

**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 anti-azathioprine, an immunosuppressant 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 Also found were drugs withdrawn from the U.S. market for safety reasons, improperly packaged drugs shipped loose in sandwich bags or tissue paper, and drugs with labeling not in English.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](http://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](http://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 rationale 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 effective 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 card 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 medication 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

illness and neurological diseases resulting in severe epileptic episodes under the new provisions 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 that Medicare beneficiaries have clinically appropriate access to pharmaceutical treatments for mental illness, including but not limited to schizophrenia, bipolar disorder, depression, anxiety disorder, dementia, and attention deficit disorder/attention deficit hyperactivity disorder and neurological illnesses resulting in epileptic episodes." My question, Dr. McClellan, is what steps you will take to assure that the above provisions will be implemented, by rule or regulation, so that each plan approved to offer qualified prescription drug coverage will be required to include a full complement of pharmaceutical treatments for mental illness (within their formularies or otherwise)?

**Answer:**

I thank you for this question about important beneficiary needs. Of course, we will give a careful review to all plans to make sure their formularies and other benefit designs meet the needs of all potential enrollees, including those with mental illness. Recall, that the law already requires plans to include drugs in every therapeutic category and class, so there will be a range of mental health drugs available in every case. Within sensitive categories, such as HIV/AIDS or mental illness we will apply a very strict review to make sure that beneficiaries are protected. I look forward to working with you further on this critical issue.

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.

**Questions Submitted By Senator Santorum**

**Question 1: Local and National Coverage Processes**

In an article entitled "Focus on Locus: Evolution of Medicare's Local Coverage Policy", published 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 also an appointed member of the Medicare Coverage Advisory Committee (MCAC) of CMS, concluded 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 decisions 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.”

Please provide your comments and opinions on the issues surrounding Medicare’s Local and National Coverage processes and the article’s conclusions.

**Answer:**

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.

Achieving balance and consistency between local and national coverage decisions is important, given the impact this has on beneficiary access to new technologies. Many in the drug and device industry strongly support the flexibility and speed made possible by the local coverage process. That process does sometimes lead to variation among local policies of different contractors. However, shifting too many policies to the national level will lose some of the benefits of local policy.

Several changes have occurred since the *Health Affairs* article was written that may affect the usefulness of its conclusions. Pursuant to BIPA 2000 and CMS regulations published in October 2003, there is now a process to appeal local coverage decisions to ALJs and the Departmental Appeals Board. This will increase the likelihood that local policies are developed with adequate scientific and clinical input, and also ensure that aberrant policies can be efficiently challenged and revised, if necessary. In addition, beneficiaries, clinicians, suppliers, manufacturers, or any other stakeholder may now request a national evaluation of a local coverage policy. Under the new Medicare bill (MMA), CMS has a six to nine month timeframe to complete national coverage reviews.

I believe the appeals mechanism, greater awareness of the option to request national review of local policies, and the new MMA timeframes will go a long way toward reducing the problems with local coverage identified in Ms. Foote's article.

**Question 2: Centers of Excellence**

Medicare/CMS has utilized the concept of “Centers of Excellence” in several Coverage Decisions, such as select transplants (i.e., intestinal transplants) and the Lung Volume Reduction Surgery, National Emphysema Treatment Trial (NETT).

Please provide your opinions on the selection and utilization of “Centers of Excellence” in the Medicare/Medicaid programs.

**Answer:**

In 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

limited organ supply is used by centers most likely to have successful outcomes. I understand CMS is developing a Notice of Proposed Rulemaking regarding criteria for approving transplant centers to further ensure that our procedures reflect the latest understanding of how to achieve the best possible results in solid organ transplantation.

In the case of lung volume reduction surgery, CMS is looking at a highly invasive procedure in a very fragile patient population with chronic obstructive pulmonary disease (emphysema). This is also the situation for implantation of left ventricular assist devices, which are only covered at certain specialized centers. Because the chance of helping such patients with surgery vs. hastening their death is highly dependent on the skill of the clinical teams providing care, we believe that limiting use of these procedures to highly qualified centers will best protect seriously ill Medicare beneficiaries. We plan to work with JCAHO to ensure that the criteria for identifying such centers are valid, practical and fair.

### **Question 3: Clinical Trials**

Medicare currently provides coverage for “clinical trials” under several regulations to include Medicare coverage of clinical trials and associated costs, and IDE – Category B coverage guidelines. However, industry has voiced concerns that the coverage parameters for “associated costs” of Medicare’s “deemed” clinical trials are ambiguous and inconsistent in their interpretation by Medicare contractors.

Please provide your opinion on if and how Medicare should appropriately define coverage for clinical trials.

#### **Answer:**

CMS intends to define the "associated costs" of clinical trials with sufficient precision to ensure reasonable consistency among contractors regarding how that concept should be interpreted. Given the high degree of variation between different trials, it would be difficult to provide explicit guidance on "associated costs" and still leave contractors the flexibility they need to address the unique circumstances of each trial.

CMS would be happy to meet with parties concerned about this problem to learn more about the perceived inconsistencies. We will then consider whether guidance on our clinical trials policies should be refined.

### **Question 4: Power Wheelchairs**

I am hearing from disability advocates and medical equipment suppliers about a new Medicare policy issued in December that will make it harder for seniors to qualify for power wheelchairs.

I understand that the new policy was issued as part of an effort to prevent abuses of the wheelchair benefit. I agree that we cannot tolerate fraud and abuse in the Medicare program. 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 though 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 in 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 30<sup>th</sup>, 2005 and the eight year phase out will end on September 30<sup>th</sup>, 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](http://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 than 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 in 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 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 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. 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 it 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 bud get 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 assess 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 two 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.