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NOMINATIONS OF DR. MARK B. McCLELLAN, BRIAN ROSEBORO, DONALD KORB, AND MARK J. WARSHAWSKY

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

ON THE

NOMINATIONS OF

MARK B. McCLELLAN, TO BE ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES; BRIAN ROSEBORO, TO BE UNDER SECRETARY, DEPARTMENT OF THE TREASURY; DONALD KORB, TO BE CHIEF COUNSEL, INTERNAL REVENUE SERVICE AND ASSISTANT GENERAL COUNSEL, DEPARTMENT OF THE TREASURY; AND MARK J. WARSHAWSKY, TO BE ASSISTANT SECRETARY, U.S. DEPARTMENT OF THE TREASURY

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MONDAY, MARCH 8, 2004

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

The hearing was convened, pursuant to notice, at 2:05 p.m., in room SD–215, Dirksen Senate Office Building, Hon. Charles E. Grassley (chairman of the committee) presiding.

Also present: Senators Hatch, Snowe, Kyl, Thomas, Frist, Baucus, Rockefeller, Breaux, Graham, and Jeffords.

OPENING STATEMENT OF HON. CHARLES E. GRASSLEY, A U.S. SENATOR FROM IOWA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. Good afternoon, everybody. You can tell from the audience that this is a very important nomination hearing. We welcome everybody to it as well. We are here this afternoon to consider four nominations. One is for administrator for the Center of Medicare and Medicaid Services, and three others for the U.S. Department of the Treasury. I would welcome all of our nominees to the committee.

First, we have Dr. Mark McClellan, nominee for the administrator of Centers for Medicare and Medicaid Services. Dr. McClellan, of course, is no stranger to members of this committee because he served on the President's Council of Economic Advisors 2001–2002. There he developed a strong working relationship with the Congress, providing expertise on a number of domestic economic issues, including creating a prescription drug benefit for Medicare.

He is uniquely qualified for CMS, holding both M.D. degrees with board certification in internal medicine and a Ph.D. in economics. In recent years, Dr. McClellan has focused his research on meas-

uring and improving quality of care, particularly health care. Improving the quality of health care is what we will be talking about here today as you all know.

One of the most important issues facing this committee is overseeing the implementation of the Prescription Drug bill that we passed last year. After years of debate, after years of inaction, Congress followed through on its promise to our Nation's seniors to strengthen and improve the Medicare program by adding prescription drugs. It will be critical to have an experienced leader at the helm of CMS to ensure the agency is preparing to carry out the details of this new program.

We look forward to your testimony, Dr. McClellan, and on the programs, anything else that you might have to tell us or to answer questions.

We also have on our panel this afternoon Brian Roseboro. President Bush nominated him for Under Secretary for Domestic Finance at the Department of Treasury. He holds an MBA from Columbia. He currently serves at the Treasury Department as Assistant Secretary of Financial Markets, a position that he has served in with distinction since 2001. In this position, Mr. Roseboro was responsible for advising the Secretary on Federal credit policies, and government lending, and privatization activities.

We will also hear from Mr. Donald Korb who has been nominated to serve as chief counsel for the Internal Revenue Service, and also as assistant general counsel of Treasury. Mr. Korb is a native of Ohio, holding a masters of law in taxation from Georgetown. He has also an impressive 30-year record of tax lawyer, including service in the Office of Chief Counsel of IRS and 2 years as assistant to the IRS commissioner.

Finally, we will hear testimony from Mark Warshawsky who has been nominated to serve as Assistant Secretary of Economic Policy, Department of Treasury. Mr. Warshawsky holds a Ph.D. from Harvard, and has extensive experience as an economist, since 2002, serving the Department of Treasury as Deputy Assistant Secretary for Microeconomic Analysis.

Again, finally, I would like to welcome all of you and look forward to hearing your testimony.

We have an opportunity to have with us the Secretary of Health and Human Services, Tommy Thompson. He is with us today, as I understand it, to introduce. I am glad to have him here because I think it highlights two things: the importance of the position of CMS within the Department, but more importantly I hope to emphasize the importance of getting the prescription drug program up and running very quickly.

Senator Baucus is ready to speak.

OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA

Senator BAUCUS. Thank you, Mr. Chairman.

Today is a pretty important day. We have four people who wish to serve, and they all have very tough jobs. We live in I think somewhat uncertain times. Since December 2000, for example, as a country we have lost more than 3 million private sector jobs; that is no small matter. A lot of people are struggling to try to make

ends meet. Some are doing okay, but many not. Some businesses, particularly small business, are having a tough time retaining benefits, particularly health benefits, for their employees.

I saw an article in today's paper where it is much more expensive to build a car in the United States than it is in neighboring Canada due almost entirely to the much higher healthcare cost for American automobile manufacturers constructing autos in the United States compared to other countries, which has a very direct effect on the number of good high-paying jobs that we have in this country.

I must say to all four of you that the President has nominated you to work on these programs. They include access to affordable health care; our National debt is no small matter either; faith in our tax system; and the economic policies of our country. These are big issues.

Dr. McClellan, you have a record of public service and a reputation as a thoughtful policymaker. And because you have a reputation for caring more about sound policy than ideological rhetoric, you have good relationships with both sides of the aisle. If anyone is up to the job of administering the Centers for Medicare and Medicaid Services and implementing the groundbreaking Medicare bill that Congress passed last year, you may be the man. You have a huge job ahead of you.

Last year, Congress finally passed legislation to provide drug coverage under Medicare. The new law is long. It is complicated. It includes many new and untested ideas. I was proud to help pass that law. It is not perfect as I have often said, but neither is it as bad as some claim. And, frankly, I have been disappointed by how some on both sides of the issue have tried to criticize the bill. Rather, we should be working on how to implement it, and we should view it as something that we can build on and something that we can work together to improve upon.

For the next several months, much of that work will fall on your shoulders, Dr. McClellan, and those at CMS. And by my count, the new law contains 598 uses of the word/words "The Secretary shall" or "the CMS Administrator shall." You will, of course, be constrained by the terms of the law and congressional intent. But many of those "shall" provisions will require judicious interpretation by you within the law and attentive oversight by Congress. I for one plan to exercise vigilant oversight of Medicare implementation. And so as we move forward on this process together, my main message to you is to urge you to maintain transparency, maintain communication and maintain access. If we are to administer this law properly and provide the benefits to our seniors in the manner that they deserve, Congress and CMS must work together openly and honestly.

You might know that I am concerned that access to the CMS career actuaries has been restricted by this administration. Restricted access is contrary to the legislative history in the 1997 Balanced Budget Act, which sought to get Congress and the Administration to work together as legislation is formulated. If Congress had been given open access to the CMS actuaries during last year's debate, we would have had a much more full picture of the cost implications and operational workings of the new Medicaid law.

In Medicaid, I am also concerned about what are called 1115 waivers, experimental projects or demonstrations that you or the Secretary can approve that go against one or more of the requirements in the Medicaid statute. I believe that it is inappropriate for the administration to use these waivers to undermine fundamental underpinnings of the Medicare program, like the individual entitlement, and the states' entitlement to matching payments for services they provide. The administration's continuing push to use these waivers to cap allotments for state Medicaid programs is wrong as a matter of policy and wrong as a matter of process. Ironically, hard caps on Medicaid spending reduce the flexibility of the program, not increase it.

I oppose block grant proposals for Medicaid. I also believe that changes to Medicaid should be legislative, not simply done through the 1115 waiver process. Congress designed this waiver authority to allow demonstrations and experimentation, not wholesale change of an entitlement program that provides health security to 40 million low income and disabled Americans. If the administration does promulgate these waivers, it should put them forth in the light of day, with all stakeholders, including Congress involved.

Dr. McClellan, thanks for being here. You have proven yourself, as I mentioned, to be an able public servant, and I appreciate your contribution to our nation's healthcare programs. As head of the largest healthcare buyer in the world, and as steward of programs assuring tens of millions of Americans, you have important tasks ahead of you. I look forward to working with you as you take on these tasks, and I urge my colleagues to support your nomination.

Brian Roseboro, you have served the Treasury since 2001 as Assistant Secretary for Financial Markets. In that capacity, you have been responsible for managing the debt of U.S. Treasury, which unfortunately has been growing by leaps and bounds. This is a critical job, and you have done it well. We know that you are going to have to increase the ceiling on debt yet again this year, and I want to find out from you today how soon you will need to act. The President has nominated you to the higher position of Under Secretary for all domestic finance, and I feel that you are well-qualified to take on these additional responsibilities.

Mark Warshawsky, you have served at the Treasury since 2002 as Deputy Assistant Secretary for Microeconomic Analysis at Treasury and the Acting Assistant Secretary for Economic Policy. And now the President has nominated you to be the Assistant Secretary for that Treasury office. I believe that you are also well-qualified.

This is a critical time for determining the economic policy of this country. We have lost more than 3 million private sector jobs since December 2000, and things are not getting much better. Last Friday, we learned that the economy created just 21,000 new jobs in February. That is not enough. The private sector created no new jobs last month. All the new jobs came from the government, and manufacturing jobs declined for the forty-third straight month. We have to do better, and, Mr. Warshawsky, you have an important role.

Finally, Donald Korb, you are a well-regarded pick to be the country's next IRS chief counsel. In the past few years, we have

witnessed more than enough corporate accounting scandals. Consumer investor confidence has been shaken. At the same time, the integrity of our voluntary tax system is under attack by those engaged in the promotion of abusive tax transactions.

We are also witnessing growth in outright tax fraud. Everyday there are press reports describing ways in which unscrupulous actors are cheating the tax collector and their fellow taxpayers. Just as the Congress has taken steps to restore accountability and transparency in the markets, it must take similar steps to ensure the integrity of our tax system.

Actions speak louder than words. I know the administration has made some progress in the area of issuing regulations to address tax shelters, but they have not been enough. It has been almost 2 years since Enron, and the Congress has yet to enact major tax shelter legislation and response. We need the Baucus-Grassley Shelter bill in the law. The bill includes these provisions. It is time to get them signed into law. And, Mr. Korb, I am looking forward to hearing from you today about how we are going to better enforce our tax laws, and more precisely, if not eliminate, substantially reduce that $311 billion tax gap.

Again, thank you for your willing to serve. It is a tough job all of you have, and I know a lot of Americans very much appreciate the time and dedication you are going to put in to serving them. Thank you.

The CHAIRMAN. I apologize to our distinguish ranking member. I almost forgot to call on him. That is a tradition, and I should not have done that.

But, Mr. Secretary, you are going to have to wait just a minute because we also have another tradition. If leaders, Democrat or Republican, come, we usually let them speak or ask questions because they have other obligations. So I call on Senator Frist. And if Senator Daschle comes, I will also break in for anything he has to say.

OPENING STATEMENT OF HON. WILLIAM FRIST, A U.S. SENATOR FROM TENNESSEE

Senator FRIST. Thank you, Mr. Chairman. I do want to thank the chairman and the ranking member for holding this important nomination hearing, and want to recognize all four of the nominees, and thank them for their willingness to serve at a very important time in the history of this country.

Mr. Roseboro, Mr. Korb, Mr. Warshawsky, I, again, wanted to welcome you in particular. I know much will be said about them.

Mr. Secretary, thank you for being here, as always, and your commitment to big issues, big issues before the United States of America and big issues in particular to the field that I care very, very much about as a physician. I am extremely pleased to join my colleagues in welcoming all of you.

And then, in particular, Dr. Mark McClellan, the current commissioner of the Food and Drug Administration and future administrator of the Centers for Medicare and Medicaid Services.

It was a real delight for me, as I was preparing for all of our nominees today, to go back to Dr. McClellan's bibliography and read such things as Risk and Cost of End Stage Renal Disease after Heart Transplantation. Those are sort of the articles, in par-

ticular, that I focused on. I doubt that anybody else in the panel with me spent a lot of time. Or Trends in Hospital Treatment for Ventricular Arrhythmias Among Medicare Beneficiaries. I found that in particular of interest.

The CHAIRMAN. We are glad we only have one of you.

[Laughter.]

Senator FRIST. That is right.

So anyway, you are going to have a very complete look today as we look at, both the responsibilities of CMS, and in particular, your qualification for this particular position. It is in this day and time one of the most crucial positions in our U.S. Government, especially in light of the fact that we have just passed really landmark legislation, in large part, by members on this particular committee. The administrator also oversees programs that provide health coverage for nearly 80 million people, health care which does affect every American. But these programs oversee the health care for 80 million individuals. That is seniors, individuals with disabilities, low-income children, pregnant women, and the list goes on.

The challenges that CMS faces today are perhaps greater than at any other time in the agency's history, not just because of the numbers, but the unique challenges that face us today in interpretation and implementation of what we have just passed in this landmark legislation and facing issues such as the uninsured, 40 million individuals that over the course of a period of time do not have health insurance.

It is important that we act quickly. And again, I thank the chairman and the ranking member for holding this hearing, particularly for the nomination of Dr. McClellan, in an expeditious way because of the issues that we have laid out in that most recent legislation.

Dr. McClellan is well known to members of this committee. He has held a series of high-level executive branch positions in both the current administration and in the past administration throughout his service and throughout the years. He has really provided invaluable, objective insight that we might not otherwise have access to. I say this having personally benefitted from his thoughtfulness, for the care with which he has approached very, very complex issues. He is a clear-headed thinker, a superb policy analyst, a bold leader, and, yes, a physician who has traveled through that eye of the needle of the very best residency programs in the United States of America, in Boston, and having been on the faculty at Stanford on the West Coast, again, an outstanding academic healthcare center. Again and again, he has demonstrated this objectivity, this hard work, this discipline way of thinking that we all have been able to benefit from.

Mr. Chairman, I will put the remainder of my remarks in the record because I know that there are a number of people who would like to speak and want to hear from the Secretary. But I do want to close by saying that Mark's unique background in coupling and understanding of economics, and we know that the cost issues of health care are first and foremost on everybody's mind, with that aspect of personalization, doctor-patient relationship, having spent time with patients, knowing the importance of prescription drugs, of appropriate counseling, of trust in the doctor-patient relationship

That background makes him uniquely qualified to serve as the administrator.

So I look forward to hearing the testimony this afternoon. I look forward to the confirmation itself. And look forward, especially, in working with Dr. McClellan in the coming weeks, months, and years as we all together try to develop and foster an environment where we can deliver the highest quality health care possible.

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

The CHAIRMAN. Thank you. I have already introduced the Secretary, so we would receive your testimony now.

STATEMENT OF HON. TOMMY G. THOMPSON, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Secretary THOMPSON. Thank you very much, Mr. Chairman, Senator Baucus, and other members of the Finance Committee. Thank you for giving me this opportunity to introduce Mark McClellan.

I have heard all of your comments, and, like you, I am very impressed by this very wonderful young man. I am delighted to be able to have this opportunity to present a brilliant economist, a compassionate doctor, and our enthusiastic choice to lead the Centers for Medicare and Medicaid Services, Dr. Mark McClellan. You all know Dr. McClellan and his stellar background and qualifications. I do not know anyone who has a better grasp or more thorough understanding of healthcare economics.

Over the past year and a half, Dr. McClellan's leadership has been critical in transforming the FDA into a more responsive, more transparent, and more consumer-oriented agency. These characteristics are exactly what should define the Centers for Medicare and Medicaid Services as they tackle the new challenges and priorities which are presented by the Medicare Modernization Act.

Mr. Chairman, this is a critical time for CMS, and an incredibly hopeful time for American seniors. CMS is working hard to implement the reforms that this Congress has enacted, and to help seniors understand the generous benefits you and your colleagues have given them. As a result of the Medicare Modernization Act, seniors will save money on their prescription drugs, receive greater preventative benefits, and experience more flexibility in care. We are close to realizing the promise of a modern Medicare system, but some challenges remain in implementing these reforms.

To navigate these exciting new waters, CMS will need a new leader with bold vision, a wealth of experience in health care, and a depth of insight into complex economic issues. Ladies and gentlemen, Dr. McClellan is absolutely that leader. I urge this committee to quickly send his nomination to the floor. And thank you for giving me this opportunity to present Dr. Mark McClellan.

The CHAIRMAN. Thank you, Secretary Thompson. And I would ask now Dr. McClellan and the three nominees from the Department of Treasury both to come to the table at this point.

I think what we will do is ask each of you to introduce any family members you want to introduce. That is a custom of this committee, any supporters you have here with you. And then we will go back and receive any opening statements you want to make.

First of all, could I have you, Mr. Korb, introduce anybody you would like to introduce to the committee?

Mr. KORB. Yes, Mr. Chairman. With me today are my wife, Patricia, who is an American history teacher at the Lee Burneson Middle School in a suburb of Cleveland, Ohio; my son, Patrick, who is a junior at MIT; and my daughter Laurel who is an 11th grader at Hathaway Brown School for Girls, also in Ohio. And they are sitting right here in the second row.

The CHAIRMAN. Please stand, will you? Thank you.

All right. Now, Mr. Warshawsky.

Mr. WARSHAWSKY. Thank you, Senator.

With me today is my wife, Laura, and my son, David.

The CHAIRMAN. Please stand. Thank you.

And now you, Mr. Roseboro.

Mr. ROSEBORO. Thank you, Mr. Chairman.

With me today is my best friend of 30 years and godfather to my children, the chief of the Uniform Division of the Secret Service, Curtis Eldridge.

The Chairman. Would you please stand? Congratulations.

And now you, Dr. McClellan.

Dr. MCCLELLAN. Mr. Chairman, I would like to introduce my wife, Stephanie McClellan, who is a prosecutor from our time in California, and right now is spending a lot of time with our daughters, 5-year-old twin girls, who are busy doing more important things right now, like sharing time and learning about the Mars rover at Annie Elementary.

Senator BAUCUS. I might say to all of you that stood to take a good look, because that is the last you are going to see of them.

[Laughter.]

The CHAIRMAN. All right. Now, each of you in the order that we previously have introduced you, would you give us any opening statements you have, and then we will go to questions.

Mr. KORB. Thank you, Mr. Chairman.

The CHAIRMAN. Let me say to each of you, if you have a longer statement, it will be included in the record without your asking.

Mr. KORB. Thank you.

STATEMENT OF DONALD L. KORB, A NOMINEE TO BE CHIEF COUNSEL, INTERNAL REVENUE SERVICE AND ASSISTANT GENERAL COUNSEL, U.S. DEPARTMENT OF THE TREASURY, WASHINGTON, DC

Mr. KORB. Good afternoon, Mr. Chairman, Senator Baucus, and members of the committee. It is an honor to appear here today before this committee as President Bush's nominee for the position of Chief Counsel for the Internal Revenue Service. Before taking your questions, I would like to discuss two subjects: why I want to assume the post for which you are considering me today, and the brief summary of the goals that I have set for myself if I am confirmed.

This opportunity for public service is a great honor. I am humbled by the confidence that the President, Secretary Snow, and Commissioner Everson have placed in me by giving me the opportunity to serve my country in this capacity. The opportunity for public service at the national level is a rare privilege and one that

I gratefully welcome. I believe that all Americans should find some time during their lives to serve their country and their fellow citizens. The extraordinary sacrifices of our armed forces in Iraq and Afghanistan immediately come to mind. However, there are other ways to use one's talents and experiences for the benefit of the American people, and President Bush has given me such an opportunity by nominating me to be the Chief Counsel for the Internal Revenue Service.

If I am fortunate enough to be confirmed by the Senate, I will begin my third tour of duty with the IRS. Thirty years ago this past January, I began my legal career there as an attorney-advisor in the Office of Chief Counsel, in Washington. In the mid-1980's I served again, this time for 2 years as an Assistant to Commissioner Roscoe Edgar. So in a real sense, I would be returning home to the IRS if I am confirmed for this position. More importantly, I believe that the experience and institutional knowledge that I gained during these two stints with the IRS will be invaluable to me as Chief Counsel.

In the late 1990's, this committee identified serious concerns regarding the operations of the IRS. I commend the committee because the reforms instituted at that time are having a positive impact, both in the way the Service conducts its operations and on compliance by the taxpaying public with our tax laws. In line with these reforms, Commissioner Everson has set three goals for this service: (1) continue to enhance the service that the IRS provides the taxpayers; (2) to modernize the information technology systems of the service; and (3) strengthen the integrity of our Nation's tax system through enhanced enforcement activities. If confirmed, my top priority as Chief Counsel will be to help Commissioner Everson achieve these three goals.

This committee has also identified serious compliance issues that confront our tax system, particularly with respect to tax shelters. My predecessor in this position accomplished a great deal to help the Service enhance its enforcement efforts. Just like my predecessor, I want taxpayers and tax petitioners to have a healthy respect for the Internal Revenue Service. I also want to help bring the struggle against abusive tax shelters to a successful conclusion, and I look forward to working with this committee to achieve that goal.

Let me conclude by assuring that if I am confirmed, I will do my utmost to successfully carry out the responsibilities entrusted to me as chief counsel. Thank you.

The CHAIRMAN. Thank you. And now, Mr. Warshawsky.

Mr. WARSHAWSKY. Thank you, Mr. Chairman.

STATEMENT OF MARK J. WARSHAWSKY, A NOMINEE TO BE ASSISTANT SECRETARY, U.S. DEPARTMENT OF THE TREASURY, WASHINGTON, DC

Mr. WARSHAWSKY. Chairman Grassley, Ranking Member Baucus, and members of the committee, thank you for the opportunity to appear before you today. I am honored to President Bush's nominee to be Assistant Secretary of the Treasury for Economic Policy, and I am grateful to Secretary Snow for his confidence in me. And I am most grateful to my family for their support and encouragement.

Growing up in Chicago, the son of an immigrant factory worker with little formal education, I have realized in a direct and personal way that the United States is a great country of opportunity, growth, innovation, and openness. My parents stressed the importance of a good education, and indeed, I have had the great fortune of receiving an excellent education through a formal course of study in economics and mathematics at Northwestern and Harvard universities at the undergraduate and graduate levels respectively. Along the way, including a stint as an actuary at an insurance company, I developed a particular interest in insurance and asset markets and the public policies pertaining to them, including their combined ability to allow the transfer of economic risk and the reduction in overall risk exposure.

My career started with the Federal Government, first at the Federal Reserve Board, and then at the Employee Plans Division at the IRS, where I gained an understanding of the operation of monetary policy and the enforcement of our tax laws, respectively. I also deepened my interest in pensions and health benefits. And so after the civil service, I moved my family to the New York area in order to work at TIAA–CREF, a large private sector pension and insurance provider. There I saw firsthand how savings can be efficiently collected and funneled into productive investments, and how risks can be insured.

For the last 2 years, I have been privileged to be Deputy Assistant Secretary at the Treasury for Microeconomic Analysis, and for the last several months I have been Acting Assistant Secretary. In these positions, I have worked on a variety of economic issues with the talented and dedicated career staff at the Department, and with the talented and dedicated people President Bush has chosen to lead his administration. I am proud to play a part in implementing President Bush's vision and policy agenda for protecting and enhancing the economic prosperity and security of our Nation.

Thank you again, Mr. Chairman, for the privilege of appearing before this committee. If confirmed, I can assure you I will work closely and enthusiastically with you and members of this distinguished committee. I would be pleased to respond to your questions.

The Chairman. Thank you, Mr. Warshawsky.

Now, we go to Mr. Roseboro.

STATEMENT OF BRIAN ROSEBORO, A NOMINEE TO BE UNDER SECRETARY, OFFICE OF DOMESTIC FINANCE, U.S. DEPARTMENT OF THE TREASURY, WASHINGTON, DC

Mr. ROSEBORO. Chairman Grassley, Ranking Member Baucus, and members of the committee, thank you for this opportunity to appear before you today. It has been my privilege to have served President Bush for the past two and a half years as Assistant Secretary of the Treasury for Financial Markets, and I am greatly honored that the President has nominated me to serve as Under Secretary of the Treasury for Domestic Finance. If confirmed, I look forward to the opportunity to work in this new role with Secretary Snow, the Treasury staff, others in the administration, and the Congress, on the broad range of issues addressed by the Office of Domestic Finance.

The past few years have been an especially important time for public service, and the future expects to be just as demanding. The Treasury Department will continue to play a vital role in working to develop and implement policies that promote the economic well-being of our nation. I hope to have the opportunity to continue to work with this committee on formulating policy and legislation in the areas of public debt management, capital markets, financial institutions, government financial management services, Federal lending, and fiscal affairs.

Serving as Assistant Secretary for Financial Markets, I am quite proud of the progress we have made in the management of our Federal debt. We have taken significant steps to broaden our investor base: we have built and are improving systems to make the opportunity to invest in the best credit in the world more available to the average American; we have greatly improved the transparency of our financing plans of the financial markets; and we have made ourselves accountable by clearly defining our objective of achieving the lowest cost of financing over time for the American taxpayer.

Mr. Chairman, thank you again for the opportunity to appear before the committee, and I hope the members of the committee will again support me. I promise to work diligently and with an open mind on all matters that this committee may wish to raise with my office. I hope to continue the strong working relationship I have had the pleasure to experience with this committee over the past two and a half years.

Finally, I would like to thank Secretary Snow for the confidence he has shown in me by supporting me for this office. I would like to thank the career staff of the Department of Treasury for their support, hard work, and diligent efforts on behalf of the American taxpayers. I would like to thank my wife, Valerie; daughter, Cleo; and son, Brian, for their continued sacrifices as I seek to continue my public service. And I would like to especially thank in remembrance, my grandparents, Cleo Duncan Roseboro and James Benjamin Roseboro, Jr., who instilled in me the values of hard work, personal responsibility, perseverance and faith, which has led me to be here today.

The CHAIRMAN. Thank you, Mr. Roseboro.

Now, Dr. McClellan.

STATEMENT OF MARK McCLELLAN, M.D., A NOMINEE TO BE ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. MCCLELLAN. Mr. Chairman, Senator Baucus, distinguished members of this committee, it is great to be here with you today. Thank you for your consideration of my nomination as Administrator of the Centers for Medicare and Medicaid Services. I especially want to thank my wife, Stephanie, who you met a few minutes ago, who has been with me every step of the way. I have been working for the Federal Government for most of the lives of our 5-year-old twin daughters, and public service definitely means a number of sacrifices, and Steph made them for us.

Helping Americans get the most out of Medicare, Medicaid, the State Children's Health Insurance Program, and other CMS-administered programs is one of the most critical functions of the Federal Government. These programs have a daily and profound impact on well over 70 million seniors, persons with disabilities, and many other of America's most vulnerable citizens. I am proud and honored that the President has chosen me for this duty, and should you concur, I assure you that I will not let you down.

The main reason I am confident is that if confirmed, I expect to work in partnership with the members of this committee and the Congress. In my previous jobs in government, in medicine, and in academic research, I have appreciated the opportunity to work with you on a range of healthcare issues.

Since my nomination was announced, I have especially appreciated the time that you all have made to let me know about critical health concerns for the new administrator to address. I am also looking forward to hearing more from the many individuals and groups outside of this Congress who care about these programs, including people who may not agree on everything about Medicare or Medicaid, but who share our goal of affordable and vibrant health care. It includes working with our partners in the state and local governments, health professionals and providers, and, most importantly, the beneficiaries of these programs. My help would also come from the professional staffs of CMS, HHS, and the administration who are working full steam on implementing the newly enacted Medicare Prescription Drug Improvement and Modernization Act of 2003.

CMS is staffed with very smart, talented people who are dedicated to the agency's mission, which I believe includes a critical public health role. It is a public health agency. I am honored to have the opportunity to join the CMS workforce, particularly at a time when the challenges and rewards of working at CMS have never been greater.

Thanks to this committee, the Congress, and the President, we have a new Medicare law that provides new drug benefits, strengthens Medicare's managed care programs, and provides more preventive care. This act calls on Secretary Thompson and CMS to act quickly to do many things to improve benefits for beneficiaries, sick and healthy, urban and rural. But Medicare needs to do more than keep up with modern medicine. If confirmed, I intend to help Medicare and CMS drive modern medical care forward. Our new laws allow us to take bold, new steps to help patients get higher quality and safe and effective treatments delivered at the right time and without errors.

In closing, I want to renew a promise that I made when I was before the Senate during my confirmation for FDA commissioner. If confirmed as administrator, I pledge to listen and to act on what I hear from all of our partners in achieving the goal of affordable, innovative, high-quality health care for the beneficiaries of CMS programs, and for all Americans. As at FDA, I will work to ensure that careful analysis, based on the facts and the science, integrity and thoughtful decision-making, are the foundation for all of our work. We will not always agree, but I hope to make it possible for us to work together effectively to meet the challenges ahead.

My mother, who spent her career in public service, likes to say, "It's not the dollars you make; it's the difference you make." As CMS administrator for the sake of patients today and the patients of tomorrow, I will take prompt and decisive steps necessary to help make our medical future brighter, healthier, and more secure than ever. Thank you for your consideration of my nomination. At this historic time, I have some expanded remarks I would like to have read into the record. And I, like everyone else up here on this panel, would be happy to answer the questions that you might have.

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

The CHAIRMAN. This would be my plan. I have a few housekeeping questions I have to ask, and then Senator Baucus and I will take our five-minute turn. And then we will go to every other member for their five-minute turn. I have been notified by our staff that keeps track of this that it will Grassley; Baucus; Hatch; Rockefeller; Graham; Thomas; Breaux; Jeffords; Frist; Snowe; and Kyl, in that order. If Senator Frist needs to go, then just notify me.

The first housekeeping thing would be to the members of the committee. Because of the recess next week and the desire to move these nominees along, I am asking, if it is not too much of a burden, if any questions for response in writing would be submitted to my office by 6:00 today, if that is possible. And then for each of the nominees, we have three questions that we ask a nominee that comes before the committee. I will read the question, and then I would ask each of you to give me your separate answer.

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

Mr. KORB. No.

The CHAIRMAN. Mr. Warshawsky?

Mr. WARSHAWSKY. No.

The CHAIRMAN. Mr. Roseboro?

Mr. ROSEBORO. No, sir.

The CHAIRMAN. And Dr. McClellan?

Dr. MCCLELLAN. No, sir.

The CHAIRMAN. Thank you. The second question. 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 which you have been nominated? Mr. Korb?

Mr. KORB. No, sir.

The CHAIRMAN. Mr. Warshawsky?

Mr. WARSHAWSKY. No, sir.

The CHAIRMAN. Mr. Roseboro?

Mr. ROSEBORO. No, sir.

The CHAIRMAN. Dr. McClellan?

Dr. MCCLELLAN. No, Mr. Chairman.

The CHAIRMAN. All right. 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? Mr. Korb?

Mr. KORB. Yes.

The CHAIRMAN. Mr. Warshawsky?

Mr. WARSHAWSKY. Yes.
The CHAIRMAN. Mr. Roseboro?
Mr. ROSEBORO. Yes, sir.
The CHAIRMAN. And Dr. McClellan?
Dr. MCCLELLAN. Yes, sir.
The CHAIRMAN. And then, for Dr. McClellan I have an additional followup on the last question. I want to particularly note for you the importance of the commitment to testifying before Congressional hearings. I recently received a letter from a number of House Members, both Republican and Democrat, that expressed concern that you had not agreed to testify before an oversight hearing. I am going to place that letter in the record, and so I will just do that now.
[The letter appears in the appendix at page 50.]
The CHAIRMAN. In addition, Senator McCain has asked you to testify before the Senate Commerce Committee on the issue of reimportation. I recognize that you had a difficult job at the FDA, and have had an even tougher job before you coming up at CMS; however, our Constitution gives Congress a vital role of oversight of the Executive Branch. The truth is that we do not do enough of this here on the Hill. That is my personal opinion. I am not condemning any of my colleagues about that, but that is why I do so much oversight.
I want to make certain that you will be responsive to all committee and subcommittee requests for testimony, and, in particular, that you would work to satisfy the concerns of Congressman Burton who is the person that talked to me about the letter from the House, as well as Senator McCain. And specifically, would you agree today, on the record, that after we complete the nomination process this week that you would appear before the Commerce Committee on the subject of reimportation?
Dr. MCCLELLAN. Mr. Chairman, I know how deeply you care about the interactions between the agencies and the members of Congress who care deeply about what we do in turn. I absolutely want to be responsive to any kinds of requests that members of Congress have. In fact, under my leadership at FDA, not only have I testified multiple times before appropriations, authorizing committees and others on many topics, including importation, but FDA has been represented at every single committee hearing where we have been asked to testify. And I would intend to make sure that same kind of commitment continues.
I have had a chance to talk with Senator McCain about his specific interest in importation, and I hope that some of the same topics will come up today so we have a chance to discuss them in this forum as well for my confirmation. But I would be glad to agree to testify before his committee as soon as this confirmation process is concluded to make sure that we have the full and most effective airing possible of all of the difficult issues around importation. I want to make sure that both FDA, while I am there now, and CMS, if I am confirmed, will be effectively represented on the matters that our oversight committees and other committees care about from our actions.
The CHAIRMAN. All right. Now I would ask the staff to start the 5 minutes for each one of us as we do our round of questioning.

This is not a hearing about the FDA or about Food and Drug Administration issues. Your past experience and government service, however, are certainly relevant. Why I think we need to focus on your views about your upcoming job, overseeing Medicare, Medicaid, SCHIP, et cetera, I am going to ask you a question about reimportation. I am focusing on this issue right at the beginning of this hearing because your past statements in this area have been the subject of debate since your nomination was announced.

During your tenure at FDA, the issue of reimportation of drugs from Canada and other countries became very prominent. Today reimportation is no longer limited to organized bus trips across the border to pharmacies in Canada, instead it is becoming a booming mail-order pharmacy operation with customers all across the United States. We see press accounts on a regular basis describing Americans who log on to the Internet to purchase drugs in Canada or even elsewhere. I believe that free trade principles argue in favor of permitting reimportation from Canada and perhaps from other developed countries as long as we can implement a system of safe reimportation. Today is there no assurance of safety in products that are coming in from all over the world.

As you and I have already discussed in our private meeting, I am working on bipartisan legislation in this area. This legislation has two objectives. First, it will put an immediate end to the unregulated and the unsafe situation with drug imports that we have today by default. This is key because the situation today threatens the safety of our Nation's prescription drug supply and puts patients who obtain these in harm's way. Secondly, the legislation would provide FDA with the resources and authority to assure safety of imported drugs, and importation will only be permitted by registered exporters who submit to FDA authority and oversight.

So my question is, first of all, do you agree that the situation today with reimportation has swung out of control and now threatens the safety of the patients who are purchasing these drugs, and can you elaborate on the kinds of resources and authority FDA needs to legalize the importation of drugs?

Dr. MCCLELLAN. Mr. Chairman, I think you raise some of the safety issues in your own comments, and I agree with the concerns that you raise there and with your concern about getting affordable medicines to patients safely through all means that we can find that work.

We have seen a lot of examples of unsafe imports into this country. And as you pointed out, there is a big difference between when people go across the border to a pharmacy that serves Canadians and that is following all of the strict regulations under Canadian law, and we work very closely with our counterparts in Health Canada to make sure that we are both trying to keep our regulatory practices up to date for the patients in each of our countries that are served by our pharmacy systems and our drug systems. That is very different from some of the importation activities that we are seeing today, where instead of pharmacies that serve Canadians, we are seeing for-profit enterprises set up that are wholesalers that really are designed only to serve Americans. Some of these may be located in Canada. We have seen a lot of examples of safety problems and practices with these large commercial

wholesale operations. Some of them may even be located somewhere else. There are a number of Internet sites that we have found that claim to be importing Canadian drugs, but may actually be importing drugs from elsewhere around the world, India and other places, in recent examples.

When we have looked closely at the border, what is actually coming in, we see a lot of examples of controlled substances. DEA Administrator Tandy just a week ago said that she views some of these international Internet Web sites as nothing more than a modern version of drug pushers that are making available substances that are addictive and that can be misused when not prescribed and overseen under proper circumstances.

We have seen examples of drugs that require close risk management programs, such as Accutane, where we are worried about both the benefits of the drug getting to patients who can use it, and the risk, especially associated with pregnancy. So we have implemented a very tight oversight program in this country that is not monitored effectively in the international and Internet setting. So there are lots of examples of problems like this of unsafe drugs entering the country.

The CHAIRMAN. I was going to ask a follow up to that. I am just going to assume that you would be willing to work with me to get legislation drafted that will accomplish those two goals.

Dr. MCCLELLAN. That is right.

The CHAIRMAN. I want to hastily go on to the False Claims Act.

Dr. MCCLELLAN. I absolutely am committed to doing that. We have a task force set up that intends to work with you and other members who want to find ways to address importation safely just as you are talking about doing in your legislation.

The CHAIRMAN. Will you as the administrator of CMS vigorously support the False Claims Act and other Federal laws that we use to investigate, prosecute, and suppress fraud in CMS programs? Will you do your best to ensure that CMS does everything in his power to eliminate fraud and abuse from these programs? Will you and your staff cooperate fully with the Department of Justice, the HHS Office of Inspector General, and whistle-blowers—and I want to emphasize whistle-blowers—to investigate, prosecute, and suppress fraud in Medicare and Medicaid? And finally, will you agree to take no administrative initiative that would weaken the effectiveness of the False Claims Act or other laws and authorities used to investigate, prosecute, suppress fraud in Medicare and Medicaid? And the last point is made because I think some people, not just in this administration, over a lot of administrations, have tried to weaken that and not work fully with it.

Dr. MCCLELLAN. Mr. Chairman, I know from our own meetings how deeply you care about the issues covered by the False Claims Act and how important it is today to make sure we are getting the most for the money that we spend in Medicare, Medicaid, and these other critical programs overseen by CMS. So absolutely, I want to work with you closely on all of those issues, and I look forward to making that a priority under my time at CMS.

The CHAIRMAN. Senator Baucus? And I thank you very much for your response to my question.

Senator BAUCUS. Thank you, Mr. Chairman.

Dr. McClellan, we all know that you have many, many decisions to make, particularly implementing the last Medicare bill that was just passed. I would like to read a quote, and I want you to tell me if you agree or do not agree with it. This is by Deputy CMS Administrator Leslie Norwalk. She said, "I can assure you that we have no intention of implementing a fallback plan."

As you well know, the Fallback Plan was insisted upon by many of us in drafting that bill to help rural parts of America make sure they have a good solid drug benefit. As you well know, the bill provides that there be a fallback.

Dr. MCCLELLAN. Senator Baucus, all of us at CMS and throughout the administration are committed to implementing the drug benefit effectively for everyone. Everyone in the country, urban or rural, young or old in the Medicare program, with chronic conditions or otherwise, deserves to have access to benefits. I know Leslie well. She is very committed to implementing this drug benefit effectively. I believe that what she meant was that because of the way you all designed the bill, we do not think that we are going to need to get a fallback in any particular area. The reason for that is that the benefit was set up to limit the amount of risk that drug benefit plans would have to bear, and to give the Medicare program an ability to ratchet down further on a risk if it is difficult to get a particular drug plan and drug plan choices into a particular area. We are absolutely to committing to making sure that every beneficiary gets a drug benefit. If it comes to that, that means making sure a fallback plan is available. But if confirmed, I would hope to implement the drug benefit in a way that we do not have to get to that, and I think that is what Leslie's intent was as well.

Senator BAUCUS. Well, your answer is a little troubling, because as you well know, the statute says there will be a fallback.

Dr. MCCLELLAN. Right.

Senator BAUCUS. And it will be in place in advance of whether or not there are two private plans.

Dr. MCCLELLAN. Right. And let me be clear. We would intend to have a fallback mechanism in place to make sure that beneficiaries will get the benefits that they are entitled to. My hope would be that we can meet those benefit needs without needing to go to the fallback, but absolutely we will have it there if it is necessary.

Senator BAUCUS. My hope is that in exercising and pursuing that hope you do not dilute your efforts to have a fallback.

Dr. MCCLELLAN. Right, I agree with you.

Senator BAUCUS. And you are going to tell me that you will not, dilute your efforts.

Dr. MCCLELLAN. I am not going to dilute those efforts. And as you said earlier, Senator, we are going to have a lot of chances over the coming weeks to make sure that we are going forward on this effectively.

Senator BAUCUS. All right. Low-income eligibility. That is another decision you have. And as you well know, the law grants you authority to determine whether individuals who are already receiving low-income assistance through the various programs will automatically be eligible for low-income subsidies and the drug benefit. That will affect millions of Americans.

Your decision?

Dr. MCCLELLAN. I would like to use all the authorities we have under the law to get people into this benefit. Obviously, I fully agree with you, that having an automatic enrollment or something like it is the best way to make sure all these people get signed up, so I am certainly going to work for that.

Senator BAUCUS. Could you address risk adjustment? As you know, MEDPAC is quite critical of this administration's higher payments to plans versus fee for service. Already under the law recently passed, plans would get about 100 percent of what is paid to fee for service. Add to that, you in effect under Phase 1 of your risk adjustment gave more money to the plans, not less. MEDPAC is saying that plans are being paid way too much, and plans should be paid under a budget neutral basis. Do you agree with MEDPAC? And if you do not, why?

Dr. MCCLELLAN. Well, I agree that we need to be implementing risk adjustment as effectively as possible. There were steps taken this year to expand the risk adjustment provisions in Medicare, and I am fully committed to making sure we go forward with an even more comprehensive risk adjustment system as quickly as possible. With building in the drug benefit information, we can make sure that the plan payments are targeted to the expense associated with their beneficiary. So I am fully committed to making sure that happens as quickly as possible.

Senator BAUCUS. But you did not answer whether you agree with MEDPAC.

Dr. MCCLELLAN. Well, Senator, the overpayments that you are mentioning I think are happening in some areas. There also have been areas in Medicare where the plans have been underpaid in the past. Legislation, as you know, added another prong to get plans up to 100 percent reimbursement on par with fee for service. The hope would be that through these steps, enhanced Medicare private plan payments, we can give beneficiaries a more reliable and more secure set of private plan choices, and that is starting to happen now. But I am absolutely committed to working with you to make sure that we are achieving the goal intended by Congress, which is to give seniors reliable choices, and to have a level playing field competition between the private plans and the traditional Medicare plan.

Senator BAUCUS. Do you think that the additional $12 billion fund tilts it too much against fee for service?

Dr. MCCLELLAN. You are referring to the Stabilization Fund, which I do not expect to be a main stay of financing for either the private plans or otherwise. Remember, that $12 billion is an estimate. It could well be less than that, depending on how things work out.

It has been a challenge for private plans in the Medicare program because they basically face the full risk of the cost associated with their beneficiaries; whereas, in the traditional plan, all the costs are basically covered. If a beneficiary has an additional cost, it gets picked up. Risk adjustment can help us address that problem by making sure that the more expensive beneficiaries get appropriately higher payments for their needs. I am really going to be pushing on that if I am confirmed. But in addition, I do think that there are ways to build a basic system that will hopefully help

us get away from needing to rely on any stabilization payments or any additional payments like that.

Senator BAUCUS. One final question, and that has to do with accessibility and transparency. It is a bit disturbing that this is the first time in. I do not know how many years the administration has not sent up its actuary estimates 10-year baseline assumptions on both aggregate and a specific basis. As you know, we had a huge discrepancy between HHS and CBO with respect to the cost of the Medicare bill.

This is the President's budget. This is the people's budget. It should be open. The public has a right to know the assumptions behind the President's budget, and certainly the assumptions that go to the Medicare portion of it. Can you tell us if the actuaries' 5-year and 10-year baseline, in both the aggregate and the specific nature, will be made available to the public on a primary basis?

Dr. MCCLELLAN. Senator, I do want to make available the actuaries and their projections to the public, in as transparent to you, in as transparent of a way as possible. You mentioned this when we met individually. I also have discussed it with Secretary Thompson, and he also is firmly committed to improving the process for interaction between the administration and the Congress on getting out key actuarial assumptions and the like. And I agree with you fully that we need to have a transparent process for doing that.

Senator BAUCUS. That has been made available in prior years, in past administrations.

Dr. MCCLELLAN. Right.

Senator BAUCUS. And for the first time this year, it was not.

Dr. MCCLELLAN. As soon as I am confirmed, if I am confirmed, I would like to sit down with you and work through the details of how we can have a more effective sharing of information between CMS actuaries and the Congress.

Senator BAUCUS. I think it is pretty clear. You just make it available as it has been in the past.

Dr. MCCLELLAN. All right.

Senator BAUCUS. It does not take much working out; make it available.

Dr. MCCLELLAN. Well, that sounds like a pretty straight forward solution——

Senator BAUCUS. I am glad you think so. Thank you.

Dr. MCCLELLAN. —so I will look forward to working on that with you.

Senator BAUCUS. Thank you.

The CHAIRMAN. Senator Hatch?

Senator HATCH. Thank you, Mr. Chairman.

Mr. Korb, I do not know if you are familiar with the annual report to Congress of the National Taxpayer Advocate. This report serves as a road map both to the IRS and to Congress, to the most significant problems facing taxpayers today, and makes recommendations about what to do about them, both administratively and legislatively.

One of the topics discussed in the report is that of offers and compromise cases. As you surely know, an offer and compromise is an agreement between the taxpayer and the IRS that resolves the

taxpayer's tax liability. Under the program, the IRS has the authority to settle or compromise Federal tax liabilities by accepting less than full payment under certain circumstances. Based on all I hear from our constituents and also from this Taxpayer Advocate report, the offers and compromise program is badly broken. It often takes many months just for a taxpayer to get a reply to an offer, which is many times rejected, leaving the taxpayer to start the process all over again. So I hope that you will look at that and see what you can do to correct that aspect of the program. I just wanted to raise that one issue with you.

Mr. KORB. Senator, I have had experience with offers and compromise. And if I am confirmed, I will take a look at it.

Senator HATCH. I think I cited it pretty correctly there.

Mr. KORB. Yes.

Senator HATCH. Now, Dr. McClellan, you seem to be the person we all want to question here today.

Dr. MCCLELLAN. Please, go right ahead.

Senator HATCH. Well, I appreciate the leadership role that you have taken on the Medicare prescription drug law. And I believe that our hard work on the Tripartisan bill 2 years ago laid the foundation for the Medicare and prescription drug law that was signed into law last December. Please know that I recognize the great efforts that you have put in, seeing you there day after day.

Dr. MCCLELLAN. Thank you.

Senator HATCH. We are going to try and help you and your staff in the implementation of this new law.

Dr. MCCLELLAN. Thank you.

Senator HATCH. In fact, I think the education of Medicare beneficiaries is very important because a lot of people are mixed up on the law and do not realize how really important that law is and how beneficial it is.

I just received a call from a Utah constituent before coming here who wanted to know qualifications for the new drug benefit, details on the co-payments, and what exactly would be covered. I am really pleased to have you in this position because I believe you can bring a lot of sense to this particular problem.

But, again, I would like to just ask another question on reimportation. With regard to reimportation, from your experience as an FDA commissioner, have we begun to see a growing criminal enterprise, or enterprises, develop that are looking for profits while Americans suffer the consequences? And if so, could you take just a few minutes to talk and give us a few more details on that? It is my understanding that neither former HHS Secretary Donna Shalala, nor Secretary Thompson, could assure the safety of reimported drugs. Are you aware of any facts in this assessment that may have changed?

Dr. MCCLELLAN. Well, the situation we are facing does involve more sophisticated criminals today. The methods that they have available, the dye cast, the molds, the communication tools via the Internet, enable criminals to work together internationally much more extensively than in the past.

Just in the past year we have seen a number of very sophisticated operations for making counterfeit versions, for example, of cholesterol lowering medicines. Just a couple of weeks ago, we

worked with international authorities to shut down a Web site that was advertising FDA-approved drugs and legitimate European drugs that were actually counterfeit versions that did not work coming from India. So there are these elements out there. That is why I think the kinds of steps that Chairman Grassley outlined earlier, about responding not by taking away FDA authorities at a time when we are facing more security challenges than ever before, but rather by identifying effective steps that could be taken to address the safety and security issues raised by these kinds of operations, is so important.

There are criminals out there who will take advantage of any weakness in our drug safety systems. We saw this recently as well with controlled substances being advertised on the Internet that you can get without a prescription from international Web sites. It truly undermines the security and the benefits of important drugs available today.

Senator HATCH. If we open the doors and allow Americans to purchase drugs directly from foreign sources, don't we risk an exponential increase in prescription drug crimes against the elderly and unsuspecting consumers?

Dr. MCCLELLAN. Well, that is why Secretary Thompson and, before him, Secretary Shalala could not certify the safety of drug importation given the resources and the authorities that are currently available to FDA. Those resources and authorities are not designed for what the Washington Post has called "a drug system under attack," including from many of these international sources. And that is why I think we need to work carefully and together to identify just what it would take to address the safety of these additional types of imports and to keep out the potentially dangerous imports that too often are making their way into the country today.

Senator HATCH. Given the volume of drugs that illegally enter our country today, and the tremendous growth and volume that we will see if we open the doors to reimportation, give us some estimate of what it would take to effectively police a system so that we protect the health of our consumers and our patients in this country?

Dr. MCCLELLAN. That is a very good question, Senator, and that is one of the questions that the administration's task force, as directed by Congress, is trying to answer right now.

Senator HATCH. We offered 23 million bucks, and I was against that because I knew that could only cover one port. Give us an estimate.

Dr. MCCLELLAN. It is hard to say exactly. It depends on what the specifics of the bill would be. The Import Task Force was also directed by Congress to determine which kind of drugs, which kind of new authorities, we would need to assure safety, and so the question of cost is tied up with that. But to give you a comparison, for imported foods, Congress came together on a bipartisan basis in 2002 to give us new authorities and new resources to ensure imported food safety, including advance notice so that we can target our border activities effectively, recordkeeping requirements, registration for foreign suppliers, and a much more effective authority for keeping out unsafe products. To implement that, we have $100 million in additional border resources and authorities. The USDA

for potentially riskier foods, like meat and poultry, get substantially more resources to actually inspect plants and limit the number of import sites and things like that. Those are the kinds of questions that we are trying to answer with this task force right now, and we want as much public input as quickly as possible to enter those questions.

Senator HATCH. Drugs are even more complex than foods.

Dr. MCCLELLAN. That is generally true.

Senator HATCH. Much more.

The CHAIRMAN. Senator Rockefeller?

Senator ROCKEFELLER. Thank you, Mr. Chairman.

I do not mean, gentlemen——

Dr. MCCLELLAN. I am not sure they mind.

Senator ROCKEFELLER. Mr. Roseboro, I want you to get a question; I really do, but I am not going to ask it.

Twenty seven years ago, or something, when I was Governor of West Virginia—this is a fairly basic question, but it is real to us—we started a prescription drug discount plan at pharmacies called Gold Mountaineer. It is still in existence. It is not just for 65 and older, but also for 60 to 65. It has worked very, very well during all this time. The card is free. With very few exceptions, the participating pharmacies pay for the cost of the discounts themselves, and have done so over all of these years.

Now, along comes the card in the bill. I just need to have an understanding to tell the people of West Virginia what is going to be the conflict or interaction between the discount card, which affects folks from 60 on for prescription drugs with good cuts, and the one that is contemplated in the law.

Dr. MCCLELLAN. First, Senator, I would like to work closely with you to make sure that we are addressing any questions that West Virginians have about these important new benefits. Quickly, for West Virginians in particular, the $600 that is associated with this new drug card for lower income Medicare beneficiaries—and as you well know, there are a lot of them in West Virginia—that starts right away. People can start signing up in May, and the money starts flowing in June. So we need to get people enrolled in these programs as quickly as they can.

The short answer is that they can continue to participate in their Mountaineer card and participate in the Medicare program as well. They are not in conflict with each other. But my hope is that we can do even better than that, to work with the state, get people who are already taking advantage of some of the benefits in the Mountaineer card to sign up for the Medicare card as well, and find out which one really does help them the most in their individual prescription purchases. For the lower income beneficiaries in particular, the $600 that they will get starting in June is an important reason to add this on to what they are already trying to do with the Mountaineer card.

Senator ROCKEFELLER. Are you suggesting there might be a combination of the two based upon income?

Dr. MCCLELLAN. Well, I would like to find ways to help the people of West Virginia and the United States take advantage of all of the programs out there as effectively as possible under the law. And there certainly are ways that we could work with the state to

help enroll people in the Medicare card, just like the state has been doing to get people into the Mountaineer card before, and let them know when they have better options available, and potentially larger discounts or some financial help. So I would like to have that kind of interaction, and that is possible under the law.

Senator ROCKEFELLER. This will be very important because it is something the people have really come to depend upon.

Dr. MCCLELLAN. That is right. And the state has done a good job of reaching out to them, and we want to build on that.

Senator ROCKEFELLER. The second question is on rural provider budget cuts. I was very, very pleased about the $25 billion over 10 years for the rural hospitals and providers that was included in the Medicare bill. It is going to help a lot. It is going to help a lot of folks in West Virginia. However, because of the size of the commitment of that, and the budget situation which we appear to be heavily in—that is a budget deficit situation which will discourage discretionary spending—then on top of that, the President proposes significant cuts to things like HRSA, the Health Resources and Services Administration. The President's budget for fiscal year 2005 eliminates funding for the Rural Hospital Flexibility Grant program, for the area health education centers, and for the community access programs, which is very important to us, and other discretionary programs, and other discretionary programs for rural health are slated for cuts as well.

Now, well done on the $25 billion, but I think on a net basis I am as, or more, nervous about the implications of these other cuts and what the justification for them is.

Dr. MCCLELLAN. Well, I certainly do not want you to be nervous, and I do promise to work with you on not only implementing all of the new funding and the Medicare bill, but you mentioned the $25 billion DISC funds, other additional payments for rural hospitals, and other rural facilities. The administration also strongly supports community health centers, which can be an important part of outreach, and programs through out commissioned corps to get more help from health professionals into underserved areas. I think there are a lot of ways that we can work together to build on these new programs and additional funding to get more help to the rural beneficiaries who need it most. So I will look forward to working with you on that.

Senator ROCKEFELLER. Well, I look forward to working with you too, Dr. McClellan, but the problem is they have already been cut, and I am not sure that you and I together can change that. And that is why I was trying to get a sense of direction because there is what is in the Medicare bill, but then there is a whole lot of other rural healthcare things that the $25 billion may have taken attention away from. But in terms of services to the people I represent in West Virginia, they are still left with all these other programs.

Dr. MCCLELLAN. Sure. I understand your concerns, but $25 billion is a lot of resources that I think can do a lot of good. In addition to the rural money, there is new money through the discount card program, new money through the drug benefit that we absolutely intend to deliver effectively to rural beneficiaries. So I do

think we can strengthen our rural health care, and that is going to be one of my top priorities as administrator.

Senator ROCKEFELLER. I just do not want that to be a generic answer. When you said you do not want me to be nervous, I am always very happy to be nervous; I just want programs to work out. Thank you, sir.

Dr. MCCLELLAN. That is my goal as well. Thank you.

The CHAIRMAN. Senator Graham?

Senator GRAHAM. Thank you, Mr. Chairman.

My question is going to be asked of Dr. McClellan. I would like to ask three questions. I will try to state them directly, and would appreciate a succinct answer. And if further elaboration is desired, I will include that in the written request for answers.

Dr. MCCLELLAN. All right.

Senator GRAHAM. The first has to do with the issue of medical errors. I know that in your previous life as FDA commissioner, you were very interested in this issue, including bar codes and other modern technology.

Dr. MCCLELLAN. Absolutely.

Senator GRAHAM. My question is, how would you plan to use your new position as administrator of CMS to improve patients' safety and reduce medical errors among the Medicare and Medicaid populations?

Dr. MCCLELLAN. Senator Graham, the new Medicare legislation includes a lot of ideas, I know from discussions with your staff in the past, that you supported to get better delivery of health care to seniors. One of my priorities at FDA, reflecting things that I heard from you and other members of Congress earlier when I worked at the Council of Economic Advisors in really looking for ways to deliver health care more efficiently, was a push for electronic prescribing. At FDA, in addition to the bar coding rule that you mentioned, we have made major steps towards switching over all the information, that FDA provides to doctors and patients and others, to electronic forms that can be integrated with these handheld devices and other tools used for electronic prescribings. That is in the bill. That is something that I expect to push along as quickly as possible.

There also are many new opportunities for disease management programs and use of other types of technologies that are being proven to work to get better benefits to people, such as telemedicine. We are going to push forward on all those quickly as well.

So I definitely intend to work closely with you on all that. I know there are a number of specific programs in CMS now and in the bill that we are intending to move forward on quickly, and I will get those into my written answer to you.

Senator GRAHAM. Thank you very much, and I look forward to working with you on that.

Dr. MCCLELLAN. Thank you.

Senator GRAHAM. The second question relates to the state's efforts to reduce drug costs through their Medicaid program. A number of states have adopted programs of negotiation with prescription drug companies in order to secure lower costs.

The Governor of Michigan, Ms. Granholm, recently told a conference that her state had its negotiation program terminated, and

that this had a very significant potential effect on the cost of prescription drugs. I know a number of other states have had similar programs in effect. It is my understanding that Secretary Thompson, when asked about this termination, said that the proposal was "under review."

Dr. McClellan, I understand this review has been ongoing for over a year. When do you anticipate this coming to a conclusion? And would it be your inclination to recommend to the Secretary that states continue to have the authority under the Medicaid program to negotiate such lower drug prices for their beneficiaries?

Dr. MCCLELLAN. First, on that point, I do think that states need to work with CMS to find ways to get costs down safely and legally and negotiating better arrangements with pharmaceutical companies, which is something that Florida has done to a considerable benefit for the state budget and their beneficiaries, and it is a very effective way to do that. Many states are going beyond, now, the legislated, government-required Medicaid rebates to get better prices for their beneficiaries, and that is one very important tool for getting costs down. There are many others, and I want to work with the states on doing that.

My understanding of this proposal is very much like what Secretary Thompson said, which is that it is under review. I do not think it has been a year since CMS acted on it. I think there has been some dialogue back and forth with the state of Michigan. And this often happens. They submitted a proposal. There are some further questions that need to be asked of the state to clarify, and then things get resolved from there. I can tell you, if I do get confirmed, I will work quickly to try to bring this to resolution within just a few months.

Senator GRAHAM. My final question has to do with an unexpected development within the Prescription Drug bill. As we know, the new estimate for the cost of the bill over 10 years is $530 billion, approximately $135 billion higher than had originally been estimated. Twenty-five percent of that additional cost comes from one difference. And that is, first, how many of the Medicare beneficiaries will elect to join the Medicare Advantage program. CBO estimated it would be 9 percent; the White House estimate is 32 percent. And then the second and more surprising development is that the White House has estimated that this higher rate of participation in the Medicare Advantage program will actually cost Medicare money as opposed to what had been anticipated, that higher participation would be associated with reduced costs. In fact, the differential, as I say, is 25 percent of the $135 billion additional cost is the additional cost estimated for higher participation in the Medicare Advantage programs.

What is the explanation for this higher cost, and are there any recommendations of what might be done to bring it back into its original expected cost?

Dr. MCCLELLAN. Senator, first, as you know, CBO has not changed its estimate. They still think the program is going to cost $400 billion. This shows you what happens. When we are talking about a big complex piece of legislation, it is hard to know exactly what is going to be the result. I cannot predict exactly what the cost is going to be, but I can predict that we are going to do every-

thing we can to get the costs down. I talked earlier in response to some of Senator Baucus' questions about the Medicare Advantage plan, about how we can take more steps to help make sure we are giving seniors the most benefits there. Additional risk adjustment steps, additional steps to promote competition to get costs down, all of that I think can bring those costs down and maybe make them low or more in line with what CBO projected.

Senator GRAHAM. The concern that I have is that it appears as if you get more people involved in competitive programs. Instead of competition saving money, this competition, according to the White House estimate, actually costs about $32 billion more over the next ten years than if people had stayed in fee for service.

Dr. MCCLELLAN. I think that is a piece of that particular projection. And as I said, my main goal will be taking the law that has been enacted, and also further advice and further action by the Congress, and doing all I can to give seniors and the Treasury the most for their money, the most benefits at the lowest possible cost. I think there are a lot of steps that we can take to bring down the cost of the private plans in Medicare.

As you know, in addition to some of these differences in projections about private plans, the main reason for the CBO and actuaries' difference in projections were the Title 1 benefits, the drug benefit itself, and as you said, how many low-income beneficiaries were going to enroll. Well, there are some places that I do not want to save money. I do want to try to get as many low-income beneficiaries into the program as possible. But I think there are a lot of steps that we can take to bring down those costs and make competition work to increase value, and to give seniors and the Treasury more for their money, and I will look forward to working with you on that.

Senator GRAHAM. And I would like to submit some written questions.

Dr. MCCLELLAN. Absolutely. We will be happy to answer them promptly, Senator. Thank you.

The CHAIRMAN. Senator Graham, I was asking if we could have the written questions in my 6:00 tonight. I hope we can.

Senator Breaux?

Senator BREAUX. Thank you, Mr. Chairman, and thank all of the witnesses. And it is not because we do not like you all. We are not ignoring you intentionally. We wish you the very best.

Dr. McClellan, you will be taking this job at an incredibly interesting time in history. I dare say there is probably as much apprehension about the new Medicare program as probably they had when in 1965 we added insurance coverage for hospitals. There were many people who said it will never work. The concept of the government paying for that was almost unheard of. And now we have a new Medicare program with a prescription drug insurance plan, which some will argue will not work. So it is a huge challenge, but it also presents great opportunities as well. If you had to think about which agency in government is more responsible for health care, it is obviously HHS and underneath that your department of CMS.

I guess as just a general question, you get health care in this country, depending on what box we put you in. I have said this so

many times. If you are old, you are in the Medicare box. If you are a veteran, you are in the VA box. If you are poor, you are in the Medicaid box. If you are a poor child, you are in the CHIP box. And if you are not in any one of those boxes, you are one of the 43 million uninsured who have no health insurance at all, and spend a lot of time in the emergency rooms.

Wouldn't it be better if every American citizen had a basic health insurance plan than having all of these boxes that you try to administer, each one of them with red tape and bureaucracy, and waste, fraud, and abuse that we all talk about? Wouldn't it be better just to have this government move toward saying that everybody is going to have health insurance not because they are in a box, but because they are an American citizen?

Dr. MCCLELLAN. Well, I think that this bill actually helps move in that direction by making available a broader array of modern kinds of health plan choices, the same kinds of health plans——

Senator BREAUX. Yes, but you are still in the Medicare box, and you still have to be 65 years or disabled.

Dr. MCCLELLAN. Well, that is right. But people who are over 65 and might have disabilities may need more help than people who are workers. I think that the goal here is to have an overall healthcare system in which doctors and patients are making informed decisions based on the latest and best medical science. Having special help for people who are over 65 and people with disabilities is an important step in getting there. They do need more help.

Senator BREAUX. I mean, I agree. Look, we are doing good things for the Medicare population, but we still have the box system. And now my question is, wouldn't it be better if everybody had basic health insurance because they were an American citizen?

Dr. MCCLELLAN. I think that is right. But I guess what I am saying is that thanks to, in large part, your leadership over many years to get to this point with the Medicare program, I think we are moving away from the box system. I think we are moving towards a system where people can choose the plan that best meets their needs, and that plan can better keep up with the best available technologies and just what the patient requires at the same time as we are continuing and strengthening the traditional Medicare program that so many seniors have depended on. In terms of getting out of boxes, and making sure that everyone has access to high-quality, affordable health care, and the good information they need to make good medical choices, this seems like a big step in the right direction.

Senator BREAUX. I think one of the most important things in the new Medicare bill obviously is prescription drugs. But almost as important is the baseline health plan, the baseline exam, that will be made available to everyone coming into the Medicare program. I think it is clear that many people become eligible for Medicare but do not see a doctor for the next 5 years. And then it is a $500,000 problem. Had they seen them when they first came in, it could have been a $100 problem. I wish it was mandatory. It is not. And I really think that Medicare and CMS ought to do everything they can to advertise or make that information available about how important it is to have that baseline health exam that is now going to be covered by Medicare for the first time.

Dr. MCCLELLAN. I agree with you fully. We have a lot of outreach to do, not just about the new drug card, and the new drug assistance, and the new drug benefit, but also about the new preventive benefits. As I said in my opening statements, Medicare has been behind for a while in covering preventive care and other kinds of modern treatments that help people live better, longer lives, and this is a big step forward.

Senator BREAUX. Unfortunately, a lot of seniors do not take advantage of the preventative studies and preventative tests, so we really have to emphasize this.

Dr. MCCLELLAN. That is right.

Senator BREAUX. Senator Rockefeller talked about the discount card. It is incredibly important. We have a hearing tomorrow in the Aging Committee on the discount cards. It is very important that after this Medicare discount card comes into effect, seniors are not going to be faced with having 25 discount cards—one from Pfizer, one from Eli Lily, one from West Virginia, one from AARP, one from Medicare. So to the extent that CMS can try, through the use of computers, to come up with something so that seniors will have a minimum number of discount cards, that plan can just show which ones are available to them on one card. We have to work towards that. It may not be possible in the beginning, but that is our goal.

Final question. In the budget, they adopted an amendment on drug imports that basically said that the Secretary was authorized to allow for the safe reimportation of FDA-approved prescription drugs from certain western countries. I think it is a little over 20. How difficult would that be to implement under the current set of circumstances? Is that possible to do?

Dr. MCCLELLAN. Well, it is a challenge. I think it would be extremely difficult under current law because our drug safety laws are not set up to deal with those kinds of imports. In fact, the drug safety statutes that FDA is charged with carrying out, and the courts have confirmed that we are charged with carrying out, require us to assure that drugs are safe and effective before they can be legally used in the United States. Congress in the 1980's, in response to some serious problems of unsafe drug imports, made it illegal to bring in those kinds of drugs. So our drug safety systems are not set up to deal with these additional categories of medicines.

We are working on a task force right now to determine whether and under what circumstances, and for what expense and so forth, it would take to allow broader classes of drugs to be imported safely. And that is why I think, again, Chairman Grassley's approach of not trying to solve this problem by striking out more of FDA's authorities at a time when we are facing bigger problems with drug security than ever before, but adding on additional types of protections and additional resources to police the safety of these imports, is the better overall direction. But it will be a real challenge, and that is why we are looking for a lot of input from everyone who cares deeply about this issue on both sides to figure out how it can be done effectively.

Senator BREAUX. Well, thank you. And I will look forward to working with you. I think you will be a terrific CMS administrator.

Dr. MCCLELLAN. Thank you, Senator, and thank you for your leadership.

The CHAIRMAN. Senator Breaux. Now, Senator Snowe?

Senator SNOWE. Thank you, Mr. Chairman, and welcome all of you here today. And no surprise, I will ask Dr. McClellan first on his questions.

It is getting to the reimportation issue. And you and I have already had discussions on this issue. It is critical because, obviously, Americans are paying the highest prices for the cost of medications. That is why seven out of ten Americans support reimportation of drugs. Certainly, that has been the case with my constituents who have traveled to Canada and, fortunately, have not experienced any serious or adverse consequences with personal reimportation.

The point here is that we need to hear a "can do" approach. We need a productive dialogue on this with you. I am pleased to hear that you are going to be testifying before the Senate Commerce Committee because I do think it is important to explore the issues, what it is going to take, what resources, what authority, to move this process forward. We need a constructive approach to this issue.

Frankly, I think we ought to start, for example, with wholesalers and pharmacists. I mean, it seems to me that there are steps that could be taken to begin to address this problem. As I have read the counterfeiting issue, it is primarily with domestic markets. We gave FDA the authority 10 years ago, obviously before your time, the mandate for establishing pedigrees in the chain of custody of drugs. So it seems to me we ought to get this process rolling, because the end result is to really benefit the consumers in America, and seniors most especially, from the high prices of medications.

Can we do this? I mean, that is the issue here; can we do it? Yes, it has passed before. In the previous administration and in this administration it has been passed I think three times by Congress. The intent is clear. What is it going to take to move this forward? I know we have the task force, but there are some steps that ought to be able to be taken now.

Dr. MCCLELLAN. I think the kinds of steps that you outline, like potentially restricting the scope and type of drugs that can be imported are important steps. That is exactly the kind of thing that the task force has been charged by Congress with trying to address fully and as quickly as possible. We have a meeting, for example, next week with a number of consumer groups, including many that are advocates now for importation, like AARP, but also want to make sure it is done safely with additional restrictions on the types of drugs that could be imported legally and the entities involved in that, and with additional resources for the agency in order to do it safely.

I agree with you completely that the right way to move forward is with a constructive attitude of addressing what additional resources and authorities FDA would need in order to do this safely. Too much of the debate in the past has been about either asking us to declare drugs safe when they clearly are not in many cases. And I am not talking about the people from Maine who go across the border to community pharmacies in Canada and get well-regulated and safe drugs in that way. I am talking about Internet operations and the like where there are real problems. So what does

it take to do it safely, and how can we expand the resources and authorities for the Federal Government to support that, rather than just strike out entire sections of FDA oversight of the safety of drugs in the United States.

Senator SNOWE. So what is the time frame do you envision for this task force?

Dr. MCCLELLAN. Well, I would like to do it as quickly as possible. Congress gave us a number of tasks, and they required us to do a very careful analysis of the mechanisms for doing importation, the impact on prices, the impact on research and development, costs, different parties in the system. We have public meetings and input from public stakeholders scheduled over the next six weeks or so to do this, and we will certainly work as quickly as we can.

Senator SNOWE. All right. On the issue of negotiating price authority, as you know, there is a prohibition barring the Secretary from having the negotiating authority for prices of medications. That is obviously a central concern. I would like to explore this issue with you for a moment, because it seems to me, more than anything else, the concerns that have surfaced with respect to the implementation of the new prescription drug benefit is the cost of medications; that (1) there is no incentive to keeping the prices down; (2) it will devalue the benefit; (3) the Secretary will not even have the authority to negotiate prices in the government fallback provision.

I would like to hear from you. Senator Wyden and I have introduced legislation to grant this authority to the Secretary. We think it is important to have that incentive. Secondly, I think it is important for us to be able to ascertain the drug prices, to compare those drug prices. We would call on GAO to monitor those prices, report those prices, track them from starting 2000 all the way through to 2006. Report every year so we have an idea of how these prices are escalating or decreasing, whatever. Compare the prices that are negotiated between the private plans and those that are negotiated by the Veterans Administration and by the Defense Department.

I would like to ask you about this. We have a letter from CBO, Senator Wyden did, on the issues of negotiations and savings. In one case, there is potential for savings with the private plans when you have multiple drugs in a particular class. But what happens when you do not have that competitive alternative to a particular medication? How then are we going to incorporate price savings on some of these medications that do not devalue the entire benefit?

Dr. MCCLELLAN. I have seen that letter from CBO, Senator, and I do agree with them, that there are a lot of opportunities under the law to get drug prices down for seniors. And I agree with you that is the big issue here. Seniors are paying too much for drugs today. They are paying list prices that are the highest in the world in many cases, where they are not getting any help at all, and that is going to change.

With respect to the particular types of drugs that you are asking about, the so-called single-source drugs, remember that most of the drugs that seniors take have multiple alternatives available. For example, for cholesterol-lowering medicines there are a number in a whole class. It is possible and has been shown that the Federal Employees Plan and many other private plans can negotiate much

lower prices on behalf of their beneficiaries, and that is just what would happen under the drug benefit.

For the single-source drugs, I think of them in two categories. There are some that do not have any that work exactly in the same mechanism, but there may be other kinds of medicines available that help with the same kind of health problem. There are drugs for pain relief, for arthritis, and so forth in this category. And I think the same kind of competitive benefits would be present there as well. Also, for even the single-source drugs where there are not alternatives, having the negotiating power of millions of seniors working together is a very different situation than an individual senior walking into a drugstore off the street, getting no help at all in getting a lower price.

I think there is a lot that can be done to get drug prices down. And I agree with you that we should look very closely to see how it works. But I think based on all the evidence that I have seen—and I am going to be talking much further to other plans that have implemented these kinds of programs as well—I think we can do a lot of good for seniors.

Senator SNOWE. Thank you.

The CHAIRMAN. We will go to a second round now of 5 minutes each. I would like to use two and a half minutes for Dr. McClellan on one question and two and a half minutes for Mr. Korb on another question.

My State of Iowa has contacted me with questions and concerns regarding the process that CMS is using when deciding whether or not to approve certain state plan amendments, and I have heard other states having similar experiences. The concern is that the procedures, according to which Medicare state plan amendments are considered and approved, seem to be changing without explicit or open public process. The criterion and standards used do not appear to be clear, may not be uniform, and do not appear to be publicly announced. The approval process for state plan amendments appears also to be used as a means by which states can be forced to cease or modify a certain intergovernmental transfer, leaving aside the merits of certain intergovernmental transfer arrangements. I share some of CMS' concerns about them.

The less than clear and open procedures involved are troubling to me. If Medicare is going to be a Federal and state partnership, states need to know exactly what the Federal Government expects. Changes in Federal government programs should not be made without prior notification and consultation with their Medicare partner, the states.

Question. As administrator, do you plan to create a publicly accessible written record and/or guidance to the states in the event of changes in policy, or interpretation of policy, by your agency? How do you plan to address the concerns raised by states that CMS is not approving state plan amendments in order to force states to shut down inappropriate intergovernmental transfer?

Dr. MCCLELLAN. Mr. Chairman, as a general matter, I think under Secretary Thompson's leadership, CMS has become quite responsive to states in addressing questions and issues raised with their FPAs and getting through a backlog. And I certainly want to continue Secretary Thompson's strong emphasis on quick response

and clarity in response to requests by states for waivers and other kinds of changes in their programs.

As a more general matter, I agree with you fully that the more that we can be clear about what our policies are so that states know what they should and should not be doing, and the more that we can work constructively with them, when Iowa or any other state brings us a proposal, to find a way to address that proposal within the law and within our regulations, that requires a lot of outreach, and that requires as much clear communication as possible. I know much of that is in writing from the agency. So I do promise to work with you to make sure those kinds of traditions are strengthened during my time at the agency.

The CHAIRMAN. Before I go on, my state tells me that it is difficult to get things in writing; that people want to say what you have to do, but they do not want to be responsible for what you have to do, and they might have to be responsible if they write it.

Dr. MCCLELLAN. And I will look forward to working with you to make sure we do all we can to address that.

The CHAIRMAN. All right.

Mr. Korb, I have been troubled by recent reporting that has shown that some private foundations are engaging in serious abusive charitable status. The papers have reported about very high salaries, family vacations, fancy cars, and even weddings all paid for with money that is meant to benefit those most in need in our society. It is my concern that while the law is clear that the costs are allowed only to the extent they are reasonable and necessary for salary and administrative expenses, the IRS has not provided better guidance of where the line is for reasonable and necessary costs. This large gray area hurts private foundations that are trying to do the right thing, but also hamstrings the IRS from doing any effective oversight and audit. I would ask your commitment to review the current regulations and other guidance as necessary to make a priority of revising it to ensure that boondoggles we are reading about regarding some private foundations can be put to an end. I am confident that this can be done without harming the strong majority of private foundations that do a very good job.

You can respond now, generally, but I would ask that you provide me a detailed written response in 30 days of your plan of action on this matter.

Mr. KORB. Mr. Chairman, in preparation for this hearing, I read the series of articles that appeared in the Boston Globe about this particular issue. And during my career with my law firm Thompson Hine, I have been involved with understanding what this issue is about, and I pledge to you to work with you on this issue on a going-forward basis.

I would also like to add that one of the concerns I do have in the tax-exempt sector is the gravitation of the tax shelter industry into that sector. It is very troubling to me, and it is something that I plan to look at closely as Chief Counsel, if I am confirmed.

The CHAIRMAN. Well, I thank you for that. I have asked for a plan within 30 days. Is that any problem?

Mr. KORB. I do not see it as a problem, Mr. Chairman.

The CHAIRMAN. All right. Senator Baucus?

Senator BAUCUS. Thank you, Mr. Chairman.

Mr. Roseboro, when will the administration submit a request to Congress to raise the debt ceiling?

Mr. ROSEBORO. Our current projections now have us hitting the statutory debt ceiling currently a $7.384 trillion somewhere between the end of June and October. Following the April tax season, the beginning of May, we will be able to narrow that projection a lot more, and at that time we will be talking about notifying Congress more formally.

Senator BAUCUS. I appreciate that.

Mr. Korb, could you outline the composition of the tax gap? What are the part? Some estimates are that it is about $311 billion of income taxes uncollected annually by the United States. Could you tell me where it is? What categories?

Mr. KORB. Senator Baucus, I am not personally familiar with each of the categories, but, obviously, if I am confirmed, that will be something that I will direct my attention to, to understand that fully, and to work with this committee and with the Treasury Department to help narrow that gap.

Senator BAUCUS. You must have some feeling where it is coming from. You must have some idea. You are not just a guy that walked off the street and sat down and that table there.

Mr. KORB. Well, I think the revenue estimates that have been presented to this committee a number of times during the legislative process for a number of the bills have shown that the tax shelter problem has created some of that gap.

Senator BAUCUS. How much of that is in the corporate side and how much is on the individual side do you think, roughly?

Mr. KORB. Senator Baucus, I do not have those figures.

Senator BAUCUS. You have no idea?

Mr. KORB. No, I do not.

Senator BAUCUS. None?

Mr. KORB. No.

Senator BAUCUS. Well, why don't you just guess?

[Laughter.]

Mr. KORB. I really could not even hazard a guess.

Senator BAUCUS. Oh, no. We are not going to hold you to it. Just a guess. We have prefaced it by saying it is a guess, and you do not have the job yet. But just a guess; your feel.

Mr. KORB. Well, I understand the revenue estimate, for example, for SILOs is $30 billion, so I assume that would be part of the gap.

Senator BAUCUS. Now we are getting someplace. All right. That is corporate side. Right? Those are corporate shelters.

Mr. KORB. Yes, Senator.

Senator BAUCUS. All right. Where else besides SILOs?

Mr. KORB. Another portion would be unreported income from individuals who have dropped out of the tax system by not filing tax returns.

Senator BAUCUS. Now, what group might that be?

Mr. KORB. Oh, it could range from a whole group of people. Tax protesters might be one group. Sometimes what happens is individuals fail to file a tax return one year, and then they are afraid to come back into the system, and so they continue to be non-filers.

Senator BAUCUS. What about sole proprietorships, about Schedule C?

Mr. KORB. Keep in mind, one problem here, as I understand it, the Internal Revenue Service has not been conducting what used to be called TCMP audits, and they have this new NRP program to try to develop the data. Any data we talk about now probably goes back more than 10 years. And we have such a dynamic economy, I think that is one of the reasons it is kind of hard to hazard a guess specifically how much would be in the Schedule C taxpayers.

Senator BAUCUS. Your best guess, just a guess, just an estimate.

Mr. KORB. Senator Baucus, it would be a wild guess. I have no specific numbers in mind.

Senator BAUCUS. You are going to be Chief Counsel for the IRS, and you have not thought about these things?

Mr. KORB. Yes, I have thought about them. I have thought about them.

Senator BAUCUS. I mean, thought about them to the point where we have to do something about it.

Mr. KORB. Well, there is no question about that.

Senator BAUCUS. Can you give us a little more of your thoughts if you have thought about it? How do we get at the tax gap?

Mr. KORB. All right. One way to do that would be with respect to the tax shelter problem. I believe that the way to get at that is to attack the source where the promoters, the sales, the marketing takes place. I honestly believe that once these tax shelters are marketed, we have really lost, because then the Service has to use up a lot of resources to try to track down——

Senator BAUCUS. Do you have a sense of the degree to the way Sarbanes-Oxley nails that down?

Mr. KORB. Actually, Sarbanes-Oxley, in my private practice, based on my experiences there, is going to do a lot more than I think a lot of people anticipate.

Senator BAUCUS. To address that problem.

Mr. KORB. Absolutely.

Senator BAUCUS. So maybe we can check that box and go on to some of the other problems.

Mr. KORB. Actually, a good dent has been made in that problem; no question about it.

Senator BAUCUS. All right. So what else? What are your other thoughts in how we get at the problem, if Sarbanes-Oxley takes care of, to a large degree, the marketing of these schemes?

Mr. KORB. One of the roles that I play, based on the restructuring of 1998, is to work as team player with the Treasury Department on proposed legislation. I will commit to you that I plan to take that very seriously, and look at ways in which legislation can be enacted to deal with some of these problems.

Senator BAUCUS. When do you think the Treasury can not entirely, but effectively say we have solved the tax gap? How long is it going to take for you as part of this current administration?

Mr. KORB. To solve it entirely?

Senator BAUCUS. No, I did not say entirely. I said not entirely, but to essentially say that for all intents and purposes, we can put that one aside because we are collecting most of the taxes that were previously not being paid.

Mr. KORB. I will tell you, an observer, again, from the outside right now, I think the pendulum is swinging back where compliance will be higher. It will take some time. You cannot turn a ocean liner around in the middle of the ocean on a dime. But I think a real effort and a lot of good work out of this committee is leading to that, beginning back with the reforms back in '98.

Senator BAUCUS. Well, I hear what you are saying. To be quite candid, I just do not sense from you the sense of urgency needed to address this problem. I hope that when you take over that you will have that sense of urgency. It amounts to about 15 percent. The overall noncompliance rate is about 15 percent, and it is growing. We have done a lot in this committee. Many of the provisions that we have passed out of this committee and passed in the Senate have not been enacted into law. Basically, they are the post-Enron reforms, dealing with inversion. This committee has done a lot of hard work. Those provisions have to be enacted.

I just will tell you that I am going to be coming back on this issue, and you might tell your people over there at IRS and Treasury as well. I think the administration is not living up to its responsibility in closing this tax gap. And I think prior administrations have not done as much too. My time is up. I just urge you to get at this.

Mr. KORB. I want you to know that I commit to work with you and with this committee.

Senator BAUCUS. I do not care if you work with us. I just want you to solve it.

Mr. KORB. I will do my best.

Senator BAUCUS. Thank you.

The CHAIRMAN. Senator Breaux and Senator Jeffords? Senator Jeffords did not have a first round. I almost think I ought to call on Senator Jeffords first. Is that all right? And then we will go to you.

Senator JEFFORDS. Thank you, Mr. Chairman.

The CHAIRMAN. Yes.

Senator JEFFORDS. Dr. McClellan, I also want to welcome you. I also want to commend you for your long-term focus on patient safety, and I especially appreciate your insights in the recently enacted Medicare Quality Demonstration program. I know that Dr. Jack Wennberg, among others in the health policy community, thinks highly of your work, and is looking towards working with you in implementing the Quality Demonstration program.

I have a couple of issues to raise with you and may have additional questions for the record.

Dr. MCCLELLAN. Sure.

Senator JEFFORDS. Dr. McClellan, as the Commissioner of the Food and Drug Administration, your job was to ensure the effectiveness and safety of pharmaceuticals. But now your obligations under the law will be in large part a fiduciary one. That is, you will be responsible for ensuring that the Federal Government receives the maximum return on its investment in health care. You have been recently appointed to head a task force on drug reimportation, and hopefully will investigate ways to open markets to international sales of pharmaceuticals reimported from Canada or other developed nations, and you mentioned that earlier when

I was here. I was glad to hear of the chairman's interest in the issue, and I want to help assist you in any way that we can.

Late last year, I joined Senator Ben Nelson and 73 of our colleagues, including many of the committee, in a letter to Tom Scully noting our opposition to CMS' proposed rule to modify the outdated 75 Percent Rule for inpatient rehabilitation hospitals. In the recent letter, we urged CMS to defer any action on changing the rule until further studies could be completed. In addition to the letter, the new Medicare law includes a provision that requires CMS to contract with the Institute of Medicine on a study to obtain the information needed to update the 75 Percent Rule.

I think your deferring action on any non-critical proposed rule would be welcomed. So I would like your assurance that you would work with us and IOM to obtain the data necessary before proceeding with any interim or proposed 75 percent rehabilitation rule.

Dr. MCCLELLAN. Senator, first of all, thank you for your comments. Jack Wennberg and many of the other people at Dartmouth and working up in New England have done tremendous work on helping us find ways to get more for our money in health care, and I am absolutely going to be paying attention to all that kind of work if I am confirmed for this job.

With respect to the 75 Percent Rule, I am actually a member of the Institute of Medicine myself. I know how important their studies can be. We do have a lot of evidence relevant to this issue already, and as a general matter, I do like to move things along. What I would like to do is follow up with you, if I am confirmed, on what our concerns are about the appropriate standard for the rule. There are many members who I think would like us to move along on that as well, and I will try to find the best way forward. But I appreciate the value that an Institute of Medicine study can add. I intend to get input from them, and you, and everyone else who has strong opinions and expertise on this issue, and to try to do the right thing, and try to do it as quickly as possible.

I also, if you do not mind, would like to say one more word on importation. At FDA, I am charged with making sure that drugs are safe and effective. That is our job under the law, not just me, but our whole professional staff at the agency. But we are also charged with finding ways to improve access to care, and if we can do that without compromising safety, we are all for it. That is why we have taken major steps forward in educating the public, in changing regulations and getting laws, help through technical assistance of Congress, for example, on generic drugs. And on patient safety, as we mentioned, that can save a lot of money too. There are a lot of steps that we can take to give Americans both affordability and safety and effectiveness. I think I am going to be committed to that goal at CMS as well if I am confirmed, and I look forward to working with you on the many steps that we can take to achieve that goal.

Senator JEFFORDS. Well, thank you. Of course, coming from Vermont, a border state, this is so important because it seems so obvious to everybody that it can be done. We want to make sure that we work with you to get it done.

Dr. MCCLELLAN. Thank you.

Senator JEFFORDS. Thank you.

The CHAIRMAN. Senator Breaux?

Senator BREAUX. Thank you very much. Thank all of you for still being with us.

Specialty hospitals——

Dr. MCCLELLAN. This one is for me?

Senator BREAUX. The moratorium that we passed went into effect the date of enactment, so it is in effect now, but there are no regs out, which has been to the disadvantage of both general community-based hospitals, as well as specialty hospitals. They are not certain what to do, and time is running, so we have to get these regs out.

Dr. MCCLELLAN. Get me confirmed, and I will get them out soon.

Senator BREAUX. Soon?

Dr. MCCLELLAN. Very soon. We can do this in a matter of just a few months, or sooner.

Senator BREAUX. Because it is only a 18-month moratorium. It is in effect right now, but nobody really knows what is required and what is not because of that. The fact—can you comment on that?—is we listed it under the grandfather clause, hospitals under construction, and asked you all to consider a number of factors. The factors were whether they had architectural plans, whether the funding was there, whether they had zoning requirements that had been met, and whether the state agency approvals had been met. Those were listed not just to say, well, we found one, and therefore it fits the exemption, but to look at all of these in making a determination. You have some flexibility, but each one of those need to be looked at. That is why it is in the law, and that is why it is spelled out that way. Do you agree with that?

Dr. MCCLELLAN. That is right. The law is very clear that we need to consider all four of those factors. That does not mean there cannot be a few exceptions to the rule. We need to have a reasonable amount of flexibility, but I think those would have to be on a case-by-case basis, something pretty limited.

Senator BREAUX. The authors did not intend that you had to find all four, but also not that you can find one and feel we have met the requirements. It is taken in total.

Dr. MCCLELLAN. Yes, the law is pretty clear.

Senator BREAUX. The other question is, we listed the types of specialty hospitals, and said those that deal predominantly, or exclusively, or primarily in cardiac care, orthopedic care, surgical care, or any other specialized category, the Secretary would designate. I think it was very clear that the fact that one of those that are operating that type of a hospital, just because they also may have an emergency room attached to it that treats others would not knock it out of being a specialty hospital, and is still primarily focused in on one of those specialties. Do you have any thoughts about what we are talking about?

Dr. MCCLELLAN. Well, those other factors may be reasons to consider exceptions, but definitely those are the kinds of considerations that we are considering now, and that if I get confirmed, I would want to take into account in the regulations we issue promptly.

Senator BREAUX. But it is clear that just having an emergency room attached to one of those otherwise specialty hospitals does not knock it out of being a specialty hospital for purposes of the legislation?

Dr. MCCLELLAN. Probably not on an automatic basis. But again, you want to have some flexibility here, and that is something that we might want to consider as well.

Senator BREAUX. Well, tread very carefully on that——

Dr. MCCLELLAN. Absolutely.

Senator BREAUX. —because I think it is very clear that every specialty hospital can attach an ER to it in order to get out of being classified as a specialty hospital.

Dr. MCCLELLAN. That is why I think the guidance and the legislation are so important because that does lay out very clearly what you are looking for, and you want exceptions, if there area any, to be quite limited. That is very clear from the legislation.

Senator BREAUX. That is why it is a moratorium. It is not an absolute prohibition. It is a time to take a look at it and see how it affects——

Dr. MCCLELLAN. Right, and figure out the best way to deal with it; exactly.

Senator BREAUX. If it is determined that it is not an adverse effect on overall community hospitals, I do not have a problem with them. But if it does, that is why we have a moratorium to look at it.

Dr. MCCLELLAN. Right. Or if there are ways to modify the payment systems or deal with this through some other means; exactly.

Senator BREAUX. All right. I cannot really think of anything else I can ask you. I have some questions that we have submitted. And I want to get into some other things that we can just do in private because it is too complicated to try and set it up.

Dr. MCCLELLAN. Thank you, Senator.

The CHAIRMAN. To the folks that are from the Treasury Department, I just would like to say I have appreciated very much the administration's cooperation and your going into new jobs where I would hope the cooperation will continue on what we have tried to do, already some things that Senator Baucus has referred to, the closing of the corporate tax shelters, the inversions, the efforts that we have been trying to make to get pension legislation passed, Enron type reforms, and things of that nature. I just thought I ought to tell you that we have appreciated that past cooperation, and in your new positions look forward to continuing to work with you.

I do not have any more questions. While you are asking a couple of questions, I might slip in the back room and talk to some constituents.

Senator BAUCUS. That is not a bad idea.

The CHAIRMAN. Thank you.

Senator BREAUX. Dr. McClellan, the question goes to the so-called 1115 waiver authority. I have concerns about this, particularly about predecessors aggressive use of the authority. It is starting to appear that there is virtually no aspect of the Medicaid program, even the most core principles established by Congress that are safe from the so-called 1115 waiver.

For example, this one Governor said he intends to obtain a waiver of Medicaid's entitlement so that his state could set an arbitrary cap on the number of people who would receive Medicaid. Another state received a waiver of the requirement that Medicaid cover comprehensive health benefits for children. I think these waivers strike at the very heart of what Medicaid is suppose to do, certainly the entitlement nature and the cap attempt.

Do you believe that there are any provisions or principles of Medicaid that cannot be waived by CMS?

Dr. MCCLELLAN. Senator Baucus, as you know, Medicaid is an extremely important program for very vulnerable citizens, and as the cost of Medicaid has increased, we have had to try harder and harder to find innovative ways to get people the healthcare assistance they need, and do it in a way that the states can manage. I absolutely am committed to the fundamental principle in the law for Medicaid that this is a federal-state partnership, a federal-state matching program.

In that regard, both the Federal Government and the states need to put up funds to provide the benefits under the program. I think Federal imposed caps on spending, things like that, are not envisioned as part of this structure. It is a partnership to get the most effective health care possible to some very vulnerable Americans at the lowest possible cost.

Senator BAUCUS. So the answer is what?

Dr. MCCLELLAN. Well, the answer is that——

Senator BAUCUS. My question was, are there any provisions that cannot be waived by CMS, core principles of Medicaid?

Dr. MCCLELLAN. Well, certainly. The core principles include principles like the federal-state matching principle, that if a program is designed to assist——

Senator BAUCUS. What about caps on entitlements?

Dr. MCCLELLAN. Well, that would include a cap. Because it is federal-state matching, that would include a cap on the Federal match as well.

Senator BAUCUS. Cannot be waived.

Dr. MCCLELLAN. Right, cannot be waived.

Senator BAUCUS. Entitlements cannot be waived.

Dr. MCCLELLAN. That is right. It is not a cap program from the Federal Government standpoint; that we are there to be a partner with the states for whatever expenses they incur in providing the necessary benefits under the program.

Senator BAUCUS. The statute says that Medicaid may be waived if the administrator determines that the waiver would "promote the objectives of the program." Those are the magic words. In your view, what are the objectives of the program?

Dr. MCCLELLAN. I think delivering the highest quality health care possible to America's most vulnerable citizens, especially children, at the lowest possible cost, is the main benefit. And I think we need to be doing more and more. We have already taken steps in this direction. We need to be doing even more to focus on what the objectives of the Medicaid program are. What are we actually achieving in terms of access to health care and improvements in quality.

Senator BAUCUS. There are statutory provisions under Medicaid as to how Medicaid should be delivered.

Dr. MCCLELLAN. No, that is right.

Senator BAUCUS. It is not just generally the best care possible.

Dr. MCCLELLAN. That is right. But that is why I think the more that we can do to develop clear and effective measures of what is working and what is not in the Medicaid program, the better guidance we can give to states as to how to achieve the goals of the Medicaid program effectively. And that is the general goal. But you are right; that is too general. We need to be much more specific, and we need to be looking at what is actually working in getting better health care to Medicaid beneficiaries at the lowest possible cost.

Senator BAUCUS. That is correct. There is a Congress.

Dr. MCCLELLAN. Oh, yes, I am very aware of that.

Senator BAUCUS. And Congress does enact laws.

Dr. MCCLELLAN. That is right.

Senator BAUCUS. And laws are to be enforced.

Dr. MCCLELLAN. That is right.

Senator BAUCUS. That is the executor's job, is to enforce the laws.

Dr. MCCLELLAN. That is exactly what my job is.

Senator BAUCUS. Thank you.

Dr. MCCLELLAN. And I will look forward in continuing to talk with you about enforcing it effectively.

Senator BAUCUS. All right. What about the so-called EPSDT, comprehensive benefits for children? Is that what that is?

Dr. MCCLELLAN. EPSDT benefits for the mandatory Medicaid populations.

Senator BAUCUS. Can they be waived? Can those services be waived?

Dr. MCCLELLAN. I would be very reluctant to waive them. For the mandatory Medicaid beneficiaries, that is an important element of delivering good care, so there would have to be a pretty compelling reason; that there was some other effective way to mandatorily cover children, the benefits required under EPSDT, through some other means in order to do it.

Senator BAUCUS. I also associate myself with the remarks of Senator Breaux, with respect to specialty hospitals.

Dr. MCCLELLAN. Right. I am very well aware of your views on that.

Senator BAUCUS. Four provisions are written in the conjunctive; one, two, three, four. You got them.

Dr. MCCLELLAN. Got it.

Senator BAUCUS. I would like you to come to Montana [Laughter.]

Dr. MCCLELLAN. Senator, I would be delighted to come. Like many Americans, I have experienced Montana in the form of Glacier National Park and some very good hiking, but I know that aside from the beautiful scenery, there are some real important healthcare problems there, access to care, and cost of care. I think the best way to deal with them is to see them firsthand.

Senator BAUCUS. I appreciate that. Everyone of your predecessors has been to Montana.

Dr. MCCLELLAN. I would hate to break that tradition.

Senator BAUCUS. And stop in Iowa on the way. [Laughter.] I means a lot to people in our state, because Washington is so far away.

Dr. MCCLELLAN. I know. It is far.

Senator BAUCUS. How are we going to help rural health care when the President recommends cuts in rural hospital flexibility grant programs?

Dr. MCCLELLAN. I talked about this a little bit with Senator Rockefeller; he brought that up as well. I think you have to look at the overall content of the rural assistance programs, and there is an enormous amount of new funding in the Medicare legislation, both funding that is directly targeted to rural providers and rural areas, and also funding for the drug benefit and the like that will help enormously in improving access and quality of care for rural beneficiaries. The administration has also increased funding in other areas, community health centers, funding for commission core officers to provide care in underserved areas, including rural areas.

I would really like to work with you on the totality of programs and using them as effectively as possible. I think that gets back to my earlier point about finding what works, and supporting the programs that really do work in improving care.

Senator BAUCUS. I appreciate that. But when you do come to Montana, I am going to take you out to some places to show you just how tough it is, Mr. Chairman

Dr. MCCLELLAN. It is, I know.

Senator BAUCUS. —to either receive, access to, or even practice in the most remote parts of our country. I mean, I know you spend a lot of time in parts of the country. Just to digress slightly, one of Secretary Thompson's predecessors, Doc Bowen, prided himself as being the country doc, and I had pointed out to him that rural Indiana is not rural Montana. It does not rain west of the hundredth meridian. There are huge, vast expanses in the west. And by west, I mean the high plain states particularly.

Dr. MCCLELLAN. And there are a lot of people of limited means.

Senator BAUCUS. That is exactly right. In fact, I took one of your predecessors, Dr. Roper, on a little airplane to one of these hospitals to show him how inaccessible it was. Bill Roper, he was white knuckled as those little planes were going [Laughter.] I was glad that we had bad weather because it kind of showed to him that it is not always good weather. Sometimes there is bad weather.

The CHAIRMAN. Do not fool yourself; he planned that.

Dr. MCCLELLAN. He achieved the desired effect, I am sure. In all seriousness, I will look forward to that. We have a very diverse Medicare population that needs to be served. If it is not working for all the beneficiaries, regardless of where they are and under what circumstances they are getting care, we are not doing our job. So I will look forward to getting out there.

Senator BAUCUS. Could you also tell us on the demonstration project, the interim benefit with respect to self-injectable medications for diseases such as MS, and rheumatoid arthritis, and also

I guess the need for anti-cancer medications, when will that be implemented?

Dr. MCCLELLAN. It is not going to start on March 8th. There was a very aggressive time table envisioned by Congress in passing the bill, and the administration just cannot meet that. There are a lot of very hard questions in that demonstration, how to decide which beneficiaries should be included, and we want to have a fair and transparent way of doing that, and how to decide which drugs should be included. The guidance was pretty clear that it should be substitutes for drugs that people have to get in doctors' offices now, but medicine is complicated, and for covering all the conditions involved, not just cancer but other conditions, rheumatoid arthritis and the like.

We are going to have an announcement on that soon. That is a demonstration that I think is very important, both for what we can learn about how to deliver these alternatives to physician office care effectively, and to help 50,000 Medicare beneficiaries. I cannot give you an exact date today. I promise you it will be a top priority to get done soon. And I promise you we will cover the 50,000 people, or cover up to the $500 million limit, and learn a lot from that demonstration for purposes of implementing the drug benefit effectively.

Senator BAUCUS. I appreciate that. As you also know, several states are expected to run out of SCHIP funds in the next few years, resulting in children being excluded, kids that need health insurance. What can we do about that

Dr. MCCLELLAN. Well, we certainly can do everything we can to let states take advantage of the CHIP funds that are available now.

Senator BAUCUS. That will be your policy?

Dr. MCCLELLAN. Well, that is my immediate policy for right now, and I will certainly look forward to working with you on further steps to make sure that states that want to cover children have the wherewithal to do that. I think there are a lot of things we can do to get there.

Senator BAUCUS. Senator Chafee, and others, and I, several years ago, it was really hard to get that program through.

Dr. MCCLELLAN. Yes, I know. I worked with you some on that at the time, and I know how important the program is.

Senator BAUCUS. Every way we can to help people who do not have health insurance, and particularly low-income kids is——

Dr. MCCLELLAN. I agree, SCHIP has been a big success.

The CHAIRMAN. All right. I have concerns about the quality of care. As you know, according to recent reports by the Institute of Medicine, there are serious problems with the quality of patient safety in our nation's healthcare system, which is counterintuitive. Most Americans think it is pretty good, but they are developing alarming reports.

One study showed that patients received recommended care only 50 percent of the time. I am wondering what quality incentive, peanut policies, you might have in mind through Medicare A and B.

Dr. MCCLELLAN. As you know, Senator, through your leadership, for the first time in this legislation, we have quality-related payment incentives built in; that hospitals are only going to get the

full update if they start providing useful and proven information that can help patients decide where to get good care, and they can provide a strong incentive to improve quality of care. I think there is an awful lot more that we can do, and there is a lot of demonstration authority in this bill.

I talked with Senator Jeffords a few minutes ago about some of the quality-related demonstration programs that he is interested in, to figure out what additional payment incentives can really work, and provide the right incentives to improve quality, to give seniors better care, and to do it at a lower cost. I intend to work closely with you on that as well.

This is an area where I have done a lot of research in my previous professional life, and where I know there is a strong interest on both sides of the aisle in finding ways to get more for the money in Medicare. So you can bet we are going to be moving forward with more demonstration programs, and I will be talking with you about more ideas, even where legislation might be helpful in providing better incentives for improving quality. It is a very important issue.

Senator BAUCUS. We have talked about a lot of programs under your jurisdiction, lots of aspects, all of it very important, a little more—some might say arcane—than some others. But if you could just sit back a little bit in a broader picture, what do we do about the rate of increase in healthcare cost in this country?

Dr. MCCLELLAN. It is a huge issue.

Senator BAUCUS. And I do not know that we are really addressing the problems. We are addressing some of the symptoms, but we are not addressing some of the causes. It gets to competitiveness. I mentioned earlier how much more expensive it is to manufacture a car in the United States than it is to Canada just because of healthcare costs in this country. That is just one example. There are lots of examples. So many people are concerned about losing their healthcare coverage. Why? Because so many companies, faced with very severe competition, are trying to cut costs because they think that is a good place to cut. It is frightening people that they could lose their coverage, again, because the costs are going up so much, in this country.

As you know, our healthcare costs per capita in this country are twice that of the next highest country. We pay twice as much on health care in America than does the next highest country, which I think might be Canada. It might be Germany; I am not sure which. And I do not know that we are twice as healthy as people in those countries.

What do we do about healthcare costs? What are some of the clues, to maybe start getting at it, in a real sense, not just in a tossing off the cuffs? How do we start?

Dr. MCCLELLAN. Well, there are I think two fundamental issues that we have to deal with in health policy, and the Medicare program, and other CMS programs more generally. One is to make sure that we keep encouraging the improvements in care that we have seen in recent years. There are many more diseases that are treatable today, that people can get cured from today, and can be prevented in the first place, than ever before. There is more research and development going on that ever before to help us do

even better. That is something I saw a lot of at FDA. The problem is, it is getting awfully expensive to bring those health benefits to the American public.

At FDA we took a lot of steps to bring down those costs to try to make the development process less expensive and less costly. But still today, you are absolutely right, that too many Americans are struggling to afford their health care, and too many Americans do not have good healthcare options available.

The administration has supported a lot of ideas in this area, everything from healthcare purchasing coalitions to proven disease management programs, to our efforts at FDA and throughout the administration to make generic drugs more available. I think there is much more that we can do to bring down cost. Medicare legislation will be a big help in that regard, by helping seniors get lower prices for their drugs, and by helping them get access to much more affordable and a much broader range of health plans. But I think we need to make some more fundamental steps as well, to get better information available on what works and what does not.

Senator BAUCUS. It is a big subject.

Dr. MCCLELLAN. It is. It is a huge subject, but it is one where we really need to be focusing our efforts.

Senator BAUCUS. Some people think part of the reason our healthcare costs are higher in this country compared to others is because our prescription drug costs are so much higher. To what degree is that part of the problem?

Dr. MCCLELLAN. Well, prescription drug costs have been one of the most rapidly growing components of healthcare cost increases, but overall it is still relatively small. It is about 10 percent of all healthcare costs. And you look at what accounted for the increases in Medicare spending, hospital spending increases were a bigger component in this past year. We should not just look at prescription drug cost; we need to look at the overall spectrum of costs to get them down.

Senator BAUCUS. Oh, I am not asking you to look at this. I am just asking you what are some of the components.

Dr. MCCLELLAN. For prescription drug cost increases?

Senator BAUCUS. What are some of the components of the higher cost structure in the United States compared with other countries?

Dr. MCCLELLAN. Well, we pay more for our doctors. We pay more for our hospitals. I think in many ways we get more out of that. We have some very well-trained health professionals delivering services under difficult circumstances and doing a very good job of it. I think in many respects, the quality of care, the kinds of treatments available, are better in this country than in any other parts of the world. The problem is that more people are having trouble affording coverage, and more people are having trouble getting health insurance. Many people cannot get into what should be a very high-quality system. So I do think we need to take more steps in exactly this area to make health care more affordable, to bring down prices for drugs and other medical services for Americans.

Senator BAUCUS. Dr. McClellan, I wish you good luck.

Dr. MCCLELLAN. Thank you. I am going to need it. I am going to look forward to working with you on getting some help to get it done.

Senator BAUCUS. Yes. We have a lot of work ahead of us.

Dr. MCCLELLAN. Thank you.

Senator BAUCUS. Thank you.

The CHAIRMAN. Mr. Roseboro and Mr. Warshawsky, do not worry. The fact you were not asked any questions has nothing to do with whether or not you will get through the United States Senate.

Senator BAUCUS. I asked one.

The CHAIRMAN. Oh, you did?

Senator BAUCUS. Are you belittling the question I asked?

The CHAIRMAN. No, not at all. I really thought that only one person was asked a question.

In culmination of this meeting, I would only have this admonition. Assuming that you will get out of committee shortly, and we plan to do that shortly, when you are moved to the floor of the Senate, try to get your questions that were asked for writing, to get those right away. I hate to tell people that they ought to vote on a nominee if their questions have not been asked, unless I would suspect that there is a political motivation behind a series of questions coming at the last minute just simply to stall. But that does not happen hardly at all, so I would hope that you would respond accordingly.

With that, Senator Baucus and I thank you for your attendance, and we adjourn the meeting.

[Whereupon, at 4:20 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF MAJORITY LEADER BILL FRIST, MD

I am extremely pleased to join with my colleagues in welcoming Dr. Mark McClellan—the current Commissioner of the Food and Drug Administration and the future Administrator of the Centers for Medicare and Medicaid Services (CMS).

We all know that the responsibilities of the CMS Administrator are among the most crucial in our government. The Administrator oversees programs that provide health coverage for nearly 80 million people – including seniors, individuals with disabilities, low-income children and pregnant women.

Moreover, the challenges facing CMS today are perhaps greater than at any other time in the agency's history. Implementing the Medicare Modernization Act and educating seniors about the benefits of the new law are critical national priorities. It will require a steady and visionary leader to get the job done.

Because the challenges facing the next CMS Administrator are not only considerable, but also immediate, it is incumbent upon this Committee and the United States Senate to approve this nomination swiftly.

I commend Chairman Grassley and Senator Baucus for working together to ensure that the process for considering this nomination will be both timely, and thorough. I stand ready to assist you in moving this nomination forward.

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Dr. McClellan is well known to the members of this Committee. He has held a series of high-level Executive Branch positions in both the current Administration, and the past Administration. Throughout his service and throughout the years, he has provided invaluable guidance to this Committee and to Congress.

Mark McClellan is a clear-headed thinker, a superb policy analyst, and a bold leader. He has demonstrated time and again his ability to work across party lines and partisan divide to help shape and implement policies that protect the public and improve Americans' access to affordable, quality health care.

President Bush could not have nominated a better person to be the next Administrator of CMS.

We stand at the threshold of potentially dramatic improvements in the medical care available to seniors. Under the bipartisan legislation crafted by Chairman Grassley, Senator Baucus and this Committee, Medicare will soon offer a voluntary prescription drug benefit to all seniors—with additional assistance to those who need the most help.

- For a relatively low monthly premium, Medicare will cover a large share of a senior's prescription drug costs up to $2250 per year and 95% of all high catastrophic costs.
- Medicare will cover almost all of the costs of prescription drugs for 12 million low-income seniors.
- And in just a few short months, beginning this June, seniors will be eligible for savings of 10-25% and low-income seniors will receive $600 in additional assistance through Medicare-endorsed prescription drug discount cards.

The new law does more than simply adding a drug benefit to the Medicare program. It also:

- provides seniors with a wider range of health coverage choices;
- enhances prevention, disease management, and chronic care coordination in the traditional Medicare program;
- reduces the regulatory burden on doctors and hospitals; and
- takes a number of additional steps to improve the quality and efficiency of medical care available to seniors.

We need a leader with Mark McClellan's experience and skills to help translate the good intentions of Congress-- embodied in this new law-- into lasting improvements in Medicare that can benefit this generation of seniors, and the next.

***

When confirmed, Mark will be only the second physician and the first former Commissioner of the FDA serve as the Administrator of the Medicare and Medicaid programs.

Clearly, Mark's experience as the head of the Food and Drug Administration gives him unique insight at a time when Medicare will begin to offer prescription drug coverage to its over 40 million beneficiaries.

However, it is Mark's background and training as a physician that I believe provides us with the greatest opportunity to fully realize the benefits the new Medicare law has set in motion.

Prescription drugs are the most powerful tool in a physician's arsenal to treat and beat disease. They will now be available to seniors within the context of an overall Medicare program that will begin to place a much greater emphasis on promoting prevention, safety, disease management, chronic care coordination, and a stronger doctor-patient relationship. As a physician, I believe Mark is well positioned to help us seize this historic opportunity.

Mark, you have my full support and confidence.

I look forward to hearing your testimony this afternoon. I look forward to your confirmation. And I look forward to continuing to work together to deliver the highest quality health care possible to our nation's seniors, to others in need, and to all Americans.

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[SUBMITTED BY CHAIRMAN GRASSLEY]

Congress of the United States
Washington, DC 20515

March 4, 2004

The Honorable Chuck Grassley
Chairman
Senate Finance Committee
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510-6200

The Honorable Max Baucus
Ranking Minority Member
Senate Finance Committee
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510-6200

Dear Chairman Grassley and Ranking Member Baucus:

We are writing today regarding U.S. Food and Drug Administration Commissioner Dr. Mark McClellan's nomination to head the Centers for Medicare and Medicaid Services.

We have repeatedly asked Dr. McClellan to appear before various House Committees of jurisdiction in our proper oversight role regarding several FDA areas of interest. In particular, we have asked him to testify at a series of hearings about prescription drug pricing issues and the ongoing National interest in drug pharmaceutical market access, or re-importation, as an avenue for Americans to get access to lower cost, high quality medicines. Unfortunately, he has declined each and every one of our requests. Furthermore, it is our understanding that Senator John McCain has also asked Commissioner McClellan to appear before the Senate Committee on Commerce, Science and Transportation regarding these same important issues on at least two occasions and, again, Dr. McClellan has declined.

To date, the Commissioner has refused to appear before any Congressional Committee of jurisdiction to answer questions about pharmaceutical market access from Canada and other industrialized countries, as well as other issues concerning the pharmaceutical industry and the exceptionally high cost of prescription drugs in this country. We believe no one should be confirmed who has shown such staunch unwillingness to testify before Congressional Committees of jurisdiction, and that Dr.

McClellan has repeatedly shown an unacceptable arrogance to Congress and the American people.

Incidentally, Dr. McClellan has on numerous occasions spoken before groups across the United States expressing, among other things, his opposition to giving Americans access to affordable prescription drugs through the mechanism of pharmaceutical market access. If he can do that, why can he not find the time to appear before the American people's properly elected Representatives?

Once again, we believe that no one should be afforded a position of leadership in our government who is unwilling to testify before Committees of the U.S. Congress on a matter of such National importance.

Therefore, before he is rushed into the new position of overseeing the newly enacted Medicare prescription drug program, we respectfully request that you postpone confirmation hearings on Dr. McClellan until he agrees to appear before the relevant Committees of Congress to better explain his position on this important National issue.

Sincerely,

Rep. Dan Burton

Rep. Gil Gutknecht

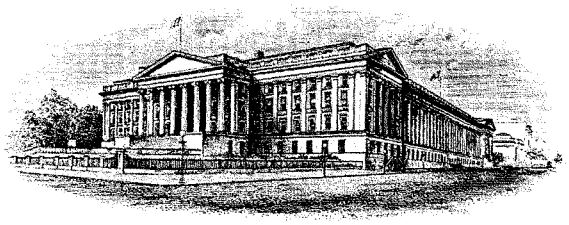
Rep. Jo Ann Emerson

Rep. Bernie Sanders

Rep. Rahm Emanuel

Rep. Rosa DeLauro

Rep. Dennis Kucinich



DEPARTMENT OF THE TREASURY
OFFICE OF PUBLIC AFFAIRS

Embargoed Until Delivery
March 8, 2004

Contact: Tara Bradshaw
(202) 622-2014

**STATEMENT OF DONALD L. KORB,
NOMINEE FOR CHIEF COUNSEL FOR THE INTERNAL REVENUE SERVICE AND
ASSISTANT GENERAL COUNSEL IN THE DEPARTMENT OF THE TREASURY
BEFORE THE COMMITTEE ON FINANCE, UNITED STATES SENATE**

Good afternoon Mr. Chairman, Senator Baucus and Members of the Committee. It is an honor to appear today before this Committee as President Bush's nominee for the position of Chief Counsel for the Internal Revenue Service. If I may, I would like to introduce my family to the Committee.

Before taking your questions, I would like to discuss two subjects: why I want to assume the post for which you are considering me today and a brief summary of the goals that I have set for myself if I am confirmed.

This opportunity for public service is a very great honor. I am humbled by the confidence that the President, Secretary Snow, and Commissioner Everson have placed in me by giving me the opportunity to serve my country in this capacity. The opportunity for public service at the national level is a rare privilege and one that I gratefully welcome. I believe that all Americans should find some time during their lives to serve their country and their fellow citizens. The extraordinary sacrifices of our armed forces in Iraq and Afghanistan immediately come to mind. However, there are other ways to use one's talents and experiences for the benefit of the public, and President Bush has given me such an opportunity by nominating me for the position of Chief Counsel.

I have over 30 years of experience in federal taxation in both public service and private practice. The core of my practice since the late 1980's has been tax controversy work. It has included representing taxpayers before the IRS in examinations, appeals, and tax litigation. It has also included mediating a number of disputes between taxpayers and the IRS which has given me an interesting perspective into how to resolve disputes between the tax collector and the taxpaying public.

If I am fortunate enough to be confirmed by the Senate, I will begin my third tour of duty with the Internal Revenue Service. Thirty years ago this past January, I began my legal career as an Attorney/Advisor in the Office of Chief Counsel in Washington. Over the next four years I worked on a myriad of issues across all areas of the tax code. Later, during the Reagan Administration, I served again, this time for two years as an Assistant to Commissioner Roscoe Egger. I was the overall coordinator of the Service's involvement in the legislative process that resulted in the Tax Reform Act of 1986. I actively participated in drafting the specifications for what became Section 469, the passive activity loss rule. I am proud to say, that following the enactment of the 1986 Act, this particular Code section was enormously successful in putting the individual tax shelter industry at that time out of business. Also, before I returned to the private sector, I developed a new approach to the published guidance process which enabled the Service to publish a significant amount of guidance in a short period of time in the immediate aftermath of the 1986 Act. I believe that the experience and institutional knowledge that I gained during these two stints in the IRS in the 1970's and 1980's will be invaluable to me as Chief Counsel.

I am already familiar with the organization and operations of both the Service and the Office of Chief Counsel. Also, I already know personally many of the people I would work with in this position. In addition, I have a solid understanding of the Department of Treasury's Office of the Assistant Secretary (Tax Policy). I worked very closely with Treasury during the time I was Assistant to the Commissioner, particularly during the 1986 tax reform process, and have closely followed its operations over the past six years as an Officer and Council Director of the ABA Tax Section. Consequently, I will be able to "hit the ground running" if my nomination is confirmed.

In the late 1990's, this Committee identified serious concerns regarding the operations of the Internal Revenue Service. The reforms instituted at that time are having a positive impact both on the way the Service conducts its operations and on compliance by the taxpaying public with our tax laws. In line with those reforms, Commissioner Everson has set three goals for the Service: to continue to enhance the service that the IRS provides to taxpayers, to continue to modernize the information technology systems of the Service, and to strengthen the integrity of the nation's tax system through enhanced enforcement activities. If confirmed, my top priority as Chief Counsel will be to help Commissioner Everson achieve these goals.

This Committee has also identified serious compliance issues that confront our tax system, particularly with respect to tax shelters. My predecessor in this position accomplished a great deal to help the Service enhance its enforcement efforts in the battle against these tax shelters. Like my predecessor, I want taxpayers and tax practitioners to have a healthy respect for the IRS; I also want to help bring the struggle against abusive tax shelters and the new generation of abusive schemes marketed to individuals to a successful conclusion much like we did in the mid-1980's with the tax shelters marketed in those days. I look forward to working with this Committee to achieve these goals.

Finally, I want the attorneys in the Office of Chief Counsel to continue becoming more client-oriented while at the same time maintaining their independent judgment. Hopefully, the result will be an operation with lawyers who will conduct their work essentially like lawyers in a traditional law firm do while at the same time serving America's taxpayers fairly and with

integrity by providing correct and impartial interpretation of the internal revenue laws and the highest quality legal advice and representation for the Internal Revenue Service.

Let me conclude by assuring you that if I am confirmed, I will do my utmost to successfully carry out the responsibilities entrusted to me as Chief Counsel. Thank you for your consideration.

I would be pleased to answer any questions.

-30-

SENATE FINANCE COMMITTEE
STATEMENT OF INFORMATION REQUESTED OF NOMINEE

A. BIOGRAPHICAL INFORMATION

1. Name: (Include any former names used.)

   Donald Lee Korb

2. Position to which nominated:

   Chief Counsel for the Internal Revenue Service, Department of Treasury

3. Date of nomination:

   December 9, 2003

4. Address: (List current residence, office, and mailing addresses.)

   Residence: 2669 Cranlyn Road, Shaker Heights, Ohio 44122
   Office: 3900 Key Center, 127 Public Square, Cleveland, Ohio 44114

5. Date and place of birth:

   April 29, 1948 in Cleveland, Ohio

6. Marital status: (Include maiden name of wife or husband's name.)

   Married to the former Patricia A. Krawulski

7. Names and ages of children:

   Patrick L. Korb, age 21, and Laurel A. Korb, age 17

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

   Graduate Law School: Georgetown University Law Center, Washington, D.C. 20001; attended September 1974 – May 1977; awarded LL.M. in Taxation on May 29, 1977

Law School: Case Western Reserve University, Cleveland, Ohio 44106; attended September 1970 – May 1973; awarded J.D. on June 6, 1973

College: John Carroll University, Cleveland, Ohio 44118; attended September 1966 – May 1970; awarded B.A. (Honors Curriculum), Magma Cum Laude on May 24, 1970

Secondary School: Charles F. Brush High School, Lyndhurst, Ohio 44124; attended September 1963 – June 1966; awarded high school diploma on June 5, 1966

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.)

July 1998 – Present
Thompson Hine LLP; Cleveland, Ohio; Partner

January 1997 – June 1998
Coopers & Lybrand L.L.P.; Cleveland, Ohio; Tax Partner

September 1986 – January 1997
Thompson Hine & Flory LLP; Cleveland, Ohio; Partner

May 1984 – August 1986
Internal Revenue Service; Washington, D.C.; Assistant to the Commissioner

January 1978 – May 1984
Thompson Hine & Flory, Cleveland, Ohio; Associate (1978-1981) and Partner (1981-1984)

January 1974 – December 1977
Office of Chief Counsel, Internal Revenue Service, Interpretative and Disclosure Divisions in National Office; Washington, DC; Attorney Advisor

January 1972 – December 1973
Nurenberg, Plevin, Jacobson, Heller & McCarthy; Cleveland, Ohio; Law clerk

June 1971 – August 1971
Brazing & Metal Treating, Inc.; Euclid, Ohio; Assembler and metal handler

August 1964 – January 1972
Fisher Foods; Bedford Heights, Ohio; Grocery clerk

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.)

Member, Ohio State Tax Commissioner's Advisory Council (2000-present)
Member, Ohio Secretary of State Operations Review Team (1999)
Tax Advisor to the National Commission on Economic Growth and Tax Reform (the "Kemp Commission") (1995)

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.)

Partner, Thompson Hine LLP (1981-1984, 1986-1997, 1998-present)
Tax Partner, Coopers & Lybrand L.L.P. (1997-1998)

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

Section of Taxation, American Bar Association: Member since 1978; LMSB Division Coordinator (2003-present); Vice Chair (Committee Operations) (2000-2002); Council Director (1996-1999); Chair, Administrative Practice Committee (1992-1994)
Director, Cleveland Tax Club (1987-1990)
Member, Board of Trustees of John Carroll University Alumni Association (1991-1992)
Member, Finance Council, Gesu Church (1992-1999)
Member, Union Club of Cleveland (1994-present)
American College of Tax Counsel: Fellow (1995-present) and Regent (2001-present)
Member, Board of Trustees, Great Lakes Theater Festival (1999-2000)
Member, Board of Trustees of Cleveland Opera (1999-present); Chair, Long Range Strategic Planning Committee (2001); Member, Executive Committee (2002-present)
Member, Board of Trustees of Musical Theater Educational Programming (2003-); President (2003-)

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.

Member, Executive Committee, Cuyahoga County Republican Organization (1998-present)
Member, Finance Committee, Cuyahoga County Republican Organization (1994; 2003-present)
Cuyahoga County Bush for President Speakers Bureau in Cleveland (2000)
Cuyahoga County Dole for President Speakers Bureau in Cleveland (1996)
Cuyahoga County Bush for President Speakers Bureau in Cleveland (1988 and 1992)
Cuyahoga County Voinovich for Governor Speakers Bureau in Cleveland (1990)

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.

2003	
Rob Portman (U.S. Congress)	$500
Doug White (Ohio Senate)	125
Bush-Cheney '04 (U.S. President)	500
Thompson Hine Good Government Program PAC/ Thompson Hine & Flory National Good Government Fund PAC	1,000
2002	
Rob Portman (U.S. Congress)	1,000
2001	
Eric Fingerhut (Ohio Senate)	500
Rob Portman (U.S. Congress)	1,000
Rob Portman (U.S. Congress)	500
Thompson Hine & Flory Ohio Good Government Program PAC/Thompson Hine & Flory National Good Government Fund PAC	1,700
2000	
Rob Portman (U.S. Congress)	750
James Petro (Ohio Auditor)	500
National Republican Congressional Committee	1,000
James Trakas (Ohio House)	500

Thompson Hine & Flory Ohio Good Government Program PAC/Thompson Hine & Flory National Good Government Fund PAC	600
1999	
Rob Portman (U.S. Congress)	250
James Petro (Ohio Auditor)	250
Thompson Hine & Flory Ohio Good Government Program PAC/Thompson Hine & Flory National Good Government Fund PAC	1,300
1998	
Republican Party Cuyahoga County	50
Rob Portman (U.S. Congress)	125
Ken Blackwell (Ohio Secretary of State)	950
1997	
Ken Blackwell (Ohio Treasurer)	500
Republican Party Cuyahoga County	50
James Petro (Ohio Auditor)	100
Cleveland City Council Leadership Fund	50
PricewaterhouseCoopers PAC	350
1996	
Rob Portman (U.S. Congress)	100
Harry Hanna (Common Pleas Judge)	150
Ken Blackwell (Ohio Treasurer)	100
Martin Hoke (U.S. Congress)	250
Mark Longabaugh (U.S. Congress)	100
Wayne Parker (U.S. Congress)	250
Thomflor Good Government Program PAC/ Thompson Hine & Flory National Good Government Fund PAC	800
1995	
Richard Lugar (U.S. President)	250
Robert Dole (U.S. President)	250
Rob Portman (U.S. Congress)	100
Phil Gramm (U.S. President)	250
Thomflor Good Government Program PAC/ Thompson Hine & Flory National Good Government Fund PAC	700
1994	
Martin Hoke (U.S. Congress)	100
Republican Party Cuyahoga County	1,000
James Petro (Ohio Auditor)	100

Ken Blackwell (Ohio Treasurer)	200
Thomflor Good Government Program PAC/ Thompson Hine & Flory National Good Government Fund PAC	800

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.)

American College of Tax Counsel (1995)
IRS Commissioner's Award (1986)
John Rufus Ranney Scholarship in Law (1973)
Alpha Sigma Nu Jesuit Honor Society (1969)
John Carroll University President's Honor Award Scholarship (1966)
National Honor Society (1965)
Eagle Scout (1962)

I have been listed in:
The Best Lawyers in America
Who's Who in America
Who's Who in American Law
Who's Who in Emerging Young Leaders in America
Who's Who in American Colleges and Universities

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

Rethinking Refund Review: Understanding Joint Committee on Taxation (Co-author) in Corporate Business Taxation Monthly; November, 2002

Sham Transaction Doctrine and Economic Substance (Co-author) in Insurance Tax Seminar sponsored by the Federal Bar Association in conjunction with the Office of Chief Counsel of the Internal Revenue Service; June, 2002

Alternate Dispute Resolution Techniques for Issue Resolution with the Service (Co-author) in 2000 Cleveland Tax Institute; October, 2000

A Second Look at the Reorganized IRS in 1999 Cleveland Tax Institute; November, 1999

Ownership of Company Real Estate a Key Choice (Co-author) in Crain's Cleveland Business; December, 1998

A First Look at the Reorganized IRS in 1998 Cleveland Tax Institute; November, 1998

A First Look at the Coming Tax Reform in 1996 Cleveland Tax Institute; October 10, 1996

The Infield Fly Rule and the Internal Revenue Code in 1995 Cleveland Tax Institute; October 19, 1995

IRS Practice and Procedure in Tulane Tax Institute; September, 1994

Use of Registered Partnerships Having Limited Liability and Limited Liability Companies by Lawyers in 1994 Cleveland Tax Institute; November 11, 1994

Survey of the 1993 Tax Legislation in 1993 Cleveland Tax Institute; November 12, 1993

Tax Incentives for Closely Held Businesses (Co-author) in Practicing Law Institute (Business Planning Under the Omnibus Budget Reconciliation Act of 1993); October, 1993

Economic Performance – The Final Regulations Under Section 461(h) in 1992 Cleveland Tax Institute; November 12, 1992

The Who and When of Tax Transactions: Miscellaneous Issues in 1991 Cleveland Tax Institute; November 15, 1991

Federal Income Tax Issues in Real Estate Workouts in 1990 Cleveland Tax Institute; November 16, 1990

A Different Perspective on the "Bubble" (Co-author) in Tax Notes; June, 1990

Admission of New Partners, Contributions of Property and Avoiding Disguised Sale Treatment in 1989 Cleveland Tax Institute; November 9, 1989

Limitations on Passive Activity Losses and Credits – Temporary Regulations, Part I in 1988 Cleveland Tax Institute; November 10, 1988

Limitations on Passive Activities Losses and Credits – Outline of Some of the Significant Rules in the Temporary Regulations Issued February 9, 1988, 88 TNT 48-11; March, 1988

Valuations and Allocations of Purchase Price Under Sections 338 and 1060 in 1987 Cleveland Tax Institute; November 5, 1987

IRS Regulations on Reporting Real Estate Transactions (Co-author) in Tax Notes; May, 1987

IRS Issues Regulations on Information Reporting of Real Estate Transactions (Co-author) in Ohio State Bar Association Report; May, 1987

IRS Issues Regulations on Information Reporting Real Estate Transactions (Co-author) in BNA-Tax Management Weekly Report; April, 1987

An Insider's View of Tax Reform in Ohio Lawyer; January/February, 1987

An Insider Looks at Tax Reform in CWRU Law School In Brief Magazine; January, 1987

Limitations on Losses and Credits from Passive Activities in Cleveland Law Institute; November 13, 1986

Korb on Technical Advice Memo 8404012 (Partnership Basis) in Tax Notes; March, 1984

Tax Planning for a Troubled Marriage – Part II in Cleveland Tax Institute; November 18, 1983

Business Start-Up Expenses in Cleveland Tax Institute; November 11, 1982

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.)

December 5, 2003 – Southwestern Ohio Tax Institute; Cincinnati, Ohio; Topic: Schemes, Shelters and Abusive Transactions

October 20, 2003 – Tax Executives Institute Annual Meeting; Atlanta, Georgia; Topic: Tax Accrual Workpapers 2003: What Documentation Should a Corporate Tax Department Generate?

October 10, 2003 – Capital University Law School Tax Institute; Columbus, Ohio; Topic: Schemes, Shelters and Abusive Transactions

June 20, 2002 – Insurance Tax Seminar sponsored by the Federal Bar Association in conjunction with the Office of Chief Counsel of the Internal Revenue Service; Washington, D.C.; Topic: Sham Transaction Doctrine and Economic Substance

February 1, 2001 – American Bar Association/AICPA Seminar; Washington, D.C.; Topic: IRS's New Tool Box to Resolve Disputes: Ethics in ADR Cases (Moderator)

May 18, 2001 – Cleveland Tax Institute; Cleveland, Ohio; Topic: Alternate Dispute Resolution Techniques for Issue Resolution with the Service

November 1, 1999 – Cleveland Tax Institute; Cleveland, Ohio; Topic: A Second Look at the Reorganized IRS

December 7, 1998 – Cleveland Tax Club; Cleveland, Ohio; Topic: IRS Reorganization

November 10, 1998 – Cleveland Tax Institute; Cleveland, Ohio; Topic: A First Look at the Reorganized IRS

October 29, 1998 – Cleveland Accounting Show; Cleveland, Ohio; Topic: A First Look at the New and Improved IRS

October 19, 1998 – Akron Tax and Estate Planning Group; Akron, Ohio; Topic: A First Look at the New and Improved IRS

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

I have almost 30 years of experience in federal taxation as a lawyer both in public service (four years in the Office of Chief Counsel of the Internal Revenue Service and two plus years as Assistant to the Commissioner) and in private practice (over 21 years with a major law firm interrupted once by my second tour of duty at the Service and once by 18 months with a Big 6 public accounting firm).

The core of my practice since the late 1980's has been tax controversy work. It has included representing taxpayers before the IRS in examinations, appeals, and tax litigation. I have also been the responsible lawyer in our law firm for the preparation of several very large tax cases for eventual trial. Notwithstanding my focus on tax controversy matters, I am also involved in tax planning matters and reviewing (and mostly recommending rejection of) tax ideas promoted by the accounting firms to our clients; in the early part of my career, the focus of my practice was more on the transactional side including extensive experience in financings, the formation of partnerships and, in the late 1980's and early 1990's, workouts of distressed companies.

I have significant managerial experience in both the private and public sectors:

- Beginning in late 1984 and continuing through September 1986, I was the Service official who led the Service's participation in the landmark 1986 tax reform process.
- I have served as Area Chair of both the Tax (1990-1997) and Employee Benefits (1990-1993) Areas of Thompson Hine.
- I created and currently lead Thompson Hine's National Tax Controversy Practice.
- For two years, I supervised the work of almost 40 committees of the Tax Section of the American Bar Association.

I have significant experience in strategic planning:

- The best example is some of the work I did at the Service during the tax reform effort in 1985-1986.
- One major program I developed was a new approach to the published guidance process which enabled the Service to publish a significant amount of guidance in a short period of time in the immediate aftermath of the Tax Reform Act of 1986.
- Recently I served as Chair of the Strategic Planning Committee of the Board of Trustees of Cleveland Opera and led a hand picked group of ten Trustees through the strategic planning process that was intended to develop the plan for the transition of the company to the Post-Founder Era.

I am quite familiar with the operations and organization of both the Service and the Office of Chief Counsel. Also, I already know personally many of the people I will be working with in this position. I have worked very hard to maintain my contacts at the Service and, just as in 1984 when I became the Assistant to the Commissioner, I will "hit the ground running" if my nomination is confirmed. I have a solid understanding of the Department of Treasury's Office of the Assistant Secretary (Tax Policy), and also know many of the people there too. I worked very closely with Treasury during the time I was Assistant to the Commissioner, particularly during the 1986 Tax Reform process, and have closely followed its operations through my various positions as an Officer and Council Director of the ABA Tax Section over the past six years.

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.

There are no conflicts of interest that need to be resolved. All potential conflicts have been disclosed on the required forms and resolved by agreement under oversight of the Office of Government Ethics. Should any additional actual or potential conflicts of interest arise, I will consult with Treasury ethics officials.

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.

There are no conflicts of interest that need to be resolved. All potential conflicts have been disclosed on the required forms and resolved by agreement under oversight of the Office of Government Ethics. Should any additional actual or potential conflicts of interest arise, I will consult with Treasury ethics officials.

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.

Lobbying activities on behalf of Eaton Corporation in 2003 in connection with adding a provision to the ETI Replacement Legislation (The American Jobs Creation Act of 2003, the Job Protection Act of 2003, and the Jumpstart Our Business Strength Act of 2003) which would reauthorize the use of the optional gross income method of allocating interest expense between U.S. and foreign sources.

Lobbying activities on behalf of Student Loan Funding Corporation in 1995-1996 in connection with adding Section 150(d)(3) to the Internal Revenue Code permitting tax-exempt entities to cease their status as qualified scholarship funding corporations.

Lobbying activities on behalf of a coalition of private debt collection firms in 1995-1996 in connection with the use of private debt collection companies by the Internal Revenue Service to help the Service collect delinquent federal tax debt.

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 C.1. above.

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.

   I pleaded guilty to a charge of trespassing (Cod. Ord. of Cleveland Heights 979.01) on August 24, 1970 and was fined $25 plus costs. The charge was brought for swimming in a municipal pool after hours on August 12, 1970. The case number is 63738 and the record may be found in Cleveland Heights Municipal Court, 2953 Mayfield Road, Cleveland Heights, Ohio 44118.

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 D.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.

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

Questions for the Record: Senator Max Baucus

Hearing Regarding the Nomination of Brian Roseboro, Mark Warsharsky, Don Korb (McClellan)

Questions for Donald Korb

1. In 2003, the National Taxpayer Advocate's Annual Report to Congress estimated that in the year 2001 a gross tax gap of $311 billion existed. The gap consisted of ($30 billion) due to non-filing, ($249 billion) due to underreporting, and ($32 billion) due to underpaying, resulting in an overall non-compliance rate of 15 percent. The Report notes that the gap is growing, and as a consequence, law-abiding taxpayers are being asked to pay more than their fair share of taxes to make up for the resulting revenue shortfall.

- **Mr. Korb, in your opinion, what makes up the tax gap? Can you break down where the gap is coming from? What can Chief Counsel's office do to help IRS close this gap?**

As I understand it, the gross tax gap is the amount of tax imposed by law for a given tax year that is not paid voluntarily and timely. The gross tax gap is comprised of three main components – filing noncompliance; payment noncompliance; and reporting noncompliance. I do not believe that it is possible to state with any degree of certainty either the current size of the gross tax gap or the relative sizes of its three main components. The estimates from the National Taxpayer Advocate's Annual Report that you cite are, for the most part, extrapolated from Taxpayer Compliance Measurement Program (TCMP) compliance studies. The last TCMP study of individual tax returns was for the tax year 1988, more than 15 years ago. Data for corporations and other entities are even older and less reliable. The ongoing National Research Program (NRP) will provide much more current information on taxpayer compliance that will allow the Internal Revenue Service (IRS) to better analyze the reasons for noncompliance and better prioritize the allocation of its resources to address noncompliance.

I have been told that based on the IRS's evaluation of TCMP data, the IRS believes the largest portion of the current tax gap is attributable to underreporting for income and employment taxes. This corresponds with the fact that the individual income tax and employment taxes are the largest revenue sources for the Federal government. Again, as the IRS evaluates more current data through the ongoing NRP, it will be able to better analyze the sources of the current tax gap.

I believe that the Office of Chief Counsel can help the IRS do a better job of ensuring compliance with the tax laws, and thereby address the tax gap in a number of ways. As I testified at my hearing, if I am confirmed, I would use my position as head of the Office of Chief Counsel to help bring the struggle against abusive tax shelters and the new generation of abusive schemes to a successful conclusion. I also would use the Chief

Counsel position to continue to increase the respect that taxpayers and tax practitioners have for the IRS which would certainly help to close the tax gap.

It is clear to me that that the Office of Chief Counsel plays a central role in ensuring compliance with the tax laws. The Office of Chief Counsel provides legal advice to the IRS at every stage of the tax administration process. This includes:

- Published guidance
- Review and advice on the forms and publications that guide taxpayers in how to meet their filing obligations
- Advice on the processing of returns
- Working with revenue agents during examinations by assisting with interpretations of the tax laws and efficient development of appropriate issues in ways that reduce the burden on taxpayers and the expenditure of resources by the IRS
- Providing advice to the Examination function and to the Office of Appeals
- Representing the Commissioner in the Tax Court
- Referring tax matters to the Department of Justice for civil action

The Office of Chief Counsel works closely with the Department of Justice on a wide range of civil and criminal matters, including summons enforcement, enjoining abusive tax shelter promotions, criminal referrals, providing the IRS position in refund litigation and recommendations regarding appeals of tax cases. In addition, the Office of Chief Counsel works closely with the IRS and the Department of Treasury to publish guidance for IRS employees and the taxpaying public about the proper interpretation and application of the tax laws. Prompt and clear guidance on emerging issues promotes compliance by informing taxpayers how to comply with the law. It also allows the IRS to make better use of its resources, reduces taxpayer burden, and facilitates the identification and targeting of those issues where taxpayers' reporting positions vary from the published guidance.

The Office of Chief Counsel has taken a particularly active role in working with the Department of Justice to enjoin the promotion of abusive tax shelters and to identify and examine the returns of those taxpayers who invested in them. The Department of Treasury, the IRS, and the Office of Chief Counsel have identified over 30 "listed" abusive tax avoidance transactions. These abusive transactions typically are marketed to corporations and high net-worth individuals. In addition, within the last few weeks and again working with the Department of Treasury, the IRS published a number of revenue rulings addressing the most common tax schemes as well as a notice warning taxpayers of the frivolous arguments typically used in tax schemes. These tax schemes are marketed to individuals of all income levels as well as to small businesses. This guidance will help to educate taxpayers who encounter promotional information about these tax schemes and will assist tax practitioners in dissuading taxpayers who may have considered investing in them. This guidance serves the public and it provides a roadmap for the IRS in enforcing the tax laws. The Office of Chief Counsel can continue to help the IRS improve compliance by continuing to issue prompt and clear guidance on

developing issues.

The Department of Treasury and the IRS also recently published proposed Circular 230 regulations addressing best practices for tax advisors who practice before the IRS. Those regulations include more rigorous requirements for "marketed" tax shelter opinions (i.e., those used by third parties in promoting a transaction) as well as revised proposed rules for all tax shelter opinions that conclude that the purported tax treatment of a transaction is more likely than not the correct treatment.

All of these activities are essential in the effort to close the tax gap.

- **The President predicts that the deficit will be cut half in the next five years. Can you predict when the IRS will close the tax gap? Is this part of the part of the strategy for reducing the deficit?**

The IRS is constantly seeking to increase voluntary compliance and reduce the size of the tax gap. However, I understand it is not possible to predict with any degree of certainty that the tax gap will be reduced by a specific amount in a given time period. Apparently, there are at least two reasons for this. First, as noted above, the IRS does not have a reliable estimate of the current gross tax gap and its constituent parts, although the ongoing NRP should be able to provide the IRS with the necessary information when it is completed. Second, the exact relationship between the size of the tax gap and the impact that IRS actions has on it has not been determined to the extent necessary to make such predictions.

Finally, I have been informed that the Administration's FY 2005 Budget includes $300 million for IRS efforts to ensure compliance with the tax laws, and increases the total IRS budget by 4.8%. This is a material increase that will provide the necessary resources. If approved by Congress, this Budget would substantially restore the enforcement presence of the IRS. I understand that the Budget would bolster enforcement ranks by 2,900 FTE. These additional resources are expected to help improve voluntary compliance levels which should help recoup lost revenues, and all else being equal, help contribute to reduced budget deficits.

2. In 1996, you testified before the House Committee on Government Reform and Oversight that IRS does not possess the systems and resources to adequately deal with all of the taxpayers accounts that are in delinquent status. Specifically, you stated that IRS does not have sufficient resources due to budget constraints to adequately deal with (1) the relatively small dollar amount cases and (2) the cases that require greater effort to contact the taxpayer, locate the taxpayer's assets or sources of income, or otherwise collect the amount owed. You testified that serious consideration should be given to the concept of contracting with private collection agencies to collect these types of accounts. In the FY 2005 Budget, the Administration proposes to use private collection agents to help collect delinquent tax debts. The Administration believes that the use of private collection agencies will allow the IRS to concentrate its enforcement resources on more complex cases

and improve the fairness of tax compliance for all Americans.

- **In your opinion, does IRS have the necessary resources to collect delinquent unpaid taxes in 2004/05?**

I understand that despite process improvements, efficiency gains and some hiring authority, the IRS cannot continuously pursue all outstanding tax liabilities. I have been told that the IRS's total potentially collectible inventory (PCI) has increased by 21% between September 2000 and January 2004, with the inactive portion of this total growing by 38%. As of January 2004, the IRS designated over $16.6 billion of this inactive portion as currently not collectible due to IRS collection and resource priorities, although many of these accounts could be collected if the taxpayers were contacted and offered the opportunity to pay either in full or in installments.

The Administration's FY 2005 budget proposes to permit the IRS to use private collection agencies (PCAs) to address many of the accounts that have been designated as currently not collectible due to collection and resource priorities. The Department of Treasury believes that many accounts in deferred status could be addressed effectively and efficiently by PCAs. PCAs would permit the IRS to focus its resources on more complex cases and issues. Lastly, to address those potentially collectible liabilities that cannot be addressed by PCAs would require a significant change in business practice of the IRS. Otherwise, the number of potentially collectible tax liabilities will continue to grow.

- **Do you support the Administration's proposal to use private collection agencies to help collect delinquent tax debts?**

Yes. The use of PCAs to supplement existing and future IRS resources, as outlined in the Administration's proposal, would be an efficient and effective solution to help address the growing inventory of accounts receivable. This proposal carefully defines the activities of PCAs, allows them limited authority (with no enforcement authority), requires strict adherence to guidelines and procedures, and, most importantly, includes full protection of taxpayer rights and privacy. Additionally, PCAs would be evaluated and compensated based on a "balanced scorecard" approach, which will evaluate quality of service, taxpayer satisfaction, and case resolution, in addition to collection results. It is clear to me that with current and anticipated staffing the IRS cannot pursue each taxpayer who fails to pay an outstanding tax liability. The growing PCI, if left unaddressed, undermines the fairness of our tax system. The use of PCAs is consistent with the approach successfully used by private entities and other governmental organizations, and I believe it is a sound approach for collecting delinquent tax debts.

- **What cases should the PCAs handle? What cases should the IRS handle? Why?**

PCAs should handle cases that are likely to be the simplest to collect, where factors indicate that the taxpayer would likely pay the outstanding tax liability if located, and

contacted by telephone. Examples of such cases would be (a) where a taxpayer filed a return indicating an amount of tax due but did not remit payment for that full amount, or (b) where the taxpayer has made a number of voluntary payments on a tax debt that was assessed by the IRS because of failure to file a return or report all income received.

The IRS should not refer to PCAs cases where there is any indication that enforcement action would be required to collect the tax liabilities or that the liability is contested by the taxpayer. Enforcement powers granted by Congress to the IRS to collect delinquent tax debt must remain solely with the IRS. The IRS also should not refer any case that would likely require IRS expertise or the exercise of discretion. Discretion is required, for example, in determining how best to obtain payment of a delinquent tax liability where the taxpayer will not voluntarily enter into repayment terms; this could include the determination to use enforcement tools such as a lien or levy.

The use of PCAs would allow the IRS to focus its limited resources on more complex cases and issues, as well as enable the IRS to handle more collection cases at an earlier stage in the process – before accounts become stale and harder to collect.

- **What are the legal concerns for IRS in using PCAs to collect unpaid taxes?**

One of the Administration's main goals for the PCA proposal is the full protection of a taxpayer's rights. The protections taxpayers have when working with the IRS would apply if they were contacted by PCAs. Under this proposal, existing taxpayer protections would be preserved under existing law and through a combination of explicit contractual provisions and detailed oversight by the IRS over PCAs. More importantly, this proposal has been designed to minimize the possibility that any PCA would be engaged in an activity that may violate a taxpayer right or protection in the first place.

Under the proposal:

- PCAs would be made fully subject to all of the requirements under the protections provided by the Fair Debt Collection Practices Act, including those specifically applicable to IRS employees under Section 6304 of the Internal Revenue Code (Code). PCAs, for instance, would be prohibited from communicating with taxpayers at an unusual or inconvenient time or place, or engaging in conduct that is harassing, oppressive, or abusive.

- The proposal would make the provisions of Sections 6103(n) and 7431(a)(2) of the Code applicable to PCAs. These statutes protect against unauthorized disclosure if PCA employees were to inspect or disclose tax information in a manner not consistent with the PCA contracts. This proposal would require annual reports outlining the safeguards in place at the PCAs to protect taxpayer confidentiality and PCA compliance with the taxpayer confidentiality provisions.

- PCAs would be required to inform taxpayers of their right to obtain assistance from the Office of the National Taxpayer Advocate and to

immediately refer any case where such assistance is requested to the local Taxpayer Advocate Office. All efforts by the PCA to collect would be suspended until the Office of the National Taxpayer Advocate decides whether to act upon the taxpayer's request for assistance.

- PCAs would be required to notify the IRS if the PCA intends to make a communication with third parties governed by Section 7602(c), and must receive specific, written authorization from the IRS before the communication could be made.

- Any installment agreement between the IRS and a taxpayer who is contacted by a PCA would be subject to the protections provided by the Code, including the prohibition on levy during the consideration and term of the installment agreement, as well as immediately after a proposed rejection or termination of an installment agreement, and the taxpayer would have a right to a hearing with the IRS Office of Appeals following the termination or rejection of an installment agreement.

- PCAs would be required to comply with Code provisions governing notices reflecting balances due, penalties, and interest.

- PCAs would be required to comply with Code and Internal Revenue Manual provisions governing taxpayer interviews by IRS employees.

- PCAs would be required to comply with the provisions of Section 1203 of the IRS Restructuring and Reform Act of 1998, including to the extent permissible under applicable law, the removal or termination of PCA employees who violate the requirements of this provision.

- Section 7433, which generally permits civil actions by taxpayers for unauthorized collection actions, would be amended to extend to actions by employees of a PCA. Taxpayers, therefore, could bring actions for damages against a PCA employee if the employee violated a protection provided by the Code.

- **In 1996, you testified before the House Committee on Government Reform and Oversight that you represented Diversified Collection Services, Inc., a national collection agency specializing in the collection of defaulted Federal student loan debt.**

  - **Is the collection of Federal student loan debt similar to the collection of Federal tax debt?**

In the case of a Federal student loan debt, the source of the debt is a legal obligation imposed by agreement of the debtor. By contrast, in the case of a Federal tax debt, the obligation is imposed by the tax law.

Decision-making authority, i.e. the exercise of discretion, cannot be delegated to PCAs and would not be given to them under the Administration's proposal. This is a fundamental difference from the collection of federal student loan debt. The Administration's proposal is designed to allow PCAs to address taxpayers having the ability to pay either immediately or over time; the proposal strictly prohibits PCAs from threatening or intimidating taxpayers, or suggesting that enforcement action will or may be taken. PCAs could not go beyond a general, specific statement provided by the IRS that could be sent or verbally delivered to taxpayers regarding benefits of paying and potential consequences of failing to do so. The proposal is clear in that decisions regarding enforcement remain with the IRS and in no case would a PCA be permitted to take enforcement action.

The Administration's proposal also embeds full taxpayer rights and protections within all its processes and procedures. I understand that the Department of Treasury worked closely with the National Taxpayer Advocate, the Office of Chief Counsel and the IRS to ensure that all aspects of taxpayer rights, disclosure, and privacy were fully addressed and properly built into all program aspects, and that procedures were adequate to ensure adherence during program administration. Additionally, PCAs would be independently audited to ensure adherence to all access regulations, and subject to the same penalties and damages for violations of taxpayer rights or privacy as IRS employees.

- **Based on your experience, what should IRS do to facilitate its collection of delinquent tax debts?**

As stated previously, the growing PCI of tax debt, if left unaddressed, will undermine the fairness of our tax system. IRS resources have not kept pace with this growing inventory. Without a change in business practice, it seems to me that the IRS will be unable to curtail, or even contain its growth. The use of PCAs, as outlined in the Administration's proposal to supplement existing and future IRS resources, will allow a steady focus of IRS resources on the complex cases and issues requiring the expertise of its employees, while enabling the IRS to handle more collection cases at an earlier stage in the process. The use of PCAs plus the steady focus of IRS resources at an earlier point in the collection process would attack the growing inventory of delinquent tax debt "from both ends."

I believe that this proposal represents an important step that the Government should take to reinforce the fundamental fairness of our tax system. Honest taxpayers who do their best to pay their taxes on time should not be burdened by those who hide from their obligations. At the same time, it appears to me that the Department of Treasury and the IRS have developed a program that is focused and carefully monitored, makes business sense, and respects all taxpayer rights and protections.

- **Can Chief Counsel's office take legal action to help IRS do a better job in collecting delinquent tax debts? What type of action and why would it be effective?**

The Office of Chief Counsel assists the IRS by furnishing it with legal opinions and assistance relating to the collection of taxes, representing the Commissioner in cases before the U.S. Tax Court where the collection of tax is at issue, and by referring civil tax matters to the Department of Justice and providing the Department of Justice with the information needed to institute civil actions under the Code and other laws that lead to the recovery of delinquent taxes.

The Collection Due Process (CDP) rights afforded taxpayers in the IRS Restructuring and Reform Act of 1998, and unresolved individual cases involving these CDP rights, impose significant procedural requirements on the IRS in connection with the use of liens and levies to collect delinquent tax debts. In CDP cases filed in the Tax Court, the Office of Chief Counsel directly represents the Commissioner. For other types of collection cases, either administrative or arising in courts other than the Tax Court, the Office of Chief Counsel serves principally in an advisory role. The Office of Chief Counsel is working in a number of areas to assist the Government to more effectively collect delinquent tax debts. These include:

- Improving the implementation of CDP procedures by providing training to Appeals' officers and settlement officers, who are responsible for considering CDP cases in the administrative stages of these cases. The Office of Chief Counsel is also working with the Office of Appeals, other stakeholders, and the Department of Treasury to revise the regulations implementing the CDP procedures, which should improve the speed and utility of these procedures for both the IRS and taxpayers.

- Developing significant guidance for the IRS and taxpayers in the tax collection area concerning legal developments. For example, in September 2003, the IRS issued a notice on collection issues related to entireties property to provide guidance regarding the Supreme Court's opinion in United States v. Craft, 535 U.S. 274 (2002). Notice 2003-60, 2003-39 I.R.B. 643.

- Providing early assistance to the IRS in selected large dollar tax collection cases to prevent the loss of tax revenue or to recover assets to satisfy existing tax liabilities. For example, in September 2003, the Office of Chief Counsel has been involved in making sure all the necessary facts are gathered by the IRS and in suggesting innovative legal strategies to the Department of Justice for dealing with the large employment tax delinquencies that often result from abusive, multi-employer employee leasing arrangements and from the insolvencies of other large payroll company providers.

- Streamlining IRS procedures for referrals to the Department of Justice. In the area of combating abusive tax schemes, the Office of Chief Counsel has worked with the IRS and the Department of Justice to pinpoint the

types of facts that would support an injunction case, so that such arrangements may be shut down as early as possible.

- Representing the IRS as Special Assistant U.S. Attorneys in certain bankruptcy matters. In many of the larger U.S. cities, the Office of Chief Counsel attorneys are appointed Special Assistant U.S. Attorneys, which permits them to represent the IRS directly in a variety of types of frequently recurring bankruptcy controversies that often directly result in the collection of delinquent tax revenue. The IRS is probably the most frequent creditor in bankruptcy cases, filing tens of thousands of claims each year in individual and business cases. Because of the complex interaction of tax and bankruptcy law, Office of Chief Counsel advice is critical to the IRS's ability not only to maximize its recovery in bankruptcy (the IRS collected $435 million in FY 2003), but also to preserve its rights against the debtor and third parties and to protect the fisc from actions by the trustee and competing creditors.

3. In 2002, former Commissioner Rossotti stated in his report to the IRS Oversight Board that the IRS does not have the resources to pursue identified tax debtors and non-compliant taxpayers. The numbers provided in his report are staggering: 60 percent of identified tax debts are not pursued, 75 percent of taxpayers who did not file a tax return are not pursued, and 79 percent of identified taxpayers who use abusive devices (e.g., offshore accounts) to evade tax are not pursued.

- **In your opinion, does IRS have the necessary resources to enforce the tax laws? How can Chief Counsel's office help IRS do a better job in enforcing the tax laws?**

The Administration's FY 2005 Budget includes $300 million for IRS efforts to ensure compliance with the tax laws and increases the total IRS budget by 4.8%. This is a material increase that will provide the necessary resources. If approved by Congress, this Budget would substantially restore the enforcement presence of the IRS. I understand that the Budget would bolster enforcement ranks by 2,900 FTE. (Note that the Budget also includes $190 million for customer service and other activities and would allow the IRS to expand its enforcement presence while maintaining and enhancing its customer service record.)

As to how the Office of Chief Counsel can help the IRS do a better job of enforcing the laws, see the discussion contained in my answer to the first question above (Mr. Korb, in your opinion, what makes up the tax gap? Can you break down where the gap is coming from? What can Chief Counsel's office do to help IRS close this gap?).

- **What suggestions do you have for addressing the growing non-compliance rate in our tax system?**

I understand that the Administration's FY 2005 Budget would allow the IRS to focus its

resources where non-compliance is believed to be greatest:

- Domestic and offshore abusive schemes and promoters
- Abusive tax avoidance transactions
- Underreporting or nonreporting of income
- Failure to file and pay employment taxes

I believe that all of these areas are the right place to focus IRS resources at the present time.

One way that the Office of Chief Counsel can reduce noncompliance is by working with the Department of Treasury to issue prompt, clear guidance on emerging issues. When taxpayers choose not to follow that guidance, or choose to interpret it in ways that do not fairly reflect Congressional intent, then the Office of Chief Counsel can work closely with the IRS to identify noncompliant taxpayers and to fully develop those cases through examination, Appeals and on through litigation in the Federal courts. I believe that careful selection of appropriate litigating vehicles, and the considered application of penalties appropriate to the noncompliance, will go a long way towards establishing sound precedent and discouraging noncompliance by other taxpayers.

The Office of Chief Counsel also can help to reduce taxpayer burden in complying with the tax laws. For example, the Office of Chief Counsel has worked with the IRS to promote electronic filing of returns which reduces errors and facilitates faster refunds to taxpayers. The Office of Chief Counsel also helps to increase the compliance rate by providing legal advice to the IRS employees who administer the Low Income Taxpayer Clinic Program. This program, among other things, educates low income and English-as-a-second-language taxpayers about their rights and responsibilities under the internal revenue laws. The Office of Chief Counsel provides legal support for the Tax Counseling for the Elderly (TCE) program. TCE is an IRS grant program that provides tax return preparation to individuals 60 and older. The primary participant is AARP, which operates volunteer sites throughout the U.S. The Office of Chief Counsel also occasionally gives legal support to the Volunteer Income Tax Assistance (VITA) program.

- **Last year, the IRS ran an amnesty program for those concealing taxable income in offshore financial accounts and using credit and debit cards to gain access to their money. Only 1,200 came forward. The IRS estimates there are 540,000 people that may be participating in these schemes. The IRS collected approximately $170 million. The IRS estimates that we may be losing $20 to $40 billion a year from these offshore schemes. According to the IRS, it takes 300 hours to work one offshore credit card case.**

- **Does IRS have enough personnel to pursue the thousands of offshore credit card cases already identified?**

It is my understanding that as part of its FY 2005 Budget, the Administration included

funding for additional revenue agents, tax compliance officers and revenue officers to address key compliance risk areas, including offshore credit card and other schemes. In addition, the IRS started shifting existing resources to address the growing compliance issues surrounding abusive tax practices in FY 2003. The IRS continues to analyze its processes and procedures to identify ways to improve the efficiency and effectiveness of examination programs. It is working on a reengineering effort of the Small Business/Self Employed (SB/SE) Division's examination process that will help achieve this goal. Finally, the IRS is working to expand the use of technology to automate data mining techniques. This should significantly improve its ability to cope with the expected volume of cases, allow efficient management of the data received, and effectively prioritize and deliver appropriate cases to agents to be worked.

- **How can Chief Counsel assist IRS in doing this?**

I am told that the Office of Chief Counsel currently has two Grade 15 attorneys and an executive from SB/SE Division Counsel assigned to the offshore credit card project full-time to provide advice to the IRS. The Office of Chief Counsel has trained 60 attorneys, who are available to assist the IRS in the examination of offshore credit card/financial account cases, and over 1,000 revenue agents, who may be assigned to perform work on this project. In addition to providing support to the IRS, this group of attorneys provides assistance to the Department of Justice in pursuing summons enforcement actions. This group has devoted a significant amount of resources toward this project over the last two years and is currently developing strategies to move new credit card cases into the examination process.

- **How will IRS cope with the thousands of cases expected to be identified?**

The Commissioner has noted that the success of IRS offshore compliance efforts does not depend on 100% audit coverage of cases identified through the offshore credit card project. The goal of any compliance initiative is to support and encourage voluntary compliance by raising the risk of engaging in illegal activities so that such activities decrease over time. In order to accomplish this objective with abusive offshore credit cards, I understand the IRS is taking steps to more effectively manage the inventory within the confines of existing resources. For example, the IRS has:

  - Focused efforts on identifying and pursuing promoters of illegal tax avoidance schemes;
  - Delivered specialized training to large numbers of revenue agents to provide them with the skills required to apply new audit techniques to offshore examinations;
  - Created special groups of revenue agents to focus on the international aspects of these examinations;
  - Provided enhanced support from the Office of Chief Counsel and Department of Justice to assist examining agents with legal aspects of these cases; and
  - Developed new methods of case selection that will focus IRS resources on

cases having the greatest compliance impact, including high profile and egregious cases, as well as cases that are broadly distributed, both geographically and demographically (these methods involve the application of sophisticated new technology to combine internal IRS data with information from external sources in innovative ways).

- **To what extent do you think IRS focuses too much attention on those taxpayers trying to comply with our tax laws versus those who operate completely outside the system (i.e., the non-filers)?**

I believe that the IRS needs to devote more attention to a number of compliance areas, including non-filers, and as I noted in testimony before the Committee, this will be one of my priorities as Chief Counsel if I am confirmed. It is my understanding that the IRS has properly redirected its resources to focus on the most egregious pockets of non-compliance. In the area of non-filers I am told that IRS has developed a comprehensive plan to centralize some of the work and expand and automate the substitute-for-return program. I also understand that the IRS is looking at innovative approaches to tackle long-standing tax problems, including by reengineering certain processes that will allow them to focus on the highest risk cases. It is also my impression that underreporting is a significant issue; therefore, I believe we need to focus attention in that area as well.

- **What legal action can Chief Counsel's office take to help IRS address the growing non-compliance in our tax system?**

See the discussion contained in my answer to the first question above (Mr. Korb, in your opinion, what makes up the tax gap? Can you break down where the gap is coming from? What can Chief Counsel's office do to help IRS close this gap?) and the second bullet in this question (What suggestions do you have for addressing the growing non-compliance rate in our tax system?).

4. The Office of Chief Counsel publishes various types of guidance to IRS and taxpayers for use in complying with the tax laws. Treasury regulations represent the IRS's and Department of Treasury's official interpretation of the Internal Revenue Code. Revenue Rulings are the official interpretation of the IRS on the application of the Code or Treasury regulations to a particular set of facts. Revenue Procedures are official statements of the IRS's internal practices and procedures in the administration of the tax laws. Private Letter Rulings provide guidance to specific taxpayers on proposed tax transactions. Technical Advice Memoranda provide guidance to IRS on completed tax transactions under examination. Field Service Advices provide guidance to IRS on its legal interpretation of the tax laws.

- **The Office of Chief Counsel issues guidance to IRS and taxpayers in the form of regulations, revenue rulings, revenue procedures, private letter rulings, technical advice memoranda, field service advices, etc.**

- **In view of the growing non-compliance rate in our tax system, what type or types**

of guidance will you emphasize as Chief Counsel? Why?

Like my predecessor as Chief Counsel and the former Assistant Secretary of Treasury (Tax Policy), I will strive to produce guidance that is clear and administrable, if I am confirmed. Clear rules will help promote greater respect for the tax system and will allow the IRS to devote its resources to high risk compliance areas.

In addition, I will emphasize guidance of broad applicability. One of the most important functions of the Office of Chief Counsel is to issue rules of broad applicability. Thus, I favor the issuance of published guidance because it is authoritative, has widespread applicability and may be relied upon by the public as well as by IRS personnel. Regulations, revenue rulings, revenue procedures and notices are the most significant and useful types of published guidance because all taxpayers can rely on them as authority. I believe that published guidance has the salutary effect of both facilitating and promoting compliance with the tax laws. Published guidance creates greater transparency and eliminates disputes between taxpayers and the IRS, saving resources for both taxpayers and the IRS. Therefore, I strongly believe that resources devoted to preparing and issuing published guidance are well spent. In addition, the issuance of published guidance should decrease the need for private guidance and even some requests for legal advice. Consequently, while the Office of Chief Counsel would continue to issue all other categories of guidance (i.e., PLRs, TAMs and TEAMs) and legal advice, if confirmed I plan on emphasizing the issuance of published guidance.

- **In your opinion, is it more important to issue guidance to all taxpayers (e.g., revenue rulings and revenue procedures) or to specific taxpayers (e.g., private letter rulings and technical advice memoranda) or some combination? Why?**

As noted above, I believe guidance of broad applicability is the most important guidance that the IRS can issue. It is more efficient to answer questions for a significant number of taxpayers at one time rather than try to deal with the same issue over and over again on a case-by-case basis. Nonetheless, private guidance, such as PLRs, TAMs and TEAMs, is also a very important part of tax administration. Not only is it a useful tool to resolve issues at earlier stages in the process (i.e., even before the return is filed or before a case goes on to litigation), working on specific facts of individual cases can highlight areas where published guidance can then be developed to cover a large number of additional taxpayers. In addition, these tools can be used to resolve taxpayer questions more efficiently and provide greater certainty. Finally, given the complex economy and the complex tax code, we will never completely eliminate disputes between taxpayers and the IRS on questions of interpretation. It is important to have mechanisms to resolve those disputes short of litigation. Therefore, if confirmed, although I would emphasize published guidance, I would also want to continue allocating resources to issuing private guidance in cases where it is appropriate.

- **We understand that the incoming head of any organization will have ideas about how the agency or organization should be structured and managed. However,**

we also understand that change can have potentially negative impacts on agency operations as well as on employees.

- **What guiding principles will you follow in deciding what changes, if any, are needed to the policies, procedures, and practices that have been implemented in the past 5 years and that are in the process of being implemented?**

In evaluating existing policies and possible changes, I would always strive to have the Office of Chief Counsel provide the best possible service to the IRS and taxpayers. Thus, I would not want to make any changes to the current organizational structure unless I was convinced the changes were necessary to further the mission of the Office of Chief Counsel (i.e., to serve America's taxpayers fairly and with integrity by providing correct and impartial interpretation of the internal revenue laws and the highest quality legal advice and representation for the Internal Revenue Service).

I believe the Office of Chief Counsel, the Department of Treasury and the IRS have made significant strides in the areas of published guidance and abusive tax avoidance transactions. Therefore, it is my intent, should I be confirmed, to continue the policies and procedures for moving published guidance, and in particular guidance on abusive transactions, as quickly as possible. I also strongly believe in what I refer to as "front loading" – issuing guidance as quickly as possible after new legislation is enacted or a particular issue is identified. Based both on my private sector experience and on my efforts as the Assistant to the Commissioner to accelerate issuance of published guidance after the Tax Reform Act of 1986, I believe that most taxpayers will follow the rules if they know them. When there is a vacuum, there is a much greater potential for taxpayers to interpret rules in ways that are inconsistent with other taxpayers and with the IRS.

I also believe that the realignment of the Office of Chief Counsel along business lines, to reflect the changes in the IRS, has allowed Chief Counsel lawyers to provide better service to the IRS. As I set forth in my written statement to the Committee, I want to continue to make the Office of Chief Counsel more client-oriented while at the same time preserving the independent judgment of Chief Counsel lawyers. Finally, in considering any changes, I plan to consult with the Chief Counsel executives who have the experience of running the operation and the responsibility for carrying out the daily activities of the Office.

- **What is your knowledge or perception of Chief Counsel's relationship with IRS and Treasury? Do they communicate well with one another? Do you anticipate making any changes to facilitate the relationship?**

In preparation for my nomination process and in anticipation of my nomination hearing, I met with the top officials in the Treasury Office of Tax Policy (including the Acting Assistant Secretary, the Deputy Assistant Secretary, the Tax Legislative Counsel, the International Tax Counsel, and the Benefits Tax Counsel) as well as many of the top officials at the IRS (including the Commissioner, members of the Commissioner's staff, both Deputy Commissioners, three of the four Division Commissioners, the National

Director of Appeals, and the National Taxpayer Advocate, among others). Based on these discussions together with my personal observations, it is my belief that the relationship is very good at the highest levels of the IRS, Department of Treasury and Office of Chief Counsel. Still, if I am confirmed, I expect to encourage even greater communication and teamwork among the lawyers in the Office of Chief Counsel and the people they work with in the IRS and the Department of Treasury. Also, I expect to have a strong personal working relationship with my counterparts both at the Department of Treasury and the IRS (and the Department of Justice as well) and plan to work smoothly with all of them as a team. I will expect nothing less from every lawyer in the Office of Chief Counsel.

- **Mr. Korb, you worked for IRS Chief Counsel's office during the years 1974 to 1977. Is that correct? To your knowledge, does Chief Counsel's office currently operate in the same manner as it did in the mid70's? What are the differences? Is it better or worse?**

I was with the IRS Office of Chief Counsel from January 1974 through December 1977. At that time, the Office was much more compartmentalized. Now, lawyers have much broader responsibilities than they did in the 1970s (or even in the 1980s when I was the Assistant to the Commissioner and worked very closely with lawyers in the Office of Chief Counsel). I also believe that the Office is much more "nimble" now. For example, I do not believe that in the 1970s, the Office of Chief Counsel could have generated notices regarding listed transactions as quickly as it does now. When I was with the Office of Chief Counsel in the 1970s and also with the Commissioner's Office in the mid-1980s, so-called "expedited projects" were done on a much more ad hoc basis. Finally, I understand that there are procedures in place to expedite not only guidance on abusive transactions but also on other issues as well (items that may be less sensitive in nature). I believe the realignment of the Office to mirror the business units of the IRS and the broadening of the responsibilities of lawyers in the technical areas (which I discuss below) have improved the service that the Office of Chief Counsel provides to the IRS and to taxpayers.

- **It is our understanding that IRS Chief Counsel's office used to be more specialized (e.g., the L&R division and the Interp division) and today it is less specialized. How has this affected the work product of IRS Chief Counsel? As Chief Counsel would you keep it the same? If not, how would it change?**

In the mid-1970s I worked in the Interpretative Division. Then the National Office of the Office of Chief Counsel was organized along functional lines and around the specific types of work produced by the Office, such as legislation and regulations, interpretive work (i.e., GCMs), tax litigation, or collection work. At that time there was no cross assignment of work among lawyers in the various divisions. In addition, these divisions, as they were called, had overlapping responsibilities for interpreting and providing advice on provisions of the Code. While each of these divisions had attorneys who had expertise in specific areas of tax law, their expertise – and their advice – were colored by whether

they worked principally in litigation, drafting published guidance, or writing interpretive opinions.

I believe that the National Office of the Office of Chief Counsel is better organized today. The National Office, which consists of the technical subject experts who are responsible for published guidance and on providing advice on interpreting the Code, is organized into offices that specialize in related sections of the Code, such as corporate tax, income tax, or the procedural provisions of the Code. In addition, the field component of the Office of Chief Counsel – the part that is primarily responsible for litigation and providing advice to the field component of the IRS – is organized around the business units and has more expertise on the issues as they relate to particular types of taxpayers. This structure allows the field component of the Office of Chief Counsel to provide more responsive and timelier advice to their counterparts in the IRS. It also ensures that technical positions on the law are set by attorneys who have expertise in the specific area of the tax law and assures the uniform, fair and impartial interpretation of the law.

If confirmed, I do not contemplate any major reshuffling. Rather I want to capitalize on the nimbleness of the Office and take it to the next level by streamlining the management of projects and experimenting with the use of "swat teams" under the direction of various senior Chief Counsel executives to address high priority issues more quickly.

- **What steps will you take to assure us that any major changes will be decided in consultation with Congress, employees, and appropriate outside stakeholders?**

As part of my nomination process, I have met with the staff of the Senate Finance Committee and also met with the Chief of Staff of the Joint Committee on Taxation. (If confirmed, I plan to meet soon with the staff of the House Ways and Means Committee.) If I am confirmed, I would like to meet regularly with the staffs to ensure that there is good communication and the kind of consultation this question contemplates. Likewise, in considering major changes, I would seek serious input from Chief Counsel executives as change can only come about through their efforts. Further, I am very familiar with some of the stakeholder groups such as the ABA, AICPA and TEI and expect to meet with them on significant matters. I also hope to identify other stakeholder groups and seek their input. Finally, I have an excellent relationship with the National Taxpayer Advocate and plan to seek her advice on issues especially pertaining to taxpayer rights.

March 11, 2004

Statement of
Dr. Mark McClellan
Nominee for Administrator of the Centers for Medicare & Medicaid Services
Department of Health and Human Services
Before the
Committee on Finance
United States Senate

March 8, 2004

Mr. Chairman, Senator Baucus, distinguished Members of the Committee, thank you for your consideration of my nomination as Administrator of the Centers for Medicare & Medicaid Services. And I especially want to thank my wife Stephanie, who is with me here today and has been with me every step of the way. Our twin daughters are five now, and for most of their lives I've been working for the Federal government. I still remember, soon after they were born, going into my office every morning at the Treasury Department, with all of the policy controversies around Medicare proposals and new savings proposals and the like and thinking to myself, what a restful and relaxing place! Public service means a number of sacrifices, and Steph's been making them for us.

Helping Americans get the most out of Medicare, Medicaid, the State Children's Health Insurance Program (SCHIP), and other CMS-administered programs is one of the most critical functions of the federal government. These programs have daily and profound impacts on more than 70 million seniors, people with disabilities, and many other of America's most vulnerable citizens. I am proud and honored that the President has chosen me for this duty, and should you concur, I assure you that I will not let you down.

The main reason I'm confident of success is that, if confirmed, I expect to benefit from the advice and guidance from many parties. I view this as a partnership. The partnership would start with the members of this committee and the Congress. In my current job, and in my previous jobs in government, in medicine, and in academic research, I have appreciated the opportunity to work with you all on a range of healthcare issues. Since my nomination was

announced, I have especially appreciated the time that you have made to let me know about critical health care concerns for the new Administrator to address, particularly those related to the new era of an expanded Medicare program that is starting right now as a result of the newly enacted Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). I am looking forward to continuing to talk about all of these issues with Senators from both parties who are strongly committed to Medicare, Medicaid, and SCHIP.

I am also looking forward to hearing more from the many individuals and groups outside of the Congress who care about these programs, to make sure we are finding all the ways possible to work together. That includes working with people who may not agree on everything about Medicare or Medicaid, but who are willing to roll up their sleeves and do everything possible under our laws to achieve our shared goal of health care that is affordable and vibrant for beneficiaries. It includes working with outside groups, our partners in state and local governments, health professionals and providers, and most of all, working with the beneficiaries of these programs to help make sure they know how to get the most out of their benefits and that we are responsive to their changing needs.

And the help would also come from the professional staffs of CMS and HHS and throughout the Administration, who are all already working full steam on implementing this legislation. CMS is staffed with very smart, talented people who are dedicated to the Agency's mission. My experience with CMS goes back to my first research project as a graduate student, and has continued during my career in academics and government. I have especially valued the firsthand experience with CMS programs through many of my patients during my medical training in Boston and my work as a professor of medicine at Stanford. What I have learned from that experience with patients served by CMS, and with the CMS staff, is that this program is about much more than paying insurance claims and financing health care. I believe CMS is one of the nation's most important public health agencies, just like FDA and CDC and NIH, with an absolutely critical public health role to play not only in helping millions of Americans get access to high-quality health care, but also in making our health care system fundamentally better. I am honored to have the opportunity to join the CMS workforce, particularly at a time when the challenges and rewards of working at CMS have never been greater.

Before 1965, fully half of American seniors and millions of low-income Americans lacked health insurance. Health insurance coverage was lowest among the youngest and the oldest in our nation - the very people who had the most to gain from modern medicine. Like thousands of other doctors in this country, I have too often seen patients that did not have the money to pay out-of-pocket for needed medicines. And too often they did not have enough information to make informed decisions.

Since 1965, especially for seniors with fixed incomes, for children whose parents are struggling to get by, for Americans with disabilities, and for people with limited means, the services that the Agency provides are literally lifelines – lifelines to modern medicine and lifelines to a measure of financial security.

But in the forty years since then, modern medicine has changed dramatically. In 1965, if you had a heart attack, you counted yourself lucky if you did not die. You were lucky to go through weeks of hospitalization and surgery and rehabilitation, and to live just a few more years with much less ability to get around and do things. Today, if you have a heart attack, you should not only expect to live, but you should expect modern medicine to head off the heart attack as it's happening and then, after just a few days in the hospital, you should expect a full and healthy and active life – working longer, or spending time with your loved ones, or doing all the things that makes life in this country so wonderful. Similarly, Americans with cancer have better odds of beating the disease than ever – in many more cases, avoiding prolonged exposure to toxic drugs that were the mainstay of therapy just a decade ago through new, targeted treatments that attack the disease, and not the patient. And there is more medical knowledge than ever to catch cancers early or prevent them in the first place. The same is true for many other diseases.

Yet Medicare has not kept up. Seniors not only have lacked drug coverage, they have too often lacked access to other preventive treatments, like a physical exam and monitoring that can prevent the complications of heart disease or diabetes and many other chronic illnesses. They were just an illness or accident away from destitution.

I have seen the problems in my own practice, and I have heard about them from countless doctors, nurses, researchers, and other health professionals. These problems include paper records that are incomplete or cannot be found; too much time spent on paperwork; systems designed for the care of yesterday, when the potential for better outcomes and lower costs from the care of today and tomorrow has never been greater; and, patients getting no help with prices for new drugs that too often are the highest in the world -- and as a result having to compromise the quality of their care by cutting pills in half, skipping doses, delaying refills, or buying cheaper drugs from outside of our comprehensive regulatory system for assuring that drugs are safe and effective.

As with any profound government commitment, there has been a lot of debate about the best way to help Medicare keep up – the best way for Medicare to help seniors today and to help improve medicine for seniors in the future. Debate is a great way to make sure we are considering all possible ideas for making the lives of Americans better and better, and we need to keep this up. But now thanks to this Committee, the Congress, and the President, we have a new Medicare law. And thanks to Secretary Thompson and other senior leaders, there is a deep commitment to implementing it effectively. And so as CMS Administrator, I would have a very special responsibility at a very special time.

As we enter this new era, CMS is working hard to create a brand new drug benefit for America's seniors, to strengthen Medicare's managed care program to offer more choices, better benefits and more stability for beneficiaries, and to provide more preventive care, including a "Welcome to Medicare" screening to assess beneficiaries' health needs as soon as they are eligible for the program. The Medicare Modernization Act calls on CMS to act quickly to do all of these things and much, much more to improve benefits for beneficiaries sick and healthy, urban and rural.

But Medicare needs to do more than keep up with modern medicine. If confirmed, I intend to help Medicare and CMS drive modern medical care forward. Our new laws allow us to take bold new steps to help patients get higher quality, safe and effective treatments, delivered at the right time and without errors. This includes electronic prescribing and quality information; disease management programs; disease prevention; better information for doctors and patients to

improve their lives at the lowest possible cost; and, stronger partnerships with all those who care deeply about Medicare to try out the best new ideas and then get the benefits to Americans. We have better opportunities than ever to create a health care system in which patients and doctors can make informed decisions about the most innovative medical care based on timely access to the latest evidence. We have better opportunities than ever to create an environment that supports the latest medical science for helping patients prevent disease and avoid complications from diseases, and that allows us to spend our health care dollars much more effectively as a result. CMS can do much to create that environment for innovative, affordable, effective medical care.

As part of this effort, no responsibility is greater than making sure seniors and other people who depend on these programs get all the relief possible under the law, especially lower drug costs and lower prices, safely.

Likewise, I will continue the Agency's efforts to maintain a strong partnership between CMS' staff and the states with which they partner the Medicaid and SCHIP programs. I believe that through an open dialogue, clear policies and guidance, and prompt and thoughtful answers from us, we can work with our state partners to succeed in these challenging times.

And so in closing, I want to renew a promise I made when I was before the Senate during my confirmation for FDA Commissioner. If confirmed as Administrator, I pledge to listen and act on what I hear from all of our partners in achieving the goal of affordable, innovative, high-quality health care for the beneficiaries of CMS programs and all Americans. CMS has many initiatives in place to make sure that stakeholders get clear explanations from me and my staff, an opportunity to get a fair and complete hearing of your point of view, and the confidence that our decisions will be based on a full and timely evaluation of the empirical evidence and the science. As at FDA, I will work to ensure that careful analysis based on the facts and the science, integrity, and thoughtful decision-making are the foundation for all of our work. We will not always agree, but I hope to make it possible for us to work together effectively to meet the challenges ahead.

We all share the goal of affordable, innovative, high quality health care. Clearly, there is a tremendous amount of work to do right away to achieve this goal -- both at CMS and throughout our nation's health care system. To keep the promise of Medicare, Medicaid, and many other Federal programs to patients today and patients tomorrow, we have a unique opportunity to make safe medicines much more affordable right now, and pave the way for preventing more diseases and their complications through better medical care in the future. This is a historic time, and it is a profound honor and privilege to get a chance to be a part of it.

My mother, who has spent her career in public service, likes to say, "It's not the dollars you make, it's the difference you make." As CMS Administrator, for the sake of patients today and the patients of tomorrow, I will take the prompt and decisive steps necessary to help make our medical future brighter, healthier, and more secure than ever. Thank you for your consideration of my nomination at this historic time, and I would be glad to answer any questions you may have.

SENATE FINANCE COMMITTEE
STATEMENT OF INFORMATION REQUESTED OF NOMINEE

A. BIOGRAPHICAL INFORMATION

1. Name: (Include any former names used.)

   Mark Barr McClellan

2. Position to which nominated:

   Administrator, Centers for Medicare & Medicaid Services

3. Date of nomination:

   February 26, 2004

4. Address: (List current residence, office, and mailing addresses.)

   Residence: 4456 Sedgwick Street NW, Washington DC 20016

   Office/Mailing: 5600 Fishers Lane, Rockville MD 20857

5. Date and place of birth:

   June 26, 1963, Austin TX

6. Marital status: (Include maiden name of wife or husband's name.)

   Stephanie Ridgway McClellan

7. Names and ages of children:

   Elizabeth Carole McClellan – age 5
   Alexandra Sara McClellan – age 5

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

9/88 to 5/93, Massachusetts Institute of Technology, Ph.D., Economics, degree granted: 5/93

9/85 to 5/92, Harvard Medical School-MIT Division of Health Sciences and Technology, M.D. *cum laude*, degree granted: 6/92

9/87 to 6/91, Harvard Kennedy School of Government, MPA, degree granted: 6/91

9/81 to 5/85, University of Texas at Austin, BA in English, Biology, and Plan II, *summa cum laude* with Special Honors in English and Biology; degree granted: 5/85

09/77 to 05/81, Austin High School, Austin TX, valedictorian, degree granted: 5/81

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.)

Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 11/02 to present

Member, Council of Economic Advisers, Executive Office of the President, EEOB, 17th St. & Pennsylvania Avenue, Washington, DC 20502, 3/01 to 11/02

Associate Professor with tenure, Department of Economics and Department of Medicine, and Director, Program on Health Outcomes Research, Stanford University, 579 Serra Mall, Stanford, CA 94305, Fall 1999 to present (on unpaid leave since 3/01)

Deputy Assistant Secretary for Economic Policy, U.S. Department of Treasury, 1500 Pennsylvania Avenue, NW, Washington, DC 20220, 6/98 to 7/99

Assistant Professor, Department of Economics, and Attending Physician, Department of Medicine, Stanford University, 7/95 to 6/98

Resident in Internal Medicine, Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115, 6/93 to 6/95

Research Associate, National Bureau of Economic Research, 1050 Massachusetts Avenue, Cambridge, MA 02138, 7/00 to 9/00

Faculty Research Fellow, National Bureau of Economic Research, 1050 Massachusetts Avenue, Cambridge MA 02138, 7/96 to 9/96, 7/97 to 9/97, and 8/99 to 9/99

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.)

National Institute on Aging Advisory Committee on Behavioral and Social Research (peer review expert advisory committee), approximately 7/95 to 7/98

Full-time Federal employment 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.)

Consulting and advisory activities:

RAND Corporation, Research Affiliate,1989-1990
Harvard Medical School Department of Health Care Policy, Research Associate, 1993-95
Pfizer Pharmaceuticals, 1996-97, technical adviser on health outcomes analysis
National Bureau of Economic Research, academic papers and book chapters, 1996-2001
Journal of Health Economics, Associate Editor, 1997-2001
Roche Pharmaceuticals, 1997-98, technical adviser on evaluating economic consequences of immunosuppressive therapies
Acumen Corp, 1997-98, 2000, technical adviser on data and analytic methods for studies of medical care use
National Academy of Sciences, National Cancer Policy Advisory Board, 1999-2001
Arnold and Porter, LLP, 1999-2000, technical consultant on projecting medical outcomes and expenditures
University of Michigan, Co-Principal Investigator, Health and Retirement Survey, 1999-2000
Merck Corp., 2000, presentation on health policy
Unicon Corp., 2000, technical adviser on evaluating health and medical utilization in surveys of older Americans
ESRI (non-profit think tank), Washington, DC, 2000, health policy issues
University of Chicago, 2000, book chapter
University of Minnesota, 2000, policy research methods

Texas A&M University, visiting scholar in public economics, 2000
American Enterprise Institute, 2000-2001, visiting scholar on health policy issues
Hoover Institution, National Fellow, 2000-2001

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

Diplomate, American Board of Internal Medicine
Fellow, American College of Physicians
Member, National Academy of Sciences Institute of Medicine
Member, Aesculapian Club, Harvard Medical School

Former member of the following professional associations: American Medical Association, American Economic Association, American Statistical Association, Econometric Society, Association for Health Services Research/ AcademyHealth

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.

Campaign volunteer for Carole Keeton Strayhorn (mother), current Comptroller of Texas, in multiple campaigns (Republican since 1984) prior to entering government service. Campaign volunteer for Lowell Lebermann (Democrat) in multiple campaigns in 1970s and 1980s. Occasional unpaid technical assistance for George W. Bush presidential campaign in 2000, and unpaid service to President Bush's transition team in December 2000- January 2001.

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.

RNC Victory: $500, 10/00
Friends of Carole Keeton Strayhorn (mother): approximately $200 in 1994 and 1998 campaigns, and $100 in 2001

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.)
Phi Beta Kappa, 1985; John F. Kennedy Fellowship in Public Policy (Harvard University), 1988; Henry Kaiser Fellowship in Health Policy (MIT), 1988; FIRST Award, National Institute on Aging, 1993; *Review of Economic Studies* Award, Outstanding Dissertation in Economics, 1994; Finalist, Outstanding Dissertation, National Academy of Social Insurance, 1994; Finalist, Best Research Paper, Association for Health Services Research, 1995; John M. Olin Faculty Research Fellowship (Stanford University), 1996; Kenneth Arrow Award, Best Research Paper in Health Economics, 1997; Career Development Award, National Institute on Aging, 1999; Griliches Award, Best Empirical Paper in *Quarterly J. Econ/ J. Political Econ.*, 1999; National Research Fellowship, Hoover Institution, 2000; Kenneth Arrow Award, Best Research Paper in Health Economics, 2001; Fellow, American College of Physicians, 2001; VIDA Leadership Award, National Alliance for Hispanic Health, 2003; Member, Institute of Medicine, 2003; Nathan Davis Leadership Award, American Medical Association, 2004.

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

Articles:

1. "Appropriateness of medical care: A comparison of methods to set standards," with R.H. Brook, *Medical Care* 30: 565-586, July 1992.

2. "Does more intensive treatment of acute myocardial infarction reduce mortality?" with B.J. McNeil and J.P. Newhouse, *Journal of the American Medical Association* 272(11): 859-66, September 1994.

3. "Uncertainty, Health Care Technologies, and Health Care Choices," *American Economic Review Papers and Proceedings* 85(2): 38-44, May 1995.

4. "The uncertain demand for medical care," *Journal of Health Economics* 14(2): 239-242, June 1995.

5. "Do doctors practice defensive medicine?" with D.P. Kessler, *Quarterly Journal of Economics* 111(2): 353-90, May 1996.

6. "The marginal returns to technological change in health care," *Proceedings of the National Academy of Sciences*, 93(23):12701-08 (Nov 12, 1996).

7. "The marginal cost-effectiveness of medical technology: a panel instrumental-variables approach," with J.P. Newhouse, *Journal of Econometrics* 77(1): 39-64, March 1997.

8. "Hospital reimbursement incentives: an empirical analysis," *Journal of Economics and Management Strategy* 6(1): 91-128, Spring 1997.

9. "The effects of malpractice pressure and liability reforms on physicians' perceptions of medical care," with Daniel P. Kessler. *Journal of Law and Contemporary Problems* 60(1): 81-106, Winter 1997.

10. "The econometrics of outcomes research," with J.P. Newhouse, *Annual Review of Public Health* 19:17-34, 1998.

11. "Are medical prices declining? Evidence for heart attack treatments" with D.M. Cutler, J.P. Newhouse, and D. Remler, *Quarterly Journal of Economics* 113(4): 991-1024, November 1998.

12. "Technological change in heart-disease treatment: does high-tech mean low value?," with H. Noguchi, *American Economic Review Papers and Proceedings* 88(2): 90-96, May 1998.

13. "What has increased medical-care spending bought?," with D. Cutler and J. Newhouse, *American Economic Review Papers and Proceedings* 88(2): 132-136, May 1998.

14. "Risks and costs of end-stage renal disease after heart transplantation," with J. Hornberger, J. Geppert, and J. Best, *Transplantation* 66(12): 1763-70, December 1998.

15. "Medicare reform: Who pays, and who benefits?" with J.S. Skinner, *Health Affairs* 18(1): 48-62, January 1999.

16. "A global analysis of technological change in health care: Preliminary report from the TECH research network," with D.P. Kessler on behalf of the TECH Investigators, *Health Affairs* 18(3): 250-5, May 1999.

17. "Is hospital competition socially wasteful?" with D.P. Kessler, *Quarterly Journal of Economics*, 2000.

18. "How does managed care do it? Prices and productivity in managed care," with D.M. Cutler and J.P. Newhouse, *RAND Journal of Economics*, 2000.

19. "Designing a Medicare prescription drug benefit: Issues, opportunities, and challenges," with I. Spatz and S. Carney, *Health Affairs*, March 2000.

20. "Medicare reform: Fundamental problems, incremental steps," *Journal of Economic Perspectives*, Spring 2000.

21. "Are we inhibited? Renal insufficiency should not preclude the use of ACE inhibitors for patients with acute MI and depressed left ventricular function," with C.D. Frances, H. Noguchi, W. Browner, and B. Massie, *Archives of Internal Medicine*, September 2000.

22. "Does physician specialty affect survival of elderly patients with myocardial infarction?" with C.D. Frances, M.G. Shlipak, H. Noguchi, and P. Heidenreich, *Health Services Research*, December 2000.

23. "Trends in Treatment and Outcomes for Acute Myocardial Infarction, 1975 - 1995," with P. Heidenreich, *American Journal of Medicine*, February 2001.

24. "Health care productivity," with D. Cutler, *American Economic Review Papers and Proceedings*, May 2001.

25. "Reducing uninsurance through the nongroup market: health insurance credits and purchasing groups," with Baicker K, *Health Affairs*, 2002.

26. "Optimal liability policy in an era of managed care," with D. Kessler, *Journal of Public Economics*, May 2002.

27. "Racial and sex differences in refusal of coronary angiography," with Heidenreich PA, Shlipak MG, Geppert J, *American Journal of Medicine*, August 2002.

28. "The effects of hospital ownership on medical productivity," with D. Kessler, *RAND Journal of Economics*, Autumn 2002.

29. "Trends in hospital treatment of ventricular arrhythmias among Medicare beneficiaries, 1985 to 1995," with McDonald KM, Hlatky MA, Saynina O, Geppert J, Garber AM, *American Heart Journal*, September 2002.

30. "Association of renal insufficiency with treatment and outcomes after myocardial infarction in elderly patients," with Shlipak MG, Heidenreich PA, Noguchi H, Chertow GM, Browner WS, *Annals of Internal Medicine*, October 2002.

31. "How liability law affects medical productivity," with D. Kessler, *Journal of Health Economics*, November 2002.

32. "Ensuring safe and effective medical devices," with Feigal DW and Gardner SN, *New England Journal of Medicine*, January 2003.

33. "Cardiac procedure use and outcomes in elderly patients with acute myocardial infarction in the United States and Quebec, Canada, 1988 to 1994," with Pilote L, Saynina O, Lavoie F, *Medical Care*, July 2003

34. "Is More Information Better? The effects of health care 'report cards'," with D. Dranove, D. Kessler, and M. Satterthwaite, *Journal of Political Economy*, 2003.

Book:

Technological Change in Health Care: A Global Analysis of Heart Attacks, edited with D.P. Kessler, University of Michigan Press, October 2002.

Book chapters:

1. "Medicare reimbursement and hospital cost growth," in D. Wise, ed., *Advances in the Economics of Aging*, University of Chicago Press, 1996.

2. "What is technological change?" with David Cutler, in D. Wise, ed., *Inquiries in the Economics of Aging*, University of Chicago Press, 1998.

3. "Insurance or self-insurance? Variation, persistence, and individual health accounts", with M. Eichner and D. Wise, in D. Wise, ed., *Inquiries in the Economics of Aging*, University of Chicago Press, 1998.

4. "Where does the money go? Medical expenditures in a large corporation," with D. Wise, in A. Garber, ed., *Issues in Health and Aging in the United States and Japan*, University of Chicago Press, forthcoming.

5. "Incitations et financement des hospitaux: le partage prospectif et retrospectif des couts," in S. Jacobzone, ed., *Economie de la Sante*, Paris: INSEE, 1998.

6. "The feasibility of medical savings accounts," with M.Eichner and D. Wise, in J. Poterba, ed., *Tax Policy and the Economy, Vol. 11*, MIT Press, 1997.

7. "Diagnosis and medical expenditures at the end of life," with A. Garber and T. MaCurdy, in D. Wise, ed., *Frontiers in the Economics of Aging*, University of Chicago Press, 1998.

8. "Health events, health insurance, and labor supply: evidence from the Health & Retirement Study," in D. Wise, ed., *Frontiers in the Economics of Aging*, University of Chicago Press, 1998.

9. "Persistence of medical expenditures among elderly beneficiaries," with A. Garber and T. MaCurdy, in A. Garber, ed., *Frontiers in Health Policy Research, Vol. 1*, MIT Press, 1998.

10. "The distributional effects of Medicare," with J. Lee and J.S. Skinner, in J. Poterba, ed., *Tax Policy and the Economy, Vol. 13*, 1999.

11. "Evaluating health care providers," with D. Staiger, in A. Garber, ed., *Frontiers in Health Policy Research, Vol. 2*, MIT Press, 1999.

12. "The quality of for-profit and not-for-profit hospitals," with D. Staiger, in D. Cutler, ed., *The Changing Hospital Industry: Comparing Not-For-Profit and For-Profit Institutions*, University of Chicago Press, 2000.

13. "Prices and productivity for heart disease," with D. Cutler, J. Newhouse, and D. Remler, in E. Berndt, ed., *Medical Care Output and Productivity (Studies in Income and Wealth)*, University of Chicago Press, 2001.

14. "Productivity change in heart attack care, 1975-1995: A literature review and synthesis," with P. Heidenreich, in E. Berndt, ed., *Medical Care Output and Productivity (Studies in Income and Wealth)*, University of Chicago Press, 2001.

15. "Biomedical research and then some: The causes of technological change in heart disease care," in K. Murphy and R. Topel, eds., *Measuring the Gains from Medical Research*, Chicago: University of Chicago Press, 2003.

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.)

European Federation for Pharmaceutical Sciences Conference--December 8, 2003

Drug Information Association, Ottawa, Canada --November 18, 2003

Protecting and Advancing America's Health Through 21st Century Patient Safety -- Urban Institute November 12, 2003

Fifth Annual David A. Winston Lecture, National Press Club--October 20, 2003

First International Colloquium on Generic Medicine--September 25, 2003

National Press Club-- August 8, 2003

Harvard School of Public Health -- July 1, 2003

Biotechnology Industry Organization--June 23, 2003

Commonwealth Club of San Francisco--June 9, 2003

Physician Insurers Association of America--May 24, 2003

National Food Policy Conference--May 8, 2003

Food and Drug Law Institute--April 1, 2003

Pharmaceutical Research and Manufacturers of America--March 28, 2003

National Food Processors Association's Food Safety Summit--March 20, 2003

Generic Pharmaceutical Association--January 29, 2003

Farm Journal Forum--December 3, 2002

Health Services and Outcomes Research Conference--Houston, Texas--
November 25, 2002

Phase 2 groundbreaking at White Oak, Maryland -- November 15, 2002

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

My medical training and experience treating patients provides a very useful perspective on how CMS can best serve the millions of beneficiaries who depend on the program for access to safe and effective treatments to meet their medical needs as effectively as possible. My background in economics and health policy would also be useful for using the authorities, resources, and opportunities available to CMS to bring the most health benefits to beneficiaries as efficiently as possible, today and in the future, and to help beneficiaries and the Medicare and Medicaid programs achieve financial security. My experience working with both parties in the executive branch, and in leading a public health agency dedicated to protecting and improving the health of the public based on sound science, will help assure that the best science and policy ideas guide the agency's decisions at this critical time for public health, in which there are unique opportunities for improving the well-being of seniors, persons with disabilities, lower-income persons, and all other Americans.

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.

   Since entering government service, I have been on unpaid leave from my professorship at Stanford University.

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.

   As noted above, I am on unpaid leave from Stanford University, and can

return to my professorship upon completing government service.

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.)

N/A

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.

N/A

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

**ANSWERS FOR THE RECORD TO QUESTIONS
FROM THE SENATE FINANCE COMMITTEE HEARING ON
THE NOMINATION OF MARK B. MCCLELLAN, TO BE ADMINISTRATOR
OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES
March 8, 2004**

Questions Submitted by Chairman Grassley

Question 1: Reimportation

First of all, do you agree that the situation today with reimportation has swung out of control and now threatens the safety of the patient's who are purchasing these drugs? Can you elaborate on the kinds of resources and authority FDA would need to legalize reimportation?

Answer:

Chairman Grassley asked this question at the confirmation hearing on March 8, 2004 and Commissioner McClellan responded to it at that time. This written response is intended only to supplement the Commissioner's response to the question at the hearing.

FDA has amassed a great deal of experience with the types, scope and volume of unapproved products entering our borders through the mail, via Federal express, via the Internet. Last year, spot examinations of mail shipments of foreign drugs to U.S. consumers conducted by FDA and U.S. Customs and Border Protection revealed that these shipments often contain dangerous or unapproved drugs that pose potentially serious safety problems. These included unapproved drugs such as alti-azathioprine, an immunosupressant drug that can cause severe bone marrow depression and can be associated with an increased risk of infection and cancer development; and human growth hormone, a drug that can have serious side effects if used inappropriately or in excessive doses. FDA found over 25 different controlled substances, including diazepam; Xanax; Valium, lorazepam, clonazepam and anabolic steroids. Also found were drugs withdrawn from the U.S. market for safety reasons, improperly packaged drugs shipped loose in sandwich bags or tissue paper, and drugs with labeling not in English.

With respect to the kinds of authority and resources needed to allow the importation of drugs by others than the manufacturer, and do so in a safe way, the conference report of the Medicare Modernization Act gave the Secretary of Health and Human Services specified requirements for a study of drug importation. Among these requirements, the conference report asked the Secretary to "identify the limitations, including limitations in resources and in current legal authorities, that may inhibit the Secretary's ability to certify the safety of imported drugs" and to "estimate agency resources, including additional

field personnel, needed to adequately inspect the current amount of pharmaceuticals entering the country." At the Secretary's direction, I am spearheading the effort, in conjunction with numerous agencies within the Department, to complete the study as required by law.

Some people have consistently misinterpreted my views on importation and I appreciate the opportunity to be clear for the record. I have raised concerns about specific legislative proposals, such as H.R. 2427, that would open a wide channel of drug importation by weakening or removing existing safety protections rather than providing the necessary resources or additional authorities to enable the Agency to assure drug safety and security. Furthermore, our economic experts as well as many others have raised legitimate concerns about the limitations of potential longer term benefits and savings that could be realized from imported drugs. And these are legitimate concerns, but that does not mean, and I have repeatedly said this, that we are opposed to exploring whether and how importation could be accomplished safely. But this cannot be accomplished by fiat or with a presumption of safety.

I applaud Congress for recognizing this when, in the MMA, it directed the Secretary to conduct a comprehensive look at whether and how importation could be accomplished and what impacts it would have on drug safety, the drug supply, and innovations in pharmaceutical development. As Chair of the Task Force I intend to ensure that these critical safety questions are answered using the best available information in order to advise and assist the Secretary in making recommendations to Congress. To move forward with importation without addressing these critical questions would be imprudent.

Recently, we have been dealing with the first case of BSE infective cow in the United States – a cow that came down from Canada and was diagnosed as having a BSE infection. In response to this public health risk, we have in place a multi-layered safety approach that includes numerous firewalls to protect the U.S. consumer from being exposed to infected product. As a result of these firewalls (to which we just recently announced further enhancements) the risk of getting vCJD is extremely low. Even so, there are many who support continuing to prohibit or ban the importation of beef from Canada and other countries where BSE infections have occurred. Yet, some have argued for legalizing drug importation in a situation where we don't even have all of these firewalls in place. This is problematic. Today, in part thanks to laws recently passed by Congress to ensure the safety of imported foods from the threat of a bioterrorist attack, we have specific authorities to protect the food supply, including authorities to detain such foods, require importers to register with the FDA, require adequate recordkeeping and prior notification of incoming shipments. When it comes to beef, we go further to restrict entry points and USDA inspection facilities as well as employ animal health protections as needed to assure safety. And yet, when it comes to drug importation, the some of the legislation pending before Congress is absent these types of protections. Furthermore, the law as enacted was not set up to handle the volume and scope of products that would be imported. In order to seriously consider importation, it would be necessary to take into account how to authorize and fund fundamentally different Agency

programs to assure imported drug safety, in a manner similar to that which was done for imported foods.

Question 2: Reimportation

What's wrong with these drugs? Aren't they just as safe as the drugs that Americans buy from their local pharmacy?

Answer:

Chairman Grassley asked this question at the confirmation hearing on March 8, 2004 and Commissioner McClellan responded to it at that time. This written response is intended only to supplement the Commissioner's response to the question at the hearing.

All imported drugs are required to meet the same standards as domestic drugs, and thus cannot be unapproved, misbranded, or adulterated. Drugs imported by individuals that are unapproved, misbranded, or adulterated, are prohibited by the Food, Drug and Cosmetic Act. This includes drugs that are foreign versions of FDA-approved medications, and drugs that are dispensed without a prescription, because there is no assurance of their safety and effectiveness.

Sixty-five years ago, Congress responded to widespread fears of unsafe and ineffective domestic drugs by directing FDA to create a system for assuring that Americans have a drug supply they can trust. Fifteen years ago, Congress responded to serious safety problems created by imported drugs that were not tightly regulated by passing the Prescription Drug Marketing Act. Congress limited access to these foreign drugs because of safety concerns it identified with the importation of significant volumes of adulterated and counterfeit drugs.

Under Section 801(a) of the FD&C Act, a drug is subject to refusal of admission into the U.S. if it appears that it: 1) has been manufactured, processed or packed under unsanitary conditions, 2) is forbidden or restricted for sale in the country in which it was produced or from which it was exported, or 3) is adulterated, misbranded or in violation of section 505 of the FD&C Act, relating to new drugs. To determine whether a product is in compliance, FDA may collect an analytical or documentary sample from the shipment for evaluation, and the shipment is held until the results of the examination are known. In some instances, a product may be detained as soon as it is offered for entry into the U.S. This procedure -- detaining a product without physical examination -- is based on past history and/or other information indicating the product may violate the FD&C Act. At mail facilities, Bureau of Customs and Border Patrol (BCBP) officials identify parcels that should be brought to FDA's attention. BCBP places these packages in a secure location that they maintain for FDA and other agencies. As with all imports, if it appears that the product is subject to refusal, FDA may issue a notice to detain the product and provide the owner or consignee an opportunity to respond.

Unfortunately, the drug supply is under unprecedented attack from a variety of increasingly sophisticated threats. This is evident in the recent significant increase in efforts to introduce counterfeit drugs into the U.S. market. FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990s. Although counterfeiting was once a rare event, we are increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well-funded and elaborately organized networks. At the same time, inadequately regulated foreign Internet sites have also become portals for unsafe and illegal drugs. Evidence strongly suggests that the volume of these foreign drug importations is increasing steadily and presents a substantial challenge for the Agency to adequately assess and process these parcels, resulting in an increased workload for Agency field personnel at ports-of-entry, mail facilities, and international courier hubs.

FDA is doing its best to stop the increasing flow of violative drugs into this country but the task is daunting. Each day thousands of packages containing prescription drugs are imported illegally into the U.S. FDA's Office of Regulatory Affairs has inspectors who work in the field who perform investigational work pertaining to imported prescription drugs, a job that is not limited to inspections at ports of entry. But while the volume of imported drugs has increased enormously, FDA has not received additional resources or authorities to address these shipments, in contrast to the case for food security at the border.

Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Currently, when the Agency decides to approve a new drug product for marketing in the U.S., it has made this decision in part, based upon FDA's review of the manufacturing process the product undergoes, as well as the packaging and labeling conditions the product is subject to. Even if an FDA-approved drug is produced in a manufacturing site overseas, the facility is inspected by FDA to ensure that it operates in conformance with FDA's current Good Manufacturing Practice (GMP) requirements. Therefore, when FDA ultimately decides to approve a drug, that drug has gained FDA approval in many respects, including, but not limited to the fact that it has been manufactured in an approved manufacturing location; and that the drug's formulation, source, specifications, ingredients, processing methods, and manufacturing controls have been inspected. However, FDA's approval of a drug is "product" and "process" specific. In other words, where a drug, other than an FDA-approved medication, has been produced in a foreign manufacturing location, one cannot, presume that this product, too, has been subject to the same stringent controls as an FDA-approved product.

FDA has stated that it cannot assure the American public that drugs imported from foreign countries are the same as products approved by FDA. Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore

important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent against degradation, and there is no assurance that these products were manufactured under current good manufacturing practice standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening.

Patients also are at greater risk because there is no certainty about what they are getting when they purchase some of these drugs. Although some purchasers of drugs from foreign sources may receive genuine product, others may unknowingly buy counterfeit copies that contain only inert ingredients, legitimate drugs that are outdated and have been diverted to unscrupulous resellers, or dangerous sub-potent or super-potent products that were improperly manufactured. Furthermore, in the case of foreign-based sources, if a consumer has an adverse drug reaction or any other problem, the consumer may have little or no recourse either because the operator of the pharmacy often is not known, or the physical location of the seller is unknown or beyond the consumer's reach. FDA has only limited ability to take action against these foreign operators.

Due to the huge volume of drug parcels entering the U.S. through the international mail and courier services, the current requirements for notice and hearing on a case-by-case basis, and FDA's limited resources, it is difficult for FDA to detain and refuse to admit mail imports for personal use. In addition, considerable storage space is needed to hold the large number of detained parcels while a notice, opportunity to respond, and Agency decision are pending. The recent rise in Internet purchasing of drugs has significantly compounded this problem.

The Agency has responded to the challenge of importation by employing a risk-based enforcement strategy to target our existing enforcement resources effectively in the face of multiple priorities, including homeland security, food safety and counterfeit drugs. As an example, the Agency utilizes Import Alerts to identify particular shipments that may pose significant potential risk to public health, e.g., drugs that require careful risk management and products from shippers known to present significant safety problems. However, this system as it works today is already overwhelmed by the number of incoming packages and this presents a significant ongoing challenge for the Agency.

Question 3: Reimportation

What about the cost of these foreign drugs? Even though they may be taking greater risks, sometimes that's the only way these people can afford to fill their prescriptions.

Answer:

The perceived cost benefit of foreign drugs is an issue that many economists have been discussing and it is certainly an important consideration. But let me reiterate that, as FDA Commissioner, it has been my responsibility first and foremost to assure drug safety, security and efficacy. Part of that is to evaluate the wisdom of different proposals

that impact on the quality of the U.S. drug supply. But as part of that, it is important to ensure that our food and drug policies are also economically sound ones, and if confirmed as Administrator for CMS, I intend to continue to ensure that our public health objectives are accomplished in an economically sound manner.

The need to ensure the greater access to more affordable prescription medications has been a top priority for me, and as FDA Commissioner I have guided several changes to accelerate the approval of lower cost generic drugs, enhance generic competition, and, working with Congress, provide additional resources to the Office of Generic Drugs to improve their reviews. In many cases, the price of FDA-regulated products, such as many generic drugs, are already lower than brand name and even some generic drugs in foreign countries. Put another way, while many people think ordering foreign drugs via the mail or Internet will always be more affordable, in fact, where there are a generic alternatives available in the United States, it is often less expensive and more accessible to get that product from a local pharmacy. In fact, a study published by FDA in November 2003, looking at the biggest-selling chronic-use drugs with a generic version introduced in the last ten years, showed that for six out of the seven drugs reviewed, the U.S. generic was priced less than the brand name version in Canada. This is why as FDA Commissioner I have focused my attention on providing greater access to more affordable generic drugs by increasing funding for generic drug approval and by proposing a regulation to enhance generic drug competition. The Medicare Modernization Act codified and expanded upon some of these improvements.

Question 4: Reimportation

Will you agree to work with me to develop and refine this legislation so that we can put an end to unsafe drug imports while also creating a newly organized and safe system?

Answer:

Chairman Grassley asked this question at the confirmation hearing on March 8, 2004 and Commissioner McClellan responded to it at that time. This written response is intended only to supplement the Commissioner's response to the question at the hearing.

Senator, I am committed to working with you, and FDA is always willing to provide technical assistance to Members of Congress on legislation affecting their authorities. In my view, the most appropriate way to consider whether importation should proceed is to answer the safety and economic questions posed by Congress on this subject under the study required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The work on this study has begun, and FDA will work with its sister Agencies to complete the necessary analysis. The Task Force for this study, which I Chair, will provide a helpful forum for fair, open and transparent dialogue on these issues. It will ensure that the review of issues related to reimportation is balanced and employs the best available information on the questions raised by Congress.

Question 5: Reimportation

Finally, my good friend Senator McCain has asked that you testify before the Senate Commerce Committee on the issue of reimportation. Would you agree today on the record that after we complete the nomination process this week that you would appear before the Commerce Committee on the subject of reimportation?

Answer:

Chairman Grassley asked this question at the confirmation hearing on March 8, 2004 and Commissioner McClellan responded to it at that time. This written response is intended only to supplement the Commissioner's response to the question at the hearing. As I stated during the nomination hearing, I would be happy to appear before Senator McCain's committee to discuss this issue upon completion of the nomination process. The Agency has testified on this subject before the Senate Committee on Commerce, Science and Transportation most recently on November 20, 2003 and the FDA has testified on eight separate occasions on importation during 2003 – this represents each and every time the Agency has been asked to testify on this topic last year. Last year the Agency provided Congressional testimony on drug importation more than on any other matter before it and the Agency has never refused to provide a witness to any Congressional committee requesting FDA participation in a Congressional hearing on this topic.

Questions 6 and 7: Long Term Care Pharmacy

6)Would you please explain for the committee your understanding of the steps CMS is taking to implement the long term care pharmacy study?

7) How will the agency, under your leadership, work with advocates and the industry to ensure delivery of the new Part D benefit integrates seamlessly with the existing safety standards and procedures?

Answer:

It will be very important to make sure that the Part D drug benefit works seamlessly for beneficiaries as they move in and out of nursing homes, especially now that the dual eligibles will get their drug benefits under Medicare rather than Medicaid. That's why the MMA called for CMS to undertake a study within 18 months of enactment to look at the question of how best to coordinate the drug benefit with the needs of nursing homes.

Because of the tight timeline to get a regulation out, what you may very well see on this question is a draft policy that will be revised later based on comments to our proposed regulation as well as findings from the study. CMS is working diligently to implement these provisions – a massive undertaking as you are aware – with many details that are still being determined with careful consideration. They are prioritizing based on our tight timeline. I look forward to joining these efforts pending my confirmation, and I plan to

oversee MMA implementation in an open, transparent process with input from all stakeholders, including the Congress.

Question 8: Coverage of Treatment for Macular Degeneration

CMS should be commended for making the national coverage decision on January 28, 2004, to expand Medicare coverage of OPT with verteporfin therapy to treat patients with occult age related macular degeneration (AMD).

This was an important decision since the evidence shows that in the expanded indications approved for coverage by CMS, outpatient treatment with verteporfin therapy reduces the number of patients who will suffer severe vision loss from this condition by 50%.

The damage to a patient's sight from age related macular degeneration is progressive and irreversible. It is vital to the affected Medicare patients that the newly approved therapy is made available to them as soon as possible.

CMS has not indicated, however, when it will implement this coverage decision. Medicare already pays for outpatient verteporfin therapy for some patients with AMD. As a result, there are no new codes that have to be established to implement this expansion of coverage.

Considering that no new codes need to be established and considering the progressive and irreversible nature of the disease, it appears as though CMS should be positioned to implement the decision by April 1, 2004.

What is the status of implementation for this coverage decision, and will it be implemented by April 1, 2004?

Answer:

I understand that you are very concerned about this issue. At FDA, one of my top priorities has been to find ways to help patients get access to valuable new medical treatments more quickly and at a lower cost. At CMS, I intend to work closely with the staff to achieve the same goal.

As you know, age-related macular degeneration (AMD) is the leading cause of severe vision loss in the Medicare population. CMS' new coverage policy will provide an additional treatment option for physicians to consider for patients with the "wet" form of AMD.

I understand CMS is working diligently to ensure that the new verteporfin instructions to the CMS contractors will be released as soon as possible.

Question 9: DME Competitive Bidding

The Medicare Modernization Act requires CMS to begin competitive bidding for durable medical equipment for selected products in selected geographic areas by 2007. While I agree that there is room for payment reductions in the industry and that waste, fraud and abuse must be weeded out, I have serious concerns about how CMS is going to institute nationwide competitive bidding even on a phased-in basis.

As we were negotiating this legislation in November 2003, staff experts at CMS indicated to me that no formal plan had been developed and that, if there were a plan in place, it could take up to 150 full-time employees at CMS just to implement the plan.

How do you plan on implementing the competitive bidding provisions in the new law in a way does not create uncertainty and confusion for Medicare beneficiaries and providers?

Answer:

I understand that CMS has begun to develop a formal plan to implement competitive bidding. In fact, to date, CMS has accomplished the following:

1. Begun to develop a detailed planning and implementation process that includes tasks and timelines that will facilitate project planning and organization
2. Formed an intra-agency competitive bidding workgroup of the various components that will be responsible for the implementation of this provision and held the initial kick-off meeting to discuss plans for implementation of this provision
3. Developed the Statement of Work for the contract that will be for assisting CMS in developing the policies and procedures for the implementation of competitive bidding
4. CMS has learned a great deal from the DME competitive bidding demonstrations that ended on December 31, 2002, and is incorporating knowledge from these demonstrations into the permanent competitive bidding program.

As you can see, CMS has taken significant action to get competitive bidding going to ensure that once the program is implemented it will be an effective and efficient process for beneficiaries and providers to use.

Question 10: Education for Family Caregivers

To date, public education on the changes to Medicare has been directed exclusively at Medicare beneficiaries. We know, however, that family caregivers--usually adult children--often play an important role in healthcare decision-making for elderly individuals, such as those living with Alzheimer's Disease and being cared for at home by a family member.

Under your leadership, what efforts will be made to ensure that specific educational efforts also target the family caregiver?

Answer:

I understand that CMS' ad campaign has always been targeted not only to Medicare beneficiaries, but also to family caregivers, such as adult children. I understand that CMS is continuing to work diligently to ensure that public education on the changes to Medicare will continue to be easy to understand. I can assure you that CMS will continue to aim educational efforts at both Medicare beneficiaries and their caregivers, if applicable. For example, a caregiver can go onto www.medicare.gov and find out all kinds of information about Medicare to help their family member or other Medicare beneficiaries for which they may be caring.

Question 11: Nursing Home Quality

As you know, I have been very interested in improving the quality of care in nursing homes at least since I became chairman of the special committee on aging in 1997.

Since that time, congressional hearing, as well as studies by the General Accounting Office and the Office of the Inspector General, have consistently reported that an unacceptably high proportion of nursing homes have serious quality problems that result in harm to residents. Moreover, GAO has pointed out serious weaknesses in federal and state nursing home oversight. In response to these findings, CMS, and the Health Care Financing Administration before it, have undertaken initiatives intended to address many of the weaknesses identified by GAO. However, last year before this committee GAO testified that weaknesses persist in state survey, complaint investigation, and enforcement activities and that, despite increased CMS oversight and some improvement in quality measures, continued attention is required to help ensure compliance with federal nursing home requirements. In short, CMS has made progress but more needs to be done.

As a major source of funding for nursing homes, and as the managing agency responsible for oversight of the nursing home reform act, CMS, in my view, has a major responsibility for assuring quality of care in nursing facilities.

- As the prospective administrator of CMS, can you assure me that improving the quality of care in nursing homes will be a high priority for your leadership at CMS?

Answer:

I very much appreciate the support and leadership you continue to provide on this critical nursing home quality issue. Your efforts have been instrumental in achieving positive changes in the care provided in nursing homes. Please be assured that, like my predecessor, I am committed to improving the well being of the nation's nursing home residents. Nursing home quality is an important initiative – one I take very seriously. CMS is doing a lot in this area already, and I plan on doing more. Pending my confirmation, I look forward to working with you as we undertake efforts that will result in improved nursing home quality.

Question 12: Nursing Home Quality Indicators

During the tenure of the former Administrator, quality improvement organizations were charged with helping assess the quality of care in nursing homes and other health care entities through the development of quality indicators. I considered this a promising development then and do now.

However, the development and use of quality indicators must receive a high priority by CMS leadership and CMS has to continue to work to be sure that quality indicators are accurate and user friendly, especially for prospective residents and their families. If quality indicators are not a helpful and accurate guide to facility quality, and thereby affect consumer choice, their whole purpose is subverted in my view.

- Can you tell me whether, as CMS Administrator, you will make it a priority to ensure that quality indicators are optimally useful to those choosing a nursing facility?

Answer:

I appreciate your interest in nursing home quality indicators, a set of measures that continues to evolve. Ensuring the accuracy of these measures is a priority of mine, and a critical component of improving the quality of care in nursing homes. These measures are vital in assisting prospective residents and their families who must make very tough decisions in choosing a nursing home. I agree with you that these indicators are most beneficial when they are helpful and accurate.

It is my understanding that CMS has made progress in improving these measures and their usefulness to consumers. On January 22, 2004, CMS introduced enhanced measures as part of their ongoing commitment to use public reporting to improve the quality of care available in the nation's nursing homes. These measures build on the original ten used in the initial Nursing Home Quality Initiative and can be found at www.medicare.gov. Pending my confirmation, I look forward to working with you to ensure the usefulness of these measures to seniors and their families.

Question 13: Part B Covered Drugs

Medicare has been overpaying for drugs administered in doctors' offices that both the Office of Inspector General and the General Accounting Office have concluded are priced far higher than their actual cost.

The Medicare Modernization Act requires the Medicare program to pay doctors for Part B covered drugs consistent with the doctors' actual acquisition cost, using information about market transaction prices.

At the same time, the law stipulates that physicians will receive a boost in payment for their time and effort administering these drugs.

Certain specialty physician practices impacted by the new pricing changes are alleging that the new payment system has prompted at least some physicians around the country to reduce the care they provide and in some cases to close satellite offices and eliminate nurses and other staff.

What are you planning to do to monitor the impact of this policy on beneficiary access and payment adequacy?

Answer:

I am cognizant of the need to monitor access and payment adequacy. My understanding is that CMS has a number of longstanding approaches that are brought to bear, including calls from beneficiaries to our 1-800-MEDICARE number and other environmental scanning activities conducted by our Office of Research, Development and Information. In addition, the CMS Regional Offices are always in close contact with providers and beneficiaries in their areas on potential access issues. These sources have not indicated a systemic access problem to cancer care since these payment changes went into effect on January 1, 2004. CMS will continue to monitor the situation closely and will work with Congress if access issues arise. In addition, CMS plans to work closely with other organizations such as OIG and MedPAC, which are conducting studies related to access to cancer care.

Questions 14 and 15: Sustainable Growth Rate

In 2003, Congress spent more than $54 billion over ten years to address reductions in Medicare payments to physicians. As the result of the Medicare Modernization Act of 2003, physicians will receive a 1.5 percent payment rate increase in Fiscal Years 2004 and 2005.

I am concerned, however, that we are only putting a bandage on a gaping wound that is the flawed sustainable growth rate (SGR) factor. We need a long-term proposal to address the physician fee schedule in order to ensure access to physician services.

14) What are your thoughts on how to stabilize physician payments? Since 1997, Medicare has updated physician fee schedule payments using the sustainable growth rate (SGR) system. The SGR is a spending target. If spending exceeds the target, the update is reduced. If spending is under target, the update is increased. While its actual operation is complex, the SGR generally allows Medicare spending for physicians' services to grow at a target rate. The SGR target fully reflects growth in prices and numbers of fee-for-service beneficiaries, but allows the volume and intensity of services to grow at the same rate as the economy.

Answer:

Unfortunately, the update system would have led to a large reduction in physician payment rates for 2004 and 2005. To avoid this result, Congress established updates for

2004 and 2005 at 1.5 percent. However, to avoid increasing spending over the long term, the Congressional action in the MMA will lead to additional physician fee reductions beginning in 2006 without another change in law.

While the MMA dealt with the physician update for 2004 and 2005, it does give the Administration and Congress two years to consider long-term modifications that will lead to fair and equitable reimbursements for physicians with predictable and controlled spending for Medicare physicians' services.

15) Additionally, Congress has urged CMS to remove Medicare covered drugs from the calculation of the SGR.

Do you plan to use your administrative authority to remove Medicare covered drugs from the SGR?

Are there other administrative changes CMS has looked into to correct errors in the physician payment formula?

Answer:

I understand that there has been an issue about inclusion of expenditures for drugs in the SGR. If I were to become the CMS Administrator, I would review the system used to update Medicare payments for physicians' services, including examination of areas of administrative authority. If there is administrative authority and if there would be an impact on physician updates, I would give serious consideration to removing drugs from the SGR. It is my understanding is that the physician payment formula presently does not have errors.

Question 16:

As you know, current law limits part B outpatient therapy services to $1500 per year per beneficiary for physical therapy/speech language pathology and $1500 per year per beneficiary for occupational therapy.

Congress continues to place a moratorium on the implementation of this law until alternatives to this cap on therapy services can be evaluated. CMS is overdue in submitting a report that discusses these alternatives.

While I recognize the need to control the growth and over-utilization of part B therapy services, I am concerned that this limit may hurt some of the neediest and frailest of patients such as those with Parkinson's disease or who have survived a stroke.

Please update us on the status of this report. What are your views on possible alternatives to the $1500 cap?

Answer:

As you know, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) renewed Congress' prior moratorium on payment caps for outpatient physical therapy, speech-language pathology, and occupational therapy services performed from December 8, 2003 through December 31, 2005.

The MMA also sets a new deadline of March 31, 2004 for the submission of reports on therapy caps and therapy utilization that were originally required by the Balanced Budget Act of 1997 (BBA) and the Balanced Budget Refinement Act of 1999 (BBRA).

The MMA requires GAO to identify conditions that may justify waiver of the payment caps and to recommend criteria for such waivers. A GAO report is due to Congress by October 1, 2004.

I share your concern about the potential impact on beneficiaries of the statutory caps on therapy services, and look forward to working with you to explore possible alternative policies when the CMS and GAO reports are completed.

Question 17: Medicare Contractor Reform

As CMS administrator, you will be shepherding the most sweeping changes to the Medicare program since its enactment. While these changes are underway, you will also be responsible for modernizing Medicare's contracting process, a legacy of relationships hospitals had with insurers like Blue Cross in 1965. As required by the Medicare Modernization Act, all of the functions of Part A contractors and Part B contractors will be consolidated under a single authority for a new contractor.

- What will you do to ensure that the Medicare Administrative Contractors will be sufficiently prepared to carry out their current responsibilities, including claims processing and implement the Medicare prescription drug benefit and to ingeducate (sic) and outreach to beneficiaries and providers, while the fundamental nature of their contracts with Medicare and providers are is (sic) changing?

Answer:

I have every confidence that Medicare claims processing contractors will be able to handle the every day details of managing and fulfilling the obligations of their contracts while transitioning from the current system of Carriers and Fiscal Intermediaries to a system with Medicare Administrative Contractors.

It is true that the fundamental nature of Medicare claims processing contracts will change. The Administration believes that these reforms will not only bring Medicare contracting in line with standard government contracting procedures, but in doing so, it will allow the Centers for Medicare & Medicaid Services (CMS) to contract with the most efficient and responsive entities available, vastly improving claims processing

services for beneficiaries and providers. I will work to ensure that CMS has a detailed implementation plan as the agency transitions to this new competitive environment.

I will ensure that CMS continues to be vigilant in its oversight of the Carriers and Fiscal Intermediaries and the performance of their contract functions, including their education, training and outreach duties as well as the new duties created in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). As CMS transitions to the new Medicare Administrative Contractors, oversight of these key contractual requirements will continue to be an important priority.

I believe that the most critical juncture will come as the Medicare Administrative Contractors first come on-line. At that time, as Administrator, I will work to ensure that there is a smooth transition from the existing contracts to these new competitive contracts. It will be critical that the entire transition process is managed effectively and that all contract transitions are fully and thoughtfully prepared before they go into place. With good forethought and preparation, I believe that we can ensure that there is only limited, if any, disruption in the current claims processing contracting process.

Additionally, I would point out that the staff at CMS have had significant experience and a long track record in managing contracts and contractor transitions. I am confident that I will be able to call on this expertise and experience to ensure a smooth transition during the Medicare modernization process.

Questions Submitted by Ranking Member Baucus

Question 1: Prescription Drug Plan Regions

The 2003 Medicare Act establishes new prescription drug plans (PDPs). The Secretary is given discretion in establishing between 10 and 50 regions across the nation, which may conform to the PPO regions. Congressional intent is to ensure that rural areas have the same number of choices in drug plans as urban areas. How many regions should CMS divide the country into and will a plan be required to serve beneficiaries in more than one state? How will CMS ensure that rural seniors have the same choice in plans as urban areas?

Answer:

The question of how to define the regions is very important, as the plans' service areas will affect many of their business decisions. We are very interested in making sure that rural residents have choices, and we will work diligently to construct regions that maximize plan availability throughout the country.

As you know, the MMA directs us to undertake a market study to establish regions for both the regional PPOs and the drug plans. The statutory deadline for that study is January 1, 2005.

I understand that you are very concerned about this issue. Pending my confirmation, I will look into this issue further and I look forward to working with you regarding your specific concerns. CMS will issue a proposed rule on Medicare Advantage and the new Part D drug benefit in the next few months. We look forward to public discussion and public input to resolve this issue as effectively as possible for beneficiaries in our final regulation.

Question 2: Prescription Drug Plans - Risk Adjustor

The 2003 Medicare Act requires that CMS implement a risk adjustor for the direct subsidy for prescription drug plans. The risk adjustor is to be applied across all beneficiaries that are enrolled in the Part D benefit. This application would include beneficiaries that are enrolled in fallback plans. Does CMS plan to include beneficiaries enrolled in fallback plans when it applies the risk adjustor to prescription drug plans?

Answer:

As you know, the MMA directs CMS to construct an entirely new bidding and payment system for prescription drug plans and Medicare Advantage. The risk-adjuster is one of a host of bidding and payment structures that must all work properly in order to bring plans in and give beneficiaries the benefit of competition for their enrollment.

CMS is working diligently to implement these provisions – a massive undertaking as you are aware – with many details that are still being determined with careful consideration.

I understand that you are very concerned about this issue. Pending my confirmation, I will meet with our actuaries and program staff and look into this issue further. I look forward to working with you regarding your specific concerns. CMS will issue a proposed rule on Medicare Advantage and the new Part D drug benefit in the next few months. We look forward to public discussion and public input to resolve this issue as effectively as possible for beneficiaries in our final regulation.

Question 3: Medicare Advantage – Risk Selection

As you know, there have been long documented problems with risk selection in the Medicare+Choice program. Prior to changes made during the Balanced Budget Act of 1997, plans engaged in clear risk selection practices, for example, by only marketing to the healthiest seniors. The clear policy intent is to ensure that all Medicare beneficiaries have access to a choice of affordable drug plans. What can be done to ensure that the past risk selection practices are not repeated in the newly created prescription drug plans?

Answer:

For the Medicare Advantage program, a significant step toward our goal of minimizing risk selection is the introduction of risk adjusted payment, through which plan payments

are adjusted based on the health status of enrollees. A plan whose enrollees are sicker and thus require more health care services will receive higher payments than a plan whose enrollees are healthier. Risk adjusted payment was initiated in 2000 and for the period 2000-2003, 10 percent of payment was adjusted for health status (with 90 percent of payment based on the prior demographic-only adjustment system in use since risk-based private plan contracting began early in the Medicare program). The system used only inpatient hospital data to determine health status. Beginning in 2004, CMS has implemented a more refined health status risk adjustment system, known as the Hierarchical Condition Category HCC) model, that utilizes both inpatient and ambulatory data. The current phase-in schedule for the HCC risk adjustment method is 30 percent in 2004, 50 percent in 2005, 75 percent in 2006, and full 100 percent health status risk adjustment beginning in 2007.

With respect to prescription drug plans, we are working to develop a risk adjustment system that will pay accurately for enrollees depending on their health status and prescription drug requirements. Drug plans are required to take all beneficiaries who wish to enroll and they are required to serve an entire region. CMS will also be providing information to all beneficiaries on their drug plan options. We believe that these provisions will allow all beneficiaries to be informed about the new drug benefit and to enroll in the private plan of their choice, if they wish to have this coverage, and preclude risk selection by drug plans. We will be issuing a proposed regulation for the Medicare Advantage program later this year, and we look forward to public input on these issues and using the process to resolve matters related to beneficiary protections in our final regulation.

Question 4: Prescription Drug Plans/Fallback

The 2003 Medicare Act requires the Secretary to study geographic differences in prescription drug spending and to make recommendations on how to adjust the premium subsidy if variations in spending are determined. This provision is intended to ensure that beneficiaries in high cost areas are not penalized for spending that is beyond their control and to limit variations in premiums across the country. If the study does determine geographic differences in prescription drug spending, do you agree that the premium subsidy should be adjusted to reflect these spending differences?

Answer:

This will be a very important issue to follow as the drug benefit is implemented and as we all gain experience with providing a drug benefit with Medicare.

The MMA directs the administration to adjust for price only. As with all other drug benefit questions, we will be raising issues related to how we might adjust premiums for price factors in the proposed rule and I look forward to full discussion and comment on this issue. The statute also directs CMS to undertake a study of geographic variation and present results and recommendations to Congress by January 1, 2009. Although I cannot at this time pre-judge what its contents or recommendations will be, I intend for this

study to provide information on geographic variations in benefit costs for reasons other than price. We will complete this study as quickly as we can, on or before January 1, 2009.

In the meantime, the MMA already calls for the bidding system to adjust for any regional variation in price. I think it will take a couple of years of program experience to see exactly what kind of drug utilization and premium variation we will get under the existing process. We will continue to examine the best ways to implement this provision. I look forward to working with you regarding your specific concerns.

Question 5: Prescription Drug Plans/Fallback

The 2003 Medicare Act requires that the Secretary solicit bids from fallback contracts in all regions of the country to ensure that all Medicare beneficiaries have access to the benefit if prescription drug plans do not materialize in their region or if plans abruptly exit the program. The fallback contract is required to be established for a three-year period. As I mentioned at the hearing this afternoon, Deputy CMS Administrator, Leslie Norwalk, was recently quoted in the press as saying that CMS may not plan to implement the fallback contract as directed in the statute. What is CMS interpretation of the statute? Were the statements of Leslie Norwalk an accurate reflection of the Administration's position?

Answer:

Mr. Baucus asked this question at the confirmation hearing on March 8, 2004 and Commissioner McClellan responded to it at that time. This written response is intended only to supplement the Commissioner's response to the question at the hearing.

Of course, CMS intends to follow the law and will have a fallback process in place. What Leslie meant, and what's clear from the context of the story, is that we are optimistic that we will not have to actually *use* the fallback plans, since we are seeing great interest from a variety of companies in the drug card and the drug benefit. We will be presenting this issue in the proposed rule and look forward to comments and detailed discussion.

You may recall, that the MMA calls for us to set up a fallback contracting process separate from the bidding process for the insurance-based plans – the prescription drug plans and Medicare Advantage plans. And we will conduct that fallback process as the law directs. However, the law also says that we only use the fallback contingency plans in areas where fewer than two insurance-based plans participate, one of which has to be a stand-alone prescription drug plan.

There are two factors that make us confident that fallback plans will not be necessary:

1. We have received 106 bids from organizations to participate in the drug discount card, and many plans are saying that participation in the card is their strategy to get familiar with the Medicare in order to participate in the drug benefit.

2. The MMA allows the insurance-based plans to bid as either "full risk" or "limited risk" by modifying the risk corridors specified in statute.

With lots of plan interest, and several ways for plans to participate, we expect full and vigorous participation in all parts of the country.

Question 6: Non-Interference/Cost Containment

The 2003 Medicare legislation explicitly prevents the federal government from using its purchasing power to reduce the prices of drugs covered under the new Medicare drug benefit. Is it your opinion that private sector negotiations between the prescription drug plans and drug manufactures will produce price reductions greater than the Secretary would be able to obtain in direct negotiations, and if so, what is the rationale for this opinion?

Answer:

I believe that the model chosen by the MMA – using insurance plans and Pharmacy Benefit Managers – is the best model for Medicare. PBMs negotiate every day on behalf of insurance companies and large employers. There's every reason to expect that they'll do a great job for Medicare. The Congressional Budget Office and our Actuaries at CMS both estimate that PBMs could achieve cost management on the order of 25% over time. That's a significant savings, resulting from both price discounts and other cost management tools such as generic substitution and utilization management.

Risk-bearing insurance plans, using their Pharmacy Benefit Management tools, have all the incentive in the world to drive hard bargains with manufacturers. Medicare Part D features a competitive bidding system, where plans will compete to attract beneficiaries on premiums, benefit design and formulary – and their ability to achieve cost savings will be the single biggest factor in setting premiums.

Question 7: Controlling Costs of Prescription Drugs

Spending on prescription drugs continues to rise faster than both overall inflation and average health spending. Growth in drug spending was 15.3% in 2002 and has been projected to be 15.3% in 2003. As administrator of CMS, what steps do you intend to take to control the cost of prescription drugs?

Answer:

I fully agree that it is vital to make prescription drugs more affordable, and I have long supported vigorous generic drug competition to bring drug prices down. Generic drugs are just as safe and effective as their brand name counterparts at a much lower cost. In my last job at FDA, we worked hard to make sure that generic drugs met the highest standards of purity and therapeutic equivalence, and I was pleased to see that the MMA worked to speed generic entry into the market. That, combined with disease management tools and better information for doctors as part of the e-prescribing initiative should help make medicine more cost effective.

If there's any good news in the Medicare drug estimates it's that a slowdown in costs is already predicted. Both CBO and our actuaries at CMS have looked at the trends in drug spending and project that average cost increases will slow down and remain below 10 percent per year. A main driver of this is that many drugs that are patent-protected today will be going off patent in the coming years, and the resulting generic competition should save Medicare beneficiaries a significant amount of money.

We believe that the model chosen by the MMA – using insurance plans and Pharmacy Benefit Managers – is the best model for Medicare to control costs. PBMs negotiate every day on behalf of insurance companies and large employers. There's every reason to expect that they'll do a great job for Medicare. The Congressional Budget Office and our Actuaries at CMS both estimate that PBMs could achieve cost management on the order of 25% over time. That's a significant savings, resulting from both price discounts and other cost management tools such as generic substitution and utilization management. Our actuaries expect that with this cost management in effect, Medicare drug spending will grow at an average annual rate of about 7.5 percent.

We believe that risk-bearing insurance plans, using their Pharmacy Benefit Management tools, have all the incentive in the world to drive hard bargains with manufacturers. Medicare Part D features a competitive bidding system, where plans will compete to attract beneficiaries on premiums, benefit design and formulary – and their ability to achieve cost savings will be the single biggest factor in setting premiums. All these factors will help control costs.

Question 8: Reporting Savings

The 2003 Medicare Act requires the Secretary to establish the manner for prescription drug plans to report the discounts that are passed on to beneficiaries. The intent of the provision is to ensure that all discounts and price concessions that are negotiated by prescription drug plans are passed on to beneficiaries and the taxpayers. How will CMS establish this reporting system to ensure that all discounts and price concessions are reported and passed on?

Answer:

The MMA calls for CMS to set up a host of complex bidding and payment structures and the plans' discounts play a role in several of them.

CMS is working diligently to implement these provisions – a massive undertaking as you are aware – with many details that are still being determined with careful consideration. They are prioritizing based on our tight timeline. I look forward to joining these efforts pending my confirmation, and I plan to oversee MMA implementation in an open, transparent process with input from all stakeholders, including the Congress. CMS will issue a proposed rule on Medicare Advantage and the new Part D drug benefit in the next few months. We look forward to public discussion and public input to resolve this issue as effectively as possible for beneficiaries in our final regulation.

Question 9: Medicare Advantage

The 2003 Medicare Act requires the Secretary to establish the manner for prescription drug plans to report the discounts that are passed on to beneficiaries. The intent of the provision is to ensure that all discounts and price concessions that are negotiated by prescription drug plans are passed on to beneficiaries and the taxpayers. How will CMS establish this reporting system to ensure that all discounts and price concessions are reported and passed on?

Answer:

The MMA calls for CMS to set up a host of complex bidding and payment structures and the plans' discounts play a role in several of them. I agree with the goal of an effective mechanism for reporting and understanding how discounts are passed on.

CMS is working diligently to implement these provisions – a massive undertaking as you are aware – with many details that are still being determined with careful consideration. They are prioritizing based on our tight timeline. I look forward to joining these efforts pending my confirmation, and I plan to oversee MMA implementation in an open, transparent process with input from all stakeholders, including the Congress. CMS will issue a proposed rule on Medicare Advantage and the new Part D drug benefit in the next few months. We look forward to public discussion and public input to resolve this issue as effectively as possible for beneficiaries in our final regulation.

Question 10: Medicare Advantage

The 2003 Medicare Act establishes new regional PPOs under the Medicare Advantage program in 2006. The Secretary is given discretion in establishing between 10 and 50 regions across the nation. How many PPO regions should CMS divide the country into and will a plan be required to serve beneficiaries in more than one state?

Answer:

The question of how to define the regions is very important, as the plans' service areas will affect many of their business decisions. We are very interested in making sure that

both rural and urban residents have choices, and we will work diligently to construct regions that maximize plan availability throughout the country.

As you know, the MMA directs us to undertake a market study to establish regions for both the regional PPOs and the drug plans. The statutory deadline for that study is January 1, 2005.

I understand that you are very concerned about this issue. Pending my confirmation, I will look into this issue further and I look forward to working with you regarding your specific concerns. CMS will issue a proposed rule on Medicare Advantage and the new Part D drug benefit in the next few months. We look forward to public discussion and public input to resolve this issue as effectively as possible for beneficiaries in our final regulation.

Question 11: Medicare Advantage Payment Levels

Following up on the question I asked at the hearing, I would like further clarification on your position on the current payment levels for private plans. As I mentioned, MedPAC recently reported that payments to Medicare HMOs are 7 percent higher, on average, compared to fee-for-service costs. Do you believe that this payment subsidy is appropriate? And if so, what is the rational for the overpayments? If competition is truly able to reduce long-term health care costs, don't you agree that payments should be set on a budget neutral basis compared to the traditional fee-for-service program?

Answer:

For too long, payments to Medicare+Choice (M+C) plans have been inadequate, causing plans to pull out of the program and leaving seniors without a valuable option for receiving their Medicare benefits. In many counties where M+C plans operate, M+C rates have lagged far behind the cost increases faced by plans. Their rates have increased by only 2% or 3% compared to much higher health care cost increases. The result is that many enrollees have lost important benefits and faced higher cost sharing, and some have also faced upheaval when their plan has left the M+C program.

In the MMA, Congress maintained the Balanced Budget Act of 1997's policy of using higher rates in areas where fee-for-service spending is relatively low while reestablishing MA payment rates based on fee-for-service (FFS) spending in areas where the rates have not kept up with FFS spending. This will allow private plans in areas where M+C rates lagged behind FFS costs to compete on a level playing field with FFS Medicare.

Let me also take the opportunity to reiterate my strong commitment to more complete risk adjustment. Implementation of full risk adjustment for payments means that more money will be directed to less healthy beneficiaries in private plans and away from healthier ones, which means in turn that any favorable selection into MA plans should be

diminished. My goal is to make sure that all beneficiaries, including chronically ill beneficiaries, will have a broad range of choices available.

Question 12: Medicare Advantage

And following up on the question I asked at the hearing about risk adjustment, in implementing risk adjustment last year, CMS increased plan payments. If plans are found to be enrolling a healthier population on average, do you not agree that risk adjustment should reduce overall plan payments? And I would like to clarify, do you support MedPAC's recommendation to implement risk-adjustment without offsetting any potential payment reductions?

Answer:

Let me also take the opportunity to reiterate my strong commitment to more complete risk adjustment. Implementation of full risk adjustment for payments means that we will pay plans appropriately for providing care to sicker beneficiaries, which means in turn that any favorable selection into MA plans should be diminished. My goal is to make sure that all beneficiaries, including chronically ill beneficiaries, will have a broad range of choices available.

Question 14: Reconsideration Process in the Discount Card

What are the plans for the reconsideration process for individuals who are denied eligibility for the prescription drug discount card or the $600 transitional assistance? Who will do the reconsiderations? What will be the time frame by which they will be required to issue a decision? Will there be an additional appeal available?

Answer:

I share your concern in getting as many seniors who are eligible enrolled in the transitional assistance of the discount drug card and having an enrollment and reconsideration process that is straightforward and timely. It is my understanding that the interim final regulation issued by CMS in December of 2003 established a reconsideration process where if an individual is determined ineligible to enroll in an endorsed discount card program or to receive transitional assistance, the individual (or the individual's authorized representative) has a right to request that an independent review entity under contract with CMS reconsider the determination. Under the reconsideration process, decisions must be issued by the independent review entity in writing and contain an explanation of the reasoning of the decision. Also, decisions will be issued within 30 days of receiving all materials. Pending my confirmation, I would be happy to work with you on this issue to address any additional concerns you may have.

Question 15: Pharmacies Informing Enrollees at Point-of-Sale Price Differences

There is a requirement for pharmacies to inform enrollees at point-of-sale of any differences between price of prescribed drug and price of lowest priced available generic alternative. How will CMS enforce this requirement?

Answer:

This issue is extremely important and we will be doing all we can to enforce this requirement. We will be monitoring what is happening in the marketplace. Also, program integrity contractors will be monitoring what is actually happening at the pharmacies with the point-of-sale transactions and we will be monitoring beneficiary complaints and receiving claims data at our request.

Question 16: Discount Card Changing Drug Prices Often

Are there limitations on how often discount cards can change the drug prices? How will CMS monitor whether the prices changes are appropriate?

Answer:

Even though drug prices are updated weekly on Price Comparison, this does not mean that the prices are constantly changing. Sponsors have stable contracts with their pharmacy network. They do not routinely re-negotiate the guaranteed discounts that must be provided to beneficiaries. Therefore, the only price changes that one can expect to see from time to time are due to changes in the average wholesale price (AWP) to which the discount is applied.

CMS will closely monitor any changes in AWP and in prices on Price Compare to ensure this explains the price changes, if any.

Question 17: Waiver of Coinsurance in the Drug Card

Does CMS have a plan to address transitional assistance enrollees who are unable to pay the co-pay for their prescription drugs at the point-of-service?

Answer:

I know that CMS is working diligently to implement the MMA- a massive undertaking, as you are aware- with many details that are still being determined with careful considerations. I look forward to joining these efforts pending my confirmation, and I plan to oversee MMA implementation and will insist on an open, transparent process with input from all stakeholders, including the Congress.

I do, however, understand that the Medicare Prescription Drug, Improvement, and Modernization Act allows for pharmacies to waive the application of coinsurance to transitional assistance beneficiaries only in certain circumstances, as follows:

the waiver is not to be advertised; the coinsurance is not routinely waived; and the coinsurance is waived only after determining (in good faith) that—

- the eligible beneficiary is in financial need;
- or the pharmacy has made reasonable collection efforts but still failed to collect the coinsurance due.

Question 18: Therapeutic Class Definitions

The Medicare legislation requires the United States Pharmacopeia to develop model guidelines for prescription drug plans to follow for therapeutic class definitions in the development of their formularies. The intent of the provision is to limit prescription drug plans' ability to cherry-pick healthier seniors through limited definitions of therapeutic class. Do you agree that a standard for therapeutic class is crucial in order to ensure that plans cover at least two drugs in all classes and to prevent discrimination against beneficiaries with specific health care conditions? If one common therapeutic class definition is not used, will beneficiaries be able to make accurate comparisons of plans on the basis of their formularies?

Answer:

The MMA strikes a balance between the need for standardization and the need for plans to have flexibility. The organization US Pharmacopoeia – which is already involved in many aspects of drug standards – will come up with a generally accepted list of therapeutic categories and classes for plans and for CMS to use as a baseline standard. This list will form a kind of "safe harbor" for plans. If they choose to use the USP classification schema, then their classification is deemed acceptable. If, however, plans would like to supply their own schema, then CMS will conduct a rigorous review of the proposal to make sure that its' not driven by a desire for favorable selection of enrollees. We think this approach – combining standardization and flexibility with rigorous review – strikes the right balance.

You suggest that variation in drug classes across plans may confuse beneficiaries. While that's certainly a risk, in the main we expect the comparison will be fairly clear. Beneficiaries will most likely not be asking about *classes* of drugs – say, ACE inhibitors or statins. Rather, they will probably be asking about *specific* drugs like Lipitor, and they will want to know what tier of the formulary the specific drug is on. We expect this kind of information to be readily available and reasonably clear to beneficiaries, though we certainly understand that the MMA presents an enormous challenge in beneficiary education, but I believe CMS is up to this challenge.

It will also be vitally important for plans and doctors to help educate beneficiaries on ways that they can save money by switching drugs – both within classes and across classes – while receiving the exact same health benefit. Such therapeutic substitutions, when clinically appropriate, are critical to providing cost-effective health care. And the new e-prescribing initiative should help in these efforts, since it will put formulary information in the doctor's hands at the point of prescribing.

CMS will issue a proposed rule on Medicare Advantage and the new Part D drug benefit in the next few months. We look forward to public discussion and public input to resolve this issue as effectively as possible for beneficiaries in our final regulation.

Question 19: Formularies

The Medicare Act of 2003 requires that formularies developed by participating plans include drugs within each therapeutic class and category of covered Part D drugs, although not necessarily all drugs within the categories or classes.

1. How will category and class be defined by CMS?
2. How many drugs will be required in each class?
3. Where a formulary includes only one drug per category or class, what protections will be provided when standard treatments require the patient to take more than one drug – for example, HIV/AIDS drugs or antipsychotics?
4. What protections will be provided in situations where switching medications (including switching brand to generic) poses serious health problems?
5. What protections will be provided to nursing home residents who may have had access to a particular drug while on Medicaid, but who no longer have access under Medicare? For example, if a particular individual's formulary does not cover IV antibiotics, would the resident have to go to the hospital to receive treatment?
6. In the above example, standard treatment may require the administration of antibiotics within 8 hours. If IV antibiotics are not covered, or if the antibiotic that is needed is not on the formulary, will the CMS appeals process work quickly enough so that a decision can be made within 8 hours?

Answer:

1. As stated in the MMA, we will work with US Pharmacopoeia to arrive at definitions of categories and classes.

2. The MMA calls for plans to have "drugs" plural in each category and class, which we are taking to mean at least 2 drugs. We believe this was clearly the intent expressed during the drafting process.

3. The special cases of drug classes for HIV / AIDS drugs, and other diseases where drugs are often used in combination will need careful scrutiny. I plan to give these issues careful attention in the implementation process. I can assure you that CMS is well aware of these needs. In its recent solicitation for the drug discount card, potential card sponsors were directed to pay special attention to classes such as the anti-HIV drugs, and our review of their applications is currently underway. We will give the same attention to these issues when implementing the drug benefit.

4. The MMA sets up clear rights for beneficiaries to challenge formulary decisions in cases where a physician determines that a non-formulary or a non-preferred drug would either not be as affective or would pose risks for adverse events. In these cases, beneficiaries can ask plans to reconsider the decision, and failing, that, beneficiaries have access to multiple levels of external appeal. In addition, in emergency or urgent cases, there are provisions for expedited appeals. We plan to make these appeal rights meaningful, so that every beneficiary has access to the right drug for them. At the same time, we fully believe in the power of well-constructed formularies to steer utilization to cost-effective drugs and to enable plans to extract rebates from manufacturers. We look forward to working with you to strike the right balance.

5. It will be very important to make sure that the Part D drug benefit works seamlessly for beneficiaries as they move in and out of nursing homes, especially now that the dual eligibles will get their drug benefits under Medicare rather than Medicaid. That's why the MMA called for CMS to undertake a study within 18 months of enactment to look at the question of how best to coordinate the drug benefit with the needs of nursing homes. Because of the tight timeline to get a regulation out, what you may very well see on this question is an interim policy that will be returned to later once the study is completed. CMS is working diligently to implement these provisions – a massive undertaking as you are aware – with many details that are still being determined with careful consideration. They are prioritizing based on our tight timeline. I look forward to joining these efforts pending my confirmation, and I plan to oversee MMA implementation in an open, transparent process with input from all stakeholders, including the Congress.

6. Again, it will be vitally important to make sure that the new Part D benefit integrates seamlessly with the long-term care settings. Some drugs in nursing home settings will be covered under the Part A per diem methodology, others will fall under Part D. The boundary lines need to be clear to both beneficiaries and providers. That's why it is so important for us to do a thorough study of these issues, the results of which should be available next year. One fact about drug plans should help allay your concern. Closed formularies are very rare in the insurance world. In the main, we are expecting that Medicare prescriptions plans will not implement closed formularies, though they certainly may do so. What we are more likely to see is open formularies with tiered cost sharing. In this kind of open formulary, all drugs are covered, but the amount of cost sharing varies by drug. So, more often it will be a question of what co-pay applies, not whether the drug is covered at all. And of course, there are emergency appeal rights that should cover cases as you describe. Pending my confirmation, I will meet with staff and look into this issue further. I look forward to working with you regarding your specific concerns.

CMS will issue a proposed rule on Medicare Advantage and the new Part D drug benefit in the next few months. We look forward to public discussion and public input to resolve this issue as effectively as possible for beneficiaries in our final regulation.

Question 20: Prescription Drug Plans - Formulary

When participating prescription drug plans change their formularies, the plans only have to make information available if it is requested by the plan enrollee. What process will CMS require to assure that all beneficiaries, including the majority of beneficiaries without Internet access, will be informed on a timely basis of formulary changes?

Answer:

I fully agree that it will be very important for beneficiaries to have key information about their drug plans, including formularies. Understanding both the benefit design, as well as the incentives built into the formulary, will be crucial for delivering the highest quality cost-effective care. However, we also want to be sure that we do not place undue burdens on the drug plans or provide beneficiaries with too much information to the point where it becomes confusing. I look forward to working with you regarding your specific concerns.

CMS will issue a proposed rule on Medicare Advantage and the new Part D drug benefit in the next few months. We look forward to public discussion and public input– especially from consumer organizations and other beneficiary advocates – to resolve this issue as effectively as possible for beneficiaries in our final regulation.

Question 21: Employers

The 2003 Medicare Act provides a subsidy to employers that maintain their prescription drug plans to their retirees. The Act requires that employers' retiree drug plans must be actuarially equivalent to the Medicare Part D benefit. The intent of the provision is to require that employers provide at least as generous a benefit as the Medicare Part D benefit. The Wall Street Journal has recently reported that some companies may incorrectly interpret the actuarial equivalence requirement, thereby reducing the value of their retiree benefits, shifting a greater share of costs onto retirees. How does CMS interpret the actuarial equivalence requirement?

Answer:

We understand that there has been some confusion among employers about the effect of the law. As Secretary Thompson said in a letter to House Ways & Means Chairman Bill Thomas just this week, it is incorrect for anyone to argue that the law calls for employers to be subsidized for costs they are not incurring.

The MMA calls for employers to be eligible for the subsidy provided they require a benefit "at least equal to the actuarial value of standard prescription drug coverage" in

Medicare Part D. And while there is some debate over the precise meaning of this actuarial equivalence test, the intent of Congress is perfectly clear: to use federal dollars to leverage private dollars and keep employers offering prescription drug coverage to their retirees.

CMS is working diligently to draft a regulation that will implement this provision, one that correctly articulates Congress' goal. I look forward to working with you as the regulatory process moves forward. CMS will issue a proposed rule on Medicare Advantage and the new Part D drug benefit in the next few months. We look forward to public discussion and public input to resolve this issue as effectively as possible for beneficiaries in our final regulation.

Question 22: $1 Billion in Administrative Funding

Section 1015 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides CMS with $1 billion for fiscal years 2004 and 2005 to implement the bill. How specifically does the Administration plan to spend this funding?

Answer:

It is my understanding that CMS is in the process of developing a spending plan that utilizes the $1 billion in the most cost effective and efficient way to administer the new law with the funds available. Certainly, the vast majority of the $1 billion startup funding is going to the nuts-and-bolts activities necessary to implement the MMA, including hiring the right people to get the job done, getting contracts with Vendors into place, making systems modifications, establishing systems for eligibility determinations, etc -- all the activities CMS believes are essential to building the infrastructure necessary to get the drug card, prescription drug benefit, and other key provisions up and running. Additionally, I'm certain that outreach activities including educating beneficiaries on the Medicare program and how the new law enhances their benefits under Medicare are certainly a piece of this effort.

Question 23: Medicare Education/Outreach-SHIPs

It is our hope that increased funding for State Health Insurance Assistance Programs (SHIPs) and the Office of the Inspector General must be made available out of the $1 billion set aside for implementation costs. Do you share our concern and agree that part of $1 billion should be spent on SHIPs and MIPs?

Answer:

The SHIPS play a very important role in educating seniors about Medicare. In regards to using the $1 billion in the MMA for the SHIPs, CMS will be increasing funding for the SHIPS in 2004 and particularly in 2005 as they gear up and begin large-scale efforts to ensure that Medicare beneficiaries understand all new benefits they will begin receiving in 2006, especially the new drug benefit.

Question 24: Medicare Education/Information to Beneficiaries

In addition, what information will CMS provide to beneficiaries each year about the Part D plans available to them? And how will the information be provided? Will the information include details about formularies, pharmacy networks, co-payments, and appeals processes?

Answer:

Under the MMA, the Secretary is required to conduct activities to broadly disseminate information to beneficiaries, similar to those currently conducted under Medicare + Choice, including dissemination of information through 1-800-MEDICARE, Medicare.gov and beneficiary mailings. The Secretary must provide comparative information on benefits, premiums, quality, cost sharing and consumer satisfaction. Plans must provide a range of information to beneficiaries including information on benefits, formularies, cost savings and medication therapy management programs. Plans must also provide information on coverage, utilization and grievance and appeals process upon request. And, plans must have a process to answer beneficiaries' questions in a timely manner, including access to a toll-free telephone number and must make available information on the Internet about formulary changes.

Question 25: Letter to Physicians

According to CMS officials, the agency mailed Medicare physicians a letter in early January explaining the drug card and the drug benefit. What proportion of the total participating Medicare physicians were part of the mailing, and if all physicians did not receive this mailing, what further actions does CMS intend to pursue broad provider education?

Answer:

It is my understanding that in an effort to educate the physicians who serve Medicare beneficiaries about the most significant improvements to the Medicare program since its inception, the Medicare Prescription Drug and Modernization Act (MMA), CMS instructed their carriers to send a letter from the Secretary to all physicians no later than January 12, 2004. This letter not only discussed the new law, but it also informed physicians about the fee schedule increase and the extension of the participation enrollment period and described the Medicare-Approved Drug Discount Card Program.

I am told that the mailing address used by carriers comes from the enrollment files, which is from the address given by the physician. CMS has heard, anecdotally, that most physicians leave it to the business office staff to determine what the physician actually sees. Regardless, pending my confirmation as Administrator, if there is any physician who did not receive the letter, get us information (name, provider number) we will check into it.

Question 26: Late enrollment penalty

H.R. 1 provides that the Secretary calculate the late enrollment penalty. Due to that fact that the penalty may be based on the base beneficiary premium, do you expect that the late enrollment penalty could differ by plan or by region? Will the penalty increase as premiums increase? If an enrollee switches in subsequent years to a more costly plan, will the penalty increase in that situation as well?

Answer:

I appreciate your attention to the issue of beneficiary premiums. There are few elements of the new Medicare drug benefit that will be as carefully watched as the premium charged for the benefit, and I will make sure that the premiums beneficiaries pay are appropriate under the law.

It is a new idea to provide a benefit using private insurance plans *and* to charge a late enrollment penalty for beneficiaries who fail to sign up at the first opportunity. Consequently, it is proper that the MMA gives the agency some discretion with how it designs the penalty, and how those funds are shared between the federal government and the plans. The MMA calls for the actuaries at CMS to weigh in on these and other design elements. I cannot say at this point where those deliberations will lead.

I understand that you are very concerned about this issue. Pending my confirmation, I will look into this issue further and I look forward to working with you regarding your specific concerns. CMS will issue a proposed rule on Medicare Advantage and the new Part D drug benefit in the next few months. We look forward to public discussion and public input to resolve this issue as effectively as possible for beneficiaries in our final regulation.

Question 27: Low Income Beneficiary Protections

For many dual eligibles, the array of drugs covered by Part D plans may fall short of those currently covered under Medicaid. While Medicaid programs generally are required to cover all medically necessary drugs, Part D plans have far more flexibility to limit the array of drugs that they will cover. Although beneficiaries can appeal a decision by their Part D plan to deny coverage of a particular drug, it is not yet clear how well these appeals procedures will work, particularly for dual eligibles with limited financial resources who may have trouble meeting the appeal thresholds and, in many cases, may have physical or cognitive impairments.

In addition, Medicaid prescription drug co-payment requirements for dual eligibles in many states are lower than the levels that most dual eligibles will face in 2006 when enrolled in a Medicare Part D plan. Medicaid beneficiaries also will no longer be protected by the Medicaid provision that requires pharmacists to fill the prescription of a beneficiary even if he or she cannot make a co-payment, or the provision that requires

pharmacists to fill a three-day emergency supply of medication if the prescription requires prior authorization for a full 30-day supply. Based on these provisions, I am concerned that some dual eligibles may be worse off as result of this legislation. Will you commit to working with me to address these concerns through regulations or legislative corrections?

Answer:

I appreciate all of your hard work to enact a new Medicare prescription drug benefit for all beneficiaries, including dual eligibles. If confirmed as the CMS Administrator I will work with Members of Congress to ensure that all beneficiaries, and particularly those who are dual eligibles have access to affordable prescription drugs.

Unlike state Medicaid programs, the Medicare Part D benefit provides broad protections to all enrollees regardless of the state in which they reside. In comparison to the tenuous Medicaid prescription drug benefit, which is optional for states, Part D enrollees are assured that their coverage is uniform and is guaranteed for covered drugs.

Today, state Medicaid programs use a variety of techniques to control drug costs, including limits on the number of prescriptions, limiting the maximum daily dosage, limiting the frequency of dispensing a drug, limiting the number of refills, or pharmacy lock-in programs which require beneficiaries to fill their prescriptions in one designated pharmacy. This will not be permitted under the new Part D benefit. Except for one, which is explicitly excluded by the statute, all drug classes are available to beneficiaries.

Beneficiaries who elect to enroll in this new open-ended drug benefit will have no limits on the number of prescriptions filled, no limits on the maximum daily dosage, and no limits on the frequency of dispensing a drug. Pharmacy lock-in programs are not permitted.

For example, the Act establishes beneficiary protections similar to those that exist in Medicare + Choice today, and adds new protections that are specific to prescription drug coverage. These protections are extended to all enrollees in Part D including full benefit dual eligible beneficiaries and other low-income beneficiaries.

Finally, like the Medicare drug card, the Medicare Modernization Act allows for pharmacies to waive the application of coinsurance for low-income Part D enrollees under certain circumstances:

- The waiver is not to be advertised;
- The coinsurance is not routinely waived; and
- The coinsurance is waived only after determining (in good faith) that—
    - The eligible beneficiary is in financial need; or
    - The pharmacy has made reasonable collection efforts but still failed to collect the coinsurance due.

When a particular drug is not available, physicians may request a specific drug should be made available. And should a beneficiary continue to be denied the drug, like all Part D beneficiaries he or she will have access to all the beneficiary protections afforded by the Act.

Question 28: Waiver Process

I was pleased to hear at the nomination hearing that you believe the federal matching rate and EPSDT are two components of Medicaid that cannot be waived. Following up on this question, are there other provisions or principles of Medicaid that cannot be waived by CMS? If so, what are they? Further, I am concerned that the process through which waivers are approved is not sufficiently transparent. Specifically, there is no opportunity for the public to comment on, or even see, final waiver applications before they are granted or denied by the Secretary. Would you commit to having final versions of waiver applications available to the public prior to approving them?

Answer:

At the hearing, I stated that the Medicaid matching rate cannot be waived, and that the intent of the Medicaid law is to make sure that the Medicaid program provides the most health benefits to the vulnerable populations it serves at the lowest possible cost. To accomplish this, I want to work in partnership with States to identify which coverage methods work best to achieve the health goals of the Medicaid program, to make sure that any waivers include a creditable alternative to achieving the intended goals of the Medicaid provisions that are waived, and to assess whether the waivers are achieving their intended goals.

I share your concern that there be an opportunity for public input into the waiver approval process. Rather than committing to a specific approach to achieve this, I would like to review this process if confirmed and work on ways to improve public input into the waiver process.

Question 29: Medicaid Program Integrity (UPL/IGTs)

Following up on the question Senator Grassley asked at the hearing, the President's budget includes a proposal to eliminate what the administration has termed 'inappropriate IGT arrangements' in state Medicaid programs. I understand that many states have also been subject to CMS threats for using IGTs even under current law, including in cases where the arrangements had been approved by CMS in the past. CMS has not put anything in writing to let States and the Congress know how its thinking has changed or what constitutes an "inappropriate" IGT arrangement. It is my firm belief that states have a right to know what CMS considers now considers "inappropriate" IGT arrangements so that they can respond, or even know whether they are affected. Would you not agree? If confirmed, will you provide written guidance on this matter as soon as possible?

Answer:

It is my understanding that CMS has not changed its position with respect to "inappropriate" IGTs. It has always been the position of CMS, as established by Title XIX, that a Federal dollar in the Medicaid program may only be expended to match an actual expenditure by the state for Medicaid services for a Medicaid beneficiary. Moreover, the intention of the IGT law was to permit public providers to incur expenditures for the care of Medicaid beneficiaries, which could be used by the state as part of the state share of Medicaid expenditures. In turn these expenditures can be matched by Federal Medicaid dollars. If the state does not return the provider's contribution to the provider once Federal payment is received, this is not an appropriate IGT.

Both the General Accounting Office and the HHS Office of Inspector General have issued reports about inappropriate IGTs, and CMS is taking the findings of those reports seriously. I understand that CMS has formed a National Institutional Reimbursement Team to review state financing arrangements, and as the team has gained expertise, they have unfortunately learned about the prevalence of inappropriate IGT arrangements in many states and are working with states to end these arrangements in the future in order to preserve the fiscal integrity of the Medicaid program and to ensure that taxpayer dollars are spent for Medicaid services.

I share your concern about working with states on this issue. If confirmed, I assure you that I will give it a high priority and make sure that the process is fair and equitable.

Question 30: State Fiscal Relief:

In May 2003, Congress provided $10 billion in temporary fiscal relief for states and local governments through changes in Medicaid financing. This temporary fiscal relief helped states ease their budget problems and avoid making additional and deeper cuts to their Medicaid programs. According to a recent survey of state Medicaid officials, states expect a significant adverse impact on their Medicaid programs when the temporary fiscal relief expires of this year. Given the importance of the Medicaid program and the on-going state budget crises, do you support extending the temporary federal fiscal relief beyond June?

Answer:

On May 28, 2003, President Bush signed into law (P.L 108-27) the Jobs and Growth Tax Relief Reconciliation Act of 2003 (TRRA), which provides $20 billion in fiscal relief to states of which $10 billion was provided through a temporary FMAP increase and grants to states.

The President's FY 2005 budget does not include a proposal to extend this temporary relief. Another temporary FMAP increase does nothing to address any of the underlying fiscal problems at either the Federal or state levels, nor would it address the need for underlying structural reform.

Temporary FMAP increases shift the problem from one level of government to another. The same total amount of tax revenues still will need to be collected to pay for the Medicaid program. Adjusting the Federal match simply changes which level of government must collect more of the taxes: the Federal government in place of the states.

We believe a more effective way to help states is to modernize Medicaid. If confirmed, I will work with Congress and other stakeholders to achieve a systemic reform that is a more effective approach to addressing the financial problems in states as a result of increased demands on Medicaid.

If confirmed, I will work with States to find the most efficient, proven ways to achieve their public health goals of the Medicaid program at a lower cost. For example, many states have substantial Medicaid expenditures on prescription drugs where equally effective generic alternatives exist, while some have implemented effective generic substitution programs. I intend to help states identify and implement proven programs like these to reduce costs without compromising beneficiary health.

I would also note that I intend to work with states to give them billions of dollars of financial relief provided in the Medicare Modernization Act, including increased disproportionate share hospital payments, relief for drug costs through the provision of Part D drug coverage for dual eligibles and participants in State Pharmacy Assistance Programs, and payments for the costs of care of undocumented aliens.

Question 31: Coverage of Childless Adults in SCHIP

As noted in a recent letter to Secretary Thompson, Senators Grassley, Kennedy, Hatch, and I are very concerned about the approval of Section 1115 Medicaid and State Children's Health Insurance Program waivers which permit states to divert funds designated by Congress solely for children's' health coverage to programs serving childless adults. This use of CHIP funds is in direct conflict with Congressional intent in enacting the CHIP program. Do you support the use of 1115 waivers to permit states to use CHIP funding for programs for childless adults?

Answer:

I understand and agree that the primary purpose of the SCHIP law, under Title XXI, is to expand health insurance coverage to low-income children. However, when Congress wrote Title XXI, it also included demonstration authority similar to that of the Medicaid statute under section 1115. The inclusion of this authority in statute is significant, as it specifically enables the Secretary of Health and Human Services to approve experimental projects that, in his or her judgment, further the broader goals of Title XXI. The Administration believes providing coverage for adults who do not have children furthers the goal of Title XXI by making a direct impact on the health of the communities in which low-income children reside.

It is my understanding that in the section 1115 waivers in which HHS has approved for coverage of childless adults, special terms and conditions have been established to ensure that throughout the course of the demonstration, the state will protect children's rights to these funds by not closing enrollment, instituting waiting lists or decreasing eligibility standards with regard to children. It is also my understanding that funding priority in these states will always be given to children eligible under Title XXI-- and only thereafter to adults under the demonstration.

I understand that you are very concerned about this issue. Pending my confirmation, I will look into this issue further and I look forward to working with you regarding your specific concerns.

Question 32: SCHIP Expiring Funds

Under the CHIP statute, States receive annual allotments for the federal portion of their CHIP programs. Unused amounts of the allotments may be redistributed to other states, and eventually, the leftover dollars expire and must be returned to the Treasury. Because CHIP spending started more slowly in the early years of the program than anticipated, there are still some leftover dollars from the year 2000 that are set to expire at the end of this fiscal year. Last year, Congress passed legislation to retain the prior year's expiring funds. Legislation to do so again will cost approximately 1.1 billion. Estimates indicate that several States may run out of CHIP money and have to reduce their programs within the next year or two if other states' expiring money is not retained and redistributed. If confirmed, will you support proposals to retain expiring CHIP funds this year? If not, what will you do to ensure that CHIP does not have to stop enrolling children in some states in the next few years?

Answer:

The President's FY 2005 budget does not include a proposal to retain expiring SCHIP funds. However, I know that the Administration is sensitive to the needs of the states, as evidenced by the President's signing State Children's Health Insurance Program Allotments Extension (P.L. 108-74), and I can assure you that CMS will continue to be actively watching this issue as the year progresses.

Also, I share your concern that we should do everything we can to make sure that as many eligible children as possible participate in the SCHIP program. I understand that a couple of states may be short on SCHIP funds this year; however, I assure you that we will work with any state that may have such an issue to help continue to cover children.

Question 33: Reimbursement for Part B Covered Drugs

As commissioner of the Food and Drug Administration, you were instrumental in approving many innovative new cancer drugs. However, many of those drugs carry a significant price tag. For example, one drug was recently priced at $10,000 per month. As CMS administrator, do you believe payment and coverage of those drugs should be

restricted in any way under Medicare and how would you balance the high cost of those drugs with the mounting spending pressures on the program? For example, does CMS have the authority and, if so, should it use its authority to negotiate lower average wholesale or average sales prices for these Part B drugs?

Answer:

I don't believe that the price of an expensive new drug should be the basis for whether or not Medicare covers the drug. What matters in coverage decisions is the value of the drug – how effective it is in improving health, and potentially in reducing the costs of disease complications.

Medicare has an obligation to take the steps available under the law to get the most value for beneficiaries and taxpayers from the drugs it pays for. The new law provides new ways to get more value for currently covered Medicare Part B drugs. The AWP reform provisions of MMA specify that Medicare's payment for Part B drugs, beginning in 2005, is 106 percent of the Average Sales Price (ASP). The statute lays out the mechanism for CMS to calculate the ASP based on data submitted from manufacturers, and Medicare has an obligation to make sure that accurate data is used for these calculations. Beginning in 2006, the MMA also gives physicians the option of receiving drugs directly from a contractor competitively selected by Medicare or purchasing drugs themselves and being paid 106 of ASP. If a physician chooses to have drugs furnished by a competitively selected contractor, Medicare will pay the contractor for the drug and not the physician.

In addition, there are many other steps besides these approaches to lowering prices that Medicare can use to get more value for its drug purchases. For example, thanks to funding for comparative effectiveness studies in the law, and the steps toward electronic prescribing and electronic data systems, we can develop better information on the effectiveness of a drug and on alternatives that may be more cost-effective, thereby helping doctors and patients make better medication choices.

Question 34: Coverage of PET Scans to Diagnose Alzheimer's Disease

Medicare faces several coverage decisions on expensive technology, including whether to cover PET scans to diagnose Alzheimer's disease. How should CMS evaluate such a request, given that the available treatments for Alzheimer's fall short of reversing or completely stopping the progression of the disease?

Answer:

I understand your concern about this issue. At FDA, one of my top priorities has been to find better ways to help patients get access to valuable new medical treatments more quickly and at a lower cost. At CMS, I intend to work closely with the staff to achieve the same goal for Medicare and Medicaid.

I understand CMS completed a national coverage determination (NCD) analysis last Spring on the use of FDG-PET in Alzheimer's disease, based on the best available scientific evidence and extensive consultation with medical experts and advocates. That analysis concluded that the addition of an FDG-PET scan to the standard evaluation of Alzheimer's disease does not result in improved patient outcomes.

On October 7, 2003, CMS began a reconsideration of this NCD, for the use of an FDG-PET scan in a more limited patient population who have had a complete standard clinical evaluation, six months of documented cognitive impairment, and other requirements dependent on provider's judgment.

I plan to pay close attention to the progress of this review, and will keep interested members informed, as information becomes available.

Question 35: Section 641 Demonstration on Replacement Prescription Drugs

Congress included an interim drug benefit in last year's Medicare bill, available in 2004 and 2005 to seniors who need self-injectable medications for diseases such as Multiple Sclerosis and Rheumatoid Arthritis, as well as those who need oral anti-cancer medications. Can you give us a sense of when that demonstration project will be implemented? Also, I am interested in how you would interpret – or ignore – the report language, which has some obvious errors and has generated some misunderstandings. For example, Congress did not intend to limit the demonstration to six states, as the report language states. There is also some confusion over whether Congress truly intended to apportion 40 percent of the available funding to oral anti-cancer drugs relative to other drugs that might be covered by this interim demonstration. What is your position?

Answer:

Mr. Baucus asked this question at the confirmation hearing on March 8, 2004 and Commissioner McClellan responded to it at that time. This written response is intended only to supplement the Commissioner's response to the question at the hearing.

I understand CMS is working to design and implement this complex demonstration as quickly as possible. As you know, the provision presents many challenges including: What drugs should be covered? How should beneficiaries be enrolled? What is the most feasible way to limit enrollment to 50,000 beneficiaries, limit spending to $500 million, and apply Part D cost-sharing rules (as the statute requires)?

CMS is developing specifications for a contractor to operate the demonstration, including outreach and enrollment of beneficiaries. CMS also held a special "Open Door Forum Listening Session" on January 30 to elicit public comments on the demonstration. About 600 people participated, including drug manufacturers, clinicians, patients, and advocacy groups.

Regarding the committee report language for this provision: CMS is aware that the reference to six states was an error and that Congress intended the demonstration to be available nationally.

I understand the allocation of demonstration funding to anti-cancer drugs relative to other drugs is of great concern to members of Congress, with differing views regarding Congressional intent. I appreciate your input on this issue as CMS works to finalize a workable design for the demonstration.

I will also make sure that the project's final design will provide the full benefits allowed under the statute's parameters (50,000 patients and $500 million in funding).

I look forward to providing the coverage this demonstration will offer so that some beneficiaries can benefit from expanded access to drug therapies in advance of the full Medicare drug coverage effective in 2006. I will contact you and other interested members as soon as further details on the demonstration's design and schedule are available.

Question 36: Specialty Hospital Moratorium

In the 2003 Medicare bill, Congress included an 18-month prohibition on physician self-referral in specialty hospitals, exempting existing facilities as well as those 'under development.' Facilities will only be considered 'under development' if they had architectural plans, met zoning requirements; received State approval; and received funding. And yet, I understand CMS may be interpreting the grandfather clause to mean one or more, not all, of the above. As CMS Administrator will you commit to examining all four factors in establishing the definition of 'under development?'

Answer:

Mr. Baucus asked this question at the confirmation hearing on March 8, 2004 and Commissioner McClellan responded to it at that time. This written response is intended only to supplement the Commissioner's response to the question at the hearing.

In determining whether a specialty hospital is "under development", the MMA directs the Secretary to consider whether:

-- architectural plans have been completed;
-- funding has been received;
-- zoning requirements have been met; and
-- necessary approvals from State agencies have been received,

plus any other evidence the Secretary believes would indicate whether a hospital was "under development".

Given this statutory directive, I would expect to consider all four factors, while recognizing that some flexibility may be appropriate in particular cases. Thus, a limited number of physician-owned specialty hospitals, on a case-by-case basis, may be allowed to move forward if completion of all four factors was not feasible. I appreciate the input you have provided CMS on this issue.

CMS plans to issue instructions soon on how a hospital may apply for a determination that it was "under development" for purpose of this exemption.

Question 37: Rural Health Funding

Last year Congress passed the largest rural package in Medicare's history, which should help improve rural Americans' access to quality care. This bill will go a long way to help struggling rural hospitals and doctors, rural ambulance providers and home health providers, and other rural health care providers. I am pleased with the rural Medicare package, which represents priorities I have worked on for years. But I am concerned that in the wake of these rural health improvements, the Administration has proposed significant cuts to rural health initiatives under the Health Resources and Services Administration (HRSA). The President's budget would eliminate the Medicare Rural Hospital Flexibility Grant Program, even though that grant was reauthorized in the 2003 Medicare Act. Other discretionary programs for rural health are slated for cuts as well. How is this budget cut on the Flex program justified in the light of Congress' and the Administration's ongoing efforts to improve rural health care?

Answer:

Addressing the needs of rural America has been, and continues to be, a top priority for this Administration and for me personally. The recent passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) proved to be one of the most generous packages for rural providers, bringing an estimated $25 billion dollars of needed relief. The new provisions in the bill directly address the concerns that had been raised about continued access to care for beneficiaries residing in rural areas and appropriate payment for rural providers. I look forward to working with you to use this broad array of programs and big funding increases to provide the best possible health services for rural beneficiaries.

Currently, rural residents tend to have more difficulty accessing health care and have poorer health outcomes than their urban counterparts. This Administration has taken a straightforward approach to the issues facing rural areas by directing funds to various programs that are currently expanding health care to rural areas. The Health Center program, since FY 2001, has significantly impacted over 600 communities serving 3 million more patients, over 13 million in total. Of these patients, forty percent have no insurance coverage and many others have inadequate coverage.

The budget for FY 2005 includes $1.8 billion for these critical safety net providers, an increase of $219 million from FY 2004. As a result, services for an additional 1.6 million individuals in approximately 330 new and expanded sites will be available. With this increased funding, 15 million uninsured and underserved individuals will receive comprehensive preventive and primary care services at over 3,800 health center sites across the nation. Nearly 7 of the 15 million patients served by health centers in FY 2005 will be from rural communities.

Another program that rural America will continue to benefit from is the National Health Service Corps (NHSC). Throughout its 30-year history, the NHSC has seen more than 24,500 health professionals commit to service in underserved areas across the country. A targeted management reform initiative that began in FY 2002 has allowed the NHSC to become more effective at assisting the neediest communities. The ratio of loan repayments compared to scholarships has increased by over 30 percent, enabling the NHSC to immediately place more health professionals into service in underserved areas. This has increased the current field strength to more than 4,200 clinicians. At this time, half of NHSC clinicians serve in health centers. The FY 2005 budget continues the expansion of the NHSC with an increase of $35 million, for a total of $205 million. Twenty five million of the $205 million total will be directed towards a specific new effort to recruit nurses and physicians to serve in health professional shortage areas.

Independent evaluations indicate that these rural health programs are effective and achieve results. Information also shows that a less fragmented and more seamless Federal effort could help maximize access, generate effectiveness, yield cost efficiencies, and reduce the number of specific and geographically targeted projects funded each year. The Administration's FY 2005 budget request for rural health care follows the lessons learned from these evaluations and research.

The President's Budget did not include funding for the Rural Hospital Flexibility Grant program, which received $40 million in the 2004 budget. The program was created in 1997. The primary purpose of Flexibility Grants is to provide support to the States to determine if rural hospitals might benefit from conversion to critical access hospital (CAH) status. The intent was to create a program to help rural hospitals make the transition, when appropriate, to CAH status. To date, more than 800 hospitals have been designated as CAHs and the States have had five years to identify those facilities that would benefit most from conversion. The majority of those conversions have taken place.

You may recall that in the early and mid 1990s, the Centers for Medicare & Medicaid Services (CMS)—then the Health Care Financing Administration (HCFA)—ran a program called the Rural Hospital Transition grants. These grants were to help rural hospitals make the transition to providing a range of services that more appropriately matched their community need and to adapt to new payment provisions such as Sole Community Hospital status, Medicare Dependent Hospital status, and the introduction of swing beds into rural hospitals. That program played a valuable role, but, by 1996, the need for these kinds of grants had waned. Similarly, the Rural Hospital Flexibility Grant

program has achieved its original goals. With the enactment of the MMA and the move toward greater payment equity and flexibility for rural hospitals, there is less need for this program especially given the great pressure on the Federal budget at this time. In addition, as mentioned above, the reduction in funds will be offset by approximately $25 billion from the rural provisions in the MMA.

The MMA starts to "level the playing field" for rural providers. More specifically, the rural provisions in the MMA will provide substantial support to rural communities by increasing Medicare reimbursement for rural hospitals, which are a focal point for health care in rural communities. For example, Congressional Budget Office estimates indicate that about $3 billion will be spent to equalize the urban and rural standardized amounts under Medicare's hospital inpatient prospective payment system. This will establish a single base payment for hospitals in all areas in the 50 states, the District of Columbia, and Puerto Rico, starting in FY 2004. There are also substantial increases in reimbursement and flexibility for CAHs. Consequently, the Administration believes there is no longer a need for the Rural Hospital Flexibility Grant program.

I know that CMS is working diligently to implement the MMA. Continued implementation of these important rural provisions will further ensure that the needs of rural America are addressed. Pending my confirmation, I look forward to joining these efforts and working with you to build on the access improvements beneficiaries received and the payment increases rural providers gained in the MMA.

Question 38: Chronic Care Improvement/Disease Management

With respect to Sec. 721 of the 2003 Medicare Act, how does CMS plan to design the demonstration multiple disease management program to identify successful models, address patient comorbidities, and encourage physician buy-in? Will there be a randomized study design for this program, and if so, how will the randomization be done?

Answer:

Section 721 is a new voluntary program within traditional FFS Medicare. This program will target congestive heart failure and diabetes, as the evidence from private sector disease management programs is strongest that disease management works for these populations. At the outset, this program will be a large-scale pilot program that is estimated to serve 300,00-400,000 chronically ill FFS Medicare beneficiaries.

CMS is looking at models that actively engage the physician community. I understand that CMS wants to work with physicians who are an integral part of the care of these patients and strengthen their ability to care for very ill patients. Organizations that participate in the Section 721 program will potentially provide nurse call lines, in-home monitoring equipment, or other tools to help patients with their self-care.

In regards to randomization, the MMA requires a randomized study design. We plan to comply with standard procedures for randomization.

CMS has every confidence that this program will succeed and as such, are diligently working now on how to operationally implement this program nationwide in the most effective and efficient way.

Programs such as these that target beneficiaries with chronic conditions are extremely important, and I'm also committed to using the broader demonstration authority under the statute to continue to find ways to get higher quality and lower cost care for these beneficiaries.

Question 39: Information Technology

Almost a year ago, several different federal agencies, including the Department of Health and Human Services, reached agreement on a set of technical standards for the electronic exchange of health information. HHS requires reporting of health information for quality, public health, research, and drug approval purposes. However, much of this data is not formatted in accordance with the standards agreed upon last year.

- How will you work with FDA, CDC, NIH and other HHS agencies to ensure that all data electronically reported to HHS uses the agreed health information exchange standards?

Answer:

The federal government, through the Consolidated Health Informatics (CHI) eGovernment Initiative led by Secretary Thompson and the Department of Health and Human Services (HHS), has made significant progress toward identifying and adopting voluntary industry clinical data interoperability standards for use in the federal health care enterprise. These standards will enable all federal agencies in the federal health care enterprise to electronically exchange clinical information and "speak the same language." It is our expectation that the federal government's endorsement and use of these standards will provide a "tipping point" for more widespread use of the standards within the industry as well.

As of March 2003, standards had been adopted in five areas. Since that time, subject matter expert teams have been working to evaluate existing standards and provide recommendations concerning standard(s) to adopt in the remaining 19 areas identified in the CHI portfolio. These recommendations have been endorsed by the National Committee on Vital and Health Statistics as well as every participating federal agency in the CHI eGovernment Initiative. Adoption of these standards for use in the federal health care enterprise will continue over the next few months.

CHI adopted standards are being implemented as part of the Federal Health Architecture Initiative (FHA) and are being phased in to agency reporting systems as new health

information systems are initiated and as major upgrades and improvements are made to existing information systems. Implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), while a massive undertaking, is also serving as the catalyst to upgrade and improve Medicare's outdated computer systems and software, presenting a perfect opportunity for the information systems of the Centers for Medicare & Medicaid Services to phase in the CHI adopted standards.

I understand the importance of data interoperability, especially in the field of health care, and share your commitment to reaching this goal. Pending my confirmation, I will look forward to working further with the other HHS agencies to ensure that the clinical data interoperability standards that we are adopting will be implemented in a timely fashion.

Question 41: HCAHPS

I strongly support efforts to educate consumers and improve health care quality; but I am concerned that the length of the proposed survey may be too long. Some hospitals have expressed concern that this HCAHPS survey will be difficult to administer and must replace their existing patient satisfaction tools. Will you consider developing a 5-10 question federal report card to which hospitals might continue using their existing patient satisfaction surveys as a supplement? If not why do you think a longer survey is more appropriate than a shorter report cared supplemented by individual hospital patient satisfaction surveys?

Answer:

As you know, quality of care for people with Medicare is a priority for the Centers for Medicare & Medicaid Services (CMS), and I look forward to continuing this important work.

I understand that some hospitals may have concerns about the length of the HCAHPS survey. The survey was designed to measure patient perspectives on the care they received in the hospital, and was not intended to be overly burdensome. In fact, as you suggest, it was designed to allow hospitals flexibility, by serving as a core set of questions to which a hospital may add a broader set of questions if it so chooses.

The current version of the survey instrument includes 24 core HCAHPS questions concerning the care from nurses, care from doctors, hospital environment, and patient experiences in the hospital. It also includes eight additional items for the purpose of adjusting the mix of patients across hospitals and for analysis. The current instrument embodies many different inputs and much feedback. It will be further refined as a result of public input from the most recent Federal Register notice (December 5, 2003) soliciting comments on the instrument and its implementation strategy. CMS received over 500 responses to the Federal Register notice and the agency is carefully reviewing them to determine where modifications need to be made. We are also conducting some additional research with consumers to ensure that the final, revised instrument meets their needs. Following CMS and Agency for Healthcare Research and Quality revisions of the

current instrument and implementation strategy, there will be another opportunity for public comment through the Federal Register process.

Pending my confirmation, I will continue to work through these issues in order to pursue CMS' goals of providing the public with useful and reliable information on the quality of hospital care.

Question 42: Medicare Buy-In

An estimated 1.5 million adults ages 55 to 64 with chronic conditions are uninsured. This problem is only increasing as retiree health insurance has become less affordable and accessible as employers have cut retiree health benefits in response to rising costs and as private insurers charge increasingly high premiums for health insurance for this population. What is the administration's position on legislation to permit adults ages 55-64 to purchase health care coverage through Medicare?

Answer:

The President's FY 2005 Budget did not include such a proposal. However, we share your concerns about the uninsured. Pending my confirmation, I look forward to working with you on innovative ways to address their needs.

The President has proposed a refundable tax credit to help low and moderate income people under age 65 to buy health insurance. The credit would subsidize up to 90 percent of the health insurance premium, up to $1000 per adult and $500 per child for up to two children. The full tax credit would be available to individuals with no dependents and a modified AGI up to $15,000 and to other filers with a modified AGI up to $25,000 and would be phased out for individuals with a modified AGI of $30,000 and families with a modified AGI of $60,000.

The Administration also has advocated expansion of Community Health Centers and the National Health Service Corps to provide additional resources to meet the health care needs of individuals without health insurance coverage. In addition, the Trade Adjustment Act of 2002 (TAA) contains two provisions relevant to the issue you raise. It allows advanceable, refundable tax credits to help individuals over age 55 receiving a pension benefit from the Pension Benefit Guarantee Corporation pay for health insurance. It also provides funding for states to start and to operate high-risk pools, to provide health insurance for individuals with health conditions that make it difficult for them to find affordable private health insurance.

In addition, through the Medicaid program, States and the Federal government have used a variety of innovative State programs to reduce the number of uninsured low-income individuals.

Questions Submitted By Senator Hatch

Question 1: Chiropractic Services Demonstration

Dr. McClellan, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 included a provision, which created a chiropractic care demonstration project for Medicare beneficiaries. This provision, Section 651, directs the Secretary of Health and Human Service to establish demonstration projects to evaluate the feasibility and advisability of covering chiropractic services under the Medicare program. Could you tell me the status of this demonstration project?

Answer:

While the MMA requires that the Secretary not implement this demonstration project before October 1, 2004, I understand that you are concerned about this issue. Pending my confirmation, I will look into this issue further and I look forward to working with you regarding your specific concerns.

Question 2: Coverage of Treatment for Macular Degeneration

I appreciate CMS making the national coverage decision on January 28, 2004 to expand Medicare coverage of OPT with verteporfin (Visudyne) therapy to treat patients with occult age related macular degeneration. This was a critical decision since evidence indicates that in the expanded indications approved for coverage by CMS, OPT with verteporfin therapy decreases the number of patients who will suffer severe vision loss from this condition by 50 percent. Since the damage to a patient's sight is irreversible, it is important that this approved therapy be made available to these Medicare patients as quickly as possible. However, CMS has not indicated when it will implement this coverage decision. Medicare already pays for OPT with verteporfin therapy for some patients with AMD. Accordingly, there are no new codes that have to be established to implement this expansion of coverage. I believe that once these new therapies are approved, they should be available to patients without undue delay. I see no reason why the decision should not be implemented by April 1, 2004. I am interested in knowing whether or not you believe that Medicare coverage of OPT with verteporfin therapy will be implemented by April 1, 2004?

Answer:

I understand that you are very concerned about this issue. At FDA, one of my top priorities has been to find ways to help patients get access to valuable new medical treatments more quickly and at a lower cost. At CMS, I intend to work closely with the staff to achieve the same goal.

As you know, age-related macular degeneration (AMD) is the leading cause of severe vision loss in the Medicare population. CMS' new coverage policy will provide an additional treatment option for physicians to consider for patients with the "wet" form of AMD.

I understand CMS is working diligently to ensure that the new verteporfin instructions to the CMS contractors will be released as soon as possible.

Questions Submitted by Senator Nickles

Question 1: Temporary c-codes in the OPD

As you may be aware, one issue I was particularly involved in during the Medicare debate was making changes to current Medicare rules regarding coverage and payment in the hospital outpatient setting. One important provision we added in the MMA was Sec. 621(a)(15), which directs CMS to reimburse drugs not yet assigned a temporary c-code at 95% of AWP. This provision was necessary because historically, CMS has taken anywhere up to 10 months to assign a temporary code, leaving patients without access to new therapies in the hospital outpatient setting. In rural areas like Oklahoma, hospital outpatient departments are often the only treatment setting available to seniors and it is absolutely inappropriate for folks to be denied access to cutting edge therapies over a CMS coding issue.

Unfortunately, although the law specified the new reimbursement rate to be in effect on January 1, 2004, I understand that CMS has not yet implemented this provision of MMA. Delaying the implementation of this provision does not further our intent, which is to ensure immediate access to new drugs for seniors.

Clearly, I am concerned about the speed with which CMS provides code assignments and its response to the recently enacted legislation. As such, please let me know why this provision has not yet been implemented, and what is being done to ensure it will be implemented immediately.

Answer:

Within the Medicare claims processing system, in order to receive proper payment for drugs or biologicals under the hospital outpatient prospective payment system, hospitals must bill Medicare using that drug or biological's assigned code. It is my understanding that CMS is in the process of determining how hospitals would bill Medicare for a drug prior to assignment of a code. They consulted with the group of providers that make up the Advisory Panel on Ambulatory Payment Classification Groups and I know it is CMS' utmost concern that this provision be implemented in a way that does not add a reporting burden for providers or leave beneficiaries without access to new drugs or biologicals.

I understand that you are concerned about this issue. If I am to become Administrator, I will work with CMS to implement this provision as effectively, efficiently and as quickly as possible. I look forward to working with you.

Questions Submitted by Senator Snowe

Question 1: Disproportionate Share Hospitals

Good communication is essential. There is always the potential for problems when using an intermediary. A number of hospitals have encountered such a problem in that, after filing data precisely following the fiscal intermediary's specific instructions... using an intermediary which *isn't* selected by the hospital. They have found that the method which was dictated by the intermediary was *not* correct. Our Maine hospitals are currently facing a proposed reopening of cost reports to reduce their Disproportionate Share Hospital (DSH) adjustment as a result of such an error by the intermediary. The calculation of the DSH adjustment plays a crucial role in compensating institutions which serve those least-advantaged in our society.

Two transmittals regarding cases in Pennsylvania and New York have made clear that hospitals properly reporting in accordance with the intermediary's instructions should be held harmless for such a calculation error. However, hospitals in Maine now appear in jeopardy for this same intermediary error... with an estimated liability of up to $30 million. I am concerned for my State, and those of other members facing such similar problems with intermediaries' instructions.

- Will you prevent such repeated collection actions against institutions which acted on the CMS intermediary's instruction?

- How will you improve oversight of intermediaries to prevent this sort of error from occurring?

Answer:

Maine hospitals are experiencing a problem specific to one set of miscommunications and incorrect communications between a fiscal intermediary and 13 hospitals in Maine. It is true that the Centers for Medicare & Medicaid Services (CMS) and the fiscal intermediary followed a course of action to no longer allow these specific hospitals to count certain dually eligible beneficiaries in their disproportionate share hospital (DSH) calculation, despite the fact that at one point in time the fiscal intermediary told the hospitals the contrary. CMS and the fiscal intermediary have also taken action to recoup the inappropriately distributed funds.

> To provide a little background on this issue, it is important to understand that the DSH adjustment increases hospital inpatient prospective payment system payments to certain hospitals that treat higher percentages of low-income patients. The DSH percentage is the sum of two fractions: the "Medicare fraction" and the "Medicaid fraction." The Medicare fraction divides the number of patient days for patients who were entitled to both Medicare Part A and federal Supplemental Security Income by the total number of patient days for patients entitled to Medicare Part A. The Medicaid fraction divides the number of patient days for patients who were eligible for Medicaid (but are not entitled to benefits under Medicare Part A) by the total number of patient days during the same period. If a hospital's DSH percentage meets a certain threshold, then it receives a DSH adjustment to its hospital inpatient diagnosis related group (DRG) payments.

> The confusion in Maine relates to dually eligible beneficiaries—those who are eligible for both Medicare and Medicaid. Dually eligible beneficiaries (known as Type 6) are not included in the DSH threshold calculation.

As I understand the Maine case, 13 hospitals did receive payments that included payment for dually eligible beneficiaries, and based on those payments, the fiscal intermediary began its initial process to recover the money incorrectly paid. Those efforts are now on hold.

I understand that, initially, correctly citing the Medicare statute, the fiscal intermediary refused to count beneficiaries who are eligible for both Medicare and Medicaid in the hospitals' DSH calculations. Including these patients in a hospital's DSH calculation would inappropriately increase the payments the hospital receives from Medicare. The fiscal intermediary agreed to administratively resolve the dispute rather than represent the case before a review board (Provider Reimbursement Review Board, or PRRB), and administratively settled the unclear issues. The fiscal intermediary paid DSH payments to the 13 hospitals that included the patient days that it previously denied. After consultation with CMS, the fiscal intermediary determined that its administrative resolution incorrectly included those disputed days.

CMS policy requires that fiscal intermediaries "reopen" a hospital's cost report and correct errors. I understand that the fiscal intermediary's actions taken to comply with this requirement have caused concern among Maine hospitals and the Maine Hospital Association. CMS has agreed to meet with the Maine Hospital Association to discuss this matter further. In addition, the fiscal intermediary has suspended all efforts to collect the approximately $25 million that it may have paid incorrectly. Pending my confirmation as the CMS Administrator, I will look into this issue further to ensure the most appropriate and equitable solution.

On a more general note, there are several steps that are currently being taken to deal with contractor errors in the future. Section 903 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) recognizes that providers should not be penalized for relying upon the erroneous guidance received from their Medicare contractor. The provision states that the collection of penalties and interest are prohibited if a provider follows written, erroneous guidance from the government and its agents, including guidance provided by Medicare claims processing contractors, including fiscal intermediaries. The provision is effective for guidance provided after July 24, 2003.

The MMA also includes reforms for Medicare contracting, which will authorize the use of financial performance incentives, allow for competition among contractors, and contribute to more effective oversight of contractor activities. I believe that this increased competition and the authority to use financial performance incentives will encourage better performance such that errors like the one in this example are minimized. Additionally, section 921 of the MMA directs the Secretary to use specific claims payment error rates or similar methodologies to give Medicare contractors an incentive to

implement effective provider education and outreach. Section 921 also enhances provider education and technical assistance efforts. It requires prompt responses from contractors to provider and beneficiary questions while requiring that the Secretary monitor the accuracy of contractor responses.

I believe that changes such as these will not only increase the oversight capabilities of the CMS, but will also increase the incentives for Medicare claims processing contractors to perform their duties more effectively and accurately.

Questions 3&4: 641 Demo

Your answer to Senator Baucus regarding the oral drug demonstration project includes one inaccuracy which is a concern.

Section 641 of the Medicare Modernization Act provides for coverage of drugs which fit in either of two categories. The first consists of oral drugs which are replacements for drugs or biologicals which were provider-administered. This category is referenced as Section 1861(s)(2)(A). An oral drug *also* qualifies if it replaces a drug described under Section 1861(s)(2)(Q). These are oral cancer drugs which contained the same active ingredient as were in a previous provider-administered form. This was a previous allowance for some limited coverage of oral equivalents for IV therapy.

Thus under Section 641 qualifying oral cancer drugs may be either a replacement for an existing therapy which was provider-administered, or a replacement for the oral form of a drug which was previously covered under 1861(s)(2)(Q). Section 641 language was written in this way to ensure that all oral anticancer mediation could qualify, as some were never available in an IV-administered form.

I have worked with other members to promote coverage of oral drugs to treat cancer. Among these are drugs such as tamoxifen, which provide essential tools in cancer treatment. As 40% of the demonstration project funds are dedicated to oral anticancer drugs, proper interpretation of this section is important as we provide interim relief while we await implementation of the Part D benefit.

Has any determination been made on the plans for implementing the anticancer drug portion of the demonstration project?

Specifically, has tamoxifen been listed for coverage under this demonstration project?

Answer:

As you noted, Section 641 requires a demonstration project that would cover drugs prescribed as "replacements" for drugs otherwise covered under existing Medicare Part B. This would include replacements for oral anti-cancer drugs as well as replacements

for injectible drugs furnished in a doctor's office, which are currently covered by Medicare.

Report language for Section 641 also specifies that at least 40 percent of the funding for the demonstration (limited to $500 million overall) shall be allocated to oral anti-cancer drugs.

CMS is aware of these directives, and is working to design a demonstration that will reflect Congressional intent as closely as possible. CMS has also received input from industry and beneficiary groups, which will be considered in the project's design.

However, no final decisions have yet been made regarding coverage of any specific drugs under the demonstration.

I understand CMS is working to design and implement this complex project as quickly as possible. We will contact interested members of Congress and other stakeholders as soon as further details on the design and schedule are available.

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Questions Submitted By Senator Thomas

Question 1: Prescription Drugs for Mental Illnesses

Dr. McClellan, as you may know, I worked with my colleague Senator Domenici and others, including Chairman Grassley to get report language in the Medicare Prescription Drug Improvement, and Modernization Act of 2003 underscores Congress intent to ensure that Medicare beneficiaries have clinically appropriate access to prescription drugs for the treatment of mental illness. Specifically, the language says: " It is the intent of the Conferees that Medicare beneficiaries have access to prescription drugs for the treatment of mental illness...To fulfill this purpose the Administrator shall take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriate access to pharmaceutical treatments for mental illness..." It goes onto say: " Competition will necessitate plans offering the full complement of medicines including atypical antipsychotics, to treat the severely mentally ill. If a plan chooses not to offer or restrict access to a particular medication to treat mentally ill, the disabled will have the freedom to choose a plan that has appropriate access to the medicine needed. The Conferees believe this is critical as the severely mentally ill are a unique population with unique drugs needs as individual responses to mental health medications are different." I know that you share our commitment to ensuring that all seniors, particularly the most vulnerable populations such as the mentally ill, maintain access to the drugs

they need and experience as little disruption as possible as they transition from Medicaid into Medicare. Can you explain the steps you would take as CMS Administrator to effectuate Congressional intent as it relates to prescription medication for the treatment of mental illness?

Answer:

I know that CMS is working diligently to implement the MMA – a massive undertaking as you are aware – with many details that are still being determined with careful consideration. I look forward to joining these efforts pending my confirmation, and I plan to oversee MMA implementation and will insist on an open, transparent process with input from all stakeholders, including the Congress.

I share your concern about the needs of individuals with Alzheimers and severe mental illnesses. If confirmed, I will work within the framework permitted by the MMA to ensure their success to needed medications.

Question 2: People with Cognitive Disabilities and the Appeals Process

Let's take an example. Say I am a Medicare recipient with Alzheimer's disease or a severe mental illness like schizophrenia, and a Part D plan denies me access to a particular medication. Frankly, under the new law it is simply not clear what role the new Beneficiary Ombudsman will play in assisting me to appeal the plan's decision. What precautions will CMS take to help people with cognitive disabilities navigate the appeals process?

Answer:

As CMS Administrator I will be committed to ensuring that all eligible beneficiaries have access to the medications they require. The MMA establishes beneficiary protections similar to those that exist in Medicare + Choice today, and adds new protections that are specific to prescription drug coverage. I share your concern about the needs of individuals with Alzheimer's and severe mental illnesses, particularly as they relate to the appeals process under Part D. If confirmed, I will work within the framework permitted by the MMA to ensure their success to needed medications.

Question 3: Plan Formularies and Prescription Drugs for Mental Health

Dr. McClellan – Under Section 1860D-11(e)(D)(i) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("DIMA"), the Centers for Medicare and Medicaid Services is directed to reject a plan proposed by a plan sponsor only if the agency "does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan." The Statement of Managers explanation of DIMA also makes it clear that "It is the intent of the Conferees that Medicare beneficiaries have access to prescription drugs for the treatment of mental

llness and neurological diseases resulting in severe epileptic episodes under the new rovisions of Part D. To fulfill this purpose the Administrator of the Center for Medicare Choices shall take the appropriate steps before the first open enrollment period to ensure hat Medicare beneficiaries have clinically appropriate access to pharmaceutical reatments for mental illness, including but not limited to schizophrenia, bipolar disorder, lepressio n, anxiety disorder, dementia, and attention deficit disorder/attention deficit yperactivity disorder and neurological illnesses resulting in epileptic episodes." My uestion, Dr. McClellan, is what steps you will take to assure that the above provisions vill be implemented, by rule or regulation, so that each plan approved to offer qualified rescription drug coverage will be required to include a full complement of harmaceutical treatments for mental illness (within their formularies or otherwise)?

nswer:

thank you for this question about important beneficiary needs. Of course, we will give a areful review to all plans to make sure their formularies and other benefit designs meet he needs of all potential enrollees, including those with mental illness. Recall, that the aw already requires plans to include drugs in every therapeutic category and class, so here will be a range of mental health drugs available in every case. Within sensitive ategories, such as HIV/AIDS or mental illness we will apply a very strict review to nake sure that beneficiaries are protected. I look forward to working with you further on his critical issue.

MS will issue a proposed rule on Medicare Advantage and the new Part D drug benefit n the next few months. We look forward to public discussion and public input to resolve his issue as effectively as possible for beneficiaries in our final regulation.

Questions Submitted By Senator Santorum

uestion 1: Local and National Coverage Processes

n an article entitled "Focus on Locus: Evolution of Medicare's Local Coverage Policy", ublished in the July/August Vol. 22 issue of *Health Affairs,* Dr. Susan Foote, Division Head, Health Services Research and Policy, University of Minnesota School of Public Health, and als n appointed member of the Medicare Coverage Advisory Committee (MCAC) of CMS, oncluded that,

> "The focus on locus, framing the debate in terms of local versus national, obscures fundamental policy issues of access, equity, and quality in Medicare" and "If policymakers decide to retain a decentralized policy structure, the solution must rationalize the defined geography areas. The solution must also allocate policy decision between the decentralized and central decisionmakers based on explicit criteria for the assignment. Finally, the solution must integrate the local and national processes so that

the pathway to coverage is predictable, less complex, and appropriate for the specific coverage policy questions presented. "

'lease provide your comments and opinions on the issues surrounding Medicare's .ocal and National Coverage processes and the article's conclusions.

ınswer:

ıt FDA, one of my top priorities has been to find ways to help patients get access to 'aluable new medical treatments more quickly and at a lower cost. At CMS, I intend to 'ork closely with the staff to achieve the same goal.

ıchieving balance and consistency between local and national coverage decisions is mportant, given the impact this has on beneficiary access to new technologies. Many in ıe drug and device industry strongly support the flexibility and speed made possible by he local coverage process. That process does sometimes lead to variation among local ıolicies of different contractors. However, shifting too many policies to the national ɜvel will lose some of the benefits of local policy.

ieveral changes have occurred since the *Health Affairs* article was written that may affect he usefulness of its conclusions. Pursuant to BIPA 2000 and CMS regula tions published n October 2003, there is now a process to appeal local coverage decisions to ALJs and he Departmental Appeals Board. This will increase the likelihood that local policies are leveloped with adequate scientific and clinical input, and also ensure that aberrant ıolicies can be efficiently challenged and revised, if necessary. In addition, beneficiaries, linicians, suppliers, manufacturers, or any other stakeholder may now request a national 'valuation of a local coverage policy. Under the new Medicare bill (MMA), CMS has a ix to nine month timeframe to complete national coverage reviews.

believe the appeals mechanism, greater awareness of the option to request national eview of local policies, and the new MMA timeframes will go a long way toward educing the problems with local coverage identified in Ms. Foote's article.

)uestion 2: Centers of Excellence

Medicare/CMS has utilized the concept of "Centers of Excellence" in several Coverage)ecisions, such as select transplants (i.e., intestinal transplants) and the Lung Volume Reductio ɜurgery, National Emphysema Treatment Trial (NETT).

'lease provide your opinions on the selection and utilization of "Centers of Excellence" in the Medicare/Medicaid programs.

ınswer:

n the case of solid organ transplants, for which the supply of organs is very limited, the Medicare program limits transplant procedures to qualified centers in order to ensure that this

mited organ supply is used by centers most likely to have successful outcomes. I understand
MS is developing a Notice of Proposed Rulemaking regarding criteria for approving transplan
enters to further ensure that our procedures reflect the latest understanding of how to achieve
ıe best possible results in solid organ transplantation.

ı the case of lung volume reduction surgery, CMS is looking at a highly invasive procedure in
ery fragile patient population with chronic obstructive pulmonary disease (emphysema). This
lso the situation for implantation of left ventricular assist devices, which are only covered at
ertain specialized centers. Because the chance of helping such patients with surgery vs.
astening their death is highly dependent on the skill of the clinical teams providing care, we
elieve that limiting use of these procedures to highly qualified centers will best protect seriousl
l Medicare beneficiaries. We plan to work with JCAHO to ensure that the criteria for
lentifying such centers are valid, practical and fair.

)uestion 3: Clinical Trials

ledicare currently provides coverage for "clinical trials" under several regulations to include
ledicare coverage of clinical trials and associated costs, and IDE – Category B coverage
uidelines. However, industry has voiced concerns that the coverage parameters for "associated
osts" of Medicare's "deemed" clinical trials are ambiguous and inconsistent in their
ıterpretation by Medicare contractors.

lease provide your opinion on if and how Medicare should appropriately define coverage for
linical trials.

ınswer:

:MS intends to define the "associated costs" of clinical trials with sufficient precision to ensure
:asonable consistency among contractors regarding how that concept should be interpreted.
iiven the high degree of variation between different trials, it would be difficult to provide
xplicit guidance on "associated costs" and still leave contractors the flexibility they need to
ddress the unique circumstances of each trial.

:MS would be happy to meet with parties concerned about this problem to learn more about the
erceived inconsistencies. We will then consider whether guidance on our clinical trials policie
hould be refined.

)uestion 4: Power Wheelchairs

am hearing from disability advocates and medical equipment suppliers about a new
ledicare policy issued in December that will make it harder for seniors to qualify for
ower wheelchairs.

understand that the new policy was issued as part of an effort to prevent abuses of the
/heelchair benefit. I agree that we cannot tolerate fraud and abuse in the Medicare
rogram. The government has been using its existing authority to prosecute suppliers

who have been abusing the Medicare program – which I applaud, and I urge the Administration to keep up its valuable efforts to protect the Medicare program.

At the same time, we owe it to our seniors to make sure that Medicare policy does not prevent them from getting medically necessary equipment.

As I understand it, under this new policy, (CMS classifies it as a "clarification, but providers claims that it is new policy), if a beneficiary can walk even one or two steps with a walker, they will not qualify for a power wheelchair - even if they have a medical condition that makes it unsafe to do so.

We need to have a Medicare power wheelchair policy that makes sense – one that provides seniors with equipment consistent with medical best practices, while protecting the Medicare program through rational pricing and coding structures. We are only going to get that rational policy if we listen to all the affected parties – beneficiaries, clinicians, and suppliers – and address the power wheelchair policy as a whole.

If confirmed, what will be your approach to working with the Medicare contractors to revisit this policy, and work with beneficiaries, clinicians, and suppliers to make needed reforms in Medicare power wheelchair policy – so we can protect Medicare program dollars while providing medically-appropriate care for our seniors.

Answer:

I recognize how important of an issue power wheelchair coverage is to beneficiaries, physicians, and suppliers, and I know that the agency is actively seeking the input of all these groups. Specifically, CMS has already held an Open Door Forum and two Listening Sessions dedicated solely to power wheelchair coverage issues in a concerted attempt to hear concerns and suggestions from these groups. In addition, I plan for the agency to maintain a close working relationship with the DMERCs and a collaborative relationship with suppliers, providers, and beneficiaries. I'll continue to ensure that CMS provides adequate education on this specific coverage area. If confirmed, I certainly will place the needs of beneficiaries first and foremost and will be committed to ensuring access to the services they need.

Questions Submitted By Senator Smith

Question 1: Community Health Centers

As you know, President Bush and bipartisan majorities in the Senate and House have supported the work of community health centers. These providers play a unique role in ensuring that people without insurance, people in rural areas, people who are turned away from other providers, have a health care home that they can turn to. In addition, for the Medicare and Medicaid program, health centers ensure that seniors and low-income people living in underserved areas have access to benefits. And, they also save the

Federal government and the States money by providing primary and preventive care services that treat chronic illness, keep people healthy, and out of more expensive specialty and inpatient care settings.

What role do you think that health centers should play in Medicare, Medicaid and SCHIP and will you look for ways to better use health centers that have a proven track record of treating chronic illness, expanding access to preventive services, and maintaining access for Medicare and Medicaid beneficiaries in medically underserved areas?

Answer:

Health centers are an important part of the safety net, and the President has recognized their importance by creating an initiative to expand the number of people served by health centers. Health centers now care for approximately 15 million low-income individuals in urban and rural areas across the United States.

Because health centers are located in medically underserved areas and are required to serve all who come to them for care regardless of ability to pay, they are a critical provider of care for Medicaid and SCHIP beneficiaries. Also, many health centers serve as outstationed eligibility sites to help Medicaid and SCHIP beneficiaries gain access to these programs.

Health centers also serve a large number of the most vulnerable Medicare beneficiaries – the dual eligibles – and are an important source of care for them.

I share your beliefs that health centers can be important resources for CMS in administering our programs. CMS is working closely with health centers to provide outreach to low-income beneficiaries eligible for the drug discount card and low-income transitional assistance. If confirmed, I plan to work with them on outreach efforts to dual eligibles and other low-income beneficiaries as CMS implements the new drug benefit and the low-income subsidies.

I also would be happy to from you about other innovative ways that health centers can help CMS implement the Medicare, Medicaid and SCHIP programs.

Question 2: Medicaid SPAs

Dr. McClellan, my state, like so many, has been struggling with a severe budget crisis and our state legislators and governor have been working hard to preserve essential services and programs for some of our most vulnerable citizens. The Medicaid program, which is administered at the federal level by CMS, funds many of these services, such as nursing home care for thousands and thousands of low-income seniors in Oregon. I have been hearing from state legislators and elected officials in my state and from health care providers, that they are very frustrated by how long it is taking for CMS to review and approve proposed Medicaid state plan amendments. They are frustrated because they are being asked to make many very difficult budget decisions that will affect the lives of

thousands of our most vulnerable citizens and they don't know yet whether federal matching funds will be available under the Medicaid program to help us care for the needs of our seniors.

What I would like to know today Dr. McClellan, is if I can count on your personal commitment to do everything in your power when you are confirmed to this position, to expedite the review and approval process for these pending Medicaid state plan amendments and to direct your agency to do the same in regard to resolving any outstanding issues that stand in the way?

Answer:

I appreciate your concerns about the expeditious review and approval of Medicaid state plan amendments and I want to assure you that this is a priority of mine.

However, I am a bit surprised that you are raising this concern. It is my understanding that in September 2001, CMS announced the clearing of a backlog of over 300 state requests for changes in their Medicaid programs, which had been pending for several years.

CMS has continued to make rapid response time the norm rather than the exception for state requests. Specifically, CMS has shared new reviewing time frames with the states to ensure that SPAs do not remain "off-the-clock" (that is, awaiting a state response to CMS questions) for more than 90 days. CMS has also developed and implemented an automated state plan and waiver (SPW) tracking system.

If confirmed, I would be happy to work with you to resolve specific problems with state plan amendments, and please do not hesitate to let me know about any problems in this regard.

Question 3: Power Wheelchairs

I am concerned about reports I am hearing from disability advocates and medical equipment suppliers about a new Medicare policy that was issued in December without beneficiary or provider input that will make it harder for seniors to qualify for power wheelchairs.

While I agree completely that we cannot tolerate fraud and abuse in the Medicare program, we also need to make sure that seniors get medically necessary equipment.

If confirmed, what do you plan to do about this policy?

Answer:

First let me assure you that I share your concern that Medicare beneficiaries are not being denied access to care. Certainly, CMS efforts to address fraud should not keep beneficiaries who qualify for power wheelchairs from receiving them, nor should it punish honest suppliers who are providing services to beneficiaries in need. It's my understanding that CMS is committed to providing ongoing communication with DMERCS to ensure adequate provider and beneficiary education on this specific coverage area. I also am aware that CMS is closely monitoring this issue internally to ensure that the agency continues to be fair in its application of national policy and is not negatively affecting beneficiary access to coverage. If confirmed, I certainly will continue to place the needs of beneficiaries first and foremost and will remain committed to providing the services they need.

Question 4 & 5: 641 Demo

I have two questions regarding implementation of the new Medicare reform Act's Section 641 Prescription Drug and Biological Demonstration, which, as you know, will provide temporary Part B coverage of certain products to treat conditions like rheumatoid arthritis and cancer.

First: Congress instructed CMS to begin this demonstration within 90 days of enactment, which is May 7. How close is CMS to getting this demonstration off the ground, and when do you expect patients to start being covered?

Second: there is some confusion over the caps. Congress wanted to keep the costs of this demonstration under control, which is why we imposed the $500 million, 50,000 beneficiary cap. The legislative history -- including a Senate colloquy and the CBO scoring -- makes it clear though that Congress intended the limit to apply to spending above what Medicare would already have spent on currently covered drugs. In other words, if the replacement therapy costs the same or less than the physician-administered treatment, those costs should not be counted towards the cap. Will CMS be complying with this legislative intent in administering the cap?

Answer:

MMA Section 641 states that the replacement drug demonstration (including coverage of additional oral anti-cancer drugs) shall begin 90 days after enactment (March 8, 2004).

I understand CMS is working to design and implement this complex demonstration as quickly as possible, but they were unable to meet the March 8 deadline. I will contact interested members of Congress and other stakeholders as soon as further details on the demonstration's design and schedule are available.

Also, as you noted, the statutory language governing this demonstration sets a $500 million limit on "funding" for the program.

I am aware of the issue you raise -- whether this limit should apply to total expenditures or should be offset by savings from the drugs that are "replaced".

This is one of many difficult issues involved in implementation of this project. CMS is working to design a demonstration that will reflect Congressional intent as closely as possible, and can feasibly be implemented quickly (given the demo's short timeframe).

We have also received input on this and other issues from industry and beneficiary groups, which we will consider in the demo's design.

Questions Submitted by Senator Bunning

Question 1: Status Of 75% Rule

Many of the rehabilitation hospitals in my state are very concerned about the impact of Medicare's proposed "75% rule" on their ability to serve patients. Last year, 75 senators signed a letter to Secretary Thompson expressing concerns with the proposed changes to rule. I worked closely with Senator Nelson and Senator Jeffords to coordinate this letter, and I have been involved in this issue for some time.

- What is the status of the 75% rule right now?

Answer:

As I am sure you are aware, the nation's inpatient rehabilitation hospitals provide an invaluable service—giving the appropriate intensive level of therapy care to patients with diverse and complex injuries. The "75% rule" is the method used to distinguish inpatient rehabilitation facilities from acute care hospitals. This rule recognizes that hospitals that treat a higher percentage of certain types of patients are different from acute care hospitals and, accordingly, should be paid to reflect that difference.

I understand that the Centers for Medicare & Medicaid Services (CMS) became aware of concerns about uneven enforcement of the 75% rule in 2002. It was discovered that three-quarters of inpatient rehabilitation facilities were not in compliance with the rule. Upon this discovery, CMS suspended enforcement of the rule and published a notice of proposed rulemaking proposing changes to the 75% rule.

As part of the rulemaking process, CMS consulted with many independent reviewers with both clinical and industry knowledge. Additionally, as work proceeds on developing the final rule, CMS and the Department of Health and Human Services are continuing to evaluate the conference and appropriations report requirements, including the language regarding an Institute of Medicine study.

I understand that you, and many other Members of Congress, are very concerned about this issue. Pending my confirmation, I will look into this issue further and work with you to address your specific concerns.

Question 2: Review Studies Before Issuing Changes To The 75% Rule

Both the Medicare prescription drug bill and the Omnibus Appropriations bill for fiscal year 2004 require studies dealing with inpatient rehabilitation facilities and the 75% rule. Both bills urge the Secretary of Health and Human Services to delay implementation of the 75% rule until the studies are complete.

- Do you agree that HHS should wait to review the studies before issuing any changes to the 75% rule? Why or why not?

Answer:

It is my understanding that, as part of the rulemaking process, the Centers for Medicare & Medicaid Services (CMS) consulted with many independent reviewers with both clinical and industry knowledge regarding the most appropriate standards to use in certifying an inpatient rehabilitation facility.

As CMS works on developing the final rule, the agency is continuing to evaluate the conference report requirements. I am confident that the final rule will reflect a great deal of thought and research into the appropriate level of patient case mix required to qualify as an inpatient rehabilitation facility.

I understand that you, and many other Members of Congress, are very concerned about this issue. Pending my confirmation, I will look into this issue further and work with you to address your specific concerns.

Question 3: Physician Update

Often I hear from physicians in Kentucky who are concerned about the formula Medicare uses to reimburse physicians. In fact, I introduced an amendment in the Budget Committee markup last week about it. I think we can all agree that the current formula is very complex and problematic and needs to be fixed. However, I believe there are several potential solutions that could be addressed through action by CMS.

For example, several years ago, CMS used its authority to include payment for certain payment Part B drugs in the physician reimbursement formula which affects the amount physicians are paid, even through doctors have no control over the cost of pharmaceuticals.

Do you believe that CMS can use its authority to reverse its original decision and remove the costs of these drugs from the payment formula? Would you recommend CMS do this?

Answer:

I understand that there has been an issue about inclusion of expenditures for drugs in the physician update formula. If I were to become the CMS Administrator, I would review the system used to update Medicare payments for physicians' services, including examination of areas of administrative authority. If there is administrative authority and if there would be an impact on physician updates, I would give serious consideration to removing drugs from the SGR.

Question 4: Sustainable Growth Rate (SGR)

CMS may also be to adjust the Sustainable Growth Rate (SGR) volume targets to more accurately reflect new coverage decisions and changes that are a result of the new Medicare law, etc. What are your thoughts about CMS making the necessary changes to the SGR?

Answer:

CMS adjusts the SGR for changes in law or regulation including for coverage of new statutory benefits. Adjustments for the new Medicare law have already been made in the SGR estimates furnished to MedPAC on March 1, 2004.

Questions Submitted By Senator Rockefeller

Question 1: Medicare Advantage

The new Medicare law includes $14 billion in excessive overpayment to private plans. And, the Administration's recent reestimate would raise that amount to $46 billion. These additional payments will increase the premiums for all seniors, even those in rural areas who do not have access to private plans. The result is that seniors in rural areas are subsidizing private plans in urban areas and receiving absolutely no benefit. In my state of West Virginia, 60% of the beneficiaries are rural. How do you explain to my beneficiaries that they are paying extra for a benefit they will not receive? How do you explain that, instead of filling in the gap in coverage for seniors in all geographic areas, Congress decided to create a slush fund for private plans?

Answer:

For too long, payments to Medicare+Choice (M+C) plans have been inadequate, causing plans to pull out of the program and leaving seniors without a valuable option for receiving their Medicare benefits. In many counties where M+C plans operate, M+C rates have lagged far behind the cost increases faced by plans. Their rates have increased by only 2% or 3% compared to much higher health care cost increases. The result is that many enrollees have lost important benefits and faced higher cost sharing, and some have also faced upheaval when their plan has left the M+C program.

With respect to rural areas, the MMA represents a significant effort on the part of the Congress and the Administration to address the long-standing concern that private plans are generally less available in rural areas than in urban areas. The MMA creates a new regional PPO program that takes effect in 2006. Regional PPOs must serve all of a large geographic region, a requirement designed to require that they serve rural as well as urban areas. The stabilization fund for private plans is designed to give the Secretary flexibility to increase the likelihood that private plans will choose to participate as regional PPOs, thus enhancing the availability of private plan choices is rural areas.

I appreciate your concerns and want to work with you on this matter.

Question: 641 Demo

As you know, Senator Snowe and I have been engaged for a number of years in efforts to establish Medicare coverage for oral anti-cancer drugs. The new Medicare law incorporates a demonstration project covering oral anti-cancer drugs and certain self-injectable drugs until the drug benefit is implemented on January 1, 2006. The deadline for implementation of the Section 641 demonstration project is today. Are you aware of the status of plans for implementing the program?

Answer:

MMA Section 641 states that the replacement drug demonstration (including coverage of additional oral anti-cancer drugs) shall begin 90 days after enactment (March 8, 2004).

I understand CMS is working to design and implement this complex demonstration as quickly as possible, but they were unable to meet the March 8 deadline. I will contact interested members of Congress and other stakeholders as soon as further details on the demonstration's design and schedule are available.

Implementation of this project involves many challenges including: What drugs should be covered? How should beneficiaries be enrolled? What is the most feasible way to limit enrollment to 50,000 beneficiaries, limit spending to $500 million, and apply Part D cost-sharing rules (as the statute requires)?

CMS is developing specifications for a contractor to operate the demonstration, including outreach and enrollment of beneficiaries. CMS also held a special "Open Door Forum Listening Session" on January 30 to elicit public comments on the demonstration. About 600 people participated, including drug manufacturers, clinicians, patients, and advocacy groups.

I look forward to providing the coverage this demonstration will offer so that some beneficiaries can benefit from expanded access to drug therapies in advance of the full Medicare drug coverage effective in 2006.

Question 3: 641 Demo Participation Cap

It is my understanding that CMS is having difficulty developing an implementation plan within the guidelines of the 50,000 person cap on program participation and the $500 million cap on program expenditures. Cancer advocates and others who are interested in prompt implementation of the demonstration program have suggested that the 50,000 person cap will be reached before the available funding of $500 million is exhausted. Will you direct the CMS staff to evaluate options for addressing the participant cap so that the full amount of funding made available by Congress can be used? If the participant cap cannot be resolved through administrative action, will you request or support legislation to remove the cap?

Answer:

As you noted, the statutory language governing this demonstration mandates both a $500 million funding cap and a cap of 50,000 participants. I do not believe CMS has the authority to disregard either of these explicit statutory directives.

I understand that many of the drugs that will likely be covered under the demonstration are very expensive. While CMS is considering estimates of potential costs and allocations as part of the demonstration's design, I do not yet know whether the funding cap or the participant cap is more likely to be reached first.

However, I am confident that we will be able to design a workable demonstration that can meet Congress' goal of providing interim coverage of these drugs as quickly as possible. I look forward to working with you to achieve that goal, but I am concerned that further legislation on this issue could delay the demonstration significantly.

Question 4: Impact of Drug Discount Card on States

Over twenty-years ago when I was Governor of West Virginia, I started a prescription drug discount card program called Golden Mountaineer. The program, which still exists today, provides seniors over the age of 60 with discounts on all prescription drugs. With very few exceptions, participating pharmacies pay for the cost of the discounts themselves. The card is free to program participants. There is some concern in my state that they will not be able to maintain the Golden Mountaineer card once the Medicare drug discount card program begins. West Virginia seniors are used to the Golden Mountaineer card and pharmacists in the state are used to it. It is unclear if pharmacists will be able to maintain the level of discounts they have already negotiated for seniors

once the Medicare-endorsed cards enter the market. I hope that implementation of the Medicare drug discount card program will allow West Virginia the flexibility to continue its efforts, particularly since the Golden Mountaineer card is available to Medicare eligible seniors as well as seniors between the ages of 60 and 65.

Dr. McClellan, what impact will the Medicare drug discount card have on existing state discount card programs like Golden Mountaineer?

Answer:

Mr. Rockefeller asked this question at the confirmation hearing on March 8, 2004 and Commissioner McClellan responded to it at that time. This written response is intended only to supplement the Commissioner's response to the question at the hearing.

Nothing in the Medicare-approved drug discount card program will prevent the Golden Mountaineer card, or other state discount cards, from operating in their respective states. In addition, seniors who are Medicare beneficiaries will be allowed to have both the Golden Mountaineer card and a Medicare-approved drug discount card if they wish. We would, however, encourage low-income beneficiaries to enroll in a Medicare-approved drug card because they will receive a $600 annual subsidy, which is not available under the Golden Mountaineer card. Moreover, the government will cover the cost of low-income beneficiaries' enrollment fee for the Medicare-approved drug card.

Each time a senior purchases a prescription, they will be able to use only one card to receive a discount on that prescription, but it is their choice which card they choose to use for each purchase. Using a discount card that offers the best discount on a particular prescription would be the most valuable use of having more than one discount card.

While CMS cannot predict whether the Golden Mountaineer card or a Medicare-approved drug discount card will have a greater discount on a particular prescription, we have every confidence that the Medicare-approved drug cards will, overall, secure considerable savings on prescription drug purchases for seniors.

Question 5: FY 2005 Health Budget

The new Medicare law includes a provision, which I championed to provide $25 billion over 10 years to rural hospitals and providers. While this provision was not enough to win my support for the Medicare bill, I am pleased it was included. This funding will go a long way to help rural hospitals, doctors, and home health providers in West Virginia. However, I am very concerned that in the wake of this critical funding commitment under Medicare, the President has proposed significant cuts to rural health initiatives under the Health Resources and Services Administration (HRSA). The President's budget for fiscal year 2005 eliminates funding for the Rural Hospital Flexibility Grant Program, Area Health Education Centers, and Community Access Programs. Other discretionary programs for rural health are slated for cuts as well. West Virginia uses a variety of grant dollars obtained under these programs to improve rural health access and quality, and the

cuts proposed by the President would jeopardize those efforts. Dr. McClellan, can you explain the Administration's rationale for these rural health cuts?

Answer:

Addressing the needs of rural America has been, and continues to be, a top priority for this Administration and for me personally. The recent passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) proved to be one of the most generous packages for rural providers, bringing an estimated $25 billion dollars of needed relief. The new provisions in the bill directly address the concerns that had been raised about continued access to care for beneficiaries residing in rural areas and appropriate payment for rural providers.

Currently, rural residents tend to have more difficulty accessing health care and have poorer health outcomes than their urban counterparts. This Administration has taken a straightforward approach to the issues facing rural areas by directing funds to various programs that are currently expanding health care to rural areas. The Health Center program, since FY 2001, has significantly impacted over 600 communities serving 3 million more patients, over 13 million in total. Of these patients, forty percent have no insurance coverage and many others have inadequate coverage.

The budget for FY 2005 includes $1.8 billion for these critical safety net providers, an increase of $219 million from FY 2004. As a result, services for an additional 1.6 million individuals in approximately 330 new and expanded sites will be available. With this increased funding, 15 million uninsured and underserved individuals will receive comprehensive preventive and primary care services at over 3,800 health center sites across the nation. Nearly 7 of the 15 million patients served by health centers in FY 2005 will be from rural communities.

Another program that rural America will continue to benefit from is the National Health Service Corps (NHSC). Throughout its 30-year history, the NHSC has seen more than 24,500 health professionals commit to service in underserved areas across the country. A targeted management reform initiative that began in FY 2002 has allowed the NHSC to become more effective at assisting the neediest communities. The ratio of loan repayments compared to scholarships has increased by over 30 percent, enabling the NHSC to immediately place more health professionals into service in underserved areas. This has increased the current field strength to more than 4,200 clinicians. At this time, half of NHSC clinicians serve in health centers. The FY 2005 budget continues the expansion of the NHSC with an increase of $35 million, for a total of $205 million. Twenty five million of the $205 million total will be directed towards a specific new effort to recruit nurses and physicians to serve in health professional shortage areas.

Independent evaluations indicate that these rural health programs are effective and achieve results. Information also shows that a less fragmented and more seamless Federal effort could help maximize access, generate effectiveness, yield cost efficiencies, and reduce the number of specific and geographically targeted projects funded each year.

The Administration's FY 2005 budget request for rural health care follows the lessons learned from these evaluations and research.

The President's Budget did not include funding for the Rural Hospital Flexibility Grant program, which received $40 million in the 2004 budget. The program was created in 1997. The primary purpose of Flexibility Grants is to provide support to the States to determine if rural hospitals might benefit from conversion to critical access hospital (CAH) status. The intent was to create a program to help rural hospitals make the transition, when appropriate, to CAH status. To date, more than 800 hospitals have been designated as CAHs and the States have had five years to identify those facilities that would benefit most from conversion. The majority of those conversions have taken place.

You may recall that in the early and mid 1990s, the Centers for Medicare & Medicaid Services (CMS)—then the Health Care Financing Administration (HCFA)—ran a program called the Rural Hospital Transition grants. These grants were to help rural hospitals make the transition to providing a range of services that more appropriately matched their community need and to adapt to new payment provisions such as Sole Community Hospital status, Medicare Dependent Hospital status, and the introduction of swing beds into rural hospitals. That program played a valuable role, but, by 1996, the need for these kinds of grants had waned. Similarly, the Rural Hospital Flexibility Grant program has achieved its original goals. With the enactment of the MMA and the move toward greater payment equity and flexibility for rural hospitals, there is less need for this program especially given the great pressure on the Federal budget at this time. In addition, as mentioned above, the reduction in funds will be offset by approximately $25 billion from the rural provisions in the MMA.

The MMA starts to "level the playing field" for rural providers. More specifically, the rural provisions in the MMA will provide substantial support to rural communities by increasing Medicare reimbursement for rural hospitals, which are a focal point for health care in rural communities. For example, Congressional Budget Office estimates indicate that about $3 billion will be spent to equalize the urban and rural standardized amounts under Medicare's hospital inpatient prospective payment system. This will establish a single base payment for hospitals in all areas in the 50 states, the District of Columbia, and Puerto Rico, starting in FY 2004. There are also substantial increases in reimbursement and flexibility for CAHs. Consequently, the Administration believes there is no longer a need for the Rural Hospital Flexibility Grant program.

I know that CMS is working diligently to implement the MMA. Continued implementation of these important rural provisions will further ensure that the needs of rural America are addressed. Pending my confirmation, I look forward to joining these efforts and working with you to build on the access improvements beneficiaries received and the payment increases rural providers gained in the MMA.

Question 6: UPL

West Virginia recently submitted an Upper Payment Limit (UPL) state plan amendment for nursing homes and hospitals, neither of which has been approved. Almost simultaneously, several other states have had UPL state plan amendments approved – Virginia, Mississippi, South Carolina and Nevada are among them. It is my understanding that nothing in federal law prohibits upper payment limits. A number of states have plans in place that use such upper payment limits. Some of these plans were in place when the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) was adopted; others were instituted, with the Secretary's approval, after BIPA was passed and new UPL regulations went into effect. It seems to me that as long as UPL state plan amendments comply with federal regulation, CMS should use a standard approval process. Can you elaborate on the process that CMS uses for approving UPL state plan amendments?

Answer:

Under the Federal/state partnership one of the fundamental precepts is that the Federal Medicaid program only matches state expenditures for Medicaid services for individuals eligible for Medicaid. CMS has published three regulations over the last year and a half to limit States' ability to increase their share of the Federal payments under Medicaid without actually spending state funds.

State payments to institutional providers under Medicaid cannot exceed the upper payment limit (UPL) established by the Federal government. Historically, states were able to develop payment methods that effectively allowed them to receive increased Federal matching payments with little or no additional state funds being provided. This loophole involved states claiming excessive federal matching funds by paying government-owned facilities at rates much higher than Medicaid would otherwise pay. States would require these facilities to put up the state match, and require intergovernmental transfers from these providers to the state to return the Federal share of these payments to finance the state share of other Medicaid expenditures. This had the effect of increasing the state's effective statutory matching percentage as they used these Federal funds in place of new state funds as state match.

To close this loophole, CMS published three regulations that limit the ability of states to increase their share of the Federal payments under Medicaid without actually spending state funds. Generally, the new UPL rules prevent states from paying each type of hospital and nursing home in Medicaid more than 100 percent of what one would expect to pay for their services.

The regulations included provisions to allow for a gradual phase down of excess Federal funds drawn down by states using the funding schemes so that there would not be an abrupt reduction in state funds. There are three phase-down periods: two, five and eight years, and states are assigned to each depending upon the length of time they had operated the funding schemes. The longer the state had relied on the excess funds the longer they have to phase out the use of them. The completion of the two-year phase out

period occurred on September 30, 2002. The five-year phase out will end on September 30th, 2005 and the eight year phase out will end on September 30th, 2008.

Question 7: State Fiscal Relief

Last year, in response to the economic downturn, I worked with several of my colleagues in Congress to successfully pass $20 billion in state fiscal relief – with $10 billion going to Medicaid. This legislation prevented states from making drastic cuts to their Medicaid and State Children's Health Insurance Programs. However, despite the slight upturn in the economy, states continue to face substantial budget shortfalls, which will limit their ability to compensate for unemployment and the loss of private health coverage. The new Medicare law adds to state fiscal problems by imposing net costs on states in fiscal years 2004, 2005, and 2006. When the fiscal relief enacted last year expires on June 30, states expect a significant negative impact on their Medicaid programs. Given the importance of the Medicaid program and the on-going state budget crises, do you support extending state fiscal relief beyond June?

Answer:

On May 28, 2003, President Bush signed into law (P.L 108-27) the Jobs and Growth Tax Relief Reconciliation Act of 2003 (TRRA), which provides $20 billion in fiscal relief to states of which $10 billion was provided through a temporary FMAP increase and grants to states.

The President's FY 2005 budget does not include a proposal to extend this temporary relief. Another temporary FMAP increase does nothing to address any of the underlying fiscal problems at either the Federal or state levels, nor would it address the need for underlying structural reform.

Temporary FMAP increases shift the problem from one level of government to another. The same total amount of tax revenues still will need to be collected to pay for the Medicaid program. Adjusting the Federal match simply changes which level of government must collect more of the taxes: the Federal government in place of the states.

We believe a more effective way to help states is to modernize Medicaid. If confirmed, I will work with Congress and other stakeholders to achieve a systemic reform that is a more effective approach to addressing the financial problems in states as a result of increased demands on Medicaid.

Question 8: Drug Reimportation

The new Medicare law effectively prohibits seniors from importing prescription drugs back into the United States from Canada and other countries at lower cost. Although the new law contains a provision allowing reimportation from Canada as long as the Secretary of HHS certifies the safety of such imports, HHS has long opposed the

reimportation of prescription drugs from other countries. Under both the Clinton and Bush administrations, HHS has refused to implement reimportation laws, maintaining that it cannot certify the safety of reimported prescription drugs. Drawing on your expertise as FDA Commissioner, can you tell us what it would take to certify the safety of drugs that are made in America and reimported from other countries?

In my view, the most appropriate way to consider whether reimportation should proceed is to answer the questions posed by Congress on this subject under the study required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The work on this study has begun, and FDA will work with its sister Agencies to complete the necessary analysis. The Task Force for this study will provide a forum for fair, open and transparent dialogue on these issues. It will ensure that the review of issues related to reimportation is balanced and employs the best available information on the questions raised by reimportation.

Answer:

With regard to certification, the study will address many important issues including identification of the limitations, including resource limitations and limitations on current legal authorities that may inhibit the Secretary's ability to certify the safety of imported drugs. In addition, it will study the scope, volume and safety of unapproved drugs, including controlled substances, entering the United States via mail shipment, the extent to which foreign health agencies are willing and able to ensure the safety of drugs being exported from their countries to the U.S and will estimate the agency resources, including additional field personnel, needed to adequately inspect the current amount of pharmaceuticals entering the country. The answers to these questions are essential for determining whether the Secretary should issue the certification permitted by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Question 9: Drug Reimportation

Despite warnings from the Food and Drug Administration, several state and local governments are exploring the possibility of reimporting prescription drugs from Canada; West Virginia is among them. States are spending a substantial portion of their annual budgets on prescription drugs - for Medicaid beneficiaries as well as for state employees. As the costs of prescription drugs continue to rise and states continue to face budget shortfalls, many states are looking at reimportation as a way to ease their financial burdens. And, quite frankly, I don't know what other options they have. We do not allow Medicare to negotiate lower drug prices for seniors. With the new federal prescription drug benefit, states have also lost some of their negotiating power under Medicaid, and we have done nothing to replace it. I noticed that the Administration's budget for this year includes no mention of the Medicaid rebate proposal that has been included in the budget the last two years. How would you respond to the concerns expressed by residents of my state regarding the ever-growing price of prescription drugs?

Answer:

As FDA Commissioner I am concerned about the high cost of many prescription medications and I have worked administratively to identify and implement ways to provide greater access to more affordable prescription medications, including generic medications. But American consumers must be required to trade safety for affordability and that is why I have been reluctant to support approaches that reduce rather than enhance FDA's ability to complete its mission – to assure the safety and effectiveness of the U.S. drug supply. I have worked closely with Congress in its enactment of the MMA which will provide drug discounts and a prescription drug benefit to seniors in order to assist them in managing the cost of their medications. As part of the legislation, we worked with Congress to include reforms to the Hatch Waxman law to accelerate introduction of lower cost generic drug products and to enhance generic competition, and I have taken steps while at FDA to provide additional resources and improve the approval process for generic drugs and these are described in more detail below.

Generic drugs typically cost 50 to 70 percent less than their brand-name counterparts. On June 18, 2003, FDA published a final rule to improve access to generic drugs and lower prescription drug costs for millions of Americans. These changes are expected to save Americans over $35 billion in drug costs over the next 10 years. The final rule provides the generic industry with enhanced predictability and certainty, while avoiding unnecessary and lengthy litigation, preserving intellectual property protections and protecting the process and incentives for developing new breakthrough drugs.

Specifically, the rule would allow only one 30-month stay for each generic drug application, clarify that certain patents cannot be listed, and improve the declaration that innovators must make about patents they submit for listing in the Orange Book, FDA's publication listing all approved drug products under section 505 of the FD&C Act.

Responding to the President's 2004 budget proposal, Congress enacted an increase of $8 million for FDA's generic drug program, the largest infusion of resources into this program ever. This increase in the generic drug budget will allow FDA to hire additional expert staff to review generic drug applications more quickly and initiate targeted research to expand the range of generic drugs available to consumers. Improvements in the efficiency of review procedures are expected to save consumers billions more by generally reducing the time for approving new generic drugs. Part of the funding will also be used for the Agency's ongoing education and outreach program directed towards patients, prescribers, and insurance providers to explain the benefits and safety of generic drugs.

Furthermore, the recent Medicare legislation, discussed in more detail below, contains provisions originally sponsored by Senators Gregg and Schumer that complement FDA's rulemaking on generic drugs. The new law codifies elements of FDA's final rule and adds a provision limiting 180-day exclusivity to accelerate generic competition in the marketplace. The increased availability of lower-cost generic drugs will benefit all Americans, especially senior citizens.

In addition, the study required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 will address many important questions including the potential short- and long-term impacts on drug prices and prices for consumers associated with importing drugs from Canada and other countries. The most appropriate way to respond to the concerns you have identified is to answer the questions posed by Congress on this subject under the study required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The work on this study has begun, and FDA will work with its sister Agencies to complete the necessary analysis. The Task Force for this study will provide a forum for fair, open and transparent dialogue on these issues. It will ensure that the review of issues related to reimportation is balanced and employs the best available information on the questions raised by reimportation.

Questions Submitted By Senator Breaux

Question 1: 18-Month Moratorium on Specialty Hospitals

Section 507 of H.R.1, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), establishes an 18-month moratorium on self-referral of Medicare patients to specialty hospitals in which the referring physician has an ownership interest. I understand that a question has been submitted for the record regarding how CMS plans to implement the grandfather clause included in this provision. I am interested in your response to this question, and would also like to seek clarification regarding the definition of a specialty hospital according to Section 507. I believe that Congress quite clearly defined what is considered a specialty hospital. It was our intent that hospitals, for example, primarily engaged in treating patients with a cardiac condition would be considered specialty hospitals. Similarly, a hospital primarily engaged in treating patients with an orthopedic condition would be considered a specialty hospital. In both of these examples, the operation of an emergency room within the hospital would not prevent the hospital from being classified as a specialty hospital.

I ask that you outline how, as CMS Administrator, you would implement Section 507 to cover all of the intended physician owned specialty hospitals (i.e., cardiac, orthopedic, surgical, and any other specialty category that the Secretary designates as inconsistent with the purpose of permitting physician ownership under Section 507). Furthermore, I ask that you assure me that as CMS Administrator you would enforce the grandfather clause as intended so that the Secretary shall consider the extent to which the four specified factors outlined in the legislation ("whether architectural plans have been completed, funding has been received, zoning requirements have been met, and necessary approvals from appropriate State agencies have been received...") have been met. Finally, I would like to know when CMS will issue instructions on how a hospital may apply for the "under development" exception and how long it will take CMS to make said determination once a hospital's application is received.

Answer:

I understand the statute clearly specified that hospitals primarily engaged in treatment of cardiac, orthopedic, or surgical services are considered "specialty hospitals" for purposes of the 18-month moratorium established by Section 507.

In determining whether a specialty hospital is "under development", the MMA directs the Secretary to consider whether:

-- architectural plans have been completed;
-- funding has been received;
-- zoning requirements have been met; and
-- necessary approvals from State agencies have been received,

plus any other evidence the Secretary believes would indicate whether a hospital was "under development".

Given this statutory directive, I would expect to consider all four factors, while recognizing that some flexibility may be appropriate in particular cases. Thus, a limited number of physician-owned specialty hospitals, on a case-by-case basis, may be allowed to move forward if completion of all four factors was not feasible. I appreciate the input you have provided CMS on this issue.

CMS plans to issue instructions soon on how a hospital may apply for a determination that it was "under development" for purpose of this exemption.

Questions Submitted By Senator Graham

Question 1: Cost of Medicare Reform Bill

If the cost of the Medicare Reform legislation is indeed $534 billion, as estimated by the Administration as opposed to the Congressional Budget Office's estimate of $400 billion, what are your recommendations for reducing costs to comply with the $400 billion figure?

Answer:

Senator, I and the rest of the Administration are committed to implementing the bill as is. I understand that some people were surprised by the Administration's higher estimate, and the Secretary has addressed some of the reasons why the CMS Actuaries believe the MMA will cost more than the CBO estimators believe. Both CBO and CMS staffs agree that both the CBO analysts and the CMS actuaries did credible, good faith estimates, however, they disagree on certain basic assumptions. I understand that CBO still is confident that the law passed will only cost $400 billion over the budget period and that remains the official estimate for Congress. I believe that the future will likely prove both sources wrong, given all the uncertainties that face the program.

I guarantee you that if and when I come to the conclusion that Medicare needs additional reforms, I will be back to discuss those with you. But for the moment I am focused on implanting the law as written.

Question 2: Cost of Increased Participation in the Medicare Advantage Program

The Administration's actuaries estimate that increased participation rates in the Medicare Advantage program lead to increased costs for Medicare.

a) Specifically, why is this the case? Please provide the analysis as prepared by the actuaries on this specific point.

b) Why do the Administration's actuaries assume 32 percent participation in the Medicare Advantage program, in contrast to CBO's assumption of nine percent participation? Please provide the actuaries' analysis of this specific point.

Answer:

a) The President's Framework had a different model for bidding and payments to the regional PPOs. The CMS actuaries believed it would save money over time through vigorous competition. We negotiated in good faith for that model, but due to some CBO scoring issues and other policy viewpoints, Congress did not adopt it. There are two key differences between the Framework and the legislation, differences that affect the cost estimate:

1. The Framework increased competition by allowing only 3 winning bidders in each region. Our actuaries, learning from TRICARE's experience with its bidding process, believed this limit would produce the lowest bids. Plans would be encouraged to produce their leanest possible bid to avoid being left out. Having only 3 plans in each region would give them greater market share, increasing both economies of scale and their negotiating leverage with providers. The legislation allows all bidders in, resulting in higher expected bids.

2. The Framework based the regional payment benchmarks on a weighted average of the bids. This would have produced a competitive dynamic over time. As beneficiaries migrated to cheaper, more efficient plans, the Framework's model would have produced a benchmark that fell below fee-for-service costs in later years, resulting in some savings to the taxpayers. The legislation constructs regional plan benchmarks that will exceed fee-for-service costs and do not use a weighted average approach. This method is where most of the extra cost comes from. It is important to note, however, that these extra payments will accrue to beneficiaries, who will see extra benefits and reduced cost sharing under Medicare Advantage plans.

b) As for the differences in the participation rates, CBO and the CMS actuaries have a different view of how much it will cost for insurance plans to serve regional areas in

Medicare. Because CBO believes the PPO costs will be above the benchmark level, it assumes that few or no plans would be willing to enter the market since they would have to charge an additional premium in that scenario. Hence, CBO projects a very low participation rate. Our actuaries, on the other hand, believe PPO costs will come in below the benchmark. This will encourage plans to participate and to provide extra benefits to their enrollees with the difference between their bid and the benchmark. This is largely responsible for the differences in participation rates.
Question 3: Drug Discount Card

Aside from the $600 annual subsidy for low-income beneficiaries, what are the benefits of the federal discount card versus cards already available on the private market? How do you propose to avoid confusion over the multiple cards which will be offered to seniors?

Answer:

I understand that a September 2003 GAO study reported that the proposed Medicare discount program will improve upon the current market for drug discount cards in several important aspects such as securing manufacturer rebates and passing them through to pharmacies and beneficiaries. Current discount programs, I understand, generally do not secure manufacturer rebates. Requiring rebates will result in overall discounts under this new Medicare-approved program that are higher than under discount card programs in the current marketplace.

I also understand that to avoid confusion over the multiple cards that will be offered to beneficiaries, CMS will have many educational resources available to beneficiaries. They can use those that are most useful to them, including:
1. 1-800-MEDICARE
2. 1-800 numbers for each drug card sponsor
3. Information about the drug card sponsors including price comparison information on www.medicare.gov
4. Small pamphlets containing a drug card program overview
5. Larger booklets with more detailed information about eligibility, enrollment, sample enrollment form, step-by-step guide to comparing and choosing a discount card.
6. SHIP and partner outreach efforts

Question 4: Medicare Preventive Benefits

I have long advocated a two-step process as follows, in regard to Medicare benefits: 1) an expert panel, such as the Institute of Medicine, advises Congress on the coverage of specific Medicare benefits, which would include both the inclusion and exclusion of particular procedures; 2) Congress, on the basis of the report of such an expert panel, would vote this benefit package up or down, much like a "fast-track" process for trade.

What is your opinion on establishing such a process, the purpose of which is to prevent the micromanagement of medicine by elected officials, and place it into the hands of practitioners?

Answer:

I understand your concern about this issue. At FDA, one of my top priorities has been to find ways to help patients get access to valuable new medical treatments more quickly and at a lower cost. At CMS, I intend to work closely with the staff to achieve the same goal.

When the Medicare statute was written in the 1960s, the value of preventive services was not well understood. Thus, the statute limits Medicare coverage to items or services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (Section 1862(a)(1)(A)).

While the statute gives the Secretary authority to add or modify coverage of new diagnostic or treatment services as appropriate, we cannot similarly add or revise a preventive benefit without an explicit amendment to the law. As you note, this process is not always responsive to the latest scientific evidence, or free from micromanagement by elected officials.

Increasing awareness of prevention and promoting healthy lifestyles is a high priority of Secretary Thompson's, and I share his interest in this area.

I understand the Department and Congress have, over the years, considered legislative proposals that would authorize the Secretary to make coverage decisions for preventive benefits using the same (or a similar) evidence-based process as CMS now uses for diagnostic and treatment coverage decisions. While we currently have no such proposal on the table, we continue to be interested in exploring ways to modernize Medicare in the area of preventive services.

As a nominee, I regret that I cannot endorse your specific legislative proposal at this time. However, I would welcome the opportunity to meet with you to learn more about this innovative approach.

I would also note that I am a member of the Institute of Medicine (IOM) and so am familiar with their expertise and capabilities in providing science-based guidance; indeed we work with them frequently at FDA. If confirmed, I would be pleased to work with you and your staff on determining how we can best use the IOM to identify ways to enhance prevention in Medicare.

I believe there may also be other routes to achieving the goals of your legislation, such as further links between Medicare and the U.S. Preventive Services Task Force. Congress has already recognized the Task Force's role in updating preventive practices, for

example by limiting the Secretary's authority to add coverage of new cardiovascular screening blood tests unless such tests are recommended by the Task Force.

If confirmed, I look forward to exploring with you these and other steps to improve the use of preventive services in Medicare.

Question 5: Michigan's Multi-State Pooling State Plan Amendment

State Drug Costs: Please keep me apprised of the status of the Michigan-Vermont state purchasing pool waiver.

As the new Administrator of CMS, will you recommend that the Secretary approve this waiver? If so, when will you make that recommendation? If you need more time to decide, how much more time do you need?

Follow-up Question (from email):
On substance, could Mark provide any additional information on what type of information CMS has requested from the state of Michigan, and how that information will inform a decision on approval of the waiver? On process, could Mark provide information on when the additional information is due, and if it is received in a timely manner, when the decision on the waiver will be made?

Answer:

The Michigan State Plan Amendment (SPA) seeks approval for multi-state pooling of supplemental rebate agreements. The SPA seeks to obtain supplemental rebates through pooling the Medicaid populations and other non-Medicaid populations in MI, VT, NH, NV and AK.

It is my understanding that CMS requested additional information from the state of Michigan on March 5. The request was issued to obtain further information on the contracting authority for the state to enter into multi-state Medicaid supplemental rebate pooling with Vermont, New Hampshire, Alaska and Nevada.

The state has up to 90 days to respond to the CMS request for additional information and CMS has up to 90 days to evaluate the state's final response. CMS cannot issue another request for information. If confirmed I will make a final determination on the SPA within the timeframe prescribed by law, and I will be happy to keep you apprised of this status of this SPA.

Question 6: Uniform Coverage of PET Scans

The recently-enacted Medicare Modernization Act requires CMS to develop a plan to evaluate local Medicare coverage determinations and achieve greater consistency among such determinations. Florida's Medicare program has some of the nation's most restrictive coverage guidelines as outlined in approximately 190 Local Medical Review

Policies (LMRPs). Florida has issued LMRPs denying coverage even when other states have issued decisions to provide coverage for the same services.

Differential access to PET scans is a prime example of the problems associated with inconsistent coverage determinations across states. There are about 17 different LMRPs relating to PET scans in various areas of the country. In Florida, PET scans are covered under Medicare for some cancers, such as lung cancer and lymphoma, but not for multiple myeloma, even though it primarily affects older Americans. The high cost of PET - it averages $4,000 - makes the lack of Medicare coverage particularly problematic.

As CMS Administrator, how would you develop a plan to achieve greater consistency among Local Medical Review Policies? What would you do to ensure that Medicare beneficiaries receive equal access to important procedures such as PET regardless of the state they live in?

Answer:

Achieving a balance between national and local coverage policy is an important objective, and I will work toward the goal of ensuring Medicare beneficiaries have access at both levels to important new technologies.

Local coverage policy allows flexibility for emerging technologies to be tried, evaluated, and made quickly available at local levels. In contrast, national policies ensure that beneficial technologies are available across the country, but are not ideal for coverage of emerging technologies for which the scientific evidence is less well developed.

While local coverage is expected to vary to some degree for new technologies (or those for which studies have not been completed to demonstrate their value), we would not expect variation among local policies for technologies known to be effective for Medicare patients. I believe the final regulations for BIPA section 522 (appeals of local and national coverage decisions), published in October 2003, will begin to solve the problem of discrepant local policies. Now such policies can be appealed to ALJs and ultimately the Departmental Appeals Board, ensuring that beneficiaries and other stakeholders have access to an independent review. Those policies that are not supported by adequate scientific and clinical evidence will be overturned and revised, thus leading quickly to greater consistency and scientifically based policies.

At FDA, one of my top priorities has been to find ways to help patients get access to valuable new medical treatments more quickly and at a lower cost. At CMS, I intend to work closely with the staff to achieve the same goal. I will also monitor the coverage appeals process and will take further steps, as needed, to ensure the quality and integrity of the local coverage process. I will also direct CMS to review local coverage policies to determine the reasons for local variation, and how our processes for developing and reconsidering these policies might be improved.

Finally, CMS has expanded coverage of PET scans at the national level several times over the past few years, and is currently reviewing a number of additional applications for PET use in cancer and other conditions. For example, a national coverage analysis is currently underway for PET usage in ovarian, brain, cervical, pancreatic, small cell lung, and testicular cancers. A tracking sheet for this analysis can be viewed on the CMS website at http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=92.

PET scans are already covered for the following types of cancer: lung (non small cell), esophageal, colorectal, lymphoma, melanoma, breast, head and neck, and thyroid.

Question7: Medicare coverage of bone-anchored hearing aid implantation

Background:
A recent ruling by CMS has decertified an important surgical procedure that improves hearing for individuals with permanent hearing problems who are unable to wear conventional hearing aids because of chronic ear drainage, skin irritation, or ear malformation. This surgery involves the implantation of a bone-anchored hearing aid into the mastoid bone of the skull behind the patient's ear. The procedure is quite costly and no alternative interventions exist. Nonetheless, Medicare has excluded from coverage not simply the hearing aid itself but also the surgical intervention to connect it.

Question:

While I understand that Medicare does not cover hearing aids, I am concerned that this important medical intervention has been inappropriately classified as a hearing aid and thus excluded from coverage. As CMS Administrator, what steps would you take to ensure that such a ruling would not be applied in a way that limits access to care for a necessary medical or surgical intervention such as the implantation of a bone-anchored hearing aid?

Answer:

It is my understanding that the statute (Section 1862(a)(7) of the Social Security Act) states that no payment may be made under part A or part B for any expenses incurred for items or services "where such expenses are for . . . hearing aids or examinations therefore. . . " This policy is further reiterated in regulations (at 42 CFR 411.15(d)) which specifically states that "hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids" are excluded from coverage. Since CMS concluded that this Bone Anchoring Hearing Aid Device did fall into the hearing aid exclusion category, it does not qualify under the Medicare statute.

Pending my confirmation, I will look into this issue further. I look forward to working with you on this and other similar access issues as I have always made beneficiary access one of my top priorities.

Questions Submitted By Senator Jeffords

Questions 1-5 - CMS' Proposed Changes To The 75% Rule

To qualify as an IRF, a freestanding rehabilitation hospital or rehabilitation unit of a hospital must satisfy a test known as "the 75 Percent Rule," among other criteria. This rule requires the facility to show that it serves an inpatient population of whom at least 75 percent require intensive rehabilitative services for the treatment of one or more of 10 specified conditions in the most recent 12-month cost reporting period.

The list of 10 conditions in the 75 Percent Rule has not been updated since it was promulgated in 1984, and therefore fails to take into account medical advances of the past two decades. On May 16, 2003, CMS published a Notice of Proposed Rulemaking (NPRM) in the Federal Register announcing its intent to enforce a narrow interpretation of the 75 Percent Rule, without modification, for cost reporting periods beginning on or after October 1, 2003. A final rule is still pending.

The conferees to both the appropriations bill, and the Medicare bill, expressed concerns about the regulations proposed by CMS on the "75% rule." Conferees to both bills requested studies on this issue, one of which is to be contracted out to IOM by CMS. We understand that CMS has a draft final rule, despite not having started or completed the 2 studies.

1. Has CMS contracted with IOM to conduct the study on the "75 Percent Rule" directed by the conferees to the appropriations bill? If not, why?

2. Does CMS plan to move forward with a final rule on the "75 Percent Rule" before completing the IOM study?

3. What percentage of facilities does CMS estimate will satisfy the new standard (a) in the September 9 rule or (b) in the draft final rule in the Secretary's office? What data does CMS have to support either position?

4. How many facilities does CMS estimate will close as a result of this rule? In what regions/states are they located? Again what data does CMS have to back this up?

5. Has CMS estimated how many Medicare beneficiaries will lose access to rehabilitation hospitals and units as a result of the rule?

Answer:

As I am sure you are aware, the nation's inpatient rehabilitation hospitals provide an invaluable service—giving the appropriate intensive level of therapy care to patients with diverse and complex injuries. The "75% rule" is the method used to distinguish inpatient rehabilitation facilities from acute care hospitals. This rule recognizes that hospitals that

treat a higher percentage of certain types of patients are different from acute care hospitals and, accordingly, should be paid to reflect that difference.

I understand that the Centers for Medicare & Medicaid Services (CMS) became aware of concerns about uneven enforcement of the 75% rule in 2002. It was discovered that three-quarters of inpatient rehabilitation facilities were not in compliance with the rule. Upon this discovery, CMS suspended enforcement of the rule and published a notice of proposed rulemaking proposing changes to the 75% rule.

As part of the rulemaking process, CMS consulted with many independent reviewers with both clinical and industry knowledge. Additionally, as work proceeds on developing the final rule, CMS and the Department of Health and Human Services are continuing to evaluate the conference and appropriations report requirements, including the language regarding the Institute of Medicine study.

Because CMS is still in the midst of reviewing the comments received and drafting an improved rule in response to those comments, the Administrative Procedure Act requires that the details of the final rule not be released until it is published. Therefore, it is difficult to provide specific answers regarding estimates of facilities or specific states that will be affected.

I understand that you, and many other Members of Congress, are very concerned about this issue. Pending my confirmation, I will look into this issue further and work with you to address your specific concerns.

Questions Submitted By Senator Bingaman

Question 1: The Administration's Medicaid Program Integrity Proposal

The Administration has proposed cutting Medicaid by $25 billion by reducing the State's ability to use intergovernmental transfers from county governments to help pay the State share of funds or through the use of provider taxes. New Mexico just implemented both to help keep the Medicaid cuts from being more severe than they would otherwise be.

In the past, Congress clamped down on provider taxes (requiring them to be broad-based and uniform and New Mexico's are) and abuse of the Medicare upper payment limit (overpaying certain providers to draw down the federal match and asking them to rebate the overpayment back to the State). Legislation was passed on both of these matters but now the Administration wants to reopen these issues.

What exactly is the Administration's proposal? When are you proposing to implement this proposal? Will it be phased in, and under what time frame? What is the effect on state revenues as the proposal is phased in (assuming it is)?

Answer:

State payments to institutional providers under Medicaid currently cannot exceed upper payment limits (UPL) that are based on Medicare payment principles. This enables States to pay public providers the basic Medicaid rate plus a supplemental payment up to the Medicare UPL. The providers then are required to transfer back to the State through an intergovernmental transfer (IGT) all, or a portion, of the supplemental payment. The funds that are transferred back are then used by the State as its share for other Medicaid expenditures or used elsewhere in their budget.

To begin to close this loophole, CMS published three regulations in 2001 and 2002 that limited the calculation of the UPL within specific provider classes. However, States are still able to pay public providers within a class a basic Medicaid rate and a supplemental payment that can be transferred back to the State.

The President's FY 2005 Budget submission includes a proposal to address both the UPL and IGT issues. The provision would effectively set the UPL at the provider's actual cost of providing the service to the Medicaid beneficiary so that there would be no supplemental payments available to transfer back to the State. The proposal would also prohibit providers from using IGTs to transfer Federal funds back to the state. I do not have any further details on the proposal at this time.

Question 2: Part D and Dual Eligibles

The 6.4 million low-income seniors that are considered "dual eligibles" are potentially worse off under the prescription drug proposal, as their copayments will increase, their access to the full array of drugs will be more limited, their ability to appeal coverage decisions will be more restricted, and the number of asset tests they face may potentially increase from 1 to 3. Would the Administration be willing to work together to see if we can, at the very least, ensure that we ensure that the bill does no harm to them?

Answer:

I believe that dual eligibles will have access to an excellent drug benefit under Part D. All dual eligibles will be deemed eligible for the Part D subsidy and will not have a separate asset test. If confirmed I will work with you to address issues affecting dual eligibles as they enter Part D.

There are extensive information requirements in Part D so beneficiaries will know what the drug plans cover before they enroll in the plan. The plan must set up a process to respond to beneficiary questions on a timely basis. Beneficiaries can also appeal to obtain coverage for a covered drug that is not on their plan's formulary if the prescribing physician determines that the formulary drug is not as effective for the individual or has adverse effects. On the same basis, a beneficiary can appeal if a drug is in the non-preferred (higher) cost-sharing tier to get it changed to preferred cost sharing.

Dual eligibles often face prescription limits under state Medicaid programs; states now use a variety of techniques to control drug costs, including limits on the number of prescriptions, limiting the maximum daily dosage, limiting the frequency of dispensing a drug, limiting the number of refills, or pharmacy lock-in programs which require beneficiaries to fill their prescriptions in one designated pharmacy. This will not be permitted under the new Part D benefit.

For those Part D drug plans that use formularies, the formularies must include at least two drugs in every therapeutic category. Beneficiaries will be able to check the coverage status of specific drugs when selecting plans.

Question 3: Open Access to Medications for Alzheimer's and Severe Mental Illnesses

The new Part D plans may fall short of those currently covered under Medicaid. As you know, a huge percentage of seniors in these chronic disease categories are dual eligibles, and now get their medications covered through Medicaid. Because states are generally prohibited from simply deciding not to cover a particular drug, I think it's fair to say that Medicaid prescription drug coverage – in any given state – is vastly more comprehensive that what's going to be available through the Part D plans since plans can narrow an entire therapeutic class to just two medications. Although beneficiaries can appeal a decision by their Part D plan, it is not clear how well these appeals procedures will work, particularly for dual eligibles with limited financial resources and may have physical or cognitive impairments.

Via regulation or legislative corrections, are you going to follow the example of over 20 states by providing a special exemption for the medications needed by people with Alzheimer's and severe mental illnesses such as schizophrenia? Will you work with me to ensure that these populations receive open access to the full complement of medicines they need?

Answer:

As CMS Administrator I will be committed to ensuring that all eligible beneficiaries have access to the medications they require.

The premise of the question, however, would suggest that Medicaid drug coverage is open ended and unrestricted. This is not the case. In fact, state Medicaid programs use a variety of techniques to control drug costs, including limits on the number of prescriptions, limiting the maximum daily dosage, limiting the frequency of dispensing a drug, limiting the number of refills, or pharmacy lock-in programs which require beneficiaries to fill their prescriptions in one designated pharmacy. This will not be permitted under the new Part D benefit. But for one, which is explicitly excluded by the statute, all drug classes are available to beneficiaries. When a particular drug is not available, physicians may request a specific drug should be made available. And should a

beneficiary continue to be denied, like all Part D beneficiaries he or she will have access to all the beneficiary protections afforded by the Act.

The Act establishes beneficiary protections similar to those that exist in Medicare + Choice today, and adds new protections that are specific to prescription drug coverage. These protections are extended to all enrollees in Part D including full benefit dual eligible beneficiaries and other low-income beneficiaries.

Beneficiaries who elect to enroll in this new open-ended drug benefit will have no limits on the number of prescriptions filled, no limits on the maximum daily dosage, and no limits on the frequency of dispensing a drug. Pharmacy lock-in programs are not permitted.

I share your concern about the needs of individuals with Alzheimer's and severe mental illnesses. If confirmed, I will work within the framework permitted by the MMA to ensure their access to needed medications.

Question 5: Medicare Education/Outreach-SHIPs

Section 1015 of the Medicare prescription drug bill provides CMS with $1 billion for fiscal years 2004 and 2005 to implement the bill. I firmly believe the best use of these funds would be to increase the budget for State Health Insurance Assistance Programs (SHIPs) rather than run television advertisements that fail to provide real information.

What part of the $1 billion is CMS planning to spend on SHIPs and how will the remaining funds be spent?

Answer:

The SHIPS play a very important role in educating seniors about Medicare. In regards to using the $1 billion in the MMA for the SHIPs, we will be significantly increasing funding for the SHIPS from the 2003 level of approximately $12 million. In 2004 and particularly in 2005 we will increase funding to the SHIPs as we gear up and begin large-scale efforts to ensure that Medicare beneficiaries understand all new benefits that they will begin receiving in 2006, especially the new drug benefit.

Question 6: Medicare Advantage

There have been long documented problems with risk selection in the Medicare+Choice program. I have introduced legislation in the past to ensure that health plans do not engage in risk selection via imposition of higher cost sharing on services that chronically ill and disabled beneficiaries utilize such as chemotherapy and dialysis. What can be done to ensure that the past risk selection practices are not repeated in the new Medicare Advantage and drug plans?

Answer:

For the Medicare Advantage program, a significant step toward our goal of minimizing risk selection is the introduction of risk adjusted payment, through which plan payments are adjusted based on the health status of enrollees. A plan whose enrollees are sicker and thus require more health care services will receive higher payments than a plan whose enrollees are healthier. Risk adjusted payment was initiated in 2000 and for the period 2000-2003, 10 percent of payment was adjusted for health status (with 90 percent of payment based on the prior demographic-only adjustment system in use since risk-based private plan contracting began early in the Medicare program).

The Medicare law required the portion of payment adjusted for health status to be set at 10 percent when the risk adjustment system used only inpatient hospitalization data to account for health status. Because many private plans are health maintenance organizations (HMOs) and HMOs focus resources on keeping enrollees out of the hospital, for example, through disease management programs, it was decided to hold the health status adjusted portion to 10 percent until a more refined system that included diagnoses from ambulatory settings (such as physician offices) was implemented. Beginning in 2004, CMS has implemented this more refined health status risk adjustment system, known as the Hierarchical Condition Category HCC) model. The current phase-in schedule for the HCC risk adjustment method is 30 percent in 2004, 50 percent in 2005, 75 percent in 2006, and full 100 percent health status risk adjustment beginning in 2007.

Let me also point out that after CMS saw significant increases in cost sharing amounts in 2001, it issued instructions to plans indicating that if plans set an out-of-pocket cap on member liability, they would have great latitude is establishing cost sharing amounts for individual services. The instructions to plans also indicated that plans that spread cost sharing across widely used health services would have some latitude if they did not have an out-of-pocket cap. And specifically to your point, CMS indicated that plans with higher caps that concentrated cost sharing on specific services, such as dialysis and chemotherapy drugs, would not be approved. The instructions are spelled out CMS' concern that cost sharing not discriminate against sicker beneficiaries or inappropriately encourage disenrollment or discourage enrollment, noting a particular concern for cost sharing levels for dialysis and chemotherapy drugs and noted that CMS would consider premiums and broad-based deductibles to be more equitable ways to spread costs than copays and coinsurance.

With respect to prescription drug plans, we are working to develop a risk adjustment system that will pay accurately for enrollees depending on their health status and prescription drug requirements. Drug plans are required to take all beneficiaries who wish to enroll and they are required to serve an entire region. CMS will also be providing information to all beneficiaries on their drug plan options. We believe that these provisions will allow all beneficiaries to be informed about the new drug benefit and to enroll in the private plan of their choice, if they wish to have this coverage, and preclude risk selection by drug plans. We will be issuing a proposed regulation for the Medicare Advantage program later this year, and we look forward to public input on these issues

and using the process to resolve matters related to beneficiary protections in our final regulation.

Question 7: Medicare Advantage

Studies indicate that payments to Medicare HMOs are 7 to 15 percent higher, on average, compared to traditional Medicare. What is the rationale for the overpayments, including payments to health plans for graduate medical education and through disproportionate share hospital, or DSH, payments? If competition is truly able to reduce long-term Medicare costs, shouldn't payments be set on a budget neutral basis compared to the traditional fee-for-service program?

Answer:

For too long, payments to Medicare+Choice (M+C) plans have been inadequate, causing plans to pull out of the program and leaving seniors without a valuable option for receiving their Medicare benefits. In many counties where M+C plans operate, M+C rates have lagged far behind the cost increases faced by plans. Their rates have increased by only 2% or 3% compared too much higher health care cost increases. The result is that many enrollees have lost important benefits and faced higher cost sharing, and some have also faced upheaval when their plan has left the M+C program.

In the MMA, Congress maintained the Balanced Budget Act of 1997's policy of using higher rates in areas where fee-for-service spending is relatively low while reestablishing MA payment rates based on fee-for-service (FFS) spending in areas where the rates have not kept up with FFS spending. This will allow private plans in areas where M+C rates lagged behind FFS costs to compete on a level playing field with FFS Medicare. The MMA also included part, but not all, of graduate medical education costs in the fee-for-service rate calculation, as well as DSH costs.

Question 8: Tax Credits and the Uninsured

The uninsured rate has increased from 40 million to 44 million people during the past three years. To put that in prospective, that is equivalent to having every single person go from full health coverage to nothing in the following places: Milwaukee, Wisconsin; Memphis, Tennessee; Tucson, Arizona; Albuquerque, New Mexico; Miami, Florida; Pittsburgh, Pennsylvania; Des Moines, Iowa; and the entire State of Montana.

Is the Administration's tax proposal fully paid for in the budget? Also, how do you foresee tax credits working to cover low-income pregnant women, children, or those with chronic illnesses to get the health coverage they need?

Answer:

The President has a comprehensive approach to dealing with the problem of the uninsured. The President has a multi-faceted approach that includes health tax credits to

expand health insurance coverage as well as Medicaid and SCHIP waivers to expand public programs, Association Health Plans to expand options for small business, and Community Health Center and National Health Service Corps expansions to provide needed primary care to under-served and low-income communities.

The Administration's FY 2005 Budget proposes a broad-based refundable income tax credit for up to 90 percent of the cost of health insurance purchased by individuals under age 65, up to a maximum credit of $1,000 for an individual and $3,000 for a family. The tax credit is intended for low and moderate-income taxpayers and is phased out for those with higher incomes. Those who have already purchased their own health insurance coverage on the private market will also be able to claim the credit, thereby assisting millions of additional individuals. The credits will not only be refundable, but also advanceable, so individuals will receive up-front assistance when they need it. The financing of the tax credit is paid for with a contingent offset. (The Department of the Treasury can provide details on how this mechanism works.) For individuals who face very high costs (and who are not eligible for assistance under Medicaid, Medicare, or SCHIP) additional assistance may be available through various state mechanisms, including high risk pools.

Question 9: Medicare Medical Director

It has come to my attention that the State of New Mexico may be the only State in the country that has had its position of medical director eliminated. Medicare participating physicians must call a medical director resided thousands of miles away to consult on questions that medical directors in other states cover for their own physicians.

- What is CMS's rationale for New Mexico being the only or one of the only states in the country not to have its own medical director? Is this something you can look into as you take over the position of CMS Administrator?

Answer:

The number, location, and area of responsibility for each Carrier Medical Director is determined by the Medicare claims processing contractors on a case-by-case basis. While some contractors may employ several Carrier Medical Directors, others may employ only one. Since many of the Medicare contractors are responsible for more than one state, it is possible that one Carrier Medical Director may serve beneficiaries and providers in more than one state.

This flexibility is an important part of ensuring physician, supplier, and provider access to Medicare contractors. If the Centers for Medicare & Medicaid Services (CMS) determined the geographic boundaries for each Carrier Medical Director without appropriating more funds to the contractors for this purpose, it is likely that contractors would have to remove Carrier Medical Directors from areas with greater beneficiary and provider needs and place them in areas where they would serve fewer beneficiary and provider needs. In short, without providing additional funds so that new Carrier Medical

Directors could be hired, a redistribution of Carrier Medical Directors would force CMS and Medicare contractors to create greater inequities in Carrier Medical Director service and coverage than currently exists.

At the same time, I can assure you that I will look into the situation in New Mexico. It is vital that all areas receive appropriate service from their Carrier Medical Director, regardless of where that person is located. Should I find any inequities in the service provided to New Mexico beneficiaries and providers, I will do my best to rectify the situation.

Question 10: Plan B Emergency Contraceptives

On December 16, 2003, The FDA's Reproductive Health and Nonprescription Drug Advisory committees held a joint meeting on the Plan B OTC application. The committee overwhelmingly recommended approval of the application on a 23-4 voted based on evidence, fact, and clinical expertise.

The committee was unanimous in its opinion that Plan B is safe enough for OTC use and in its assessment that there is no data to show that non-Rx availability of Plan B leads to substitution of EC for the regular use of other methods of contraception. Why has the FDA delayed approval of this drug?

Answer:

Since the December 2003 joint meeting of two FDA advisory committees, the sponsors of the supplemental new drug application (NDA) submitted additional information to FDA in support of their application to change Plan B from a prescription to an over-the-counter product. This additional information was extensive enough to qualify as a major amendment to the NDA. Under the terms of the Prescription Drug User Fee Act (PDUFA), major amendments such as this automatically trigger a 90-day extension of the original PDUFA deadline. Such extensions are required so that FDA staff has adequate time to review the additional material. The new goal date for a decision on the application is May 21, 2004. FDA will take into account this new information and all of the discussion by the advisory committees as we continue our review of this application.

Questions Submitted By Senator Kerry

Question 1: Power Wheelchair: Bed or Chair Confined

Concerns have been raised that the "clarification" contains inconsistencies and vague terminology that could unfairly limit access to manual and power wheelchairs. For example, it reads that only those who "bear weight" to transfer from bed to a chair should be considered for a wheelchair. This, in turn, implies that Medicare will no longer purchase a wheelchair for a significant number of beneficiaries who needs one precisely because they cannot bear any weight.

- Is its CMS' intent to now deny Medicare coverage for a manual or power wheelchair to any beneficiary who cannot bear any weight but can be transferred from bed to chair by other persons or a mechanical lift?
- If this is CMS' intent, what is the rationale for such a radical shift in coverage?
- If this is not CMS' intent, do you agree this statement is confusing and what actions will you take to remedy it?

Answer:

No, it is not CMS' intent to now deny Medicare coverage for a manual or power wheelchair to any beneficiary who cannot bear any weight but can be transferred from bed to chair by other persons or a mechanical lift. The bulletin issued by the DMERC in December 2003 stated that power wheelchairs are covered only for patients who are nonambulatory. The bulletin further explained that even those beneficiaries who could bear weight to transfer from a bed to a chair or wheelchair are also considered nonambulatory. This statement should not be construed to exclude those patients who cannot bear any weight at all. Patients who cannot bear any weight are clearly nonambulatory and are therefore eligible for power wheelchair coverage.

Question 2: Power Wheelchairs: Beneficiary Eligibility

The concern has been raised that the "clarification" contains contradictory statements about whether Medicare should ever pay for a manual or power wheelchair for a beneficiary who has the limited ability to walk or take a few steps inside their home.

- Can you clarify the agency's position with respect to this concern?

Answer:

It is my understanding that the policy restatement issued by the DMERCs does not deny power wheelchair coverage to beneficiaries who have a limited ability to walk or can only take a few steps inside their home. In fact, CMS is committed to providing a manual or power wheelchair to every single beneficiary who qualifies under long-standing national coverage criteria.

CMS national policy states that wheelchairs are covered if the beneficiary is "nonambulatory." The restatement issued by the DMERCs states that a beneficiary is considered nonambulatory when "the beneficiary's condition is such that without the use of a wheelchair they would otherwise be bed or chair confined." If a beneficiary can bear weight to transfer from a bed to a chair or wheelchair, the patient is still considered to be "nonambulatory." This statement in the DMERC bulletin has been misinterpreted to mean that if a patient can only walk a step or two then they would not be granted coverage. This is simply not true.

Question 3: Power Wheelchairs: Coverage Criteria

The concern has been raised that the new policy fails to provide physicians or DMERCs any objective criteria for deciding when a manual or power wheelchair is medically necessary for a beneficiary – thus, making it impossible to carry the policy out in a fair and consistent manner.

- Do you believe this is a valid concern and what are your reasons for reaching this conclusion?
- What actions are you prepared to take to assuage and/or address this concern?

Answer:

My understanding is that the bulletin issued by the DMERCs in December 2003 restated national CMS coverage policy and did not contain any new policy changes. The clinical criteria for deciding when a manual or power wheelchair is medically necessary and appropriate for a beneficiary has been and will continue to be a matter of clinical judgment by a physician. It's also my understanding that CMS does not want to list specific condition-based criteria since the decision to determine the appropriateness of providing a manual or power wheelchair is best left to the physician's judgment.

However, this does not abdicate the responsibility to have appropriate documentation as to the medical necessity of the claim. As a condition of coverage, CMS does require that the beneficiary's need for a wheelchair or power wheelchair is supportable. In fact, all claims for power wheelchairs must include a Certificate of Medical Necessity (CMN) which "certifies the need for the device and that it is reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body part."

Question 4: Power Wheelchairs: Moratorium

Representatives of beneficiaries, physicians and DME suppliers assert that the "clarification" is filled with inconsistencies and vague terminology like those referenced in the previous questions. They, therefore, contend the policy cannot be implemented in a fair and consistent, nationwide manner, which was CMS' stated intent for directing the DMERCs to develop and implement it. They further assert that due to all this CMS should place an immediate moratorium on the implementation of the "clarification."

- Do you believe these concerns are valid – why or why not?
- What actions are you prepared to take to assuage and/or address these concerns?
- In your view, is there a need to put such a moratorium into effect and what are your reasons for reaching this conclusion?
- If such a moratorium were to go into effect what specific impact, if any, would it likely have on CMS and/or the DMERCs' capacity to detect fraud?
- What other impact, if any, would putting such a moratorium into effect likely have on the on going operation of CMS and the DMERCs?

Answer:

It is my understanding that the national coverage policy restatement issued in the DMERC bulletin in December 2003 was issued to further explain national coverage policy. I recognize how important of an issue this is to beneficiaries, physicians, and suppliers, and I know that the agency is actively seeking the input of all these groups. Specifically, CMS has held an Open Door Forum and two Listening Sessions dedicated solely to power wheelchair coverage issues in a concerted attempt to receive input from these groups.

Question 5: Power Wheelchair: Documentation Against Fraud

CMS directed the DMERCs to develop a nationwide policy for determining when Medicare should purchase a power wheelchair that: a) could be implemented in a clear, consistent and fair manner by physicians, DME suppliers and DMERCs; and, b) assist CMS and DMERCs in better detecting fraud and abuse.

- In your view, can this policy clarification be implemented in a manner that adequately satisfies both of these objectives?
- What changes, if any, are needed in the "clarification" to make sure it meets these objectives?
- In what specific ways will the "clarification" improve CMS and DMERCs' capacity to prevent, detect and address Medicare fraud and abuse in regard to the purchase of manual and power wheelchairs?

Answer:

Yes, it's my understanding that CMS has made efforts to ensure that the restatement of national coverage policy issued in the DMERC bulletin last December has been implemented in a clear, consistent, and fair manner and has assisted the agency in identifying fraudulent suppliers. CMS is protecting itself against fraud by providing additional information regarding the types of appropriate documentation required for the submission and development of claims. It is through the examination of claims under post- and pre-payment review that CMS has been able to identify fraudulent suppliers.

Question 6: Power Wheelchair: Use at Home

The concern has been raised that a primary purpose behind the "clarification" is to put more teeth into the agency's long-standing regulation that permits Medicare to only pay for DME that is "for use in the home." The application of the rule has loosened considerably in the last 20 years in recognition that advances in health care and technology now enable seniors and others with disabilities to move about their home and community more than ever before.

The "clarification" would clearly return to a far more rigid application of the rule. In practical terms, this would mean that Medicare would no longer pay for any type of

wheelchair for a beneficiary who could "walk" inside their home but need a chair to move about their community.

- Is this an accurate characterization of what a primary intent behind and the actual impact of the "clarification" will be on Medicare beneficiaries with disabilities of all ages? Please elaborate.

Answer:

The primary intent of the restatement of national coverage policy issued in the December 2003 DMERC bulletin was to ensure the consistent application of power wheelchair coverage policy across the country. It's my understanding that this restatement of policy is in no way aimed at denying power wheelchairs to those beneficiaries who qualify under long-standing coverage criteria. Although a power wheelchair may be useful to allow the beneficiary to move extended distances, especially outside of the home, Medicare statute and national policy do not currently provide coverage for those uses.

Question 7: Power Wheelchair: Use at Home

Beneficiaries with disabilities, their physicians and advocates say that continuing to try to enforce the nearly 40 year old "in the home" rule is an approach that is doomed to failure for two fundamental reasons. The first is that people with disabilities are healthier and more able to move about their home and community. The second is it intentionally ignores the very real medical and community living needs of those with disabilities, as such, it lacks legitimacy in the eyes of beneficiaries, physicians and suppliers alike. Thus, they contend that it is likely to be ignored and become increasingly unenforceable with the passing of each day.

- In your view, is the "in the home" standard a medically and socially appropriate one for Medicare to try to enforce with regard to manual and power wheelchairs?
- What regulatory or statutory changes can be made to replace the "in the home" standard with one that:
    a. Enables Medicare beneficiaries with disabilities of all ages to be properly evaluated for and can obtain a manual or power wheelchair that is reasonable and necessary for their use in the home and community.
    b. Can be clearly, consistently and fairly applied across the nation.
    c. Can be implemented in a manner that will not lead to an unmanageable increase in claims or a higher degree of fraud.
    d. Does not arbitrarily limit the educational and employment goals of beneficiaries
- What are the estimated costs of such policy changes and how are such estimates derived?

Answer:

Medicare will not cover the cost of a power wheelchair if the use of the power wheelchair primarily benefits the patient in their pursuit of leisure or recreational activities. Although a power wheelchair may be useful to allow the beneficiary to move extended distances, especially outside of the home, federal statute and national policy do not currently provide coverage for those uses. With regards to changing the "in the home" standard, the President's 2005 budget did not include a proposal for such a change. However, I understand how important this is to you, and I look forward to working with you on this issue.

Questions Submitted By Senator Lincoln

Question 1: Respiratory Therapy Services Under Home Health

> Dr. McClellan, the Medicare statute does not recognize respiratory therapy services under the home health services benefit (Section 1861(m) of the Social Security Act). Medicare regulations recognize home respiratory therapy services that are part of a plan of care by a skilled nurse or physical therapist and that constitute skilled care (Section 409.46 of the Code of Federal Regulations). Because the services of respiratory therapists are not considered skilled visits, homebound Medicare patients suffering from chronic obstructive pulmonary disease (COPD) such as emphysema and chronic bronchitis do not have access to respiratory therapists in their homes. It is my understanding that last year, CMS approved the following language to give home health agencies the option of utilizing respiratory therapists when their services are furnished as part of a plan of care by a skilled nurse or physical therapist:
>
> "For purposes of paragraph (1) and (2), when respiratory therapy services are furnished as part-time or intermittent nursing care or physical therapy services under a home health plan of care, a respiratory therapist, acting within the therapist's scope of practice, may furnish such services."

Does CMS still approve of this language and support the intent behind this language?

Answer:

The Centers for Medicare & Medicaid Services (CMS) did not approve the language you cite in your question. It is true that Social Security Act currently does not allow respiratory therapists performing services under the Medicare home health benefit to bill separately for these services. Home health services, which are defined in Section 1861(m) of the Act, include the services of skilled nurses and physical therapists, both of which are licensed professionals who may provide respiratory care services to patients within their scope of practice. Prior to the development of the respiratory therapy discipline, the services its members now perform were among the services skilled nurses and therapists performed, and these services continue to be provided by nurses and therapists in many contexts, including home health and skilled nursing facility care.

However, respiratory therapists are not strictly precluded from providing services to home health patients under the home health benefit. The current Medicare regulations found at 42 CFR § 409.46(c) address coverage of respiratory care services furnished by home health agencies, stating:

> "If a respiratory therapist is used to furnish overall training or consultative advice to a home health agency's staff and incidentally provides respiratory therapy services to beneficiaries in their homes the costs of the respiratory therapist's services are allowable as administrative costs."

However, a visit by a respiratory therapist to a beneficiary's home is not considered a skilled visit for purposes of the Medicare home health benefit. Respiratory therapy services that are furnished by a skilled nurse or physical therapist as part of a home health plan of care are considered skilled visits for purposes of Medicare coverage. Thus, the current status of both the statute and regulations does not limit a home health agency's ability to provide appropriate respiratory care services to home health patients, nor does it limit a beneficiary's access to these services.

Similarly, respiratory therapy may be provided to patients residing in skilled nursing facilities (SNFs) as part of the comprehensive institutional package that is furnished during a Medicare Part A-covered SNF stay. This is defined in the Social Security Act at Section 1861(h), which defines the SNF benefit under Medicare Part A. Under the current regulations at 42 CFR § 409.27(b), this comprehensive Part A coverage can include respiratory therapy services that are "...prescribed by a physician for the assessment, diagnostic evaluation, treatment, management, and monitoring of patients with deficiencies and abnormalities of cardiopulmonary function." However, SNF residents who are not in a Part A-covered stay do not have respiratory coverage available to them, as there is no Part B respiratory therapy benefit under current law.

Finally, licensed nurses and physical therapists are trained to provide routine respiratory care services. CMS believes it is not outside the scope of practice to allow licensed nurses and physical therapists to provide respiratory therapy services, which allows agencies and skilled nursing facilities more flexibility while at the same time reducing burden.

Question: Sec. 649 Demo

I authored a physician care coordination demonstration that was enacted into law as part of the recently passed Medicare drug bill. This demo (Section 649) will establish a three-year pay-for-performance demonstration program with physicians to meet the needs of eligible beneficiaries through the adoption of health information technology and evidence-based outcomes. One of the demos will take place in a state with a medical school with a Department of Geriatrics that manages rural outreach sites and is capable of managing patients with multiple chronic conditions. The language directs that this site would specifically care for beneficiaries with two or more chronic conditions, including

dementia. I want to make sure that this demo at this site does indeed serve patients with multiple chronic conditions, the way I intended it to be. Can you assure me that this will happen? Can you also provide me with an update on CMS's progress in implementing this language?

Answer:

I understand that CMS is working diligently to implement Section 649, the Care Management Performance (CMP) demonstration as authorized under the MMA in the types of sites specified in the Act. The demonstration will pay incentives to primary care physicians that use modern health information technology (HIT) to improve the quality and safety of care for Medicare beneficiaries with chronic conditions. The demonstration is modeled on the Bridges to Excellence (BTE) program, which was designed and is operated by several private sector employers, including General Electric and Verizon, and the Act calls for CMS to consult with private employers on the design and development of this demonstration. In terms of status, I understand that CMS is finalizing state selection and other issues necessary to complete the waiver cost estimates for the demonstration.

Question 3: DSH Differences in States

I would like to get your thoughts on the issue of Medicaid Disproportionate Share Hospital payments. For many years, there has been a disparity between Low-DSH and High-DSH states, and the Medicare bill just widened this gap. Arkansas is a Low DSH state and has been a good steward of their DSH funding. Would you be willing to work with us to create more parity between Low DSH and High DSH states? If so, how?

Answer:

It is my understanding that the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) narrowed the gap between low and high DSH states.

For states with DSH expenditures greater than zero but less than 3% of their total FY 2000 medical assistance expenditures, MMA provides a 16% increase in allotments for each of five years, FY 2004 through FY 2008. I believe that this increase in the floor for low DSH states, coupled with no changes to the existing 12% cap for high DSH states, will help to achieve the parity you seek.

The five-year period in which low-DSH states receive increased allotments will provide the Congress and CMS the opportunity to evaluate the affect of this increase for low DSH states and its impact on safety net providers. If confirmed, I will pay careful attention to this issue and will work with you on it.

Question 4: DSH Expenditures

Currently Low DSH states can receive no more than 1% of their Medicaid expenditures.

Would you be willing to entertain increasing up to 3%?

Answer:

It is my understanding that the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) has resolved this matter. For states with DSH expenditures greater than zero but less than 3% of their total FY 2000 medical assistance expenditures, MMA provided a 16% increase in allotments for FY 2004 through FY2008.

Question 5: Redistributing Unused DSH Allotments

As I understand it, over half of the states don't use their entire DSH allotment, which means that around $800 million is left unused on the table each year. Would you entertain the idea of taking the unspent money from the states and redistributing it to the states that do use their entire allotment? Similar to how unspent CHIP funds are redistributed?

Answer:

This is an interesting new proposal that could further protect safety net hospitals and other community based providers that serve low-income, Medicaid and uninsured patients. I understand how important DSH funding is to states like Arkansas. While the President's FY 2005 budget does not include such a proposal, if confirmed, I look forward to working with you on this innovative idea and other ways to strengthen safety net hospitals.

Question 6: State Long-Term Care Survey Process

Dr. McClellan, my state of Arkansas has a high percentage of seniors and when they get really sick or can't care for themselves in their homes, they and their families turn to long- term care facilities for help. The Centers for Medicare and Medicaid (CMS) contracts with the states to provide survey teams to inspect long-term care facilities and ensure they are in compliance with the law. My nursing home providers tell me that the oversight and enforcement system used to regulate long-term care facilities is outdated, inflexible, and in many cases actually impedes quality improvement. I understand that states have applied for waivers to improve the system, but have been turned down by CMS. Dr. McClellan, can I get your commitment to examine the survey process, look for steps we can take to improve it, make sure that is it implemented consistently across states, and that survey teams work with facilities to improve quality?

Answer:

I share your concern about improving the quality of care provided by nursing homes. I understand that HHS does not have the authority to waive certain statutory requirements for survey and certification, such as the requirement for an annual nursing home survey. However, CMS has implemented the Nursing Home Oversight and Improvement Program initiative that includes activities such as implementing state survey agency

performance standards; performing unannounced nursing home surveys during weekends and other off-hours to more accurately access quality of care; and identifying poorly performing facilities to survey more frequently.

In addition, the President's 2005 Budget proposes funding for the Nursing Home Quality Initiative (NHQI), which was launched nationally by Secretary Thompson in November of 2002. This initiative is intended to complement the survey process by improving nursing home quality through the provision of enhanced consumer information and quality improvement technical assistance to nursing homes.

If confirmed, I look forward to working with you to further improve the nursing home survey process and on other efforts to make sure America's seniors and persons with disabilities receive the safe, high quality care they deserve.

Question 7: Funding Cuts for Long-Term Care Facilities

Dr. McClellan, over 47 million people rely on Medicaid for health care and long-term care. In our nation's nursing homes, Medicaid is especially significant, as the Medicaid program pays for care for almost 70% of seniors and people with disabilities. Dr. McClellan, why do you want to make cuts that will have a direct impact on the quality of care provided to seniors and people with disabilities in long term care facilities?

Answer:

I am not sure what cuts you had in mind. Both Medicaid program outlays that pay for Medicaid services, including those in nursing facilities, and Medicaid program management funding for survey and certification activities, are projected to increase in the President's FY 2005 Budget proposals.

I share your concern about providing high quality care for seniors and people with disabilities in long-term care facilities. If confirmed, I would be happy to work with you to address any concerns you may have on this issue.

Question 8: Medicare Physician Update

Last year, Congress stepped in twice to avert cuts in Medicare payments to physicians and other health care professionals. However, those actions provided only temporary relief, and we are hearing that a new round of cuts will begin in 2006 and continue for several years. Is that correct? How big will the cuts be?

Answer:

Unfortunately, the update system would have led to a large reduction in physician payment rates for 2004 and 2005. To avoid this result, Congress established updates for 2004 and 2005 at 1.5 percent. However, to avoid increasing spending over the long

term, the Congressional action in the MMA will lead to additional physician fee reductions beginning in 2006 without another change in law. If I were to become CMS Administrator, I would review the physician update system including estimated future updates.

Question 9: Medicare Physician Update

Do you agree that we need to fix/replace the current formula for determining physician fee updates and if so, how would you fix it?

Answer:

Since the current physician update formula will result in a negative update in 2006, it is clearly an issue that needs to be dealt with. While the MMA dealt with the physician update for 2004 and 2005, it does give the Administration and Congress two years to consider long-term modifications that will lead to fair and equitable reimbursements for physicians with predictable and controlled spending for Medicare physicians' services.

Question 10: Power Wheelchair: Bed & Chair Confined

Has there been a change in the definition of "bed or chair confined" that has been in place since 1996, when CMS worked through the OMB to formally change the questions on the Certificate of Medical Necessity for motorized wheelchairs? If there has been a change, would you support withdrawing the "clarification" and moving forward with a fresh attempt at developing appropriate policy and including all stakeholders?

Answer:

It's my understanding that CMS coverage policy has not changed its definition of nonambulatory as being "bed or chair confined." In fact, I believe that this definition of nonambulatory in CMS national policy on coverage of power wheelchairs has been in effect since 1985. Similarly, the DMERC Local Medical Review Policy (LMRP) defining power wheelchair eligibility coverage is also a longstanding policy. Thus, when the DMERC bulletin was issued last December, it simply restated our longstanding national coverage criteria.

Question 11: Power Wheelchair: Fraud Identification & Complaints

What systems are in place for CMS to identify and address fraud? Where do complaints from suppliers go and what action does the agency take when it receives information from the industry about potential fraudulent activity? How long does it take for CMS to investigate fraud?

Answer:

It's my understanding that CMS has several systems in place to identify and address fraudulent practices in power wheelchairs. Since CMS simply does not have the resources available to review the billing practices of all contracted suppliers of power wheelchairs who submit claims, CMS targets its efforts based on the analytical data it collects. CMS, through the Durable Medical Equipment Regional Carriers' (DMERC) Medical Review staff, identify and target specific suppliers who display aberrant billing patterns. These suppliers are identified in analytical reports generated by the national SADMERC and are provided to CMS and the DMERCs for additional analysis and review. Since the prompt identification of fraud is so important to the agency, these reports are generated and reviewed monthly, quarterly and annually.

CMS works continuously with their DMERC to educate providers on how to bill Medicare appropriately. If suppliers do not abide by CMS billing rules, the agency has and will continue to refer them to our fraud units and to law enforcement for civil and/or criminal prosecution.

Question 12: Power Wheelchair: Role of Physician

Why has the role of the physician been devalued in the claims process system while the determination of a medical reviewer holds more sway? Is this trend consistent with Congressional intent requiring "face to face examinations?"

Answer:

It's my understanding that the role of the physician continues to remain an integral and central part of the claims process. The clinical criteria for deciding when a manual or power wheelchair is medically necessary and appropriate for a beneficiary has been and will continue to be a matter of clinical judgment by a physician. CMS and DMERCs are working together through the development of educational materials to ensure that physicians and beneficiaries are educated about when power wheelchairs are appropriate.

Question 13: Medicare Preventive Benefits

One of the provisions of the Medicare drug bill that has received tremendous attention is the coverage of new preventive services. However, it is my understanding that CMS is reading the new law to cover merely the initial physician examination, and not new preventive services. Specifically, Sec. 611, entitled Initial Preventive Physical Examination, provides that new Medicare beneficiaries as of January 1, 2005 are eligible for a preventive physical examination with referrals for specified screening and preventive services, including medical nutrition therapy. CMS' interpretation of this section is that only MNT services for diabetes and renal diseases (which are already covered by Medicare) will qualify under Sec. 611. In other words, there is no expansion of the MNT benefit under the new law. I agree that this new section does not require Medicare to cover MNT services in every instance, but if a physician believed the referral to a qualified provider of MNT would "promote the health" of the beneficiary, then

referral should occur and Medicare should cover the service. Is it your impression that the new preventive services provided for by the Medicare prescription drug bill should make available additional preventive services to new Medicare beneficiaries, or are those preventive services limited to just what was covered prior to the new bill being passed?

Answer:

I understand the Medicare bill creates three new prevention benefits for Medicare beneficiaries. These include coverage of (1) an initial "Welcome to Medicare" preventive physical exam, (2) screening blood tests to detect cardiovascular disease or risk factors associated with cardiovascular disease, and (3) diabetes screening tests for persons at risk for diabetes.

The statute specifies that the initial preventive physical exam shall include measurement of height, weight and blood pressure, and an electrocardiogram, as well as education, counseling and referral related to the other screening and preventive services already covered by Medicare (including medical nutrition therapy, which is covered for beneficiaries with diabetes or a renal disease).

It is my understanding that this provision was not intended to create new prevention benefits beyond the physical exam, and cardiovascular and diabetes screening tests, or to expand other existing benefits (beyond adding education, counseling and referral in relation to those benefits). However, these new benefits can be used to screen Medicare beneficiaries for many illnesses and conditions that, if caught early, can be treated and managed, and can result in far fewer serious health consequences. For example, such conditions as obesity, diabetes, heart disease, and asthma could be made far less severe for millions of Medicare beneficiaries through the early detection, counseling and referrals afforded by the new benefits.

Question 14: Part D Coverage for Duals & Atypical Antipsychotic Medications

I am particularly concerned about how dual Medicare/Medicaid eligibles will fare once they become enrolled in Part D plans starting in 2006. Thousands of low-income and disabled people are currently eligible for both programs in my home state of Arkansas. As you know, this population has a usually high incidence of severe mental illnesses like schizophrenia and bipolar disorder – and they are more than twice as likely to have Alzheimer's disease as other Medicare beneficiaries. The new Medicare drug benefit permits Part D plans to limit to <u>two</u> the number of drugs available in any therapeutic class. But the conference report also requires the Administrator of CMS to ensure that seniors have access to "the full complement of medicines including atypical antipsychotic medications to treat the severely mentally ill." Dr. McClellan, in my judgment, that language requires Part D plans to cover all medication in this therapeutic class – at least for dual eligibles. What's your position on this issue? Do you agree?

Answer:

CMS is committed to ensuring that dual eligible beneficiaries, like all participating Medicare recipients, realize the tremendous new benefit they will receive through Part D. In fact, the statute makes no distinction between the benefits received by a qualifying dual eligible and other Part D beneficiaries but for the ability of Medicaid to cover certain excluded drugs.

However, I share your concern about the needs of individuals with Alzheimer's and severe mental illnesses. If confirmed, I will work within the framework permitted by the MMA to ensure their access to needed medications.

Lincoln 15: Continuity of Care for the Mentally Ill

One of the most important features of the Medicare bill, and one of the reasons I supported it, was the help it gave to low-income seniors. One of the many challenges facing us as this law is implemented is moving the dually eligible population, which includes our most vulnerable beneficiaries, into Medicare. As these beneficiaries move into an exclusively federal program governed by private plans and formularies, continuity of care is critical. Many of the disabled dual eligibles face devastating and complex diseases including severe mental illness where effective treatment requires a complex integration of medical and sometimes psychiatric and social interventions. Particularly with mental illness, upsetting one facet of a treatment regimen for these disease states, such as switching medications, may destabilize a patient and undo months or even years of progress. Can you tell me what you would do as CMS Administrator to ensure that as this law is implemented the mentally ill and other disabled beneficiaries have the kind of continuity of care they need?

Answer:

Individuals enrolled in Part D, particularly those who were previously covered by Medicaid, will now benefit from the national protections and standards afforded by the Medicare program. Unlike the 50-plus individual Medicaid state programs, with varying eligibility levels, benefits and beneficiary protections, and whose prescription drug coverage -- while currently provided by all states – is an optional benefit, Part D provides the best guarantee of continuity of care.

If confirmed I will work to ensure that the regulations now being developed include protections that guarantee access to necessary prescriptions. In fact, the beneficiary protections in the Medicare drug benefit are more comprehensive than those now required by state Medicaid programs.

I share your concern about the needs of individuals with Alzheimer's and severe mental illnesses. If confirmed, I will work within the framework permitted by the MMA to ensure their success to needed medications.

Question 16: Functional Equivalence

Can you give me your opinion of the Functional Equivalence standard?

Answer:

It is my understanding that the term functional equivalence was used on a single occasion in the 2003 outpatient prospective payment system final rule to describe the fact that Procrit and Aranesp use the same biological mechanism to produce the same clinical result, stimulation of the bone marrow to produce red blood cells. In this situation, CMS believed it was appropriate to rely on authority in section 1833(t)(2)(E) of the Social Security Act to make an adjustment determined "necessary to ensure equitable payments." CMS does not believe it would be equitable or an efficient use of Medicare funds to pay for these two products at greatly different rates.

It is also my understanding that upon enactment, the Prescription Drug, Improvement and Modernization Act of 2003 prohibits the Secretary from publishing regulations that apply a functional equivalence standard to drugs or biologicals for purposes of determining drug or biological payment in the hospital outpatient department. If I were to become Administrator, it is my intent to first and foremost, uphold the law.

Question 17: Elimination Of 24-Month Disability Waiting Period

Do you support legislation to eliminate the 24-month waiting period for Americans with disabilities to gain Medicare coverage? Why or why not?

Answer:

The President's 2005 budget request did not include such a proposal. However, I understand that you are concerned about this issue and I look forward to working with you regarding your specific concerns.

The Centers for Medicare & Medicaid Services (CMS) does have some concerns regarding elimination of the 24-month disability waiting period, such as the potential to create incentives for employers to discontinue employee health care coverage early.

It is also important to note that the Benefits Improvement and Protection Act of 2000 (BIPA) waived the 24-month waiting period for Medicare coverage of people diagnosed with Lou Gehrig's disease (amyotrophic lateral sclerosis, or ALS). As of July 1, 2001, individuals diagnosed with ALS are not subject to the disability waiting period.

Question 18: Mental Health Coinsurance

Do you support legislation to make Medicare cover outpatient mental health care at 80% of its approved rate, as Medicare does for all other outpatient medical services? Why or why not?

Answer:

The issue you have raised is related to "mental health parity", addressing the discrepant treatment of mental health benefits as compared to other health benefits.

As you may know, Medicare is in compliance with the limited parity requirement in current law, which only prohibits differential lifetime or annual dollar limits between mental health and other health benefits (Medicare has no such dollar limits).

However, the Medicare statute does require 50 percent coinsurance for outpatient psychotherapy, rather than the 20 percent applied to most other Part B services.

In an April 2002 speech in New Mexico, the President pledged his support for mental health parity, and his commitment to work with Congress to achieve this important goal.

At the same time, the President announced the creation of his New Freedom Commission on Mental Health, which issued its final report in July 2003. In that report, the Commission supported the President's call for Federal legislation to provide parity between insurance coverage for mental health and other health benefits.

The President believes the details of parity should be established by Congress; thus the Department has not taken a position on any particular parity bills.

Question 19: Dual Eligibles and Medicare Savings Programs

Do you support legislation to federalize administration and financing of the Medicare Savings Program?

Answer:

The President's budget does not include a proposal to federalize the Medicare Savings Programs. However, I understand this issue is important to you. CMS has been studying issues and challenges involved in the implementation of the QMB, SLMB and QI programs, and I will work with you to improve the implementation of these programs.

The Medicare Modernization Act requires States, when screening for Medicare Part D eligibility, to also screen Medicare recipients for their eligibility for the Medicare Savings Programs. The Administration is hopeful that this will increase the number of seniors enrolled in these programs.

Question 20: Prescription Drug Plans - Formulary

Do you support legislation or administrative initiatives to increase overall annual funding for State Health Insurance Assistance Program (SHIPs) to at least $3 per person with Medicare? Why or why not?

Answer:

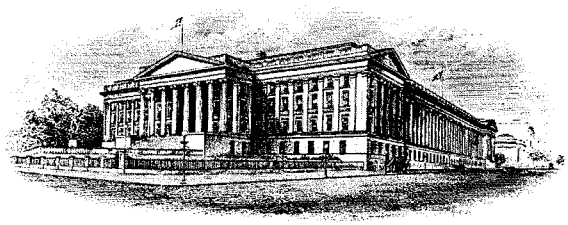
We understand that it is important that beneficiaries have key information about their drug plans including formularies. It is important that we balance the need to get beneficiary information without unduly burdening the drug plans or providing beneficiaries with too much information to the point where it becomes confusing. I look forward to working with you regarding your specific concerns.

Question 21: Drugs and Canada

Do you support legislation or administrative initiatives to ensure that Americans pay no more for prescription drugs than the median prices paid by Canadians? Why or why not?

Answer:

The study required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 will address many important questions including the potential short- and long-term impacts on drug prices and prices for consumers associated with importing drugs from Canada and other countries. The most appropriate way to consider whether legislative or administrative initiatives are appropriate is to answer the questions posed by Congress on this subject under the study required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The work on this study has begun, and FDA will work with its sister Agencies to complete the necessary analysis. The Task Force for this study will provide a forum for fair, open and transparent dialogue on these issues. It will ensure that the review of issues related to reimportation is balanced and employs the best available information on the questions raised by reimportation.



DEPARTMENT OF THE TREASURY
OFFICE OF PUBLIC AFFAIRS

FOR IMMEDIATE RELEASE
March 8, 2004

Contact: Anne Womack Kolton
(202) 622-2960

**STATEMENT OF BRIAN C. ROSEBORO,
NOMINEE TO BE UNDER SECRETARY FOR DOMESTIC FINANCE
OF THE DEPARTMENT OF THE TREASURY,
BEFORE THE SENATE COMMITTEE ON FINANCE, UNITED STATES SENATE**

Chairman Grassley, Ranking Member Baucus, and Members of the Committee on Finance, thank you for the opportunity to appear before you today.

It has been my privilege to have served President Bush for the past 2 1/2 years as Assistant Secretary of the Treasury for Financial Markets, and I am greatly honored that the President has nominated me to serve as Under Secretary of the Treasury for Domestic Finance. If confirmed, I look forward to the opportunity to work in this new role with Secretary Snow, the Treasury staff, others in the Administration, and the Congress on the broad range of issues addressed by the Office of Domestic Finance.

The past few years have been an especially important time for public service and the future expects to be just as demanding. The Department of the Treasury will continue to play a vital role in working to develop and implement policies which promote the economic well being of our nation. Some priorities in the months ahead are maintaining the strength and resilience of our financial markets and institutions, helping to promote a continuing economic recovery, and strengthening retirement security for all Americans. I hope to have the opportunity to continue to work with this Committee on formulating policy and legislation in the areas of public debt management, capital markets, financial institutions, government financial management services, federal lending, and fiscal affairs.

Serving as Assistant Secretary for Financial Markets, I am quite proud of the progress we've made in the management of the federal debt. We have taken significant steps to broaden our investor base. We have built and are improving systems to make the opportunity to "invest in the best credit in world" more available to average Americans. We have greatly improved the transparency of our financing plans to the financial market. We have made ourselves accountable by clearly defining an objective of achieving the lowest cost of financing, over time, for the American taxpayer.

I've now accumulated over twenty years of experience in capital markets. I have spent significant time in both the public and private sectors. I am privileged to have worked with only world class organizations, and I have been afforded a unique opportunity to understand and actively address many financial market issues and incorporate the perspectives of regulator, salesperson, trader, and risk manager. I've learned much from these experiences, the most important lesson being that neither the "private or public" sector should underestimate the other. Public policy must strive to be a facilitator, and not an impediment to open competitive markets and financial innovation. Likewise, the private sector must not betray the trust and confidence of investors and consumers. Any deviation, from either side, puts the U.S. economy at unacceptable risk.

Mr. Chairman, thank you again for the opportunity to appear before the Committee. I hope members of the Committee will again support me, and I promise to work diligently and with an open mind on all matters that this Committee may wish to raise with the Office of Domestic Finance. I hope to continue the strong working relationship I have had the pleasure to experience with this committee over the past 2 1/2 years.

Finally, I would like to thank Secretary Snow for the confidence he has shown in me by supporting me for this office. I would like to thank the career staff of the Department of Treasury for their support, hard work and diligent efforts on behalf of American taxpayers. I would like thank my wife Valerie, daughter Cleo and son Brian for their continued sacrifices as I seek to continue my pubic service. And I would especially like to thank, in remembrance, my grandparents, Cleo Duncan Roseboro and James Benjamin Roseboro Jr., who instilled in me the values of hard work, personal responsibility, perseverance and faith which has led me here today.

SENATE FINANCE COMMITTEE
STATEMENT OF INFORMATION REQUESTED OF NOMINEE

A. BIOGRAPHICAL INFORMATION

1. Name: (Include any former names used.)
Brian Carlton Roseboro

2. Position to which nominated:
Department of Treasury, Under Secretary for Domestic Finance

3. Date of nomination:
12/09/03

4. Address: (List current residence, office, and mailing addresses.)
Permanent address: 185 Gates Ave, Montclair, New Jersey 07042
Work address: Dept. Of Treasury, 1500 Pennsylvania Ave, NW 20220

5. Date and place of birth:
August 19, 1959, Washington, D.C.

6. Marital status: (Include maiden name of wife or husband's name.)
Married: Valerie Jeanne Walker

7. Names and ages of children:
Daughter: Cleo Margaret Roseboro, age 5 years
Son: Brian Reynolds Roseboro, age 3 years

8. Education: (List secondary and higher education institutions, dates attended, degree received, and date degree granted.)
Columbia University Graduate School of Business, New York, N.Y.
09/81 to 05/83 degree – Master of Business Administration 5/83

University of Rochester, Rochester, N.Y.
09/77 to 05/81 degree – BA in Economics 5/81

St. John's College High School, Washington, D.C.
09/74 to 05/77 degree – High school diploma 5/77

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.)

2001 – pres **DEPARTMENT OF TREASURY**, Washington, D.C.
Assistant Secretary for Financial Markets, Domestic Finance

- Manage the federal debt. Defined objectives and metrics of Treasury debt management.
- Manage financial and legislative issues on debt ceiling.
- Engage Congress and regulatory agencies on regulation of capital markets.
- Advise Iraqi Financial Task Force
- Counseled White House on post "September 11th" revitalization of New York City funding.
- Manage government lending/credit policy for US Postal Service, Bonneville Power Authority, Indian Trust Funds and others.
- Chair steering committee for President's Working Group on Financial Markets.
- Co-Chair Advanced Counterfeiting Deterrence inter-agency group
- Chair Local TV Loan Guarantee Board –overseeing establishment of Board's regulations, staffing and procedures.
- Oversaw operations of Air Transportation Stabilization Board and Presidential Commission on US Postal Service.

1996 – 2001 **AMERICAN INTERNATIONAL GROUP**, New York, NY
Deputy Director, Market Risk Management, Financial Services Division

- Initiated first corporate wide risk management function for AIG in financial services.
- Covered fixed income, foreign exchange and commodities exposures.
- Developed market limit structures and risk measures for reporting to senior management.
- Advised senior management on subsidiaries' market positions.
- Developed equity brokerage program in Russian subsidiary.

1993 – 1996 **SBC WARBURG DILLON REED**, New York, NY
Director, Risk Management Advisor, Capital Markets Division

- Dedicated foreign currency derivatives specialist; consulting/marketing resource.

1988 – 1993 **FIRST NATIONAL BANK OF CHICAGO**, Chicago, IL
Vice-President, Senior Foreign Exchange Options Trader

- Market-maker, trading and risk management of multiple currency portfolios.
- Introduced collateralized currency options program for institutional customers.
- *Previous positions: V-P, Foreign Exchange Marketer & V-P, Foreign Exchange Options Marketer*

1983 – 1988 **FEDERAL RESERVE BANK OF NEW YORK**, New York, NY
Chief Dealer, Foreign Exchange Trading, Foreign Division

- Managed execution of currency transactions for FED, US Treasury, international financial institutions and foreign central banks.
- Conducted technical assistance mission on foreign currency reserve management to Bangladesh Bank in Dhaka, Bangladesh, on behalf of US AID.
- *Previous positions: Foreign Exchange Analyst & Senior Foreign Exchange Trader*

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

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

None

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.
Bush/Cheney '04 - $1,000

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

Federal Reserve Bank of New York President's Award for Excellence 1984 for analytical work on foreign exchange futures and options markets.

Federal Reserve Bank of New York President's Award for Excellence 1986 for work on BIS Study Group on Financial Innovations.

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.)
See attached

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

I have work for the past 2 ½ years as Assistant Secretary for Financial Markets at the Department of Treasury. Prior to that, I worked in financial markets since 1983. During this period I worked as a central banker, financial markets salesperson, financial markets trader, financial markets risk management advisor and manager. This has developed my perspective and sensitivities to both "macro" issues (such as systemic risk) and "micro" issues (such as the importance of full disclosure to customers/investors/corporations of derivative risk.

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 current employer is Department of Treasury. My only connection with a previous employer is with the American International Group where I previously worked for 5 years and thus qualified for their defined pension benefit plan.

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.
My interest in AIG's defined benefit pension plan.

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 will agree not to participate in any particular matter that may directly and predictably affect AIG's ability or willingness to pay my pension

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:
N/A

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.

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

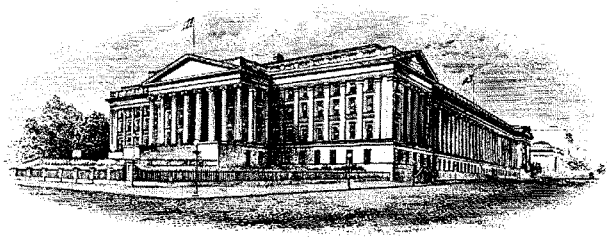
4. Have you ever been convicted (including pleas of guilty or nolo contendere) of any criminal violation other than a minor traffic offense? If so, provide details.
No

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



DEPARTMENT OF THE TREASURY
OFFICE OF PUBLIC AFFAIRS

Embargoed Until Delivery
March 8, 2004

Contact: Brookly McLaughlin
(202) 622-1996

STATEMENT OF MARK J. WARSHAWSKY
NOMINEE TO BE ASSISTANT SECRETARY OF THE TREASURY FOR ECONOMIC POLICY
BEFORE THE COMMITTEE ON FINANCE, UNITED STATES SENATE

Chairman Grassley, Ranking Member Baucus, and Members of the Committee, thank you for the opportunity to appear before you today. I am honored to be President Bush's nominee to be Assistant Secretary of the Treasury for Economic Policy, and I am grateful to Secretary Snow for his confidence in me. If you will permit me, I will take a moment to introduce the members of my family that are here today; I am most grateful to my family for their support and encouragement.

Growing up in Chicago, the son of an immigrant factory worker with little formal education, I have realized, in a direct and personal way, that the United States is a great country of opportunity, growth, innovation, and openness. My parents stressed the importance of a good education, and indeed I have had the good fortune of receiving an excellent education, through a formal course of study in economics and mathematics at Northwestern and Harvard Universities, at the undergraduate and graduate levels, respectively. Along the way (including a stint as an actuary at an insurance company), I developed a particular interest in insurance and asset markets, and the public policies pertaining to them, including their combined ability to allow the transfer of economic risk, and their reduction in overall risk exposure.

My career started with the federal government, first at the Federal Reserve Board and then at the Employee Plans Division of the IRS, where I gained an understanding of the operation of monetary policy and the enforcement of our tax laws, respectively. I also deepened my interests in pensions and health benefits, and so after this civil service, I moved my family to the New York area in order to work at TIAA-CREF, a large private sector pension and insurance provider. There I saw first hand how savings can be efficiently collected and funneled into productive investments and how risks can be insured.

For the last two years, I have been privileged to be Deputy Assistant Secretary at the Treasury for Microeconomic Analysis, and for the last several months, I have been Acting Assistant Secretary. In these positions, I have worked on a variety of economic issues with the talented and dedicated career staff at the Department and with the talented and dedicated people President Bush has chosen to lead his Administration. I am proud to play a part in implementing President Bush's vision and policy agenda for protecting and enhancing the economic prosperity and security of our Nation.

Thank you again Mr. Chairman for the privilege of appearing before this Committee. If confirmed, I can assure you I will work closely and enthusiastically with you and Members of this distinguished committee. I would be pleased to respond to your questions.

-30-

SENATE FINANCE COMMITTEE
STATEMENT OF INFORMATION REQUESTED OF NOMINEE

As of December 10, 2003.

A. BIOGRAPHICAL INFORMATION

1. Name: (Include any former names used.)

   Mark Joel Warshawsky

2. Position to which nominated:

   Assistant Secretary for Economic Policy, Treasury Department

3. Date of nomination:

   November 25, 2003

4. Address: (List current residence, office, and mailing addresses.)

   Home: 903 Brentwood Lane
   Silver Spring, Maryland 20902

   Office: 1500 Pennsylvania Avenue, N.W.
   Room 3450
   Washington, D.C. 20220

5. Date and place of birth:

   March 26, 1958, Chicago, Illinois.

6. Marital status: (Include maiden name of wife or husband's name.)

   Married to Laura B. Warshawsky, nee Margolis.

7. Names and ages of children:

   David S. Warshawsky, 15;
   Hannah L. Warshawsky, 8;
   Avi I. Warshawsky, 6;
   Sarah R. Warshawsky, 4.

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

Ida Crown Jewish Academy, 1972 - 1976, High School Diploma, June 1976.
Northwestern University, 1976 - 1979, B.A., June 1979.
Harvard University, 1980 - 1984, Ph.D., June 1984.

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.)

Actuarial Assistant, Combined Insurance, Chicago, Illinois, 1979 - 1980.
Economist/Senior Economist, Federal Reserve Board, Washington, D.C., 1984 - 1992.
Senior Economist/Special Assistant to the Assistant Commissioner for Employee Plans and Exempt Organizations, IRS, Washington, D.C., 1992 - 1995.
Manager of Pension and Economic Research/Director of Research, TIAA-CREF/TIAA-CREF Institute, New York, NY, 1995 - 2001.
Deputy Assistant Secretary for Microeconomic Analysis/Acting Assistant Secretary for Economic Policy, Treasury Department, Washington, D.C., 2002 - 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.)

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.)

Director, Federal Reserve Board Credit Union, 1988 - 1989.
Officer, TIAA-CREF, 1998 - 2001.
Trustee, Actuarial Foundation, 2000 - 2002.

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

Member, American Risk and Insurance Association, Financial Management Association, National Academy of Social Insurance, American Economic Association, Kemp Mill Synagogue, Jewish Community Center of Greater Washington, Melvin J. Berman Hebrew Academy Parents and Teachers Association.

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.)

Illinois State Scholarship, Bell and Howell Employees' Benevolent Association Scholarship, Northwestern University Dean's Lists, Phi Beta Kappa, Graduated with Highest Distinction, Sloan Foundation Dissertation Scholarship, IRS Assistant Commissioner's Award, British Institute of Actuaries Scholarly Competition Award.

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

I. BOOKS AUTHORED AND EDITED

The Uncertain Promise of Retiree Health Benefits: An Evaluation of Corporate Obligations, Washington, D.C.: American Enterprise Institute Press, 1992.

The Role of Annuity Markets in Financing Retirement (with Jeffrey Brown, Olivia Mitchell, and James Poterba), Cambridge, Mass.: MIT Press, 2001.

Long-Term Care and Medicare Policy: Can We Improve the Continuity of Care? (co-edited with David Blumenthal and Marilyn Moon), Washington, D.C.: Brookings Institution Press for the National Academy of Social Insurance, 2003.

The Evolving Pension System: Trends, Effects, and Proposals for Reform (co-edited with William Gale and John Shoven), Washington, D.C.: Brookings Institution Press, 2004, forthcoming.

Private Pensions and Public Policies (co-edited with William Gale and John Shoven), Washington, D.C.: Brookings Institution Press, 2004, forthcoming.

II. ARTICLES AND COMMENTS PUBLISHED BY TOPIC

A. PENSIONS, RETIREMENT, AND SOCIAL SECURITY

"Comments on Brookings Report by Julia Coronado and Steven Sharpe, 'Did Pension Plan Accounting Contribute to a Stock Market Bubble?'" *Brookings Papers on Economic Activity*, 2003:1, pp. 360 – 367.

"The Market for Individual Life Annuities and the Reform of Social Security: An Update and Further Analysis," *Benefits Quarterly*, Fourth Quarter 2001, pp. 24 – 43.

"Further Reform of Minimum Distribution Requirements for Retirement Plans," *Tax Notes*, April 9, 2001, 91(2), pp. 297 – 306.

"The Costs of Annuitizing Retirement Payouts in Individual Accounts," (with James Poterba), in John Shoven, editor, *Administrative Aspects of Investment-Based Social Security Reform*, Chicago: University of Chicago Press for the NBER, 2000, pp. 173 – 200.

"How Prepared Are Americans for Retirement?" (with John Ameriks), in Olivia Mitchell, P. Brett Hammond, and Anna Rappaport, editors, *Forecasting Retirement Needs and Retirement Wealth*, Philadelphia: University of Pennsylvania Press for the Pension Research Council, 2000, pp. 33 – 67.

"Choosing Retirement Plans: Comment," in Sheila Burke, Eric Kingson, and Uwe Reinhardt, editors, *Social Security and Medicare: Individual vs. Collective Risk and Responsibility*, Washington, D.C.: Brookings Institution Press for the National Academy of Social Insurance, 2000, pp. 106 – 109.

"ERISA After 25 Years: A Framework for Evaluating Pension Reform," (with William Gale and John Shoven), *Benefits Quarterly*, Fourth Quarter 1999, pp. 73 – 81.

"Minimum Distribution Requirements: Reform or Remove Them," *Tax Notes*, November 30, 1998, pp. 1133 – 1134.

"The Optimal Design of Minimum Distribution Requirements for Retirement Plans," *Benefits Quarterly*, Fourth Quarter 1998, pp. 36 – 53.

"Distributions from Retirement Plans: Minimum Requirements, Current Options, and Future Directions," TIAA-CREF *Research Dialogues* Number 57, September 1998.

"Premium Allocations and Accumulations in TIAA-CREF – Trends in Participant Choices among Asset Classes and Investment Accounts," (with John Ameriks and Francis King), TIAA-CREF *Research Dialogues* Number 51, July 1997.

"The Market for Individual Annuities and the Reform of Social Security," *Benefits Quarterly*, Third Quarter 1997, pp. 66 – 76.

"Funding of Defined Benefit Pension Plans: The Implications of Minimum Funding Requirements and Financial Accounting Standards," in Michael Gordon, Olivia Mitchell, and Marc Twinney, editors, *Positioning Pensions for the Twenty First Century*, Philadelphia, PA: University of Pennsylvania Press for the Pension Research Council, 1997, pp. 107 – 138.

"Pension and Health Benefits for Workers in Higher Education," (with John Ameriks), TIAA-CREF *Research Dialogues* Number 49, December 1996.

"Determinants of Pension Plan Formations and Terminations," *Benefits Quarterly*, Fourth Quarter 1995, pp. 71 – 80.

"Financial Accounting and the Funding Status of Pensions," in John Turner and Dan Beller, editors, *Trends in Pensions: 1992*, Washington, D.C.: Department of Labor, 1992, pp. 497 – 507.

"The Adequacy of Funding of Private Defined Benefit Pension Plans" and "The Institutional and Regulatory Environment of Private Defined Benefit Pension Plans," in John Turner and Dan Beller, editors, *Trends in Pensions*, Washington, D.C.: Department of Labor, 1989.

"Pension Plans: Funding, Assets, and Regulatory Environment," *Federal Reserve Bulletin*, November 1988, pp. 717 – 730.

"Funding of Private Pension Plans," Federal Reserve Board *Staff Study* Number 155, summarized in *Federal Reserve Bulletin*, November 1987, pp. 853 – 854.

B. INSURANCE PRODUCTS AND MARKETS

"The Life Care Annuity: A Better Approach to Financing Long-Term Care and Retirement Income" in David Blumenthal, Marilyn Moon, and Mark Warshawsky, editors, *Long-Term Care and Medicare Policy: Can We Improve the Continuity of Care?*, Washington, D.C.: Brookings Institution Press for the National Academy of Social Insurance, 2003.

"Policy Implications of An Annuity Approach to Integrating Long Term Care Financing and Retirement Income," (with Brenda Spillman and Christopher Murtaugh), *Journal of Aging and Health*, (Vol. 15, No. 1), February 2003, pp. 45 -72.

"Integrating the Life Annuity and Long-term Care Insurance: Theory, Evidence, Practice, and Policy," (with Brenda Spillman and Christopher Murtaugh), in Olivia Mitchell, Zvi Bodie, P. Brett Hammond, and Steven Zeldes, editors, *Financial Innovations for Retirement Income*, Philadelphia, PA: University of Pennsylvania Press for the Pension Research Council, 2003.

"In Sickness and In Health: An Annuity Approach to Financing Long-term Care and Retirement Income," (with Christopher Murtaugh and Brenda Spillman), *Journal of Risk and Insurance*, 68(2), June 2001, pp. 225 – 254. (Winner of prize competition sponsored in 2001 by the British Institute of Actuaries.)

"Comments on 'The Role of Real Annuities and Indexed Bonds in an Individual Accounts Retirement Program' by Jeffrey Brown, Olivia Mitchell, and James Poterba," in John Campbell and Martin Feldstein, editors, *Risk Aspects of Investment Based Social Security Reform*, Chicago: University of Chicago Press for the NBER, 2001, pp. 360 – 367.

"Primer on Life Annuities," published at www1.worldbank.org/finance/html/annuities_workshop.html, first appeared in 2000, paper given at World Bank Annuities Workshop, June 7, 1999.

"Financing Long-Term Care: Needs, Attitudes, Current Insurance Products, and Policy Innovations," (with Lee Granza and Anna Madamba), TIAA-CREF *Research Dialogues* Number 63, March 2000.

"New Evidence on the Money's Worth of Individual Annuities," (with Olivia Mitchell, James Poterba, and Jeffrey Brown), *American Economic Review*, 89(5), December 1999, pp. 1299 – 1318.

"Financing Long-Term Care: Employee Needs and Attitudes, and the Employer's Role," (with Lee Granza and Anna Madamba), *Benefits Quarterly*, Fourth Quarter 1998, pp. 60 – 72.

"Annuity Redesign: Proposing Flexibilities in Payout Arrangements," in Dallas Salisbury, editor, *Retirement Prospects in a Defined Contribution World*, Washington, D.C.: EBRI, 1997, pp. 143 – 144.

"Annuity Prices in the United States: 1919 – 1984," *Journal of Risk and Insurance*, September 1988, pp. 518 – 528.

C. FINANCIAL PLANNING

"Comparing the Economic and Conventional Approaches to Financial Planning," (with Jagadeesh Gokhale and Laurence Kotlikoff), in Laurence Kotlikoff, *Essays in Saving, Bequests, and Altruism*, Cambridge, MA: MIT Press, 2002.

"Making Retirement Income Last a Lifetime," (with John Ameriks and Robert Veres), *Journal of Financial Planning*, 14(12), December 2001, pp. 82 – 97.

"The Persistence of Morningstar Ratings," (with Mary DiCarlantonio and Lisa Mullan), *Journal of Financial Planning*, 13(9), September 2000, pp. 110 – 128.

"Discussion Comments on 'Self-Annuitization and Ruin in Retirement' by Moshe Arye Milevsky and Chris Robinson," *North American Actuarial Journal*, 4(4), October 2000, pp. 127 – 129.

D. PUBLIC FINANCE

"An Economic Approach to Setting the Contribution Limits to Qualified State-sponsored Tuition Savings Programs," (with Jennifer Ma, John Ameriks, and Julia Blohm), *Proceedings of the National Tax Association, 2000*, August 2001, pp. 107 – 115.

"Taxing Retirement Income: Nonqualified Annuities and Distributions from Qualified Accounts," (with Jeffrey Brown, Olivia Mitchell, and James Poterba), *National Tax Journal*, September 1999, 52(3), pp. 563 – 591.

"Tax Reform and Corporate Capital Structure," *Public Finance*, 44(2), 1989, pp. 295 – 307.

"Life Insurance Savings and the After-tax Life Insurance Rate of Return," *Journal of Risk and Insurance*, December 1985, pp. 585 – 606.

E. CORPORATE FINANCE

"Is There a Corporate Debt Crisis? Another Look," in R. Glenn Hubbard, editor, *Financial Markets and Financial Crises*, Chicago: University of Chicago Press for the NBER, 1991, pp. 207 – 230.

"Comments on 'U.S. Corporate Leverage: Developments in 1987 and 1988' by Ben Bernanke, John Campbell, and Toni Whited," *Brookings Papers on Economic Activity*, 1990, pp. 279 – 283.

"Determinants of Corporate Merger Activity: A Review of the Literature," Federal Reserve Board *Staff Study* Number 152, summarized in *Federal Reserve Bulletin*, April 1987, pp. 270 – 271.

F. MACROECONOMICS

"An Enhanced Macroeconomic Approach to Long-Range Projections of Health Care and Social Security Expenditures as a Share of GDP," *Journal of Policy Modeling*, 21(4), July 1999, pp. 413 - 426.

"The Cost of Annuities: Implications for Saving Behavior and Bequests," (with Benjamin Friedman), *Quarterly Journal of Economics*, February 1990, pp. 135 – 154.

"Specification of the Joy of Giving: Insights from Altruism," (with Andrew Abel), *Review of Economics and Statistics*, February 1988, pp. 145 – 149.

"Annuity Prices and Savings Behavior in the United States," (with Benjamin Friedman) in Zvi Bodie, John Shoven, and David Wise, editors, *Pensions in the U.S. Economy*, Chicago: University of Chicago Press for the NBER, 1988.

G. SECURITIES MARKETS AND FINANCIAL INSTITUTIONS

"Comments on 'Social Security Reform and Financial Markets' by Henning Bohn," in Steven Sass and Robert Triest, editors, *Social Security Reform Conference Proceedings*: Federal Reserve Bank of Boston Conference Series Number 41, June 1997, pp. 228 – 235.

"Investing Social Security Funds in Stocks," (with P. Brett Hammond), *Benefits Quarterly*, Third Quarter 1997, pp. 52 – 65.

"Margin Trading" in John Eatwell, Murray Milgate, and Peter Newman, editors, *The New Palgrave Dictionary of Money and Finance*, 1992.

"The Adequacy and Consistency of Margin Requirements: The Cash, Futures, and Options Segments of the Equity Market," *Review of Futures Markets*, 8(3), 1989, pp. 420 – 437.

"Sensitivity to Market Incentives: The Case of Policy Loans," *Review of Economics and Statistics*, May 1987, pp. 286 – 295.

"Life Insurance Companies in a Changing Environment," (with Timothy Curry), *Federal Reserve Bulletin*, July 1986, pp. 449 – 460, reprinted in T. M. Havrilesky and Robert Schweitzer, editors, *Contemporary Developments in Financial Markets*, Harlan Davidson, 1987.

H. HEALTH CARE SPENDING AND FINANCING

"Projections of Health Care Expenditures as a Share of GDP: Actuarial and Economic Approaches," *Health Services Research*, 29(3), Summer 1994, pp. 293 – 313.

"Factors Contributing to Rapid Growth in National Expenditures on Health Care," in John Turner, William Wiatrowski, and Dan Beller, editors, *Trends in Health Benefits*, Washington, D.C.: Department of Labor, 1993.

"Recognizing Retiree Health Benefits: The Effect of SFAS 106," (with H. Fred Mittelstaedt and Carrie Cristea), *Financial Management*, Summer 1993, pp. 188 – 199.

"The Impact of Liabilities for Retiree Health Benefits on Share Prices," (with H. Fred Mittelstaedt), *Journal of Risk and Insurance*, 60(1), 1993, pp. 13 – 35.

"Retiree Health Benefits: Promises Uncertain?" *The American Enterprise*, July/August 1991, pp. 56 – 63.

"Postretirement Health Benefit Plans: Costs and Liabilities for Private Employers," Dwight Bartlett III, editor, *Corporate Book Reserving for Postretirement Health Care Benefits*, Homewood: Richard D. Irwin for the Pension Research Council, 1991, pp. 90 – 110.

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.)

A. Luncheon Speech for the Florida Council of 100, November 7, 2003, "Developments in U.S. Economy, and the Important Economic Role of Health Care and International Trade."

B. Statements for the Treasury Borrowing Advisory Committee of the Bond Market Assocation, November 3, 2003 (also July 28, 2003 and October 29, 2002).

C. Presentations on the Development of Insurer and Policyholder Surveys relevant to the Terrorism Risk Insurance Act of 2002, Risk and Insurance Management Society, North Central Regional Conference, October 23, 2003, and Alliance of American Insurers and American Association of Insurance Services Underwriting Conference, September 15, 2003.

D. Testimony before the Senate Special Committee on Aging, "The Administration's Activities to Improve the Retirement Security of Defined Benefit Pension Participants," October 14, 2003.

E. Testimony before House Financial Services Subcommittee on Oversight and Investigation, "Economic Impact of the Lack of Terrorism Risk Insurance," February 27, 2002.

F. Testimony before the House Budget Committee Task Force on Social Security, "The Use of Life Annuities in Individual Accounts under Certain Social Security Proposals," June 15, 1999.

G. Testimony before the Senate Special Committee on Aging, "The Use of Life Annuities in Individual Accounts under Certain Social Security Proposals: Implications for Women," February 22, 1999.

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

I am a creative, intelligent, and hard-working economist, with considerable management experience and a good reputation for fairness and intellectual rigor. I have a comprehensive theoretical and practical knowledge of many types of insurance, financial markets, institutions and instruments, pensions, Social Security, corporate finance, monetary policy, macroeconomic forecasting, and health care. I am well trained, through graduate education, in macroeconomics, microeconomics, public finance, and statistics. I have published extensively in high quality academic journals and other professional outlets. Through my formal education and work experience in both the private sector and federal government, I have a good understanding of, and respect for, the important and appropriate roles of markets, private institutions, and government programs and regulations. I have a strong desire to contribute my talents and energies to improve the performance of our economy and the lives of current and future Americans.

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 am currently employed by the U.S. Treasury Department. Otherwise, the answer is 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.

I have conducted economic research relevant to the reform minimum distribution requirements for retirement plans and Social Security.

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.)

If I were in such a position, I would immediately recuse myself from the matter and seek the advice of Treasury ethics officials. I would take any action(s) that they deemed appropriate.

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.

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.

COMMUNICATIONS

March 4, 2004

The Honorable Charles Grassley
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, encourages the Senate Finance Committee to approve the nomination of Mark B. McClellan, MD, PhD as the Administrator for the Centers for Medicare and Medicaid Services (CMS).

The new Administrator of CMS will be charged with operating the nation's most important public health programs and will be responsible for ensuring that our nation's most vulnerable patient populations have access to quality health care. Dr. McClellan's extensive knowledge, background, and experience in health care as both a health care practitioner and researcher, and currently as the Commissioner of the Food and Drug Administration, well suit him for this role.

APhA is pleased to provide the Committee with its support for Dr. McClellan's confirmation. Medicare reform and the implementation of the new Medicare prescription drug benefit—arguably the most significant change to the Medicare program since its inception—will be one of the Agency's largest challenges in recent history. We believe that Dr. McClellan is well positioned to assume this challenge and is poised to capably lead the Agency. APhA looks forward to working with the Administrator, once confirmed, to strengthen Medicare and Medicaid beneficiaries' access to valuable medications and pharmacist-provided patient care services.

Please feel free to contact Susan Bishop of my staff should you have any questions or require additional information. Susan may be reached at (202) 429-7538 or by e-mail at SBishop@APhAnet.org.

Thank you for your consideration of the views of the nation's pharmacists.

Sincerely,

John A. Gans, PharmD
Executive Vice President

cc: The Honorable Max Baucus
Susan K. Bishop, MA, APhA
Kristina E. Lunner, APhA
Susan C. Winckler, RPh, JD, APhA