

In addition to satisfying all requirements listed here, DMERCs shall carry out all MIP CERT Support activities identified in IOM Pub.100-8 Ch. 12 and all relevant CERT Support One Time Notifications.

C.5.3.1.1. MIP CERT Support (Activity Code 21901)

Report the costs associated with time spent on MIP CERT Support Activities. These activities include, but are not limited to, the following:

- Providing review information to the CERT Contractor as described in IOM Pub. 100-8 Ch. 12 §3.3.2.
- Providing feedback information to the CERT Contractor as described in IOM Pub 100-8 Ch. 12 § 3.3.3 including, but not limited to:
 - CMD discussions about CERT findings
 - Participation in bi-weekly CERT conference calls
 - Responding to inquiries from the CERT contractor
 - Preparing dispute cases
- Preparing the Error Rate Reduction Plan (ERRP) as described in IOM Pub. 100-8 Ch. 12 §3.9. (Do not include costs of developing MR/LPET Strategy. The cost of developing the MR/LPET Strategy should be captured in MR CAFM code 21207.)
- Educating the provider community about CERT as described in IOM Pub 100-8 Ch. 12 §3.8.

DMERCs shall NOT report costs associated with the following activities in this activity code:

- Providing sample information to the CERT Contractor as described in IOM Pub 100-8 Ch. 12 §3.3. (These costs should be allocated to the PM CERT Support Code – 12901 – described in the Appeals BPR.)
- Ensuring that the correct provider address is supplied to the CERT Contractor as described in IOM Pub 100-8 Ch 12 § 3.3.1. (These costs should be allocated to the PM CERT Support Code – 12901 -- described in the Appeals BPR.)
- Researching 'no resolution' cases as described in IOM Pub 100-8 Ch 12 § 3.3.1. (These costs should be allocated to the PM CERT Support Code – 12901 -- described in the Appeals BPR.)
- Handling and tracking CERT-initiated overpayments/underpayments as described in IOM Pub 100-8 Ch 12. § 3.4 and 3.6. (These costs should be allocated to the PM CERT Support Code – 12901 -- described in the Appeals BPR.)
- Handling and tracking appeals of CERT-initiated denials as described in IOM Pub. 100-8 Ch 12. § 3.5 and 3.6. (These costs should be allocated to the PM CERT Support Code – 12901 -- described in the Appeals BPR.)

There is no workload reported for this activity.

(Reference: IOM Pub. 100-8, Ch. 11, IOM Pub. 100-8, Ch. 12)

C.5.4. Supplier/Provider Communications (SPCOM) – Supplier/Provider Education and Training

Sections 1816 (a) and 1842 (a)(3) of the Social Security Act (the Act) require that contractors serve as a channel of communication for information to and from suppliers/providers. The fundamental goal of CMS's Supplier/Provider Communications (SPCOM) program (formerly Provider Education and Training, PET) is to give those who provide service to beneficiaries the information they need to understand the Medicare program so that, in the end, they manage Medicare related matters appropriately and bill correctly.

SPCOM uses mass media, such as print, Internet, satellite networks, and other technologies, face-to-face instruction, and presentations in classrooms and other settings, to meet the needs of Medicare suppliers/providers for timely, accurate, and understandable Medicare information.

SPCOM is directed at educating suppliers/providers and their staffs about fundamental Medicare programs and policies, new Medicare initiatives, and significant changes to the Medicare program. These efforts are aimed at reducing the number of supplier/provider inquiries and claim submission errors. Unlike Local Provider Education and Training (LPET), SPCOM, for the most part, is not targeted to individual suppliers/providers or limited and confined problems or errors. SPCOM is instead designed to be broader in nature so as to meet the basic informational needs of Medicare suppliers/providers, plus have a unique focus upon training and consulting for new Medicare suppliers/providers as well. The scope of SPCOM is to identify and address issues that are of concern to the broad supplier/provider audience.

C.5.4.1. Supplier/Provider Communications – Program Elements

The DMERC shall implement the basic requirements for SPCOM stated herein.

Report costs and workload data for the SPCOM program according to the prescribed CAFM activity codes.

Effective January 1, 2005, all DMERCs shall process DMEPOS claims from IHS, tribe and tribal organization facilities in accordance with Section 630 of the Medicare Modernization Act. All work associated with the processing of these claims is the responsibility of the DMERC, including Provider Outreach and Education and Provider Customer Service. Effective upon the date of this contract, all DMERCs shall plan, conduct and report on Provider Outreach and Education and Provider Customer Service activities in accordance with Section C.5.4, and shall collaborate with other contractors in planning and conducting the Provider Outreach and Education program for IHS, tribe and tribal organization facilities.

C.5.4.1.1. Supplier/Provider Service Plan (SSP) (Activity Code 25201)

Contractors shall prepare and submit a SSP annually. The S/PSP shall address your overall plans for implementing the supplier/provider communications program in the forthcoming fiscal year. The SSP outlines the strategies, projected activities, efforts, and approaches that will be used during the year to support supplier/provider communications. The SSP shall address and support

all the activities stated herein as well as all required activities stated in the yearly BPRs for this program. The SSP shall be submitted electronically to providerservices@cms.hhs.gov and to your RO contact. The SSP shall follow the format found on <http://www.cms.hhs.gov/contractors/providercomm/default.asp>.

A draft or preliminary SSP should be sent at the time you submit your annual Budget Request to your Regional Office (RO) SPCOM or provider education and training (PET) Coordinator. A final SSP should be sent by October 31, to your RO SPCOM or PET Coordinator and to CMS central office (CO).

C.5.4.1.2. Supplier/Provider Inquiry Analysis (Activity Code 25201)

Contractors shall maintain a supplier/provider inquiry analysis program that will produce a monthly list of the most frequently asked questions (FAQs) and areas of concern/confusion for suppliers/providers. Use an organized, consistent, systematic and reproducible process to generate your most frequently asked questions. Describe this process in your SSP. Outreach and educational efforts shall be developed and implemented to address the needs of suppliers/providers as identified by this program.

C.5.4.1.3. Supplier/Provider Data Analysis (Activity Code 25201)

Contractors shall maintain a supplier/provider data analysis program that will produce a monthly list of the most frequent, collective claims submission errors from all suppliers/providers. Claims submission errors result in rejected, denied, or incorrectly paid claims. Outreach and educational efforts shall be developed and implemented to address the needs of suppliers/providers as identified by this program.

C.5.4.1.4. Supplier/Provider Communications Advisory Group (Activity Code 25204)

Contractors shall support and maintain a SPCOM Advisory Group (formerly referred to as the PET Advisory Group). This group should generally convene quarterly, but at a minimum, meet three times per year, and will provide advice and recommendations to you on supplier/provider communications matters.

Purpose of SPCOM Advisory Groups

The primary function of the SPCOM Advisory Group is to assist you in the creation, implementation and review of your supplier/provider education strategies and efforts. The SPCOM Advisory Group provides input and feedback on training topics, supplier/provider education materials, and dates and locations of supplier/provider education workshops and events. The group also identifies salient supplier/provider/education issues, and recommends effective means of information dissemination to all appropriate providers and suppliers and their staff. The SPCOM Advisory Group should be used as a supplier/provider education consultant resource, and not as an approval or sanctioning authority.

While it remains allowable for you to use SPCOM Advisory Groups to provide updates and facilitate discussion on current issues, the focus of the group meetings should remain centered on

the development and implementation of effective supplier/provider communication materials and strategies.

Composition of SPCOM Advisory Group

You should strive to maintain professional and geographic diversity within your SPCOM advisory groups. Attempt to include representatives of various supplier/provider specialties you service including state and local trade and professional associations, practicing supplier/provider or staff members they deem appropriate, and representatives of billing organizations. Suppliers/providers from different geographic areas, as well as from urban and rural locales, should be represented in any SPCOM Advisory Group. Consider inviting representatives of Quality Improvement Organizations (QIOs) from your area to participate in SPCOM Advisory Group meetings.

Consider having more than one SPCOM Advisory Group when the breadth of your geographic service area, or range of the suppliers/providers you service, diminishes the practicality and effectiveness of having a single SPCOM Advisory Group. For further guidance on this issue, you should contact your regional office SPCOM or provider education and training (PET) Coordinator.

Contractor Role

You shall maintain the SPCOM Advisory Group. While group members shall be solicited for agenda topics, it is not permissible for Medicare contractors to allow outside organizations to operate the SPCOM Advisory Group. After soliciting suggestions from the supplier/provider community, you should select the appropriate individuals and organizations to be included in the group. The main point of contact for all SPCOM Advisory Group communication shall be within your SPCOM, PET or similar department. At a minimum, you are responsible for recruiting potential members, setting-up and arranging all meetings, handling meeting logistics, producing and distributing an agenda, completing and distributing minutes, and keeping adequate records of the advisory group's proceedings.

Medicare contractors having more than one kind of Medicare contract (e.g., intermediary, Part B carrier, DMERC, rural home health intermediary, etc.) shall have separate SPCOM advisory groups for each kind of Medicare contract. It is also impermissible for contractors having geographic proximity or overlap with one another to share a SPCOM Advisory Group. Each contractor shall have its own separate group. Contractors shall not reimburse or charge a fee to group members for membership or for costs associated with serving on a SPCOM Advisory Group. Contractors shall notify their CMS regional office PET or SPCOM coordinator of the schedule and location of SPCOM Advisory Group meetings.

You are expected to consider the suggestions and recommendations of the SPCOM Advisory Group, and implement or enact them if you deem them reasonable, practicable and within your supplier/provider communications program requirements and budget constraints. After consideration, you shall explain to the group your reasons for not implementing or adopting any group suggestions or recommendations.

Meeting Specifics

Contractors may hold SPCOM Advisory Groups in-person or via teleconferencing. CMS recommends you hold at least one meeting per calendar year with group members in-person. Teleconferencing shall be made available to Advisory Group members who cannot be present for any meeting. You shall also have a specific area on your contractor Web site that allows suppliers/providers to access information about the SPCOM Advisory Group (minutes from meetings, list of organizations or entities comprising the SPCOM Advisory Group, an e-mail address for a contact point and for further information on the SPCOM Advisory Group, etc.). Notify your SPCOM Advisory Group members that information about their participation on the Advisory Group may be on your Web site. Consult with your CMS regional office PET or SPCOM coordinator if a member has objections, and on ways to mitigate them.

Meeting agendas, which include discussion topics garnered from solicitation of group members, shall be distributed to all members of the group and the CMS regional office PET or SPCOM coordinator at least 2 business days prior to any meeting. After each meeting, minutes shall be disseminated within 7 business days to all group members and others who request them.

Relationship to Other Contractor Advisory Groups

SPCOM advisory groups operate independently from other existing contractor advisory committees. While a SPCOM Advisory Group may, at its discretion, share information with other advisory groups, the SPCOM Advisory Group does not need the approval, authorization or input from any other entity for its advice, recommendations, or issuances. While an individual SPCOM Advisory Group member can be a member of another contractor advisory committee, the majority of SPCOM Advisory Group members should not be current members of any other contractor advisory group.

For more information or specific guidance on any of the above issues, contact your regional PET or SPCOM coordinator.

C.5.4.1.5. Bulletins/Newsletters (Activity Code 25103)

Unless otherwise established with CMS, produce and distribute regular supplier/provider bulletins/newsletters, at least quarterly, which contain program and billing information. When feasible and cost-effective, stop sending regular bulletins to suppliers/providers with no billing activity in the previous 12 months. Upon written request, from a corporate supplier, send suppliers with multiple sites and supplier numbers only one copy of the quarterly bulletin to a designated corporate address. Newly created bulletins/newsletters shall be posted on your Web site. All printed bulletins/newsletters shall have either a header or footer in boldface type within the first three pages that states the following: **“This Bulletin Should Be Shared With All Health Care Practitioners and Managerial Members of The Supplier/provider Staff. Bulletins Are Available at No Cost from Our Web Site [Insert Contractor Web Site Address].”**

Encourage suppliers/providers to obtain electronic copies of bulletins/newsletters and other notices through your Web site. If suppliers/providers are interested in obtaining additional paper copies on a regular basis, contractors are permitted to charge a fee for this. The subscription fee

should be “fair and reasonable” and based on the cost of producing and mailing the publication. A charge may also be assessed to any supplier/provider who requests additional single paper copies.

Easy Identification of Bulletin Information

Suppliers/providers should have easy access to relevant Medicare information that pertains to their particular type of practice or business. It is important to identify the information in your bulletin/newsletter that appears on your Medicare supplier/provider education web site so that providers can easily and quickly find information of interest to them. As such, provide within the introductory table of contents, summary, or compilation or listing of articles/information an indicator (word(s), icon, or symbol) that denotes whether the article/information is of interest to a specific provider audience(s) or is of general interest. This requirement may be disregarded if your introductory table of contents, summary, or article/information compilation is structured by specialty or provider interest groupings.

C.5.4.1.6. Seminars/Workshops/Teleconferences (Activity Code 25203)

Hold seminars, workshops, classes, or other face-to-face meetings, to educate and train suppliers/providers about the Medicare program and billing issues. Whenever feasible, activities should be coordinated with other DMERCs, quality improvement organizations (QIOs), other Medicare carriers and intermediaries, State Health Insurance Assistance Programs (SHIPs), and End Stage Renal Disease (ESRD) networks as well as interested groups, organizations, and CMS partners in your service area. Develop, and implement whenever practicable, effectiveness measures for each education and training activity. This includes, but is not limited to, customer satisfaction survey instruments, pre- and post-testing at workshops and seminars, and other feedback mechanisms.

Whenever feasible, hold teleconferences to address and resolve inquiries from suppliers/providers as a method to reach a broad audience.

Fundamentals of Medicare Billing Workshops

Conduct at least two workshops during the year, targeted to new Medicare suppliers/providers and supplier/provider billing staff. These workshops should deal with fundamental Medicare policies, programs and procedures as they relate to DMEPOS, and should also feature information on the basics of billing Medicare.

Informing External Organizations About Training Events

In order to encourage and promote maximum attendance, directly and routinely notify external groups, organizations, and other interested entities within your geographic service area of upcoming supplier/provider education and training events. Direct notification avenues you should use include mail, telephone, and e-mail. Notifications should be made sufficiently in advance of the scheduled events to allow time for registration.

C.5.4.1.7. Partnering/Collaborative Efforts with External Entities (Activity Code 25105)

Contractors shall work toward establishing partnerships with external entities to help in disseminating Medicare supplier/provider information. These types of partnerships can expand the reach of your SPCOM program and reduce the costs associated with SPCOM activities. Partnering entities may be medical, trade and professional groups and associations, government organizations, educational institutions, trade and professional publications, specialty societies and other interested or affected groups. By establishing collaborative information dissemination efforts, suppliers and providers can obtain Medicare program information through a variety of sources. Partnering or collaborative SPCOM efforts can include external entities: printing information in member newsletters, reprinting and distributing (free-of-charge) SPCOM materials, giving out SPCOM materials at organization meetings and functions, scheduling SPCOM presentations or classes to or for members, posting SPCOM information on their websites, etc.

C.5.4.1.8. New Technologies/Electronic Media

Contractors shall use new technologies and electronic media as an efficient, timely and cost-effective means of disseminating Medicare supplier/provider information to the audiences they serve.

Supplier/Provider Education Web Site (Activity Code 14101)

Maintain a Web site that is dedicated to furnishing suppliers/providers with timely, accessible, and understandable Medicare program information. To reduce costs, websites should fit into existing infrastructure and use existing resource technologies whenever possible.

This website shall comply with “Contractor Website Standards and Guidelines” posted at <http://cms.hhs.gov/about/web/contractors.asp> and shall be compatible with multiple browsers. Periodically review the “Website Standards and Guidelines” to determine your continued compliance. During the first three months of each calendar year, send a signed and dated statement to your RO SPCOM or PET Coordinator attesting to whether your website continues to comply with these guidelines and whether it is compatible with multiple browsers. The person in your organization who has authority over the website shall sign the attestation statement.

Your Supplier/Provider Outreach Web site shall contain the following:

- All newly created supplier/provider bulletins/newsletters;
- A schedule of upcoming SPCOM events (e.g., seminars, workshops, fairs);
- Ability to register for your workshops/seminars via the Web site;
- Search engine functionality;
- Features that permit suppliers/providers to download and save copies of bulletins, training materials, schedules of upcoming SPCOM events, and other items;
- A “What’s New” or similarly titled section that contains newsworthy and important information that is of an immediate or time sensitive nature to Medicare suppliers/providers;

- E-mail based support/help/customer service;
- A listing of FAQs/areas of concern updated quarterly as evidenced through your inquiry analysis program; and
- Information for suppliers/providers on how to submit claims electronically.

Develop and implement a feedback mechanism for users of your Medicare Web site. Users shall be able to easily reach the feedback instrument from the homepage of your provider/supplier education Web site. This mechanism should ask users of your site for their appraisals of the helpfulness and ease of use of the site and the information contained on it, as well as their thoughts and suggestions for improvement or additions to the site

Provide a means to allow suppliers/providers to offer reaction to CMS about your performance in their dealings with you. Use the mailing address of your CMS Regional Office PCOM Coordinator as the referral point for these reactions.

Develop a working "Site Map" feature for your provider/supplier Medicare website. This feature would show in simple text headings the major components of your supplier/provider website and would allow users direct access to these components through selecting and clicking on the titles. This feature shall be accessible from the homepage of the website using the words "Site Map."

Develop a tutorial explanation of how to use your supplier/provider education website. This explanation shall be accessible from the homepage of your supplier/provider education website. The explanation shall describe to users how to navigate through the site, how to find information, and explain important features of your website.

Your Supplier/Provider Outreach Web site shall link to:

- The Medicare program Web site at: <http://cms.hhs.gov>;
- The MLN at: <http://cms.hhs.gov/medlearn>;
- The site for downloading CMS publications at <http://cms.hhs.gov/publications/>;
- The site for downloading CMS manuals and transmittals at <http://cms.hhs.gov/manuals/transmittals/>;
- Requirements and regulations issued by CMS and of interest to suppliers/providers and are listed on CMS' Quarterly Provider Update (QPU) website page. Provide an explanation of the QPU on your website and a link to it at: <http://cms.hhs.gov/providerupdate/main.asp>;
- Suppliers/providers receive remittance advice information that can contain adjustment reason and remark codes that explain payment modifications made and other important information related to the claim. Descriptions for both of these code sets appear at: www.wpc-edi.com/services.asp. Provide a general explanation of the reason and remark codes on your Medicare education website and a link to the aforementioned site;
- Provide a general description of the information on the CMS HIPAA website and provide a link to it at: <http://www.cms.hhs.gov/hipaa/hipaa2>;
- CMS' Medicare supplier information site at <http://cms.hhs.gov/suppliers>;
- CMS' central provider page at <http://www.cms.hhs.gov/providers>; and

- Other CMS Medicare contractors, partners, QIOs, and other sites that may be useful to suppliers/providers.

Directed Website/Bulletin Article

Contractors often receive instructions from CMS to print a supplier/provider education article or other information in their supplier/provider bulletin or newsletter and also place it on their Web site. Unless specifically directed otherwise, locate the article or information from CMS on the “What’s New” or similarly titled section of your supplier/provider education Web site. Unless specifically directed otherwise, the article or information shall be put on your Web site as soon as possible after receipt, and should remain on your Web site for two months, or until the bulletin or newsletter in which it is appearing is put on your Web site, whichever is later.

Use of Current Procedural Terminology

During the first 3 months of each calendar year, determine whether your Web site complies with requirements stated in the IOM Pub 100-04, Chapter 23, § 20.7. A signed and dated attestation statement shall be sent to your RO SPCOM or PET Coordinator. The person in your organization who has authority over the Web site shall sign the attestation statement.

Easy Identification of Bulletin Information

Suppliers/providers should have easy access to relevant Medicare information that pertains to their particular DMEPOS specialty. It is important to identify the information in your bulletin/newsletter that appears on your Medicare supplier/provider education web site so that providers can easily and quickly find information of interest to them. As such, provide within the introductory table of contents, summary, or compilation or listing of articles/information an indicator (word(s), icon, or symbol) that denotes whether the article/information is of interest to a specific supplier/provider audience(s) or is of general interest. This requirement may be disregarded if your introductory table of contents, summary, or article/information compilation is structured by specialty or interest groupings.

Website Promotion and Presentation

Actively promote, market and explain your Medicare provider/supplier communications website. Present information concerning how to find, navigate and fully use your Medicare provider/supplier website. This information should be apart of, or made available at, all your provider/supplier education and training workshops and seminars, training sessions with individual providers/suppliers, and all other provider/supplier education events you have or participate in.

Electronic Mailing List/List-Serv (Activity Code 14102)

Maintain at least one electronic mailing list, or list-serv, to notify registrants via e-mail of important, time-sensitive Medicare program information, SPCOMing supplier/provider communications events, and other announcements necessitating immediate attention. At a minimum, use your electronic mailing lists to notify registrants of the availability of bulletins/newsletters or other important information on your Web site.

Suppliers/providers should be able to join your electronic mailing lists via your supplier/provider education Web site. Subscribers to your electronic mailing lists should also be able to initiate

de-listing themselves via your Web site. Post notices on your Web sites and in bulletins/newsletters that encourage subscription to the electronic mailing lists. Your electronic mailing lists should be capable of accommodating all your suppliers/providers. It is recommended your electronic mailing list(s) be constructed for only one-way communication, i.e., from you to subscribers. You are encouraged to offer multiple electronic mailing lists to accommodate the various suppliers/providers you serve.

You shall protect your electronic mailing list(s) addresses from unauthorized access or inappropriate usage. Your electronic mailing lists, or any portions or information contained therein, should not be shared, sold or in any way transferred to any other organization or entity. In special or unique circumstances where such a transference or sharing of list-serv information to another organization or entity is deemed to be in the best interests of CMS or the Medicare program, you shall first obtain express written permission of your CMS regional office SPCOM or S/PSP Coordinator.

Maintain records of your electronic mailing list usage. These records should include when your electronic mailing list(s) were used, text of the messages sent, the number of subscribers transmitted to per usage, and the author of the message. Records should be kept for one year from the date of usage.

- Targeted Mailing Lists (Listserv) – Develop, if feasible, electronic mailing lists that allow you to target DMEPOS suppliers. These targeted listserv categories should include: Home Care Equipment Supplies, Orthotics and Prosthetics, and Pharmacies.

Implement measures to actively market and promote to your supplier/provider community the advantages and benefits of being a member of your listserv(s). Use all your regular supplier/provider communications tools and channels (bulletins, workshops, education events, advisory group meetings, written materials, remittance advice messages, etc.) for this endeavor.

C.5.4.1.9. Training of Supplier/Provider Claims Submission (Activity Code 25203)

Conduct training for supplier/provider staff in electronic claims submission. This may include, but is not limited to, activities listed in Productivity Investments; use of Medicare billing and PC-Print software; use of available Medicare Electronic Data Interchange (EDI) transactions; use of new or updated Medicare software released during the year; and use of newly introduced EDI standards and/or functions or changes to existing standards or functions.

NOTE: There are multiple sources of supplier/provider training requirements associated with EDI functions. The SPCOM function covers suppliers/providers in group settings rather than contact with individuals. SPCOM covers newsletters, classes or outreach to groups of suppliers/providers and their staff on Medicare coverage, billing and benefits of EDI. SPCOM does not include instruction related to connectivity for individual suppliers/providers or the resolution of connectivity problems.

C.5.4.1.10. Internal Development of Supplier/Provider Issues (Activity Code 25201)

Hold periodic meetings with staff in appropriate areas of your organization (including personnel responsible for enrollment, medical review, EDI/systems, appeals, and program integrity) to ensure that inquiries and issues made known by suppliers/providers to these other areas in your organization are communicated and shared with supplier/provider education staff. Mechanisms to resolve these issues should be discussed. Minutes of the meetings shall be kept and filed.

C.5.4.1.11. Training of Supplier/Provider Education Staff (Activity Code 25201)

Implement a developmental plan for training new supplier/provider education personnel, and periodically assessing the training needs of existing supplier/provider education staff. The plan, which shall be written and available to your supplier/provider education staff, shall include schedules, course or instruction vehicle descriptions, and satisfaction criteria. Training materials such as workbooks, manuals, and policy guidelines shall always be readily available to your supplier/provider education staff.

C.5.4.1.12. Supplier/Provider Education Material (Activity Code 25202)

As needed, develop and produce provider information and education materials that support your SPCOM activities. (In this section, materials do not include bulletins and newsletters.)

As needed, develop and produce provider/supplier education products that use special media, (videos, web/computer based training courses, audio tapes, CD ROMs, etc) and support your provider/supplier communications activities.

C.5.4.1.13. Quarterly Provider Update Promotion (Activity Code 25203)

The Quarterly Provider Update (QPU) is a listing of the regulations and program instructions issued by CMS that impact Medicare suppliers and providers. The QPU is maintained by CMS and available to providers through the CMS website. Suppliers/providers may elect to join a CMS electronic mailing list so as to be notified periodically of additions to the QPU. Promote the existence and usage of the QPU and the electronic mailing list your suppliers/providers through your communications avenues, e.g. your Medicare supplier/provider education website, bulletins/newsletters, supplier workshops, presentations and events, and in your supplier/provider education materials.

C.5.4.1.14. Website Promotion and Presentations (Activity Code 25203)

Actively promote and market your Medicare supplier/provider communications website. Feature information concerning how to find, navigate and fully use your website. This information should be part of, or made available at, all your supplier/provider education and training workshops and seminars, training sessions with individual suppliers, and all other supplier education events.

C.5.4.1.15. Remittance Advice Supplier/Provider Communication (Activity Code 25203)

Promote the use and understanding of the Remittance Advice notice as an educational tool. Providers/suppliers receive remittance advice information that can contain adjustment reason codes and remark codes that explain payment modifications made and other important information related to the claim. Descriptions for both of these code sets appear at: www.wpc-edi.com/servicesreview.asp

Medicare contractors using the paper Remittance Advice shall use the provider messaging properties of this form to convey Medicare program information. Messages should promote usage of your Medicare supplier/provider website, alert recipients to changes in policies and programs, and give information about upcoming provider education workshops and training events.

C.5.4.1.16. Supplier Assistance Referral Program (Activity Code 25201)

Develop and maintain a supplier assistance referral program within your supplier/provider communications function. This program should be capable of handling the more complex questions that may be referred by your customer service representatives and require substantive technical experience, knowledge or research to answer.

S/PSP Quarterly Activity Report

You shall develop and submit S/PSP Quarterly Activity Reports (QAR) that summarize and recount your supplier/provider education and training activities for the previous quarter year. Use your annual S/PSP, the Budget and Performance Requirements and the supplier/provider communications program requirements herein to help formulate your QAR. The QAR shall be submitted electronically to providerservices@cms.hhs.gov and to your RO contract. The QAR shall follow the format found on <http://www.cms.hhs.gov/contractors/providercomm/default.asp>.

C.5.4.2. Charting Fees to Suppliers/Providers for Medicare Education and Training Activities

The DMERC may assess fees or charges for supplier/provider education activities in accordance with the guidelines stated herein. Supplier/provider education and training activities are separated into two cost categories: (1) no charge and (2) fair and reasonable cost. The cost of conducting these activities, or any fees you assess, shall conform to the requirements provided below. These cost categorizations distinguish supplier/provider education efforts considered to be statutorily mandated (provided at no-charge to providers and suppliers), and those considered to be enhanced or supplemental.

No Charge – Statutorily Required Training

- Activities and training materials designed to educate providers and suppliers in Medicare enrollment, coverage, reimbursement and billing requirements. The number of sessions and the scope of this training should be based on recommendations from business

partners including, but not limited to, the Supplier/Provider Communications (SPCOM) Advisory Committee, and fit within your program management resources.

- Training and materials on statutorily mandated or significant Medicare program changes, (e.g., hospital outpatient prospective payment system, home health, inpatient rehabilitation, SNF PPS and consolidated billing, and ambulance). CMS will give you advance notice on this training (including any needed follow-up training) and the availability of additional funding.
- Participation in conferences sponsored by other Medicare contractors and government agencies that are based upon recommendations from the SPCOM Advisory Committee.

Fair and Reasonable Cost – Discretionary Activities

- Individualized training requested by a supplier/provider. This may include the cost of travel, materials, accommodations, staff preparation, follow-up activities, and a fee for expenses to attend the event and make the presentation.
- Training videos, audiotapes, specialized brochures, pamphlets, and manuals developed by contractors (except for materials included in no-charge-statutorily required training).
- Presentations and training at non-Medicare contractor sponsored conferences, trade shows, conventions, annual meetings, etc. If you receive a request from a group such as a national, regional or state association or medical industry body to make a presentation at an event, you can charge the association or group a fee for travel expenses to attend the event. This fee may include the cost for materials, meeting rooms (if you shall incur that cost), accommodations, travel, staff preparation, handouts, follow up activities, and other incidentals. The travel fee shall be fair and reasonable, and based on the cost you incurred for providing the service or activity. You shall confer with your regional office SPCOM or PET coordinator about the costs associated with providing the training to ensure that the costs are reasonable.

NOTE: You may accept nominal speakers fees, or recognition gifts such as pens engraved with the host logo, coffee mugs, plaques, flowers, etc. However, you are not permitted to accept and use substantive gifts or donations associated with participation in education and training activities absent specific authority.

- Reference manuals, guides, workbooks, and other resource materials developed by the contractor designed to supplement or provide easy reference to formal Medicare supplier/provider manuals and instructions.

Revenues collected from these discretionary activities shall be used only to cover the cost of these activities and may not be used to supplement your other Medicare contractor activities.

Facilities, Food and Beverages and Supplier/Provider Communications

Holding supplier/provider education and training events for both statutorily required and discretionary activities at alternate locations (other than at your own offices or buildings) may

often reduce supplier/provider time and travel costs associated with attending these events. When such an opportunity exists, you may recover the costs incurred for meeting rooms, auditoriums and other facilities and equipment through a fee to participants. This fee or charge should be fair and reasonable and within the means of likely participants.

It is also recognized that many contractual agreements with hotels or other meeting site locations stipulate that food and beverages be purchased as a condition of furnishing a meeting or training room. In addition, light refreshments and food may be desirable to facilitate the training and/or for the convenience of the trainees or participants. If light refreshments and food are provided, a fee that covers this cost and is charged to participants shall be fair and reasonable, and based on the costs incurred by you. Providing food and beverages that exceed these guidelines are prohibited.

Keep records per event of the costs incurred and all fees charged to, and collected from, registrants. The total of fees or charges for any event should not exceed by more than 10 percent the actual costs you incurred for the event. If it does, you should refund the entire excess amount collected to all the registrants who paid a fee for that event. For example, you charge participants a \$50 registration fee for an event that cost you \$10,000 (e.g., light refreshments, meeting facility, and equipment rental), 250 individuals pay to attend and you collect \$12,500. Since the amount collected exceeded more than 10 per cent of the costs (\$1,000), the entire excess amount collected (\$2,500) is disbursed back to all paying registrants.

Refunds/Credits

In order to secure sites you may need for future supplier/provider training events, you may have to make commitments under which you will incur contractual expenses for training accommodations and services. Full or partial refunds/credits to suppliers/providers who register for an event, and cancel before the event, or do not attend the event, should be made within the context of these contractual arrangements. If training is scheduled and you cancel the event, a full refund shall be made to registrants. If there are questions concerning the implementation of this policy in a given case, contact your RO SPCOM coordinator.

Bulletins/Newsletters

Unless otherwise established, you shall furnish free of charge one paper copy of your regular bulletin/newsletter which contains program and billing information to suppliers/providers. If suppliers/providers are interested in obtaining additional paper copies on a regular basis, you are permitted to charge a fee for this. The fee for this subscription should be "fair and reasonable" and based on the cost of producing and mailing the publication. A separate charge may also be assessed to any supplier/provider who periodically requests additional single paper copies.

Mixed Training Events

In situations where supplier/provider education and training activities involve both statutorily required training and discretionary training, the contractor shall allocate the proportional costs between the activities. That is, the proportional share of the cost of a function allocated to statutorily-required training is equal to the percentage of time related to this training. For example, if it costs \$1,000 to arrange and conduct a mixed training session, with 25 percent of the session related to statutorily required training, then the proportional cost allocation for the

training would be $.25 \times \$1,000 = \250 for statutorily required training and $.75 \times \$1,000 = \750 for discretionary training activities.

Recording of Training Events

Entities not employed by CMS, or under contractual arrangement with you, are not permitted to videotape or otherwise record your training events for profit-making purposes.

C.5.5. Medicare Secondary Payer (MSP) Requirements

General

The Medicare Secondary Payer (MSP) generally refers to those situations where a party other than Medicare has primary payment responsibility for health care expenses incurred by a Medicare beneficiary. The MSP process was developed to ensure that when processing a claim for benefits, the Medicare program pays only what is consistent with statutory requirements. The MSP information gathered is also utilized by the Centers for Medicare & Medicaid Services (CMS) to aid in recovering from responsible entities both mistaken primary payments and conditional payments. CMS has established a centralized Coordination of Benefits (COB) operation to gather MSP information, by consolidating under a single contractor, Group Health Inc., the performance of all activities that support the collection, management and reporting of other insurance coverage of Medicare beneficiaries, including coverage that is obligated to pay primary to Medicare.

The COB Contractor (COBC) is responsible for the Initial Enrollment Questionnaire (IEQ), IRS/SSA/CMS Data Match, MSP Claims Investigations, and virtually all other initial MSP prepayment development. The COB Contractor is charged with ensuring the accuracy and timeliness of updates to the Common Working File (CWF) MSP auxiliary file, so that the Medicare Program pays claims in the correct order of financial liability.

IOM Publication 100-5, Chapter 1, §20.1 provides tasks and workload definitions by Activity Code that are to be performed by the DMERC for both MSP Prepayment and Post payment activities. An Activity Dictionary listing those tasks and workload is attached in J.12B.

The DMERC shall comply with all MSP instructions in the development and processing of ancillary claims where another insurer has primary payment responsibility. This development shall include, for example, creating CWF auxiliary records for beneficiaries when the claim form or other information indicates that there is a primary payer. In addition, the DMERC shall terminate auxiliary records when it is determined that the information contained on such a record is no longer valid (i.e., benefits have expired or exhausted) as discussed in C.5.5.1.4.

The DMERC shall comply with all MSP instructions relating to actions taken after the initial claim is paid, including all recoveries from prior improper payments, all Data Match and Non-Data Match and all liability, no-fault and workers' compensation cases. This also includes acknowledging and responding to correspondence within 45 calendar days including General Inquiries, those that are non-case and non-active claim related.

Medicare Secondary Payments and MSP Savings Reporting

The DMERC shall correctly calculate secondary payments when claims are received which include the primary insurer's explanation of benefits (EOB). The DMERC shall report any savings that are a result of another payer making primary payment. Reporting requirements are found in the CMS Internet On-line Manual (IOM) instructions (Chapter 5, Section 60) and Program Memoranda.

C.5.5.1. MSP Prepayment Claims

MSP Prepayment activities are those that result in the proper payment or the non-payment of an active Medicare claim and are listed in sections C.5.5.1. (.1 through .5).

All MSP prepay development is the responsibility of the COB Contractor (COBC).

The DMERC, after identifying an incomplete EOB, possible MSP claim, possible MSP situation, or CWF exclusion, shall forward the information to the COBC in accordance with IOM Pub. 100-5, Chapter 4, 10.3 and IOM Pub.100-5, Chapter 5, §§ 10.1, 10.2, and 10.7. Refer to these IOM sections for specific situations where information is forwarded to the COBC.

The DMERC shall not transfer to the COBC inquiries related to claims payment or claim denial. If the inquiry is directly related to an active claim (not yet reached final payment or non-payment decision) the inquiry is considered a general inquiry, under Activity Code 42004.

In determining whether an inquiry (i.e., call or correspondence) is to be handled by the DMERC or the COBC, the DMERC shall establish the basis of the call and the correspondence. The DMERC shall transfer, to the COBC, documentation in accordance with IOM Pub. 100-5, Chapter 5, §§ 10.2 and 10.3 and telephone calls in accordance with §§ 10.6, 10.7, and 10.8 for further development.

C.5.5.1.1. Resolution of MSP edits occurring in the claims adjudication process (Activity Code 22001)

Resolve MSP edits occurring in the claim adjudication process including those from the CWF in accordance with IOM Pub. 100-5, Chapter 5, §40. This does not include edits resulting from claim entry activities or incomplete claims that shall be returned to the provider.

No workload or costs associated to initial claim entry shall be charged to the MSP Activity Code 22001. Claim Payment activities include initial claim entry and shall be reported in the Program Management, Bills/Claims Payment function.

Initial claim entry activities that shall **not** be charged to MSP Activity Code 22001 are:

- Receipt, control of claims and attached Explanation of Benefits (EOB)/Remittance Advice (RA). Includes opening, sorting, date stamping, imaging, Control Number assignment, batching claims and activation of batches;

- Preparation of batches for keying. Includes verification that all batches are accounted for and claims are in proper order within the batch;
- Keying the entire MSP claim into the standard system to begin claims processing and
- Resolution of all claim entry edits.

Initial claim entry for a MSP claim is not complete until payment information from the primary payer's EOB/RA is keyed as part of the hard copy claim, bringing the hard copy MSP claim to the same status as the receipt of a MSP Electronic Media Claim (EMC) and preparing the claim for adjudication. Neither the hard copy claim nor the EMC shall enter claim processing if the primary payment information is incomplete. The primary payment information is crucial in determining the appropriate amount Medicare shall pay as the secondary payer, an amount calculated within the MSPPAY module during claim adjudication. The following list includes primary payer information that shall be present on the EOB/RA or shall need to be determined, then keyed, to complete entry of the hard copy claim into the standard system. All costs associated to these functions shall be charged to Bills/Claims Payment.

Note: Individual EOB/RAs may use different but similar terms.

Actual Charges	Deductible
Provider Discount	Co-pay/Co-Insurance
Contract Write-off	Non-covered Services
Primary Payer Allowed Amount	Benefits Paid
Primary Payer Paid Amount	Covered Charges
Obligated to Accept as Payment in Full	Withhold

C.5.5.1.2. Claim Determination Activities (Activity Code 22001)

Perform claim determination activities necessary to process an MSP claim through to a final payment or non-payment decision in accordance with IOM Pub. 100-5, Chapter 1, §§ 40, 50, 60, 70 and Chapter 2 §§ 10, 20, 30, 40, 50 and 60.

Examples include: comparing EOB/RA claim data to HIMR/CWF data; overriding with conditional payment codes to pay primary; making primary, secondary or denial payment decisions; working suspended claims.

C.5.5.1.3. Congressional Inquiries and Hearings related to MSP Prepayment Activities (Activity Code 22001)

These activities include contacting the designated COB consortia Congressional representative, and coordinating, as necessary, for a consolidated prepay response and follow-up with the COBC, if applicable after five (5) days; and contacting the COB consortia for the collection of information and/or documentation to respond to a hearing pertinent to MSP prepayment activities. This activity shall be performed in accordance with IOM Pub. 100-5, Chapter 5, § 10.2.

C.5.5.1.4. Prepare "I" Records and Add Termination Dates to MSP CWF Auxiliary Records, as Necessary, to Complete the Claim Adjudication Process (Activity Code 22001)

Adding "I" auxiliary records to CWF to process a claim would include those that are necessary to accommodate an override for primary conditional payment and also, when enough claim information exists to add a new CWF MSP Aux File record to process a claim as secondary. Simple terminations should be performed when the DMERC receives information pertinent to an existing and valid CWF MSP Aux file with a "Y" validity indicator. This activity shall be performed in accordance with IOM Pub. 100-5, Chapter 4, § 10.3 and Chapter 5, §§ 10.1, 10.2 and 10.7.

C.5.5.1.5. Preparation of ECRS CWF Assistance Requests and ECRS MSP Inquiries (Activity Code 22001)

Pre-payment activities include the preparation of ECRS CWF Assistance Requests and ECRS MSP Inquiries necessary to process a claim through to a final payment or non-payment decision. This activity shall be performed in accordance with IOM Pub. 100-5, Chapter 5, § 10.2, 10.5 and Attachment 1 of the IOM publication.

ECRS transmissions that shall complete the processing of a claim shall be reported under Activity Code 22001. If the ECRS transmission is a result of an inquiry and there is no active claim in process, see requirements under Activity Code 42004, General Inquiries, for proper reporting.

C.5.5.2. MSP Post Payment (42000 Series)

MSP POST-PAYMENT ACTIVITY CODES WHICH ARE THE RESPONSIBILITY OF THE DMERC ARE: 42003, 42004, AND 42021.

NOTE: MSP Liability, No-Fault, Workers' Compensation, FTCA (42002) and Outreach (42006) will not be funded.

MSP post payment recovery activities focus on the identification, recovery and financial reporting of Medicare mistaken primary payments, where it is subsequently (after claim payment) determined that Medicare is the secondary payer. COBC coordination of benefit efforts, IRS/SSA/CMS Data Match, Voluntary Data Sharing Arrangements with Insurers and/or Employers, self reports from the beneficiary or their representative, claims submissions, etc. are all examples of methods for identification of potential MSP recoveries.

Note: DMERCs are reminded that although initial MSP waiver determinations pursuant to §1870 of the Social Security Act are included in the MSP MIP line, all appeals (including any appeal of an MSP §1870 waiver determination) shall be handled as a Program Management cost.

General Reminder: This Statement of Work will not override any post payment instructions where contractors have specific instruction for pending litigation, bankruptcy, etc.

The following MSP Post payment activity codes (ACs) are listed in numerical order. The priority of the tasks are within the activity code.

C.5.5.2.1. Liability, No-Fault, Workers' Compensation and FTCA (Activity Code 42002)

DMERCs shall have no workload specific to 42002. All activities for which the DMERC had non-lead responsibility are the lead recovery contractors's responsibility. REMAS functionality will eliminate the need for non-lead interactions.

C.5.5.2.2. Group Health Plan (Activity Code 42003)

DMERCs shall process all Data Match cycle tapes received as instructed within the MSP manual. Contractors shall have 60 calendar days from the date of downloading the data contained on the cycle tapes into their processing systems to initiate the demand letters. History search parameters should be from 10/1/02 forward. If the history search identifies potential GHP mistaken primary payments that equal or exceed \$1,000, the contractor shall seek recovery. Prior to the mailing of an initial demand, the contractor shall check the Common Working File (CWF) to determine the records validity to the proposed debt. The initial demand letter for Data Match GHP shall be sent by certified mail. Upon issuance of the demand letter packages, the DMERC shall provide a copy of the demand letter packages to the insurer/Third Party Administrator (TPA) associated with the debtor (employer). The copy to the insurer/TPA does not have to be sent by certified mail. The contractor shall follow instructions regarding the GHP recovery process as defined in Pub. 100-5, Chapter 7 Sections 10-80.

DMERCs shall initiate non-Data Match GHP mistaken payment history searches every 60-90 calendar days. History search parameters should be from 10/1/02 forward. If the history search identifies potential GHP mistaken primary payments that equal or exceed \$1,000, the contractor shall seek recovery. Prior to the mailing of an initial demand letter, the contractor shall check the CWF to determine the records validity to the proposed debt. The initial demand letter for Non-Data Match GHP should be sent certified mailing. Upon issuance of the demand letter packages the DMERC shall provide a copy of the demand letter packages to the insurer/TPA associated with the debtor (employer). The copies shall not be sent by certified mail. The contractor shall follow instructions regarding the GHP recovery process as defined in Pub. 100-5, Chapter 7 Sections 10-80.

Note: If the GHP on the original demand has a "union plan", the lack of CWF information for the debt is not a sufficient reason to invalidate the debt.

DMERCs shall acknowledge and respond to 95% of all correspondence within 45 calendar days from the date of receipt in the corporate mailroom or any other mail center location, absent

instructions to the contrary for a particular activity. Correspondence sent to the contractor as a copy (cc) does not require any action.

Instructions: MSP activities are described in the ABC Dictionary (Attachment J.12B) to the BPRs, the Internet Only MSP Manual, Pub. 100-5, and the Financial Management Manual, Pub. 100-6, as well as the specific Program Memoranda (PMs) identified below:

Transmittal AB-00-11 (CR 899), Transmittal CR 2870 Financial Management (awaiting publication), Transmittal 86 (CR 3142) and CR 3181 MSP Savings. Additionally, the 4/15/03, Joint Signature Memorandum titled "Clarification/ Reminder of Medicare Secondary Payer (MSP) Post Payment Activities for FY 2003 for Group Health Plan (GHP) Recoveries" and the 1/30/04, Joint Signature Memorandum titled "Expanded Aetna/CIGNA litigation Exclusions".

C.5.5.2.3. General Inquiries (Activity Code 42004)

DMERCs shall deposit checks and transmit ECRS MSP Inquiries on all voluntary/unsolicited checks not associated with an existing case or debt in order to begin the development process at COBC as defined in Pub. 100-6 Chapter 5 Section 411.

DMERCs shall acknowledge and respond to 95% of all correspondence within 45 calendar days. Correspondence sent to the contractor as a carbon copy (cc) does not require any action.

Instructions: MSP activities are described in the ABC Dictionary (Attachment J.12B), the Internet Only MSP Manual, Pub. 100-5, and the Financial Management Manual, Pub. 100-6, as well as the specific Program Memoranda (PMs) identified below:

Transmittal AB-00-11 (CR 899), Transmittal CR 2870 Financial Management (awaiting publication), Transmittal 86 (CR 3142) and CR 3181 MSP Savings. Additionally, the 4/15/03, Joint Signature Memorandum titled "Clarification/ Reminder of Medicare Secondary Payer (MSP) Post Payment Activities for FY 2003 for Group Health Plan (GHP) Recoveries" and the 1/30/04, Joint Signature Memorandum titled "Expanded Aetna/CIGNA litigation Exclusions".

C.5.5.2.4. Debt Collection/Referral (Activity Code 42021)

DMERCs shall adjudicate and post all checks to established debts within 20 calendar days from receipt in the corporate mail center. This includes voluntary/unsolicited checks which are associated to an established debt or a known or identified case/debt. A MSP voluntary/unsolicited refund with attached documentation indicating a debt is known or identified, shall be tracked under the 42021. For example, a check from a provider with attached claim information specific to the DPP shall be reported under 42021, since 42021 is used to track costs associated with the collection and referral of a debt. (Establish the A/R and post the collection simultaneously.) The goal is to post all checks to an established debt within the same quarterly reporting period.

DMERCs shall acknowledge and respond to 95% of all correspondence (includes faxes, emails, etc.) within 45 calendar days from the date of receipt in the corporate mailroom or any other mail center location, absent instructions to the contrary for a particular activity. Correspondence sent to the contractor as a carbon copy (cc) does not require any action.

DMERCs shall upon issuance of the intent to refer letter, provide a copy of the entire intent to refer package with all attachments to the insurer/TPA of the debtor (employer). The copies do not have to be sent by certified mail. The DMERC shall send an Intent to Refer letter within a time period 1)which will ensure the debtor will have the appropriate time to respond (e.g., 60 calendar days), 2)which will ensure contractors post all check or 3)review all defenses prior to the debt becoming over 180 calendar days delinquent. The DMERC shall follow and comply with all directions contained within the MSP manual specific to debt referral, debt referral exceptions, timeframes, etc. (see Chapter 7, Section 60).

DMERCs shall refer all eligible debt to Treasury prior to or before the debt becomes 180 days delinquent to ensure compliance with CMS instructions.

Instructions: MSP activities are described in the ABC Dictionary (Attachment J.12B), the Internet Only MSP Manual, Pub. 100-5, and the Financial Management Manual, Pub. 100-6, as well as the specific Program Memoranda (PMs) identified below:

Transmittal AB-00-11 (CR 899), Transmittal CR 2870 Financial Management (awaiting publication), Transmittal 86 (CR 3142) and CR 3181 MSP Savings. Additionally, the 4/15/03, Joint Signature Memorandum titled "Clarification/ Reminder of Medicare Secondary Payer (MSP) Post Payment Activities for FY 2003 for Group Health Plan (GHP) Recoveries" and the 1/30/04, Joint Signature Memorandum titled "Expanded Aetna/CIGNA litigation Exclusions".

C.5.5.2.5. General Workload Definition

MSP Post Payment Workload categories and activity code tasks are defined within attachment J-12B.

C.5.6. Benefit Integrity

NOTE: *When Program Safeguard Contractors (PSCs) are in place, DMERCs shall coordinate with the PSCs to assure information is communicated between the DMERCs and PSCs. The Region A DMERC will not be responsible for Benefit Integrity Unit (BIU) activities. The Region A DMERC PSC will be responsible for BIU activities.*

The benefit integrity responsibilities of the Medicare carrier may be found in IOM Pub. 100-8 (Program Integrity Manual). These instructions shall apply to the DMERCs, as well. Although many activities involved in combating waste, fraud and abuse are located in the BIU, the DMERC as a whole is responsible for protecting the Medicare Trust Fund. The DMERC shall be responsible for ensuring that payments for DMEPOS claims are correct. The DMERC shall ensure that billed services were actually rendered, were medically necessary, and that the

supplier of those items complied with all applicable Medicare laws, regulations, and policies in providing and billing for the items or services.

The DMERC shall establish a BIU that is separate and distinct from other DMERC components. The BIU shall have a full time manager. The BIU shall be staffed and trained with personnel in sufficient numbers and skills to meet requirements in the IOM Pub. 100-8 and this SOW. The staff shall consist of program and systems analysts, investigators, data analysts and health professionals, as necessary.

All Benefit Integrity (BI) investigators shall complete Level I training within one year of hire (for new employees) or within one year of this SOW for current employees who have not previously completed this training. Level I training requirements include sixteen (16) hours of fraud detection techniques, four (4) hours of interviewing techniques, and sixteen (16) hours of data analysis training. BI investigators who have completed Level I training before FY 2005 shall complete Level II training during FY 2005. Level II training requirements include four (4) hours of advanced fraud detection techniques and two (2) hours of advanced data analysis training. After satisfying the initial Level I and Level II training requirements, all BI investigators will be required to complete Level II training requirements each fiscal year, thereafter.

The following outlines primarily the duties of the DMERC BIU:

- Prevent waste, fraud and abuse by identifying program weaknesses and vulnerabilities in program policy and procedures, as well as weaknesses in its own Medicare claims processing operations;
- Monitor and control inappropriate payments arising from waste, fraud and abuse;
- Propose DMERC, shared system, NSC and CWF edits for the detection and prevention of waste, fraud and abuse;
- Initiate suspension and/or sanction actions arising from waste, fraud and abuse;
- Identify potential overpayments arising from waste, fraud and abuse, and refer such overpayments to the appropriate DMERC component for action;
- Develop and refer appropriate cases to law enforcement agencies such as the Office of Inspector General (OIG) and/or the Federal Bureau of Investigation (FBI) for law enforcement action;
- Closely coordinate with other DMERC components, especially the medical review unit, to ensure unified approaches to combating waste, fraud and abuse;
- Work freely and effectively with outside entities, such as state licensure agencies, Medicaid agencies, and state insurance commissions in the exchanging of data and information and ideas related to waste, fraud and abuse issues;

- Identify problem supplier(s) and determine if previous complaints exist against it (them). Associate any such documentation of the previous complaints in order to identify patterns and/or trends of waste, fraud and abuse;
- Identify and use a variety of methods (emphasizing proactive methods, including searching the Internet, area media sources, etc.) to detect and identify fraudulent behavior and/or activity.

Additional BIU responsibilities that are not separately funded or reported above include but are not limited to:

- Keep the LRO apprised of significant investigations within your jurisdiction;
- The BIU is required to provide meaningful FID entries and updates based on the IOM Pub. 100-8 requirements and timeframes;
- Investigations shall capture information on ongoing work in the PSC or Medicare contractor BI units; investigations are entered when they are reported on the PSC ART report. For Medicare contractor BI units, investigations are entered when they are being worked in the BI unit regardless of the level of effort, but have not yet been referred to law enforcement as a case.
- For law enforcement initiated investigations, follow IOM Pub. 100-8 guidelines for FID entry.
- Refer requests from law enforcement for suspension of payments or extensions of suspension of payments to the LRO for approval; and
- Continue the application of a Quality Improvement (QI) program which meets the LROs approval and ensures decisions made by the BIU are effective in preventing, detecting and deterring Medicare waste, fraud and abuse. The BIU is required to submit a report of findings for the QI program. This report shall be submitted quarterly. This report shall be entitled "Benefit Integrity Quality Improvement Program" and submitted to the LRO and copied to the CMS CO at POB@cms.hhs.gov or other designated e-mail address.

C.5.6.1. Networking Functions (Activity Code 23001)

Report all costs associated with networking activity in Activity Code 23001.

Report the number of health care task force meetings attended by the BI staff in workload column 1; the number of fraud alerts prepared in workload column 2; and the number of presentations performed for law enforcement, ombudsmen, Harkin Grantees (also known as Senior Medical Patrol) and other grantees in workload column 3.

C.5.6.2. Outreach/Training (Activity Code 23004)

Include costs associated with establishing and maintaining waste, fraud and abuse outreach and training activities for beneficiaries, providers, and contractor staff. Beneficiary outreach activities are described in the IOM Pub. 100-8. Beyond those, training activities are limited to:

- Providing waste, fraud and abuse training to new and existing BIU staff;
- Providing waste, fraud and abuse training to non-BIU contractor staff;
- Participating in training developed for law enforcement agencies, including the FBI; and
- Providing waste, fraud and abuse training to beneficiaries and providers, including respective associations.

Report all costs associated with waste, fraud and abuse outreach and training activities for contractor staff, providers, and beneficiaries in Activity Code 23004. Report the number of training sessions (internal and external) furnished only to BIU staff in workload column 1, report the number of face-to-face presentations by BIU staff made to beneficiaries and providers in workload column 2, and report the number of training sessions furnished by the contractor BIU to non-BIU contractor staff in workload column 3.

General provider education, outreach and training activities can be performed by the BIU but costs shall be reported to the MIP PCOM activity line. Provider education specific to a BI case shall be reported in 23007-MR in Support of BI activity line

C.5.6.3. Fraud Investigation Activities (Activity Code 23005)

The BIU should only receive and investigate complaints that are likely to indicate fraud and abuse situations. The BIU should return to the appropriate PSC or contractor unit (e.g., customer service, professional relations, medical review, etc.) any complaints that are not potential fraud and abuse situations.

The BIU is responsible for the development of an investigation file that may be substantiated into a case and ultimately referred to law enforcement for investigation and/or prosecution.

The BIU shall take necessary action to prioritize and fully investigate potential fraud leads, e.g., fraud alerts, internal or external DMERC referrals, OIG hotline calls, FID leads, beneficiary complaints, etc. In addition, the DMERC shall be using the "Incentive Reward Program" (IRP) tracking database to support receiving and tracking fraud and abuse complaints related to the IRP. The DMERC shall report and track any potential fraud related complaints received from Harkin Grantees (also known as Senior Medical Patrol) via the Harkin Tracking System.

The BIU shall perform all activities set forth in the IOM Pub. 100-8 including:

- Investigate all complaints alleging DMEPOS fraud and abuse that are forwarded to the BIU from the DMERC second level screening area or law enforcement agencies, such as the OIG, FBI or Medicaid Fraud Control Units;
- Timely acknowledge (within 15 calendar days of receipt from the Medicare-Fee-for-Service second level screening area), develop, and refer complaints from any source;
- Notify beneficiaries of the status of their complaint from acknowledgment through final disposition by the DMERC (if the case is accepted by the OIG, the OIG is responsible for further case status updates and the beneficiary should be referred to the appropriate OIG official);
- Maintain a data log on the number of complaints received listed by source, category or complainant, date of receipt, date of disposition and any other requirements set forth in the IOM Pub. 100-8. The DMERC shall be able to retrieve information to facilitate the identification of problem suppliers and/or the number of complaints filed against a particular supplier or group of related suppliers;
- Evaluate and prioritize all complaints alleging fraud and appropriately investigate such complaints, when necessary contact beneficiary, physician, or supplier for clarification or verification;
- Evaluate and prioritize case work loads so the BIU is placing larger resources on investigations that have the greatest potential in preserving the Medicare Trust Funds;
- Attend training(s) or meeting(s) sponsored or supported by CMS, including the national benefit integrity training conference(s), the SACC meetings, and any others applicable;
- Provide waste, fraud and abuse training to new and existing BIU and non-BIU contractor staff; and
- Assist in promoting active beneficiary and supplier referrals for waste, fraud and abuse through the preparation of bulletins, newsletters and pamphlets to be distributed by the DMERC.
- Ensure all information gathered by and furnished to the Benefit Integrity Unit is maintained in a secure environment and kept confidential to protect the privacy of all parties (IOM Pub. 100-8 Chapter 4, Sections 4.2.2.4, 4.2.2.6 and 4.30.

Report any cost associated with fraud investigation used to substantiate a case in Activity Code 23005. Report the number of investigations opened in workload column 1. Of the investigations reported in workload column 1, report how many were opened by the contractor based on contractor self-initiated proactive data analysis in workload column 2. Report the total number of investigations closed (no longer requiring fraud investigation) that did not become a case in workload column 3.

C.5.6.3.1. Complaint Tracking and Reporting

The BIU shall meet the workload reporting requirements specified in the IOM Pub. 100-8. It shall inform CMS, upon request, of the status of an inquiry or investigation on a particular supplier.

The BIU shall maintain files on suppliers that have been the subject of complaints, prepayment flagging, BIU investigations, OIG/FBI investigations, U.S. Attorney prosecution and any other civil, criminal or administrative action for violations of the Medicare or Medicaid program. The files shall contain documented warnings and educational contacts by the DMERC, the results of previous investigations, copies of complaints and all other relevant information. Files involving related suppliers shall be effectively cross-referenced.

C.5.6.4. Law Enforcement Support (Activity code 23006)

The BIU is responsible for providing data and/or analysis as requested by the OIG and/or DOJ (including the FBI) consistent with the 1994 Memorandum of Understanding (MOU), the Health Insurance Portability and Accountability Act Privacy Provisions, and the IOM Pub. 100-8 (chapter 4, § 4.4.1). The BIU is expected to:

- Perform routine data analysis and review activities for specific cases;
- Perform non-routine law enforcement support (with LRO concurrence);
- Develop and refer fraud cases to appropriate law enforcement agencies; and
- Maintain data on referred fraud cases including, but not limited to, the amount in question and whether law enforcement accepted the case.

The BIU shall have qualified personnel to review all national and regional data to proactively detect behavior or billing practices contrary to existing Medicare law, regulations and policies to include identifying patterns of over-utilization and abuse-prone policies and items. To direct the best use of resources, the BIU should review the SADMERC Abstract in conjunction with the SADMERC reports, or data from Program Safeguard Contractors (PSCs) to help identify areas that warrant further investigation.

The BIU is responsible for:

- Preparation and submission of substantive fraud alerts, and program vulnerabilities on a timely basis to CMS CO for national distribution;
- Data analysis and monitoring activities upon receipt of a national fraud alert;
- Searching the FID to identify fraudulent activities identified by other contractors that may potentially exist in its jurisdiction.

The BIU may receive and should comply with various requests from Federal and State law enforcement agencies for data, documents, and assistance related to potential or ongoing civil or criminal health care fraud investigations. When a request is received, the DMERC should prioritize it based on the type of request and the amount of resources required. Requests include, but are not limited to:

- Information on a claim form;
- Contractor records on suppliers and other entities;
- Medicare publications furnished to suppliers or other entities;
- Contractor correspondence to and from suppliers and other entities;
- Beneficiary billing history; and/or
- Claims review and statistical analysis.

The BIU is encouraged to discuss any such requests with the requestor to identify specific needs and any potential resource issues. Such discussion may alleviate unnecessary burdens on both the BIU and law enforcement agencies.

The BIU should document all requests for assistance from law enforcement. All requests for the BIU's assistance should be in writing. The request should outline the specific task and level of effort to be performed by the DMERC (i.e., review of 100 supplier claims, data analysis of a supplier or suppliers, etc.) and include the associated law enforcement project/case number. If a project/case number cannot be associated with the request, the BIU should discuss the matter with the LRO prior to initiating any action. Any requests from law enforcement clearly beyond the scope of the MOU should similarly be made in writing to the BIU. The BIU should prepare a cost estimate and submit it, along with the written request to the LRO for review and approval, prior to initiating any action.

The BIU should maintain documentation of each request for assistance from law enforcement and provide a report of law enforcement activities to CMS on a quarterly basis.

Report any costs associated with work done to provide support to law enforcement, including data analysis costs, in Activity Code 23006. Report the total number of law enforcement requests in workload column 1, report the number of requests discussed with the LRO in workload column 2, and report the number of BIU law enforcement requests that require data analysis in workload column 3.

Report contractor self-initiated proactive data analysis associated with BI in Activity Code 23005, and BI law enforcement requests that require data analysis in Activity Code 23006.

C.5.6.5. MR Support of BI Activities (Activity Code 23007)

Report any costs associated with medical review in support of BI activities in Activity Code 23007. Because the main goal of medical review is to change provider-billing behavior through claims review and education, any BI initiated review activity that does not allow for provider education or feedback shall also be charged to this Activity Code. Report the number of investigations that the MR Unit assisted the BI Unit with in workload column 1; the number of claims reviewed by both the MR Unit and the BI Unit for the BI Unit in workload column 2, and the number of statistical sampling for overpayment estimation reviews performed by MR in support of BI in workload column 3. Report the number of claims medically reviewed by MR and/or BI staff for BI in the remarks section of the IER and the NOBA.

Contractors shall keep a record of only BI work using miscellaneous codes in CAFM II for the following information: the number of consent settlements offered (Miscellaneous Code 23007/01), the number of consent settlements accepted (Miscellaneous Code 23007/02), and the number of statistical sampling performed for overpayment estimation (Miscellaneous Code 23007/03). Report workload only for the above items.

C.5.6.6. Administrative Actions**C.5.6.6.1. Suspension Actions**

The BIU is expected to recommend payment suspension actions to the LRO when reliable information exists that (1) payments made or to be made may be incorrect (2) fraud or willful misrepresentation exists or has been occurring, although additional evidence may be needed for a determination (3) an overpayment exists but the amount of the overpayment is not yet determined, or (4) the provider fails to furnish medical records and other requested information needed to determine the amounts due to the provider or supplier.

The BIU shall, with the LROs concurrence, initiate appropriate payment suspension actions against a supplier in accordance with IOM Pub. 100-8 instructions. The BIU shall share information related to such actions with all the DMERCs. Because suspension actions by one DMERC are considered a suspension of payment from Medicare, all DMERCs shall promptly suspend payments to the subject supplier(s). The suspension-initiating DMERC shall mail the suspension letter to the supplier notifying the supplier of the suspension action.

C.5.6.6.2. Exclusion Actions

The BIU should ensure that no payment(s) for services is being made at the medical direction of or prescribed by an excluded provider in accordance with 42 CFR 1001.1901(b) and the IOM Pub.100-8.

C.5.6.6.3. Overpayment Actions

The BIU is required to initiate the development of any potential overpayment(s) arising from waste, fraud and abuse. The BIU shall close any associated fraud and abuse case in accordance with the IOM Pub. 100-8.

Any request from law enforcement that the DMERC suspend or postpone recouping an overpayment shall be referred to the LRO for review and approval.

C.5.6.7. Alert Codes

The NSC shall receive and maintain “alert indicators” from the DMERCs about, at a minimum:

<u>alert code</u>	<u>definition</u>
A	possible fraudulent or abusive claims identified;
B	overpayments;
D	violations of disclosure of ownership requirements;
E	violations of participation agreements;
L	suspend by DMERC outside alert code process;
M	supplier is going through claims appeal process.

The NSC shall append the supplier file and transfer to the DMERCs the following alert codes in the following circumstances:

<u>alert code</u>	<u>definition</u>
C	violations of supplier standards;
F	sanctioned by the Office of Inspector General or debarred by the GSA;
H	Meets supplier standards; however, the NSC recommends increased scrutiny by the DMERC (initiated by NSC only); and
N	supplier being investigated under the “Do Not Forward” initiative (initiated by NSC <u>only</u>).

The NSC shall append an Alert Code “H” for any supplier that meets present supplier standards but appears suspect in one of the areas verified by the NSC. This alert code notifies the DMERCs that a supplier may be inclined to submit a high percentage of questionable claims.

The NSC shall:

- Share the above information with the DMERCs by sending alerts within ten (10) calendar days after identification of a supplier having common ownership or business ties with a sanctioned or suspect supplier for their research and/or action;
- Share information with the OIG on suppliers related to sanctioned individuals or businesses;
- Release new supplier information and updates within one (1) week of adding them to the file;
- Release “alerts” for all associated businesses within two (2) weeks of notification by a DMERC;
- Maintain daily file transmissions to the DMERCs of updated information;
- Support the DMERCs in the “Do-Not-Forward” initiative, including controlling all material received from the DMERCs in this effort, issuing appropriate and timely alert codes when required, developing the cases to determine whether the suppliers identified are still in compliance with supplier standards, and inactivating Medicare privileges where suppliers do not comply.

C.5.6.8. Hearings and Appeals

(See Internet-Only Manuals

[http://www.cms.gov/manuals/108-IOM/IOM Pub. 100-8](http://www.cms.gov/manuals/108-IOM/IOM%20Pub.100-8)) The BIU shall keep the DMERC’s appeals department apprised of all active fraud and abuse cases. The appeals department shall notify the BIU whenever there is a request for a hearing by a supplier involved in an active fraud case. The BIU shall provide the appeals department any pertinent information necessary to assist a reviewer, a hearing officer, and an administrative law judge or appeals council in rendering a decision.

The BIU should ensure the following information is furnished to the appeals department:

- Complaints, substantiated and unsubstantiated, subject to privacy restrictions; the DMERC should strike all identifiers if such information is in violation of the Privacy Act of 1974;
- Reports of contact with complainants and associated complainants;
- Profiling reports prepared by SADMERC or in-house staff, i.e., trend analysis or other relevant data;
- Pattern evidence which is historic information on a supplier or type of service;

- Previous sanction information; and/or
- Any other information, which substantiates proper adjudication of the claim.

Extreme care should be taken to ensure information provided to the appeals department does not include any information that would endanger an ongoing investigation. Documentation presented at a hearing is shared with the appellant. The BIU shall balance the need to ensure enough information is provided to make an informed decision, while not divulging information that may adversely affect any criminal or civil action being considered.

C.5.6.9. FID Entries (Activity Code 23014)

Ensure the FID is updated to include all current suspensions of payment, investigations, and cases that have been referred to law enforcement, providing the status of the suspension, investigation and case and any actions(s) taken or to be taken. Once the DMERC BIU has referred a case to the OIG or other law enforcement agency, the investigation shall then be saved as a case within 15 days of referral. The investigation converts to a FID case. Updates to the FID case shall be made at least every three months. The BIU should monitor the disposition of all cases referred to law enforcement, including documenting calls to inquire of the status of the case and documenting the subsequent acceptance or rejection of the case. The final disposition of any case shall be logged on the FID.

For payment suspensions, the information shall be entered into the FID suspension module no later than the effective date of the suspension. The first update following initial entry of the suspension shall be made within one month; the second update shall be made within two months. Thereafter, the amount being withheld and other pertinent information on the suspension shall be updated in the suspension module every two months, until the suspension is removed. For suspensions under unlimited extension, updates shall be made every three months. When a payment suspension is removed, this information shall be entered into the payment suspension module within 15 calendar days of removal.

Report all costs associated with FID entries and updates in Activity Code 23014. Report the total number of new cases entered in the FID in workload column 1, report the total number of cases updated in the FID in workload column 2, and report the total number of new payment suspensions entered in the FID in workload column 3.

C.5.6.10. Referrals to Law Enforcement (Activity Code 23015)

The BIU shall prepare a case referral outlining the basis for the case. The referral and any relevant documentation should be submitted to law enforcement for consideration.

The OIG has 90-days in which to accept, refer (to the DOJ), or reject the case. The BIU shall maintain a log of all cases referred and periodically (no less often than every 90 days) determine the status of each case. The following is a list of items the BIU should incorporate in the case file.

- Table of contents detailing the file;
- Case referral;
- Applicable Code of Federal Regulations, Social Security Act, regional medical review policy (RMRP), national policy;
- Reports of contacts with complaints and associated complaints;
- Prior complaints, substantiated and unsubstantiated;
- Profiling reports such as trend analysis or other data that may show one supplier out of the normal billing range when compared to others;
- Medical review or audit reports;
- Educational contacts/warnings by professional relations or medical review staff;
- Results of comprehensive medical review;
- Pattern evidence – historical information on supplier or type of service; previous sanction information, prior convictions;
- Suppliers on PAL status;
- Any and all other information that may substantiate a complaint or other information that may have led the BIU to identify fraudulent or abusive activity; and/or
- All overpayment actions.

The BIU shall meet at least quarterly, or more frequently if needed, with the OIG-designated liaison in the Office of Investigations Field Office (OIFO) servicing its region. All fraud cases involving DMEPOS shall be referred to the designated OIFO, which will forward the case(s) to the appropriate OIFO servicing the state involved. If the BIU has knowledge the case is national (in scope) or can be associated with a case involving another DMERC, the Washington, D.C. office of the OIG should be notified so a coordinated investigation can be conducted by the OIG.

If a case is accepted by the OIG, the BIU shall:

- Respond to the OIG's questions and supply the OIG with any information they may require including information on medical policies, data and beneficiary information;
- Forward to the OIG any additional information that becomes available, such as pattern evidence or trend analysis;

- Forward to the OIG any new complaints or data that become available after the initial referral;
- Communicate with the OIG to monitor the status of their investigation and any case development.

If the OIG declines to pursue a case or has not accepted a case within 90-days of the initial referral but the BIU believes the case has merit, the BIU may refer the case to another law enforcement agency.

If the OIFO agrees there has been a violation but for any reason declines to pursue civil or criminal action against the perpetrator, the BIU shall take administrative actions necessary to ensure future payments made to the supplier are correct and accurate. The various actions available may include, but are not limited to, initiating an offset against any projected overpayments; placing the supplier on prepayment medical review; developing the overpayment amount and initiating an overpayment action; and, suspending payment until proper overpayment amounts can be determined.

If appropriate, the BIU should pursue sanction and/or exclusion action with the OIG, including utilizing the sanction authority under §1128(b)(6) and §1128(b)(7).

The DMERC should maintain records on the cases referred to the OIFOs within the DMERC's region and the date of disposition of each case (the DMERC shall reconcile its pending case count and disposition with the OIFOs, quarterly).

Report all costs associated with referrals to law enforcement in activity code 23015. Report the total number of cases referred to law enforcement in workload column 1, report the total number of law enforcement referrals requesting additional information by law enforcement in workload column 2; and report the total number of law enforcement referrals declined in workload column 3.

C.5.6.11. PSC Support Services (Activity Code 23201)

DMERCs who have transitioned their BI work to a PSC shall only use the PSC Support Activity Code 23201 when providing support to the PSC. These DMERCs shall keep a record of support services rendered to a PSC, and report these services in the following workload columns: report the total number of miscellaneous PSC support services (e.g., training and meetings to support the PSC) in workload column 1, report the total number of PSC requests (not law enforcement related) fulfilled by the AC to support the PSC in investigations in workload column 2, and report the total number of PSC requests for support from the AC with law enforcement requests in workload column 3. Additional PSC support work that does not fall into workload 1, 2, or 3 shall be reported under the general Activity Code 23201, and not counted in workload 1, 2, or 3.

C.5.6.12. Annual Deceased Beneficiary Post-Payment Review

Durable Medical Equipment Regional Contractors (DMERCs) shall conduct post-payment reviews to identify and recover payments with a billed date of service that is after the beneficiary's date of death. The identification of improperly paid claims shall be performed at a minimum on an annual fiscal year basis for beneficiaries who died the previous fiscal year. The associated overpayment recoupment shall be initiated as soon as administratively possible, but by no later than 1 year after it has been identified.

EXAMPLE: Services rendered to beneficiaries who died during fiscal year 2002 - DMERCs shall identify improperly paid services. Upon identification, DMERCs will refer this information to their respective contractor component for recoupment. Within one year of this referral, DMERCs shall issue associated overpayment demand letters (on or before October 1, 2005).

DMERCs are not required to perform medical review for paid claims with dates of service after a beneficiary's date of death. The "post-payment claims review" should simply be an identification of the service that has been rendered after the beneficiary's date of death, and the subsequent notification to the provider that an improper payment has been made, for which recovery is now being sought.

At a minimum, DMERCs may identify deceased beneficiaries and associated improperly paid claims by using one of the following two options:

1. Utilize Internal Beneficiary Eligibility Records:
This step would involve performing a data extract against eligibility files for all beneficiaries within the DMERC's jurisdiction and identifying those beneficiaries who have died during the applicable fiscal year. Next, once the list of deceased beneficiaries has been identified, DMERCs would then need to utilize their claims processing history files to identify any services/claims containing a paid date of service that is after the CWF posted date of death.
2. Utilize External Beneficiary Eligibility Records:
This step allows DMERCs to utilize a CMS created annual computer file of all deceased beneficiaries. On an annual calendar year basis, CMS will create a computer file of all Medicare beneficiaries who died in the preceding calendar year. This computer file should be available for DMERCs to download from the CMS Data Center by mid-February of each year. DMERCs using this option should review the format for this file to determine if any changes have been made from the previous fiscal year file.

In accordance with the Health Insurance Portability and Accountability Act (HIPAA), a security firewall has been installed to protect the privacy rights of deceased beneficiaries. This firewall prevents unauthorized users from gaining access to deceased beneficiary files. Due to the confidential information within this file, DMERCs will not be able to access these files without their secured authorized identification code being included in the CMS allowed access list associated with the files.

To have access to these files, the DMERC shall submit the name of the person(s) who will be accessing the files, their CMS mainframe user identification number, the DMERC name and contractor number, the DMERC task order number, and a telephone number. Only the person(s) identified will be allowed access to the files. Submit this information via email to the CMS CO director of the Division of Benefit Integrity and Law Enforcement Liaison.

EXAMPLE: On February 15, 2003, CMS created computer files containing information on all Medicare beneficiaries who died during calendar years 2001 and 2002. The annual computer files are located on CMS's mainframe computer and may be found using the following dataset naming convention c@pig.#dbpc.deceased.benes.dodyyyy, where "yyyy" is equal to the calendar year in which the beneficiaries died. The format for this file is a text file and may also be found using c@pig.#dbpc.deceased.benes.format.

EXAMPLE: Computer file c@pig.#dbpc.deceased.benes.dod2001 contains information on all Medicare beneficiaries who died during calendar year 2001. Computer file c@pig.#dbpc.deceased.benes.dod.2002, contains information on all Medicare beneficiaries who died during calendar year 2002. Download both computer files and manipulate the data to determine those beneficiaries who died during fiscal year 2002 (October 1, 2001 - September 30, 2002). Then utilize the respective DMERC claims processing history files to identify any services/claims containing a paid date of service that is after the posted date of death.

PSCs and Medicare contractor BI units may consider conducting analyses to determine if healthcare providers continue to bill inappropriately after the results of this review have been completed (i.e., overpayments have been demanded and education regarding inappropriate billings have taken place). The PSCs and Medicare contractor BI units may consider developing an investigation on providers whose pattern of billings remains noncompliant.

On an annual basis, DMERCs shall submit an annual report on the accounting of the improper payments identified by the DMERC and respective overpayments recouped by the DMERC. This report shall be due on December 5th of each year. A copy shall be submitted to the RO and the Director of Benefit Integrity and Law Enforcement Liaison.

C.6. National Supplier Clearinghouse (NSC)

C.6.1. Background

The regionalization of DMEPOS claims processing presented the opportunity to consolidate the identification and ownership data of all DMEPOS suppliers in the Medicare program. The NSC, acting for the Centers for Medicare and Medicaid Services (CMS), is the central entity responsible for issuing Medicare supplier numbers, maintaining supplier identification and ownership data, as well as business data, and denying or revoking supplier billing numbers. The NSC shall maintain a national master file of all suppliers and share that information with the DMERCs for their responsibilities in provider relations and claims processing. The consolidated supplier files allow the NSC to identify, qualify, and associate suppliers that serve multiple areas. The NSC accomplishes that association by assigning a unique "base" number to a supplier having a single tax reporting or employer identification number (EIN) with multiple locations.

The base number will have modifiers identifying each of the branch offices or unique locations associated with that supplier from which items are provided to Medicare beneficiaries. The resultant Medicare NSC supplier billing number is supplied to the four DMERCs and is used by the DMERCs to establish supplier eligibility for claims payment. The NSC serves all four DMERCs equally in the conduct of its functions, and is not directly involved in the day-to-day conduct of DMERC business of claims processing, to preclude conflict of interest.

Concurrently with the regionalization, the CMS implemented new provisions of legislation and regulation.

OBRA 1990 added section 1124A(a) to the Social Security Act. The legislation requires suppliers to disclose information regarding the owners, managing employees or those with control interests in the supplier.

Regulations at 42 CFR 424.57(c) establish standards that suppliers shall meet in order to obtain and retain a Medicare supplier billing number. If a supplier is found to not meet those standards, the supplier's billing number application will be denied or the supplier's billing number will be revoked. Numbers so revoked will not be reinstated until the CMS is satisfied that all necessary recompense and/or remedial action has occurred and that the supplier will comply with the standards.

Both the disclosure of ownership and enforcement of supplier standards will be accomplished through the use of a standard supplier billing number application and a site visit.

In addition to System Security Requirements specified in Section H.9., the NSC is subject to the CMS's requirements for systems security, as stated in Pub 100-17, and privacy as stated in the Privacy Act of 1974, P.L. 93-579, and the corresponding regulations and general instructions.

The NSC shall have open and reciprocating communication among various lines of business with each DMERC, PSC, and the SADMERC in order to accomplish its mission.

C.6.2. Specific Staffing Requirements

The Director of the NSC is required to direct or oversee all activities and requirements outlined in this Statement of Work. The NSC shall retain a full-time business analyst. This analyst will maintain liaison with the DMERCs and CMS, sharing information and findings concerning fraud and abuse, trends, data, and analysis of supplier information. The analyst will be responsible for preparing reports for CMS on any requested information regarding the analysis of supplier file data.

The NSC shall retain at least one supplier education specialist tasked with providing/coordinating the education of Medicare DMEPOS suppliers nationwide concerning their NSC-specific requirements and responsibilities. The supplier education specialist will prepare oral, visual, and written presentations that will be presented to supplier organization and/or published on the NSC web site. This information shall also be shared with the DMERCs and the CMS Project Officer.

In addition, the NSC will maintain a Supplier Audit and Compliance Unit (SACU) with the mission of preventing fraudulent and unqualified suppliers from enrolling in the Medicare program and revoking such suppliers who are already enrolled. The manager of the SACU shall be a Certified Fraud Examiner (CFE) or Accredited Healthcare Fraud Investigator (AHFI) or have similar education qualifications. Team leaders in the SACU shall be encouraged to obtain CFE, AHFI, or education qualifications in fraud investigations. The SACU will: educate suppliers about the Medicare application process; participate in Medicare and DMERC sponsored fraud conferences, meetings, and discussions; serve as a point of contact for organizations such as GAO, OIG, FBI on NSC-related Medicare fraud issues; establish contacts among governmental fraud prevention agencies in areas of activity such as site visits; support the site visit process in general; and take whatever steps it deems reasonable, including appropriate travel, in compliance with existing regulations and laws to prevent fraudulent suppliers from gaining and keeping access to the Medicare program. The SACU will conform to the Internal Security Guidelines set forth in Pub 100-18.

C.6.3. New Applications

C.6.3.1. Review Process

The NSC shall process all new supplier applications for billing numbers and update supplier information in accordance with this statement of work, Provider Enrollment requirements in Pub 100-08, Chapter 10, other Manual requirements and existing laws and regulations. Where the Manuals do not address requirements for the 855S, the NSC shall use instructions for the 855B, where appropriate. This statement of work has precedence over any Manual requirements where there is a conflict.

The NSC shall have a completed supplier number application on the currently authorized Form 855S before it processes the application. The supplier shall have an active billing number before it may receive payment. A billing number cannot be assigned and no payment can be made to a supplier without a complete disclosure of ownership and other business information. In general, the supplier billing number will be effective as of the date it is awarded by the NSC. In the case of a pharmacy chain or physician, the NSC may award an effective date that coincides with the license effective date and/or established date, whichever is later, as long as that date is no more than 90 days prior to the date of receipt of the application by the NSC.

The NSC shall notify suppliers that section 1834(j) of the Social Security Act requires that (with the exception of medical equipment and supplies furnished incident to a physician's service) no payment may be made by Medicare for items furnished by a supplier unless the supplier has a valid Medicare billing number.

The NSC shall maintain the history of multiple occurrences of key data, have the capability to produce reports requested by the CMS on an ad hoc basis, and maintain all records until permitted to destroy them by the CMS Project Officer. Hard copies of all materials shall be stored in a secure location and shall be readily retrievable.

The NSC shall maintain a control system to track suppliers' applications. The control system shall accommodate the tracking of applications received, status, and time-in-process from date of receipt to date of assignment/denial of a billing number. The NSC is not required to send acknowledgement of application receipt. The NSC shall provide education and outreach to suppliers and applicants on how to check for receipt by NSC of submitted applications, and how to check on the status of applications in process.

The NSC's methodology for processing applications for billing numbers includes:

- Ensuring that all applications are complete and information is consistent internally; developing applications for missing or ambiguous information in accordance with Provider Enrollment Manual Requirements;
- Maintaining on its master file the capability for tracking multiple instances of supplier effective dates and revocation/inactivation dates and reporting same to the DMERCs;
- Assigning/denying a billing number;
- Capturing and transmitting NPIs; and,
- Notifying the supplier of disposition of the application

Applicants who are adding a new location, as opposed to relocating an existing location, may complete only those data elements on Form 855S that are being added, plus the basic information needed to identify the supplier. The applicant should not complete the entire Form 855S. If a current supplier is completing sections of the Form 855S to open a new location or make another change and the NSC notices that data are missing from the supplier's existing record, the NSC may ask the applicant to complete any section that is missing from the record. IRS documents are not required for additional location applications if one is already on file. In addition, IRS documents and insurance documents are not required for large (i.e., 25 or more active locations) chains. Such documents are also not required for reenrollments and reactivations.

C.6.3.1.1. Exemptions from Manual Requirements

- The NSC shall use overpayment data supplied monthly by the DMERCs instead of PSOR data to comply with overpayment checking;
- The NSC is not required to validate or process EDI or EFT agreements.

C.6.3.2. Verification

The NSC shall establish procedures in accordance with the Medicare Provider Enrollment Manual instructions to validate the information provided by applicants on the applications for Medicare billing numbers and additional documentation furnished. The NSC shall apply these procedures to all new applicants with the following exceptions for Medicare-enrolled entities: hospitals; skilled nursing facilities; home health agencies; physicians; ambulatory surgical

centers; and requests for additional locations submitted by established, multi-location supplier chains with 25 or more active locations.

Additional validation procedures shall include, at a minimum, the following actions:

- Matching applicant address with known addresses using industry recognized software;
- Matching applicant telephone number with known, in-service telephone numbers using industry-recognized software. The software shall correlate telephone numbers with addresses;
- Querying all existing records in the supplier file to determine if common owners correlate to multiple tax identifications, and to determine if different companies are reporting common names and/or addresses;
- Matching all applicants against those previously denied and maintaining records of all denied applicants for the purpose of identifying other actions needed, (e.g. further validation);
- Conducting a site visit for those suppliers requiring a site visit according to C.6.4. and using the OMB-approved site visit questionnaire at the physical location for which a number is being requested;
- Checking against the NSC database of licensure requirements to ensure that appropriate licenses have been included;
- Tracking dates that licenses, the comprehensive liability insurance policy, accreditation (if submitted) and certifications expire and notifying the supplier 60 days prior to expiration to submit updated licenses, insurance policy, and certifications prior to expiration;
- Revoking the billing number of suppliers whose license(s), comprehensive liability insurance policy, or certification(s) have expired;
- Ensuring that multiple numbers are not assigned to the same supplier for the same location;
- Verifying insurance policy with underwriter and ensuring that the NSC is a certificate holder;
- For licenses, comprehensive liability insurance policies, and certifications submitted within 60 days of expiring, following-up with supplier within 30 days of issuance of supplier number to secure new license, insurance policy, and/or certification.

In addition to the above procedures, the NSC shall use the CMS-approved on-line database service. This service will be used to verify compliance with standards for new applicants suspected of non-compliance with standards. The NSC shall deny billing number applications for new applicants and request revocation of any existing supplier who is found in non-

compliance of supplier standards. Initial applications that do not include necessary information or documentation will be developed in accordance with Provider Enrollment Manual guidelines.

Pharmacies shall furnish only a copy of their State pharmacy license, and not local licenses. State pharmacy licenses and licenses missing information (e.g., issue date, expiration date) shall be verified with the issuing agency.

C.6.3.3. Edits and Matching Procedure

The NSC shall maintain the national supplier file and develop editing and matching procedures to identify and share with the DMERCs supplier situations that might indicate fraudulent or abusive practices. The NSC shall have the capability to produce reports from their findings, at CMS's request, on an ad hoc basis. The following edits and matching procedures are required:

- Correlation of all ownership information, such as owners, managers and related businesses, to identify individuals or businesses that are common to multiple suppliers;
- Maintenance of multiple occurrences, for an audit trail or history, of key data fields in the supplier file; this history shall include the date the field was changed and the data field content;
- Matching the OIG listings of sanctioned individuals and businesses and the GSA list of debarred business to any occurrences on the national file;
- Check all previous/current supplier numbers and all previous/current locations for those suppliers with revoked supplier numbers for fraudulent or abusive practices and transmit the appropriate alert code to the DMERCs based on the results of this validation;
- ~~Comparison of the addresses in the NSC database to the National Change of Address (NCOA) files produced by the U.S. Postal Service (USPS) by using the services of one of the USPS approved contractors, and take steps to ensure that the data on the NSC files are correct.~~

Upon CMS request, the NSC shall check claims allowed data against supplier type and products/services to confirm that required licenses and certifications are on file with the NSC; develop for licenses and certifications and revoke supplier number for suppliers unable to submit required licenses and certifications.

C.6.4. Site Visits

All suppliers are subject to an unannounced site visit upon initial enrollment or reenrollment, except that physicians, certified Medicare providers, and suppliers with 25 or more active locations will not routinely be subject to site visits. Such suppliers will be visited if the NSC has concerns about a supplier's compliance with the standards, or on a small random sample basis.

The purpose of the site visits will be to verify the supplier's compliance with the standards as outlined in 42 CFR Section 424.57(c). During the site visit, photographs of the supplier's business will be taken for inclusion in the supplier's file on an as needed basis to be used as proof of non-compliance with supplier standards. The on-site inspector will write a report using the OMB-approved questionnaire, about the supplier visit for NSC action. If a site visit cannot be completed, the NSC shall notify the supplier that their compliance with all 21 standards cannot be determined and that they can re-apply.

The NSC shall provide to the on-site inspector information from the suppliers' recent billing history before they conduct on-site inspections. The on-site inspector shall compare this information with the suppliers' inventory and/or contracts for inventory and note inconsistencies on the OMB-approved questionnaire inventory section. For suppliers reporting inventory that is primarily maintained off-site or supplied through another company, an on-site inspection will be made to these separate location(s).

The NSC will maintain records of supplier site visits to assist in investigations and trend analysis. The on-site inspector will forward copies of applicable records to the NSC to support NSC decisions for denial or revocation of a supplier billing number.

The NSC will forward all cases of suspected fraud to the affected DMERC BI unit and the OIG/AUSA, as appropriate.

As resources permit, the NSC shall conduct random, out-of-cycle site visits to confirm compliance with supplier standards.

C.6.5. Changes to Supplier Information

All requests for changes to supplier information—i.e., changes of address, changes of ownership, etc.— shall be submitted on the Form 855S and signed by an authorized individual. The NSC shall comply with PEM requirements regarding timeliness of processing requests for changes. The NSC shall acknowledge, within 7 days of the completed change, by letter, postcard, e-mail, or telephone, the completion of processing the change, and include the date the change was made.

A change of ownership, as defined by the DMEPOS Supplier Enrollment Form (855S), of a supplier enrolled in the Medicare program through the NSC results in the issuance of a new billing number, unless the new owners assume all liabilities and the tax identification number of the existing supplier. Otherwise, the billing number may not continue to be used by the new owner. Changes of ownership require the submittal of a Form 855S by the new owners within 30 days of the change of ownership, along with a bill of sale, articles of incorporation filed with the State, and any other documents that show the exact nature of the transaction.

The outgoing owner(s) shall notify the NSC in writing over the signature of an authorized party that they are not the owner(s) of record as of the date of the change of ownership. The old supplier number shall be inactivated, and the new number will be effective with the date of the change of ownership, if all is in order including valid licenses and being established at the

location. All claims for items or services furnished between the date of the change of ownership and the issuance of the new number may be submitted upon the supplier's receipt of the new number.

Attorneys may not change information regarding a supplier without authorization by proper authority; however, the NSC will give information to an attorney if one or more of the following applies:

- The supplier has employed an attorney to represent the company;
- The owner is deceased and the attorney is the executor of the estate; or
- The supplier has filed for bankruptcy and the court has appointed the attorney to represent the company.

C.6.6. Reenrollment of Suppliers

The NSC shall ensure that supplier information on the supplier master file is up-to-date:

- The NSC will reenroll suppliers each year on a basis of 3 years after the initial enrollment or reenrollment. (Refer to 42 CFR § 424.57.) The reenrollment will be performed monthly, with one-twelfth of the yearly total to be initiated each month.
- The supplier number re-issuance/reenrollment process will consist of sending the supplier a printout of current supplier account information with instructions to the supplier to make any changes on the printout and sign the certification statement. The NSC shall instruct the supplier in the reenrollment letter how to recertify data elements that are not available from the supplier data file. The information shall be returned within 35 days or the supplier is subject to inactivation of its billing number.
- The NSC will perform site visits on reenrolling suppliers according to C.6.4., using the OMB-approved questionnaire. Site visits will not be conducted on suppliers with ~~\$34,000~~ \$60,000 or less in allowed charges in the previous year; however the NSC may conduct a site visit on any supplier if there is indication that the supplier may not be in compliance with the supplier standards. For suppliers who do not receive a site visit during their reenrollment year because they had less than ~~\$34,000~~ \$60,000 in allowed charges in the previous year, the NSC shall on a quarterly basis monitor allowed charges of such suppliers and conduct a site visit within 30 days for suppliers when allowed charges were more than ~~\$15,000~~ \$30,000 in any one quarter.
- Non-responding suppliers shall be inactivated within 60 days of mailing of the reenrollment package, with the exception of large chains (i.e., 25 or more active locations), which shall be given 92 days to respond. The NSC may grant one extension to a supplier or supplier chain of 60 days.
- The NSC shall work with suppliers with multiple locations to ensure an efficient process, such as all the locations scheduled for reenrollment in a year being scheduled together.

- Reenrollments may be signed by a delegated official.
- IRS documents and insurance documents are not required for large chains (i.e., 25 or more active locations). An IRS document will not be required for any supplier if there is no EIN change.
- Suppliers shall be required to submit copies of current licenses. The NSC is required to validate licenses with issuing agencies with the exception of physicians, certified Medicare providers, and suppliers with 25 or more active locations unless there is an indication that the license may not be valid (e.g., it was tampered with).
- The NSC is not required to check reenrolling suppliers against the FID.
- The NSC shall check suppliers against the MED and GSA debarment lists.

C.6.7. Alert Codes

The NSC shall receive and maintain “alert indicators” from the DMERCs about, at a minimum:

<u>Alert Code</u>	<u>Definition</u>
A	possible fraudulent or abusive claims identified;
B	overpayments;
D	violations of disclosure of ownership requirements;
E	violations of participation agreements;
L	suspended by DMERC outside alert code process;
M	supplier is going through claims appeal process.

The NSC shall append the supplier file and transfer to the DMERCs the following alert codes in the following circumstances:

<u>Alert Code</u>	<u>Definition</u>
C	violations of supplier standards;
F	sanctioned by the Office of Inspector General or debarred by the GSA;
H	Meets supplier standards; however, the NSC recommends increased scrutiny by the DMERC (initiated by NSC only); and

N Supplier being investigated under the “Do Not Forward” initiative (initiated by NSC only).

The NSC shall append an Alert Code “H” for any supplier that meets present supplier standards but appears suspect in one of the areas that are verified by the NSC. This alert code notifies the DMERCs that a supplier may be inclined to submit a high percentage of questionable claims.

The NSC shall share the above information with the DMERCs by sending alerts within 7 calendar days after identification of a supplier having common ownership or business ties with a sanctioned or suspect supplier for their research and/or action. The NSC also shall forward alert codes submitted by the DMERCs with the other DMERCs within 7 calendar days after receipt.

C.6.8. Inactivation of Suppliers

The NSC will receive from the SADMERC a quarterly electronic listing of suppliers who have not submitted claims for four consecutive quarters within 45 days after the end of the quarter. Physicians, ASCs, suppliers with 25 or more active locations, and suppliers who have updated records within the past 4 quarters are exempt from this requirement, except that chain suppliers with 25 or more active locations are to be inactivated for non-billing for 8 consecutive quarters. The NSC will send letters to inactivated suppliers within 45 days of receipt of the SADMERC list informing them that their billing numbers are being inactivated. The numbers will be inactivated as soon as possible, but no later than within 15 days of the mailing.

The NSC shall inactivate extra supplier numbers for the same location within 30 days of discovery of the extra numbers.

C.6.9. Denials, Returns, and Revocations

C.6.9.1. Denials

The following are reasons for denial of a supplier application:

- OIG Sanctioned – owner, managing employee
- Does not qualify as a supplier of service
- False information submitted
- Non-compliance with CMS Standards (21 supplier standards)

C.6.9.2. Returns

If a site visit cannot be completed, the NSC shall notify the supplier that the NSC cannot verify the supplier’s compliance with the 21 standards and shall advise the supplier that it may re-submit an application when a complete site visit inspection can be conducted. The NSC shall not deny the application.

C.6.9.3. Revocations

The NSC shall revoke a billing number if one or more of the following occurs:

- The supplier does not meet supplier standards in 42 CFR 424.57 as determined by the NSC;
- OIG has sanctioned the entity, and/or its owner(s), and/or managing employee(s), and that sanction is still in effect.
- The supplier is found to have submitted false information.
- The supplier is found to not qualify as a supplier of services.

The NSC shall request verification of compliance from the supplier via a process that ensures proof of delivery. The notification shall request a response in 21 days. If no response is received that verifies compliance with standards identified, the NSC shall recommend revocation to the CMS Project Officer. Upon approval from CMS, the NSC will notify the entity of its revocation within 7 days by the same process mentioned previously. The notice shall inform the entity of the reason for the revocation, its right to an appeal, and the instructions on how to submit a corrective action plan.

C.6.10. Appeals and Corrective Action Plans

The NSC shall provide an appeals process for suppliers who have been denied a supplier billing number or who have had their supplier billing number revoked in accordance with 42 CFR 405.874 and Program Integrity Manual instructions. The supplier must file its request for carrier hearing within 90 days after the postmark date of the initial determination letter that denied or revoked a supplier billing number.

The NSC shall provide for submittal of corrective action plans (CAPs) for denied or revoked supplier billing numbers. Upon the approval of the corrective action plan for a denial, the NSC shall issue a supplier billing number. CMS approval is required for reinstatement of a revoked supplier billing number. Submission of a corrective action plan shall contain, at a minimum, verifiable evidence of compliance and the sufficient assurance of the intent to comply fully with the supplier standards in the future.

The decision whether to request carrier hearing or submit a corrective action plan is solely at the discretion of the supplier. If a denied or revoked supplier decides to submit a corrective action plan more than 90 days after notification of the initial action, the plan shall include a completed 855S to ensure all information previously submitted remains accurate. Denied applicants that receive a billing number after hearing or corrective action will receive a billing number effective the date of issuance of the billing number.

C.6.11. Customer Service

Language in all routine correspondence to suppliers shall be approved by the COTR prior to issuance by the NSC. The NSC shall refer all beneficiary inquiries to the appropriate DMERC(s).

The NSC shall respond to customized requests for data on participating suppliers. If the inquirer does not have website access capability, the NSC will ascertain the nature and scope of each request and furnish the desired participation information via phone or letter. The NSC shall maintain liaison with the national and state supplier industry representative groups.

The NSC shall provide written and telephone customer services in accordance with C.4.4., as applicable, with the exception of the reporting requirements for the Form 1565. The NSC shall utilize an internal review process to continuously improve written and verbal communication. The NSC shall maintain a training plan for all staff based on surveys, trend analysis, and employee feedback. The NSC shall analyze supplier inquiries (both telephone and written inquiries) to identify specific areas of concern and use information gathered from such analysis to improve customer service through outreach and education activities. Written correspondence to suppliers shall contain sufficient information to allow suppliers to readily determine the actions the supplier shall take. The NSC shall work to install a system to monitor supplier telephone calls initiated by the NSC.

Allegations of fraud received by the NSC's telephone service unit shall be entered into a log and referred to the SACU for review, development and any further action. The complaint log shall list, at a minimum, the:

- Complaint and nature of the complaint;
- Name of the NSC representative who received the complaint;
- Date the complaint was received;
- Date the complaint was referred to the SACU or resolved by the NSC; and disposition of the complaint.

C.6.12. Participation Enrollment

The NSC shall conduct the annual participating supplier (PAR) enrollment in accordance with Pub 100-04, with modifications to fit DMEPOS supplier needs (e.g., fee schedule information should not be provided).

The NSC shall submit Section 2 of the Participating Physician/Supplier Report in CROWD.

The NSC shall maintain a link from the NSC website to the CMS Supplier MEDPARD website and shall supply CMS with a monthly file for this use.

C.6.13. Systems

The NSC shall maintain an on-line inquiry system for DMERC personnel and CMS authorized personnel at central and regional offices. The system shall be available for 25 hours or more per week. (The hours will be established to satisfy the needs of the DMERCs.) The NSC shall prepare, maintain, and provide a users' manual for all users of the NSC online inquiry system.

The NSC systems, files and all application programs shall be stand-alone modules, which will be portable to another contractor. All programs shall be written in industry standard language, widely used, readily maintainable.

The NSC will forward all non-routine FOIA requests for copies of information to the CMS FOIA Coordinator. Simple requests that are within the NSC's day-to-day operating capability and do not violate the Privacy Act will be answered directly by the NSC following CMS guidance. The NSC will create a supplier file for use by the NSC to fill requests for data. The information will be made available through a data cartridge, disk, or CD, as required by the user. Requests for this data shall be approved by the COTR.

This file, of all suppliers, will contain current information only, and will be refreshed each month, and will contain the following data elements:

- Supplier Number
- Supplier Company Name
- Supplier Individual Last Name
- Supplier Individual First Name
- Supplier Individual Middle Initial
- Supplier Individual Generation
- Supplier Individual Credential
- Supplier Street Address, City, State, Zip Code
- Supplier Telephone Number
- Supplier Mailing Address, City, State, Zip Code
- Supplier Participation Status
- Supplier Participation Date
- Supplier Specialty Code (up to 10)
- Supplier Status Code
- Supplier Status Date

~~The NSC shall maintain a link to the CMS website for the web-based version of the application form that suppliers may complete on-line, print, and mail to the NSC. The NSC shall work with CMS and its representatives in the implementation of PECOS.~~

C.6.14. HIPDB

The Secretary of the U.S. Department of Health and Human Services, acting through Office of Inspector General (OIG), was directed by the Health Insurance Portability and Accountability Act of 1996 to create the Healthcare Integrity and Protection Data Bank (HIPDB) to combat fraud and abuse in health insurance and health care delivery. The HIPDB, developed by HRSA (Health Resources and Services Administration), is an alert tracking system that serves as a comprehensive review of practitioners, providers, and suppliers of adverse action.

The NSC is required to participate in the data transmission of adverse suppliers who have had their supplier numbers revoked. Revocation of a supplier number, for purposes of this instruction, is the result of the supplier location failing one or more of the supplier standards.

The Data Bank ID (DBID) will allow NSC the ability to query the HIPDB. As NSC utilizes the HIPDB for more querying initiatives, additional registration numbers may be requested. The NSC will utilize the CMS DBID when submitting reports to the HIPDB on adverse actions against suppliers.

According to the Federal Register on October 26, 1999 the time frame for submitting reports to the HIPDB will be (1) within 120 days from the date the final adverse action was taken or the date when the reporting entity became aware of the final adverse action (the NSC will allow another 30 days for appeal), or (2) by the close of the NCSA's next monthly reporting cycle, whichever is later. If an error or omission is discovered after the final adverse action is reported, then NSC shall send an addition or correction to the HIPDB within 60 calendar days of the discovery. NSC will utilize the CMS DBID for submitting reports to the HIPDB.

NSC will submit a separate HIPDB file for each adverse action being recognized by the HIPDB. For example, if a total of 120 suppliers are being reported to the HIPDB during a single data transmission, 120 separate files will be created by NSC and transmitted to HIPDB.

Only adverse findings on organizational entities will be transmitted to HIPDB. Therefore, all files submitted will be categorized as organizations.

Monthly update files may or may not include: 1) additional supplier numbers who have been revoked or 2) suppliers who had previously received an adverse action and have now submitted an appeal or 3) suppliers who have submitted an appeal and their supplier number has been reinstated.

C.6.15. Collaboration with the Program Safeguard Contractor (PSC) and other Entities

When CMS issues a Program Safeguard Contractor (PSC) task order for DMERC program integrity and medical review workloads, the DMERC affected shall coordinate with the chosen PSC, the Statistical Analysis DMERC (SADMERC) and the DMERCs to assure crosscutting information is communicated between the entities. In addition, the DMERCs/SADMERC/NSC shall work with the PSC as needed.

In addition, the NSC shall:

- Share information with the OIG on suppliers related to sanctioned individuals or businesses;
- Release "alerts" for all associated businesses within 2 weeks of notification by a DMERC;
- Maintain daily file transmissions to the DMERCs of new and updated information;

- Support the DMERCs in the “Do-Not-Forward” initiative for both checks and remittance advices, including controlling all material received from the DMERCs in this effort, issuing appropriate and timely alert codes when required, developing the cases to determine whether the suppliers identified are still in compliance with supplier standards, and inactivating Medicare privileges where suppliers do not comply;
- Collaborate with independent accreditation organization(s) selected by CMS to implement the DMEPOS quality standards;
- Collaborate with the NPI enumerator for bulk enumeration purposes.

C.6.16. Performance Standards

For performance under this contract, the contractor shall be evaluated in accordance with Attachment J.6, “National Supplier Clearinghouse (NSC) Criterion.”

C.6.17. Deliverables

The NSC shall make the following deliverables to the CMS Project Officer:

- Complete documentation of any NSC system, program, implementation, and installation changes immediately upon incorporation of such changes;
- Management Reports
 - Monthly reports on budget allocation and usage;
 - Monthly reports on timeliness and production statistics;
 - Monthly reports on applications received, pending, processed, returned, and site visits;
 - Monthly reports on number and type of denials or revocations of billing numbers;
 - Quarterly reports on DNF initiatives with a courtesy copy to LROs.

C.7. Statistical Analysis DMERC (SADMERC)

The SADMERC has four primary functions:

- 1) The Health Care Common Procedure Coding System (HCPCS) codes, described in IOM Pub 100-04, Chapter 23, are used by suppliers, physicians and other providers to describe the items and services being provided to patients. The HCPCS currently includes two levels of codes as well as modifiers.

Level I is the American Medical Association’s (AMA) Current Procedural Terminology (CPT), which was developed and is maintained by the AMA. CPT lists five-digit numeric codes with descriptive terms for reporting services performed by health care providers.

Level II contains alphanumeric codes to identify professional healthcare services not included in CPT-4, ambulance, DME, orthotics, prosthetics, supplies and drug products.

Level II code/modifiers are maintained by CMS. DMERCs will continue to use WW codes to process claims for oral anti-cancer drugs.

Each DMERC shall participate in the decision-making process of the implementation of new DMEPOS codes and modifiers. The SADMERC shall be responsible for coordinating meetings and applying for national Level II codes/modifiers and may use resources or consultants other than the DMERC Medical Directors to obtain the information that is needed to support the appropriateness of recommendations to CMS concerning coding changes.

- 2) Manipulate, analyze, distribute, and store national DMEPOS claims history data;
- 3) Establish and distribute to the DMERCs national pricing files for OACDs and other drugs;
- 4) Conduct data analysis, including trend analysis of policy groups, on regional and national totals and provide on-going feedback to the DMERCs.

C.7.1. Administrative

The SADMERC shall maintain appropriate personnel. In addition to a full time or equivalent Director, staffing shall include a Medical Advisor and appropriate numbers of statisticians, data analysts, nurses and customer service representatives to perform data analysis, produce statistical reports, review product information, render coding decisions, and/or produce pricing data. Health care consultants with the appropriate specialty may be utilized for complex product reviews or when appropriate expertise is lacking.

The SADMERC shall have open and reciprocating communication among various lines of business with each DMERC/PSC as well as the National Supplier Clearinghouse.

Customer Satisfaction Surveys may be conducted periodically with various customers and in various formats such as questionnaire, call back or survey. The results of the surveys are to be documented for review and necessary action.

C.7.2. HCPCS Function

The SADMERC shall perform the following tasks:

- A. Provide DMEPOS coding advice as agreed upon by all 4 DMERCs. The SADMERC shall provide coding guidance to FIs, Medicaid State Agencies, physicians, suppliers, manufacturers, local carriers and other callers during the year. The SADMERC shall develop coding advice in conjunction with the all DMERCs and/or DMERC PSCs. All coding guidance shall be reflective of all the DMERCs. The SADMERC shall provide this coding advice to suppliers. Coding requests that the SADMERC submits to CMS for Alpha Numeric HCPCS Workgroup Level II codes shall not use price or coverage issues as the basis for coding decisions. Coding requests shall use the uniqueness of a product, and not its price or coverage considerations, as the justification for requesting a coding change or

addition. However, the SADMERC shall collect pricing information on the application for a code. The pricing information will be used by the DMERCs.

- B. Operate a HCPCS Help Line to provide DMEPOS coding advice. The SADMERC has lead responsibility for providing the public with coding information for level II HCPCS codes even if the code represents an item for which the local carriers rather than the DMERCs have jurisdiction. The SADMERC shall meet the general acceptable contractor standards for telephone inquiries and shall respond to telephone inquiries in a manner which meets or exceeds the following performance standard, as specified below:
1. Hold time (i.e., the time a caller waits for a customer service representative (CSR)); 85% or more of telephone calls shall be answered within 60 seconds.
 2. As CMS moves to improve its Telephone Customer Service delivery, this rate should continue to decrease in the future towards the eventual rate of zero. Capture the monthly All Trunks Busy (ATB) External Rate.
 3. Acknowledge each call within 20 seconds – not more than 4 rings before an agent or Automated Call Distributor prompt is reached. Reporting of this measure will not be required but shall be submitted when requested.
 4. Maintain a telephone information service to inform callers of a temporary delay before a customer service representative is available, if appropriate, and request that the caller have certain information readily available (supplier number) for speaking with the representative. For peak periods of operation, include a message indicating a preferred time to call (i.e., not Mondays) and the standard hours of operation. The service should contain capabilities for callers to leave messages when customer service representatives are not available.
 5. Measure the quality of service, ensuring that all Hotline representatives are monitored for quality call handling and processing on at least a quarterly basis for accuracy, knowledge, responsiveness, clarity, courtesy, and tone. Monitor an average of 9 calls per quarter per CSR. Focus monitoring efforts on new and at-risk CSRs who may have the greatest potential to benefit from feedback. Individual CSR data shall be analyzed regularly, areas needing improvement identified, and corrective action plans shall be implemented and documented. Monitoring should be conducted at the beginning, middle and end of the month.
 6. Test new Hotline representatives and, as appropriate, experienced representatives, for proficiency. Develop a corrective action plan to resolve deficient performance, and maintain results on file for CMS review.
 7. Maintain basic monthly telephone statistics, i.e., all trunks busy (ATB), hold time (i.e., the time a caller waits for next available customer service representative), number of calls handled per customer service representative, etc., sufficient to document performance level. Call Handling Measures shall be captured, as follows: (Note: All specified

information shall be captured and reported to CMS on a monthly basis. This information may be captured manually, if necessary.)

- a) Capture Call Abandonment Rate, which is the percentage of provider calls that abandon their call from the ACD queue. This should be reported as two separate measures:
 - 1) Calls abandoned up to and including 60 seconds;
 - 2) Calls abandoned after 60 seconds.
 - b) Capture the monthly Average Speed of Answer. This is the amount of time that all callers waited before being connected to a Helpline representative. It includes ringing, delay recorder(s) and music.
 - c) Helpline representatives shall identify themselves when answering a call. However, the use of both first and last names in the greeting will be optional. In order to provide a unique identity for each representative for accountability purposes, when a number of representatives have the same first name, it is suggested that the individual also use the initial of their surname. If the caller specifically requests that a representative identify himself/herself, the representative should provide both first and last name. Where the personal safety of the representative is an issue, call center management should permit the individual to use an alias. This alias shall be known for remote monitoring purposes. Helpline representatives should also follow local procedures for escalating calls to supervisors or managers in situations where warranted.
 - d) Capture monthly Average Talk Time (which includes any time the caller is placed on hold by the Helpline representative).
 - e) Handle no less than 90% of calls to completion during the initial call – minimizing transfers, referrals and callbacks.
 - f) Track Call Center call handling productivity, calculated by the total calls handled divided by the total Helpline FTEs in the center.
 - g) Capture Occupancy Rate, the percent of time that Helpline representatives spend in active call handling (i.e., on incoming calls, after call work or outbound calls).
8. Report the status of those calls not resolved at first contact. Those calls shall be reported as follows:
- a) Callbacks required (This number is based on calls received for the calendar month and represents the number requiring a callback as of the last workday of the month)
 - b) Callbacks closed within 5 workdays (This number is based on calls received for the calendar month and represents the number closed as of the last workday of the month)

9. The SADMERC shall report the required telephone customer service data elements on an Excel spreadsheet and provide the sheet, with updated monthly information, to the Project Officer between the 1st and the 10th of each month for the prior month. Any data changed after the report is submitted shall be presented to the Project Officer with a written explanation as to why the data was corrected or missing from the original report.

10. Availability of Telephone Service: The CSR telephone service shall be available to callers continuously during normal business hours, including lunch and breaks. The center extends to all time zones due to the national requirements for this center. The normal business hours for live telephone services are defined for this center as 9:00 a.m. to 4:00 p.m. with a late night each Wednesday to 6:00 p.m..

If the center chooses to request permission to perform other call center work in lieu of answering telephone inquiries on Federal holiday, the Project Officer shall be notified. In cases of emergency closure of the center the Project Officer shall be notified. The call center shall notify the supplier community of any closure.

11. Due to the nature of calls coming into the SADMERC call center, an Interactive Voice Response (IVR) will not be required. In place of this automated tool, a “self-help” tool of a web based HCPCS dictionary will be maintained. This dictionary will be used for HCPCS Level II codes/modifiers that are maintained jointly by CMS.
 - a) The tool shall be available to providers 24 hours a day with allowances for normal maintenance to the web site. The tool shall be updated to include new coding and pricing information. The product is an online application that provides HCPCS coding assistance and national pricing information 24 hours a day. The product is designed to help Medicare providers and suppliers quickly classify durable medical equipment, prosthetics/orthotics, and supplies (DMEPOS) by combining information from a variety of sources to make HCPCS coding determinations for claim submission to the DMERCs easier.
 - b) The first phase of the product will include a HCPCS and fee schedule look-up with capabilities to print or download information. Future enhancements will include SADMERC Classification Lists, sample product pictures, and a coding navigator tool that categorizes and combines HCPCS codes in a format that allows one to easily determine how to code a product.

12. Toll Free Network Services: The provisions outlined in 20.1.1 apply to SADMERC operations and they use toll-free numbers provided for the supplier. The lines are provided under the FTS 2001 support. The SADMERC Project Officer shall be notified if a Disaster Recovery situation exists.

13. The SADMERC toll-free number shall be posted in DMERC Supplier Manuals and on the web sites for DMERCs and the SADMERC.

14. The SADMERC provides training to meet the needs of the customer service representatives on the helpline concerning the coding of DMEPOS. The helpline does not provide claims information. The Next Generation Desktop is not applicable to SADMERC operations.

C. The SADMERC Medical Advisor shall:

1. Provide medical advice with regard to complex product reviews and research of products;
2. Review consultants' comments on product reviews;
3. Attend select Alpha-Numeric workgroup meetings in person and participate in all other meetings by conference call;
4. Assist with special law enforcement requests for coding;
5. Participate on HCPCS conference calls (DMDs, coordinators, special project calls);
6. Participate on weekly RMRP conference calls with DMERCs and CMS;
7. Attend and participate in Statistical Analysis Coordinating Committee (SACC) meetings;
8. Assist with the efforts of the crosswalk of National Drug Codes (NDC) to HCPCS Codes quarterly. The files shall be in Excel and flat file format. The files shall be distributed to CMS, DMERCs and the DMERC standard system. The SADMERC shall post the NDC/HCPCS crosswalk file on its web site. The file will also include pricing information; and,
9. Coordinate the efforts of consolidating the current ww codes for oral anti-cancer drugs. Work with the HCPCS Committee to delete unnecessary ww codes once consolidation is complete. When assigning new ww codes, use consolidation methodology.

D. Written Inquiries

1. All written inquiries shall be processed in accordance with the guidelines provided in the IOM Pub 100-09, Chapter 3, § 20.2
2. The SADMERC shall stamp all written inquiries with the date of receipt in the corporate mailroom and control them until a final answer is sent. In addition, it shall:
 - a) Answer inquiries timely;
 - b) Not send handwritten responses;
 - c) Include a contact name and telephone number in the response;
 - d) Keep responses in a format from which reproduction is possible; and,

- e) Include the CMS Alpha Representation on all written responses, except for email responses.
- 3. The SADMERC shall develop a correspondence Quality Control Program (containing written policies and procedures) that is designed to improve the quality of written responses.
- 4. All written inquiries shall be processed using a font size of 12 and a font style of Universal or Times New Roman or other similar style for ease of reading by the beneficiary.
- 5. The SADMERC will have the flexibility to respond to supplier written inquiries by phone within 45 calendar days. A report of contact should be developed for tracking purposes. The report of contact should include the following information: supplier's name, address, and telephone number, date of contact, subject, summary of discussion, status, action required (if any) and the name of the customer service representative who handled the inquiry. Upon request send the supplier a copy of the report of contact that results from the telephone response. The report of contact should be retained in the same manner and timeframe as the current process for written responses. Use your discretion when identifying which written inquiries can be responded to by phone. For example, the SADMERC shall not respond to requests for product reviews via telephone. If you cannot reach the requestor by phone, do not leave a message for the supplier to return the call. A written response shall be developed within 45 calendar days from the incoming inquiry if the matter cannot be resolved by phone.
- E. Any email inquiry received may be responded to by email. Since email represents official correspondence with the public, it is paramount that the SADMERC use sound email practices and proper etiquette when communicating electronically. Responses that are personal in nature (contain financial information, HIC #, personal health information, etc.) shall not be answered by email.
- F. Written responses to requests for product reviews shall be completed within 90 days, unless documentation is provided that additional research is warranted or product information has been requested.
- G. The SADMERC shall utilize an internal review process to continuously improve customer service. As a minimum, the process should include such measures as ongoing quality control of telephone and written inquiries, customer satisfaction surveys and other activities to ensure that the quality of customer service is continuously improving.
- H. The SADMERC shall maintain and conduct analysis of the most common coding questions and answers and/or HCPCS information.
- I. The SADMERC shall respond to inquiries for HCPCS database copies as described below:

1. Requests for hardcopy Level I HCPCS (CPT) codes/modifiers shall be referred to the AMA.
 2. Requests for hardcopy or tape Level I HCPCS (CPT) codes/modifiers including the Medicare fee schedule data shall be referred to the CMS's Program Development and Information Group, or CMS's Web Site.
 3. Requests from the public for hardcopy Level II HCPCS codes/modifiers shall be referred to the GPO.
 4. Requests from the public for the Level II HCPCS tape shall be referred to the National Technical Information Section.
- J. The SADMERC shall participate in CMS's Alpha Numeric (ANWG) HCPCS Workgroup, which meets in Baltimore approximately once per month. The SADMERC shall attend in person or by conference call as deemed necessary by the ANWG Chair. Each DMERC will receive a meeting agenda and background material from CMS prior to the meeting.
1. After each DMERC has received the meeting agenda and background material, the SADMERC shall organize a conference call. The conference call shall include all of the DMERCs and discuss each DMEPOS coding issue prior to the CMS meeting. The SADMERC shall attend the ANWG meeting prepared to share the opinions of the DMERCs on each DMEPOS issue. Rationale or other information to support the DMERCs' opinion shall be collected by the SADMERC from each DMERC. The SADMERC is responsible for the coordination with the DMERCs to analyze the code review as well as the information coming from and going to the Alpha Numeric HCPCS Workgroup. Consultant services may be utilized, as the SADMERC deems necessary.
 2. A database with data entry and look-up capability shall be maintained by the SADMERC and accessible by the ANWG for the record keeping of requests to the ANWG. The SADMERC shall assist the ANWG as requested with quality assurance to verify the accuracy of the database, agendas, minutes, and code releases.
 3. The SADMERC shall assist members of the ANWG with research, product analysis and consultative services for non-DMERC related items if requested by the ANWG.
 4. The SADMERC shall conduct periodic analysis of HCPCS policy groups/code sets and present to CMS for discussion. These discussions may be made in person at Central Office, depending on the significant findings and recommendations of the report. The proposals may be presented to the ANWG for discussions. All coding additions, revisions and/or deletions shall be approved by the ANWG prior to implementation. The SADMERC may use resources or consultants other than the DMERC Medical Directors to obtain information that is needed to support the appropriateness of recommendations to CMS concerning coding.

5. The SADMERC shall create and maintain the Alpha-Numeric Workgroup Tracking Data Base.
 6. The SADMERC shall participate in person in the Open Door Forums (public meetings) related to the coding of ANWG items. Following the meetings, the SADMERC may be asked to assist members of the ANWG with research, product analysis and/or consultative services for both DMERC and non-DMERC related items in the Reconsideration Process. The SADMERC shall participate (by conference call or in person as deemed necessary by the ANWG Chairperson) in the Reconsideration Process meetings following the Open Door Forums. The SADMERC shall present the results of any additional research, as well as render opinions on, any items being considered in the Reconsideration Process.
- K. Throughout the year, the SADMERC shall coordinate the submission of all DMERC requests to add, revise and/or delete temporary and permanent Level II HCPCS codes and modifiers. The SADMERC shall obtain documentation supporting the request (i.e., claims volume, rationale) when needed by the Alpha-Numeric HCPCS Workgroup. A SADMERC representative shall present the requests for approval at the next workgroup meeting. All coding additions, revisions and/or deletions shall be approved by the workgroup prior to implementation. The SADMERC may use resources or consultants other than the DMERC Medical Directors to obtain the information that is needed to support the appropriateness of recommendations to CMS concerning coding.
 - L. The SADMERC shall coordinate with the DMERCs to track and analyze the utilization of miscellaneous codes, including inquiries received from the Helpline. When appropriate (based on volume of claims, frequency of calls, pricing difficulties, etc.) the SADMERC shall pursue unique Level II HCPCS codes through the Alpha-Numeric HCPCS Workgroup.
 - M. The SADMERC shall submit change request (CR) packages to implement all additions, deletions, and/or modifications of temporary Level II HCPCS codes and modifiers. CRs shall be submitted in the established format and in a timely manner to CMS Central Office with a copy to the Project Officer. Each CR shall be approved through the CMS Change Management process prior to being scheduled for implementation.

CRs shall contain, in addition to the required standard information, the following information for each code:

1. Proposed code and descriptor;
2. CWF and DMERC DMEPOS categories;
3. Type of service;
4. Place(s) of service;
5. Pricing category; and,
6. SADMERC policy group classification

CRs for all permanent Level II code additions, deletions, and/or modifications will be initiated by CMS Central Office. Such will be recognized in CWF with the implementation of the next annual HCPCS update.

CMS will notify the SADMERC of the date the new temporary Level II code will be recognized by CWF. The SADMERC shall then notify the DMERCs of this date.

- N. The SADMERC shall communicate with the DMERCs monthly via telephone conference regarding coding questions and distribute minutes of the conference calls to each DMERC.
1. The SADMERC shall develop DMERC Advisory articles, written in conjunction with the DMERC Medical Directors as needed. The articles should be submitted to each DMERC for inclusion in each of their quarterly newsletters

C.7.3. Statistical Analysis Function

The primary statistical analysis functions of the SADMERC shall include:

- A. On a daily basis:
1. Receive electronic transmissions from CMS that contain claim records processed by the DMERCs;
 2. Apply adjustments as appropriate; and,
 3. House and manipulate national DMEPOS claims history data.
- B. On a quarterly basis:
1. Generate DMEPOS data reports according to CMS specifications (minimal reporting requirements are listed in Attachment J.8);
 2. Analyze national and regional reports to identify trends, aberrancies, etc., via the SADMERC Abstract. The SADMERC Abstract should include a comparison of data from one or more DMERCs with the same or similar data from the other DMERCs and/or with the national data. In addition, the SADMERC Abstract should identify specific areas and/or situations, including data analysis of suppliers who conduct business in at least three DMERC regions, that may indicate a potential for fraud and abuse and/or over-utilization warranting possible action by one or more DMERC;
 3. Maintain reports and the SADMERC Abstract in WebI (an online warehouse containing various reports and documents). The DMERCs will use these reports and Executive Summary to guide them in the development of region wide MR policy, and for use in identifying cases for prepayment and/or post payment medical review of national and local suppliers;

4. Produce a quarterly electronic report of suppliers who have not submitted claims in four consecutive quarters. This report shall be sent to the NSC within 45 days after the end of the quarter. The NSC will use this file to determine which supplier numbers it should deactivate; and
 5. Develop and distribute the procedure report (PROC1) in an electronic format upon request to the DMERCs, CMS, CO and/or ROs.
- C. On an annual basis:
1. Generate a report which identifies the top 200 ordering physicians, and send the report to the DMERCs and CMS;
 2. Act as a resource to the DMERCs and CMS by: (1) producing up to five special request reports per month as specified by the DMERCs and up to ten special reports per month for CMS staff and (2) answering DMERC/CMS data questions as they arise;
 3. Produce and forward special request reports within 30 days; and
 4. Coordinate and facilitate meetings of the benefit integrity and medical review staff of the four DMERCs. A minimum of two Statistical Analysis Coordinating Committee (SACC) meetings per year shall be conducted. Additional meetings may be held on an as-needed basis. The SACC meetings shall be attended by staff from SADMERC management, analysts and medical review liaison. Others may be required to attend depending on the topics to be covered at the meeting.

C.7.4. National Pricing Function

The SADMERC shall:

- A. Follow CMS directives in establishing Oral Anti-Cancer Drug (OACD) pricing and distribute such to the DMERCs. The SADMERC shall include OACDs when establishing and distributing national pricing files (and updates) to the DMERCs. Pricing updates shall be associated with each OACD by the national drug code (NDC). The pricing update calculation shall be based on Average Sales Price.
- B. For National Drug Codes (NDCs), update and maintain the crosswalk between NDC to the appropriate HCPCS code. This will include the conversion factors that will be used to price the applicable DMERC billings to allow processing of claims filed using the NCPDP format. As needed, request the addition, revision, or deletion of HCPCS codes to accommodate the new NDCs as published in Redbook. The update of each HCPCS drug code applicable to DMERC billing shall be completed on a monthly basis and the crosswalk and pricing files shall be delivered to CMS. The files may then be downloaded (via NDM) by the DMERCs and the systems contractor for the DMERC standard systems. The standard systems maintainer will provide the flat file format that is appropriate to their system. The SADMERC shall post the crosswalk on the SADMERC web site.

C. For oral anti-cancer ww codes, SADMERC shall consolidate and delete unnecessary codes.

C.7.5. Collaboration with DMERCs and NSC

The SADMERC shall have open and reciprocating communication among various lines of business with each DMERC, the PSC and the National Supplier Clearinghouse. SADMERC staff should develop a list of projects or ideas for reports analysis to be conducted in a joint effort with DMERCs (i.e., special projects such as universal product numbers).

C.7.6. Collaboration with the Program Safeguard Contractor

When CMS issues a Program Safeguard Contractor (PSC) task order for DMERC program integrity and medical review workloads, the DMERC affected shall coordinate with the PSCs, the Statistical Analysis DMERC (SADMERC) and the National Supplier Clearinghouse (NSC) to assure crosscutting information is communicated between the four. In addition, the DMERCs/SADMERC/NSC shall work with the PSC as needed.

