FINANCE COMMITTEE QUESTIONS FOR THE RECORD
United States Senate
Committee on Finance
Nominations Hearing
April 30, 2009

Questions from Chairman Baucus

Questions for Mr. Corr

Question 1:

HHS and CMS will need a strong team to help pass comprehensive health reform and maintain the operations of these vital departments. This will require innovative thinking and a lot of hard work. As we look to enact health reform later this year, what resources will HHS, and specifically CMS, need to implement reform legislation?

Answer: HHS, and specifically CMS, need dedicated funding to perform the analysis of various health care proposals and, after reform passes, to determine and evaluate the implementation of those policies. Resources to enable this are included in the FY 2010 budget. In addition, strong collaborative networks are needed among the various offices and agencies within HHS, among the Obama Administration, and with outside experts to encourage innovative ideas and enable rigorous analyses and applications of those ideas.

Question 2:

HHS has a wide variety of responsibilities that are crucial not only to Congress' health reform efforts, but our entire health care and human services system. I want to make sure going forward that this agency has the tools it needs to get the job done. In the past, the Office of Assistant Secretary for Planning and Evaluation (ASPE) has played an important role in policy development and research. What are your plans to return this office to this vital role the in the future?

Answer: The Office of Assistant Secretary for Planning and Evaluation will play a central role in the development, evaluation, and implementation of health care policy. If confirmed, I will work with Secretary Sebelius to ensure that adequate staffing and funding are available to ASPE to continue and expand its work, as well as encourage collaborations between ASPE and other HHS agencies, such as CMS. We aim to make ASPE a top-notch resource for policy development, for the Administration and Congress.

Question 3:

As we speak, many demo and pilot projects are being tested in the private sector that are looking at new and progressive ways to delivery high quality, low-cost health care.

A reformed health care system will require HHS and CMS to think just as creatively, and will require collaboration between the federal government and the private sector. How can HHS and CMS work with the private sector to harness innovation and pass on the dividends to the entire country?

Answer: As we work towards the goal of a high-quality, affordable, and accessible health care system, it is important to create and test new and better ways to deliver care. Rigorous analyses of efforts being made in the private sector and evaluation of the potential applicability of such innovations to the CMS population are important components of that work. It will be important for HHS, and CMS in particular, to constantly evaluate innovations in the private sector as they emerge, so that these innovations, where appropriate, can be harnessed for other parts of the health care system. If confirmed, I will work with Secretary Sebelius to make our public programs perform on par with the best private programs.

Question 4:

Over the last several years Congress has passed several laws for which ACF is responsible for implementing. Just last year we passed the Fostering Connections and Increasing Adoptions Act of 2008. This law is waiting for you at HHS and will require your immediate attention. As will the Recovery Act Emergency Contingency Fund.

Do you have the resources you need at ACF to turn your attention immediately to implementing these new laws? How will you address HHS's role in evaluating state performance in the critical programs run by ACF with current staffing levels?

Answer: First, I applaud your steadfast leadership in shaping our nation's child welfare policy. In particular, I appreciate the central role you played in drafting and passing the Fostering Connections and Increasing Adoptions Act in 2008. Like Secretary Sebelius, I fully recognize that the Department of Health and Human Services has a special responsibility to provide for some of our most vulnerable people, including abused and neglected children.

Please be assured the timely and effective implementation of the Fostering Connections and Increasing Adoptions Act will be a priority for Secretary Sebelius and me. If confirmed, I intend to work closely with HHS leadership to ensure there are adequate resources to implement this new child welfare law so that more children receive the benefit of a safe, loving, and permanent home.

Toward that end, I look forward to working with you to identify other opportunities to improve outcomes for children served by the child welfare system, as well as to increase adoptions.

Question 5:

The Office of Child Support Enforcement program now has a vast array of enforcement/collection methods at its disposal. In FY2008, the program collected $26.6 billion in child support payments and served nearly 15.7 million child support cases. In your view, what is the primary goal of the Office of Child Support Enforcement and are there new ways to partner with both custodial and non-custodial parents to meet those goals?

Answer: Again, I want to thank you and your Finance Committee colleagues for working to invest in the child support enforcement over the past several years. Your leadership has helped lead to record collections on behalf of children.

I believe the principal purpose of the child support enforcement program is to ensure that all children have the financial support of both parents, and child support payments are vital tool in helping meet the needs of low-income working families. I also believe the Office of Child Support Enforcement should continue to innovate and learn more effective ways to engage non-custodial parents in building skills and finding work opportunities to help meet the needs of their children.

Questions from Senator Grassley

Question 1:

In the 1980's, Congress enacted the Medicare Secondary Payer (MSP) statute that was designed to protect Medicare expenditures from waste and abuse when Medicare footed the bill for services, but another insurer was supposed to pay. The MSP statute provided a right of action to either the Department of Justice or to private litigants to file suit on behalf of Medicare. This law was based largely upon the successes of other *qui tam* statutes—such as the False Claims Act—and was designed to recover monies that Medicare wrongfully paid out. However, recent court decisions have held that the MSP statute is not a *qui tam* statute for the purposes of recoveries. As a result, any monies recovered by a plaintiff are theirs to keep and not required to pay back to the U.S. Treasury. This is an inaccurate reading of the statute and creates a result contrary to the purpose of the statute.

The Department of Justice filed a brief in the Federal District Court for the Western District of North Carolina as an Intervenor defending the constitutionality of a *qui tam* provision that allows relators to file suit on behalf of the Government for misuse of patent markings (35 U.S.C § 292).

In that brief, the Justice Department expressly stated that Congress has enacted several *qui tam* provisions and expressly noted that the MSP statute (42 U.S.C. § 1395y) provided a *qui tam* cause of action for "failure to pay primary health insurance claims where Medicare is the secondary payer." Based upon this statement, the Justice Department seems to agree that the MSP statute is a *qui tam* statute similar to those such as the False Claims Act.

- **Mr. Corr, do you believe that the MSP statute is a *qui tam* statute?**

  Answer: I understand that the question of whether the Medicare Secondary Payer (MSP) private cause of action is a *qui tam* provision has been the subject of consideration by multiple courts in recent years, and that all courts have ruled that MSP is not a *qui tam* provision. If confirmed as Deputy Secretary, I will carefully examine the issue, and consult with the Department of Justice where appropriate.

- **Will you support the use of the MSP statute and the *qui tam* mechanism in the statute to help Medicare recover monies expended when Medicare should have been the secondary payer?**

  Answer: As noted above, judicial precedent to date does not consider the MSP statue as containing a *qui tam* mechanism; I do not believe I am in a position to unilaterally second-guess that precedent. Having said that, as I mentioned in my answer to the previous question, if confirmed, I commit that I will carefully examine the issue in consultation with the Department of Justice.

- **Do you believe that the Government is entitled to a share of any monies recovered under the MSP statute given that the monies recovered were lost due to Medicare paying when a secondary payer should have footed the bill?**

  Answer: Since the MSP statute is designed to ensure that Medicare avoids making payments that the program is not required to make and can recover payments that should have been made by primary payers, yes, I believe that the government is entitled to a share of any monies recovered under the statute. The private right of action in the MSP statute is only one of several tools Medicare can use to recover payments that should have been made by primary payers.

- **Will you ensure that the goals of the MSP statute are not harmed by any regulations issued by the Department of Health and Human Services regarding secondary payer issues?**

  Answer: I support the stated goal of the MSP statute – to ensure that Medicare avoids making payments that the program is not required to make and can recover payments that should have been made by primary payers. If confirmed, I will work to uphold that goal.

Question 2:

As part of the Sentinel Initiative, I understand that a joint effort is underway between CMS and FDA to link Medicare Part D claims data to other sources of data to expand the quality and quantity of information available to help ensure the safety and effectiveness of drugs on the market. In January, Chairman Baucus and I along with Senator Kennedy, Senator Gregg, and several Members of Congress sent a letter to HHS urging the Agency to fully explore the legal and public policy issues that may be associated with the use of these data sources.

- **Will you commit to ensuring the successful development and implementation of this initiative?**

  Answer: Improving information for patients and providers about drug safety and effectiveness is a priority for HHS, and the Sentinel Initiative reflects that commitment. Drug safety and effectiveness have significant implications for both health outcomes and the cost of care, and more attention is needed in these areas. If confirmed, I will work with the Secretary and the leadership at CMS and FDA to further develop and refine this initiative and other related efforts. In addition, I would note that this Initiative is an excellent example of the type of cross-agency collaboration and coordination that the Secretary hopes to foster across HHS.

Question 3:

Over the years, I've conducted oversight of publicly-funded Quality Improvement Organizations, or "QIOs." These organizations are supposed to ensure medical care is reasonable and medically necessary, provided in the most economical setting, and meets professionally recognized standards. These organizations receive over $300 million every year from American taxpayers. Yet it's difficult to measure what effect, if any, their existence has on medical care. Furthermore, as my investigations have uncovered, some of these organizations are plagued with waste, improper expenses, conflicts of interest, and other problems. Yet, in my experience, there is little to no oversight of these organizations by CMS. Even when problems are discovered, there are no repercussions and scopes of work are renewed as if it was a foregone conclusion.

- **How will HHS ensure that CMS has appropriate oversight in place to ensure that the QIOs are accomplishing the tasks given to them, and doing so in an efficient and ethical manner?**

- **If confirmed, will you pledge to hold QIOs accountable when they are found to have wasted taxpayer money and failed to perform the duties and activities as outlined in their scope of work?**

  Answer: The Administration supports the use of Quality Improvement Organizations (QIOs) as part of the effort to improve the quality of care for Medicare beneficiaries. As you know, QIOs work with stakeholders to refine health care delivery systems to ensure that patients – particularly those who are members of underserved populations – get the care they need when they need it. QIOs also investigate complaints from beneficiaries.

  If confirmed, I will work to ensure that CMS holds all Medicare contractors accountable, including the QIOs. I understand that CMS has built an information management system that is designed to improve oversight of the program and help the Agency monitor how QIOs are performing. I also understand that CMS has policies in place that address potential conflicts of interest by QIO contractors. If confirmed, I am committed to working with Congress to ensure that QIOs do the job they were intended to do efficiently and effectively, and to take appropriate action when they do not.

Question 4:

In America today, there are over 1.7 million elderly and disabled individuals in roughly 17,000 nursing home facilities. This number is going to grow by leaps and bounds as the baby boomer generation ages. Unfortunately, as in many areas, with nursing homes a few bad apples often spoil the barrel. Too many Americans receive poor care, often in a subset of nursing homes. Unfortunately, this subset of chronic offenders stays in business, in many ways keeping their poor track records hidden from the public at large, and often facing little or no enforcement from the federal government. In the market for nursing home care, like in all markets, consumers must have adequate data to make informed choices. To this end, last Congress I introduced legislation requiring greater transparency regarding nursing home staffing, ownership, whether a home has been cited for deficiencies, and other measures.

- **If confirmed, will you support greater transparency in the nursing home industry regarding nursing home ownership, staffing, and quality?**

  Answer: Yes. I know that assuring the quality of care, transparency, and accountability in nursing homes has been a top priority of yours for many years. I share your support for greater transparency in the nursing home industry, and, if confirmed, I look forward to working with you on this important issue.

- **CMS recently launched the Five-Star Quality Rating System in an effort to bring about greater transparency regarding quality of care. While this is a good beginning, the system will need a lot of work to ensure that the information presented online is useful and gives the full picture about a nursing home. Will you direct CMS to work with my office and others to continue to improve this program?**

  Answer: As you know, CMS created the Five-Star Quality Rating System to help consumers and caregivers to more easily compare and decide between different nursing homes. If confirmed, I look forward to working with your office and others to continue to improve the quality and safety of our nursing home care through programs like this.

Question 5:

In September 2008, the GAO reported that the FDA inspects relatively few foreign establishments each year to assess the manufacturing of drugs currently sold in this country. GAO also estimated that the FDA inspects about 8 percent of foreign establishments in a given year and that based on this rate, it would take the FDA more than 13 years to inspect these establishments once. Furthermore, for establishments that were inspected and found to be deficient, FDA's follow-up inspections were not always timely. According to the GAO, most of the foreign drug establishments to which FDA issued 15 warning letters had previously been found by the agency to be out of compliance with Good Manufacturing Practices.

Similarly, the GAO testified in May 2008 that FDA conducts relatively few inspections of foreign establishments that manufacture medical devices – about once every 6 years for high-risk devices and about once every 27 years for medium-risk devices.

- **What steps would you take as Deputy Secretary to ensure appropriate oversight by the FDA of foreign establishments that manufacture drugs and medical devices for the U.S. market?**

  Answer: If confirmed as Deputy Secretary, I look forward to working with the President and Congress to provide FDA with the resources it needs to meet its oversight responsibilities. In addition, I would work with FDA to ensure that it is using its inspectional resources wisely.

- **What, in your opinion, are important steps that the FDA should take to enhance its foreign inspection program?**

  Answer: As I mentioned in my answer to the previous question, I believe FDA must use its inspectional resources wisely. Specifically, I believe it can (1) expand its efforts to apply a risk-based approach when determining where and when to conduct inspections, (2) establish, where appropriate, dedicated inspectorates for the products it regulates, and (3) work with foreign allies to more effectively use the information they gather through their own inspections to help target FDA's resources efficiently.

- **What do you believe is the Department's role in ensuring the safety of drugs and devices that enter the U.S. market?**

  Answer: I believe the role of the Department generally and FDA specifically is to ensure that foreign facilities manufacture high-quality FDA-approved drugs and devices for the U.S. market.

Question 6:

On January 15, 2009, the GAO issued a mandated report on the FDA's premarket review of medical devices. Under the Medical Device Amendments of 1976, class III device types in commercial distribution before May 28, 1976 were allowed to be cleared for marketing under FDA's less stringent 510(k) review process. Devices substantially equivalent to these device types could also be cleared through the 510(k) process. According to the FDA, class III devices are devices (1) for which insufficient information exists to assure safety and effectiveness solely through general or special controls and (2) that are life-supporting or life-sustaining, are of substantial importance in preventing the impairment of health, or present a potential, unreasonable risk of illness or injury, such as pacemakers and heart valves. The Safe Medical Devices Act of 1990 required FDA to issue regulations before Dec. 1, 1995 (1) reclassifying class III device types that were on the market before May 28, 1976 as class I or II devices or (2) requiring those device types to remain as class III. In addition, the legislation required FDA to issue regulations requiring the submission of premarket approval (PMA) applications for the class III device types not reclassified as class I or II. The GAO found that after the passage of more than 14 years, FDA has yet to complete the tasks specified by the Safe Medical Devices Act. As a result, some high risk devices may be cleared with less stringent review by the FDA. The GAO recommended that the FDA "expeditiously take steps to issue regulations for class III device types currently allowed to enter the market via the 510(k) process."

In April 2009, the FDA announced that it is taking steps to complete the review of these class III devices and issued an order for 25 manufacturers to submit safety and effectiveness information to the agency for their class III devices that were marketed in the U.S. prior to the Medical Device Amendments of 1976.

- **What steps would you take to ensure a thorough review of the new data by the FDA?**

- **How will you ensure that FDA promptly identifies the devices that will require submission of premarket approval applications?**

  Answer: Pre-market approval applications will provide FDA the opportunity to review important data about marketed devices. I am pleased that this review, long overdue, is finally underway. I will work with the new FDA Commissioner and Principal Deputy Commissioner to ensure that FDA implements the review effectively. This is a very important process, and it is critical that FDA follow through.

Question 7:

The FDA regulates the promotion of off-label uses of drugs and devices to ensure that promotional materials are not false or misleading. But the GAO reported last year that not only does the FDA not screen all promotional materials but the agency also lacks a system that consistently tracks the receipt and review of promotional materials submitted to the FDA.

In comments to the GAO, FDA disagreed with GAO's recommendation to establish a tracking system to facilitate a more systematic approach to FDA's reviews of promotional materials and enhance its monitoring and surveillance efforts by providing data on materials reviewed and the findings of those reviews. What is your position on GAO's recommendation?

Answer: As you well know, one of the key responsibilities of the FDA is to oversee the promotion of drugs and devices. Like you, I am concerned about dissemination of false or misleading promotional materials, which can lead to misinformed and misguided decisions by patients and practitioners regarding the selection and use of medical products. I am interested in hearing any ideas you and others may have about improvements to FDA's regulation of medical product promotion. If confirmed, I will work with the new FDA Commissioner to ensure that the agency appropriately oversees promotional materials for medical products.

- **What steps would you take as Deputy Secretary to ensure appropriate oversight of off-label promotion by the FDA?**

  Answer: Off-label promotion is of concern both because it can lead to inappropriate use of prescription drugs and because it can unnecessarily drive up the cost of health care. This is an important issue for FDA, and, if confirmed, I look forward to working with a new FDA Commissioner and Principal Deputy Commissioner to review and improve the agency's current oversight efforts.

- **How will you ensure that FDA has the resources it needs to improve its oversight?**

  Answer: It is critical that the FDA has the necessary resources to properly oversee the promotion of off-label uses of drugs and devices. Identifying where the agency is most in need of resources and working to improve the effectiveness and efficiency of these programs are fundamental to ensuring that the FDA is protecting the health and safety of the American public. If confirmed, I would look forward to working with you and others in Congress to ensure that the FDA has the resources it needs to achieve these goals.

Question 8:

In April 2008, the Journal of the American Medical Association published troubling findings regarding the maker of the painkiller Vioxx. Based on a review of documents from recent litigation involving that drug, the authors of those articles concluded that the maker of Vioxx was not forthcoming in its communication with the FDA about the mortality risks seen in clinical trials of Vioxx conducted in patients with Alzheimer disease or cognitive impairment.

In addition, FDA has stated that companies that are legally required to register with the FDA and list all of their products in commercial distribution do not always list all products or update their listings; thus FDA does not have a complete and accurate list of products on the US market, including unapproved drugs. Without complete and accurate information, the FDA cannot take appropriate enforcement actions.

On April 23, 2009, Senator Kennedy and I introduced the Drug and Device Accountability Act of 2009 to expand the FDA's authority for ensuring the safety of drugs and medical devices in the US market, including foreign-produced drugs and devices, and augment the agency's resources through the collection of inspection fees. One of the provisions in DADAA requires senior officers in drug and device companies to certify to the FDA that none of the information and data that they submit to the agency is false or misleading. False or misleading certifications could be subject to civil as well as criminal penalties.

- **What is your position on a certification requirement for drug and device manufacturers and their senior officers who are responsible for submitting a drug or device application or supplement, reporting a safety issue, submitting clinical trial data and submitting updated information regarding their products in commercial distribution?**

  Answer: I believe FDA should have an effective enforcement mechanism to use when drug or device companies submit false or misleading information to the agency. If confirmed, I look forward to working with you, Senator Kennedy, and others to ensure the FDA has the necessary tools to address unlawful information submissions to the agency.

- **What is your position on holding the responsible senior offices criminally and/or civilly accountable for the information they provide to the FDA on behalf of a drug or device manufacturer?**

  Answer: I agree with you that industry should be held accountable for submitting false or misleading information to FDA. If confirmed, I look forward to working with you, Senator Kennedy and others on any additional requirements that should be imposed on industry to ensure FDA receives truthful and non-misleading information.

Question 9:

Practicing physicians receive billions of dollars every year from pharmaceutical and medical device companies. This money is passed along as consulting agreements, funding for research, and speaking fees. There're mountains of evidence to suggest that these relationships can have an effect on physician practice – on what drugs a doctor prescribes, or what device a surgeon implants. Only a few states have laws that let patients know if their doctors are taking this money. And when a doctor reads a journal article they do not know if this money may have tainted the research. Universities don't even know if their professors are taking this money which puts them in a tough spot when trying to comply with NIH regulations on conflicts of interest.

To bring some transparency to this issue, Senator Kohl and I have introduced the Physician Payments Sunshine Act, a bill that will require companies to report to the Department of Health and Human Services any financial relationships they have with physicians. The Department will then place these payments online, on an easy to read website. Physician Payment Sunshine provisions are currently being considered by the Committee as part of its efforts to transform health care delivery systems.

I believe that sunshine is the best disinfectant, and that a little bit of sunshine and transparency on these payments will go a long way to cure improper without burdening those that benefit the public and the health care system.

- **If confirmed, how would you ensure that the NIH and FDA take conflicts of interest seriously in federal grants and drug trials?**

  Answer: We must ensure that the public interest is always put first. If confirmed, I will work to ensure that conflicts of interest are taken seriously by all HHS departments and agencies. However, we need to be careful not to create a situation where our scientists are discouraged from sharing information or collaborating with others, including with the private sector. I do not believe that it is in our nation's best interest to create a world where university and government scientists are completely isolated from industry scientists.

  I share the President's and the Secretary's view that transparency, particularly with respect to financial and personal relationships that could potentially influence decisions made by the Department, is the key to avoiding conflicts of interest. If confirmed, I will work with Secretary Sebelius and Congress to promote such transparency, and to ensure thorough review of any and all situations where there is a real or perceived conflict of interest.

- **Do you agree that more transparency is needed in the financial relationships between practicing physicians and drug and device companies? If so, do you support federal legislation establishing this transparency?**

  Answer: Secretary Sebelius and I both believe that it is essential to promote transparency in the relationship between practicing physicians and drug and device companies. If confirmed, I will commit to examining this issue more closely, and working with you and others in Congress to develop legislative solutions where appropriate.

Question 10:

For years, I've been an advocate of whistleblowers. Too often, federal whistleblowers sacrifice their employability, their family's finances, and even their good names in order to bring to light fraud, waste, abuse, and other wrongdoing within the federal government. In fact, I've long said that the President of the United States ought to have a Rose Garden ceremony honoring whistleblowers. What a powerful message that would send to the bureaucracy and bad apples within government.

- **What steps would you take as Deputy Secretary to ensure that whistleblowers within the FDA, NIH, CDC and other agencies are protected, and that the claims they bring to light are seriously investigated?**

  Answer: The role that whistleblowers play in protecting the public interest cannot be underestimated, and Secretary Sebelius and I share a commitment to protecting these individuals. Each agency should have a clear process for investigating concerns of whistleblowers and making sure that they are not subjected to any kind of penalty or retaliation. If confirmed, I will insist that this important issue be addressed.

- **Will you advise HHS federal employees that they are free to come to Congress and discuss their concerns with Congress regarding the operation and activities of HHS? Yes or no? If not why not? If yes, when will you do that?**

  Answer: I support HHS cooperation with Congressional investigations. Congress plays an important oversight role to ensure that the public interest is protected and prioritized.

  If I am confirmed, I will also make it a priority for concerns about agency function to be handled appropriately by the agencies themselves in the first instance. Each agency must have a clear and credible process for listening to and investigating concerns raised by any of its employees, and each agency should make this process accessible to all of its employees. Each agency also has an OIG that can review complaints raised by anyone in the Department.

Question 11:

Beginning last summer, I have uncovered several incidents where prominent physicians taking grants from the National Institutes of Health (NIH) failed to follow NIH policies on conflicts of interest. As reported in the New York Times on June 8, 2008, I uncovered a physician at Harvard who is receiving NIH grants but had reported only a fraction of his outside income. On October 3, 2008, the New York Times reported on a physician at Emory University who had failed to notify Emory that he was receiving large payments from a pharmaceutical company while also receiving an NIH to study that company's drug. Even before I began my investigation, the Inspector General released a report in January 2008 noting that the NIH does not track these conflicts and does not know how they are resolved.

- **Describe what you think would be an appropriate conflict of interest policy for NIH grantees.**

  Answer: I know that NIH is fully committed to its oversight activities to prevent financial conflicts of interest. It is vital to the mission of NIH that it maintain objectivity in research, and the agency takes its responsibility to provide oversight of extramural investigators' conflicts of interest very seriously. NIH is at the forefront of an initiative to reexamine the existing regulation to facilitate regulatory compliance and effective oversight.

  In that effort, NIH, on behalf of the Department and PHS, developed an Advanced Notice of Proposed Rulemaking (ANPRM) to create an open dialogue with all affected parties on the complex issues surrounding financial conflicts of interest (FCOI). The ANPRM will invite public comments on the possibility of revising the FCOI regulation, and was crafted to highlight areas in the current regulation where there may be inherent weaknesses.

  I support these efforts by NIH, and I agree that it is time to reexamine the current FCOI regulation. If confirmed, I look forward to exploring this and other ways to ensure that PHS-supported research is conducted in a fair and unbiased manner.

My investigations have uncovered several cases where a grantee did not report their conflicts of interest as required under the current regulations.

- **What types of penalties would you put in place for grantees who failed to report their outside income when taking NIH grants?**

  Answer: It is simply unacceptable for bias to be injected into the process of awarding NIH grants, and NIH has shown that it will not tolerate it. In fact, NIH has suspended one grant at an institution because it did not comply with the requirements of the FCOI regulation. Additionally, NIH-wide special reporting requirements have been imposed to strengthen the current administrative process by which NIH identifies and then manages, reduces, or eliminates conflicting interests at a grantee institution.

  It is my understanding that, when an institution fails to comply with the terms and conditions of an award and does not demonstrate compliance with the federal regulations, Departmental policy grants NIH the authority to impose a whole range of enforcement actions. The enforcement action that is ultimately taken depends on the severity and duration of the non-compliance, and NIH will undertake any such action in accordance with applicable statutes, regulations, and policies. If confirmed, I will work with the Secretary and NIH officials to ensure that the agency takes appropriate enforcement actions in these cases.

According to documents I released in a congressional hearing, Emory University concluded in 2004 that Dr. Charles Nemeroff violated their IRB policies. Further, staff with the Office for Human Research Protection (OHRP) informed my investigators that they only investigate a handful of violations each year.

- **Please provide details of how you plan to strengthen human subject research protection in clinical trials.**

  Answer: It is my understanding that OHRP actually does evaluate every llegation of non-compliance that it receives. These evaluations determine whether the allegation provides credible evidence of non-compliance and whether it is within OHRP's jurisdiction. Whenever an evaluation finds that there appears to be such evidence, OHRP opens a compliance case and fully investigates.

  I have been advised that the number of compliances case each year, while relatively small, reflects the number of complaints being made to OHRP. Additionally, OHRP also opens a handful of not-for-cause reviews of institutions each year.

  Having said that, I believe that there is room to improve protections for research subjects. If confirmed, I will examine this issue closely and work with Secretary Sebelius to strengthen these protections.

On April 25, 2007, Senator Baucus and I released a report on industry influence on Continuing Medical Education (CME).

- **What steps will HHS take to ensure that CME is practiced in a way that is educational for doctors and free of industry bias?**

  Answer: As you may know, recently enacted legislation has directed OMB's Office of Federal Procurement Policy (OFPP) to develop and implement conflict of interest acquisition guidance for all federal agencies. If confirmed, I will look forward to working with OFPP to implement policies that avoid the conflicts of interest you have described. A major component of avoiding significant conflicts is insistence on full public disclosure of all such relationships. Case-by-case review of any situation that is not completely straightforward would ensure that we manage conflicts that arise from legitimate interests, and prohibit interests that do not further the mission of HHS.

Questions have also been raised regarding conflicts of interest in outside contractors hired by HHS. In some cases, contractors were doing work for companies while also performing regulatory work for the government on the products of these same companies.

- **As Deputy Secretary of HHS, what types of policies would you put in place to ensure transparency and reporting requirements regarding outside contractors and their conflicts of interest?**

  Answer: In addition, I understand that recently issued guidance requires government contractors to establish and maintain specific internal controls to detect and prevent improper conduct in connection with government contracts or subcontracts. It is the contracting officer's responsibility to validate that the contractor has established an appropriate internal control system within a designated time frame. If confirmed, I will work to ensure this guidance is implemented and enforced.

Question from Senator Wyden

Question 1:

What do you think should be the Department's ground game for dealing with an outbreak such as the swine flu? Tell us about some of the steps you would like to see the Department take when coordinating with state and local governments on how to implement an effective policy to contain a similar kind of outbreak?

Answer: When dealing with an outbreak such as the 2009 H1N1 flu, I believe HHS's goals should be to communicate information quickly and clearly, both to the public and to state and local governments; to rapidly address any new cases that emerge; and to have the capacity to effectively limit the spread. Fortunately, I believe the Department is doing an excellent job in each of these areas with respect to the current outbreak.

To date, HHS and the federal government have taken aggressive actions to monitor the H1N1 flu virus outbreak and protect public health. First, in order to ensure that our nation mobilizes the resources and assets needed for this developing situation, on April 26, HHS issued a nationwide Public Health Emergency declaration, which provides necessary authority for the Department to take prevention and mitigation activities. The Secretary has already exercised this authority to direct the Food and Drug Administration (FDA) to issue emergency use authorizations of drugs, devices, or medical tests under certain circumstances.

Second, the Food and Drug Administration, Biomedical Advanced Research and Development Authority, the National Institutes of Health, and the Centers for Disease Control and Prevention are working together to develop a vaccine precursor that could be used to develop a vaccine for this H1N1 flu virus.

Third, the federal government has released 11 million of the 50 million antiviral treatment courses in the Strategic National Stockpile to states to augment their own stockpile of medications and supplies needed to fight this outbreak. HHS anticipates that all 50 states will have received their share by May 3.

Fourth, CDC health officials have been deployed to California, Texas, and Mexico to support investigations into the H1N1 flu virus outbreaks, and to communicate and advise Americans on what they can do to protect their health.

Finally, HHS's many operating divisions, including CDC, NIH, the Administration on Aging, the Health Resources and Services Administration, the Indian Health Service, and HHS Regional Offices have all taken additional steps to provide the public with information regarding the H1N1 flu virus, make assistance available to vulnerable populations, and ensure our nation's health facilities are prepared.

There is no question that the situation is still very serious. However, I believe that the preparations made by the Department and its divisions over the past several years and the actions they have taken since the first cases of flu were detected are representative of what government should be doing in this and similar situations.

Questions from Senator Stabenow

Question 1:

Health quality: Recently Health Subcommittee Chair Rockefeller held a hearing on health quality. Part of the hearing focused on the diversity of quality standards even within the federal government.

With Secretary Sebelius, what would you do to help streamline or coordinate quality standards within HHS? For example, the Agency for Healthcare Research and Quality has been working with the Michigan Hospital Association to expand a program called Keystone into ten new states to reduce hospital acquired infections in intensive care units. This project uses evidence-based standards and looks at changing the culture of hospitals to reduce infections. In other words, people are not accepting that infections are just a part of running a hospital—we really can reduce them even to zero in some cases.

I recently learned that AHRQ is even planning to expand this project beyond the first ten states. But I have also learned that CDC has its own standards and its own surveillance program on infections. As deputy secretary, how will you work to coordinate the different agencies that are doing great work on quality? It seems to me the various divisions of HHS should be complementing each other in these efforts to promote quality.

> **Answer:** Coordinating and standardizing quality measures will improve health system performance. It will simplify provider paperwork, focus efforts, and encourage competition on quality. If confirmed, I will work with Secretary Sebelius, Congress, and experts both within HHS and outside of the Department to develop a set of measures that can be used to effectively measure and improve the quality of health care providers. Similarly, various agencies within HHS will need to be coordinated in their efforts to improve health care quality and outcomes. Collaboration and integration of the various perspectives and ideas that currently exist is important to achieving this goal.

Question 2:

Office of Generic Drugs: I am very concerned about funding for the Office of Generic Drugs at FDA. I recognize that part of the blame is on us in our appropriations process, which is why I am urging the Appropriations Committee to include at least $15 million for this important office.

As you are working with Secretary Sebelius on priorities for the HHS budget request, will you make funding this office a priority? Increasing the availability of generic drugs will have a huge impact on the federal budget in helping keep Medicare Part D and Medicaid costs down.

Additionally, I hope FDA will work with consumer groups, businesses, insurers, and states to educate people about the safety and high quality of generic medicines.

Answer: I agree with you about the importance of increasing the availability of generic drugs, including by ensuring that people have accurate information about the safety of generics, and by changing regulatory policies that delay their introduction into the market. I also understand the need for the Office of Generic Drugs to have adequate resources to keep pace with incoming applications and other matters within its purview. If confirmed, I look forward to working with the Secretary, the new FDA Commissioner, and Congress to strengthen this office.

Question 3:

Health IT: I am very concerned about the potential for a digital divide in health IT. Recently, I met with a group of community mental health providers who were not sure how they would be able to connect electronically with other area providers to share information securely. This is critical because we need to be able to better integrate physical and mental health care, and allowing providers to securely share information is a key part of this effort.

As deputy secretary, how will you work toward ensuring that we can ensure that our safety net providers-- such as community mental health centers, community health centers, school-based clinics, and rural health clinics just to mention a few—are not left behind as we wire and modernize our health system? I am sure given your work in Tennessee and Kentucky in primary care, this must be a concern for you, too.

Answer: It is critical that all providers, and their patients, are part of a modernized healthcare system. Community health centers, rural clinics, and substance abuse and mental health services providers all deliver critical safety net care in our communities and need to be integrated into a nationwide, interoperable health IT infrastructure. These providers want to adopt health IT, but often do not have the ability to invest upwards of $40,000 in the technology systems.

As you know, the Recovery Act gives HHS the tools to help reduce this burden by providing financial assistance for adoption and use of interoperable HIT. First, the Recovery Act authorizes grant and loan programs, as well as education and technical assistance opportunities, to help providers overcome barriers to adoption and assist them in using these systems to reduce costs and improve quality for their patients. In addition, the Recovery Act provides incentive payments through Medicare and Medicaid for the meaningful use of health IT. Safety net providers serve a disproportionate share of Medicaid patients, making this a critical tool for ensuring their inclusion in a modernized healthcare system. Finally, the Recovery Act provides an additional $2 billion for the Community Health Center program, which will support increased services, desperately needed construction and renovation, and purchase of health IT systems.

Question 4:

Islet Cell Research: Over five years ago, the Medicare Modernization Act of 2003 included a provision directing CMS and NIH to conduct pancreatic islet transplantation studies which included Medicare beneficiaries. Islet transplantation is an investigational procedure for people with type 1 diabetes that provides working cells to replace the damaged insulin-producing cells. We hope this research will lead to treatment options to help prevent costly long-term complications such as kidney disease, blindness, nerve damage, and cardiovascular disease.

I was a co-sponsor of the initial legislation in 2003. This study has not been completed more than 5 years after enactment of the Medicare bill and this provision. In fact, this important research has been repeatedly delayed because of the cost structure for organ procurement that CMS put into place in 2005. I want to be sure that federal agencies, such as CMS, take the law and Congressional intent very seriously. What will you do to assure that this important islet transplantation research takes place?

Answer: The important issue of Islet Cell Research and Transplant has long been an item of discussion between CMS and NIH. I share your concern about the need for research into kidney disease and related disorders, and, if confirmed as Deputy Secretary, I am committed to learning more about this issue.

As you know, the MMA requires Medicare to pay for the "routine costs as well as transplantation and appropriate related items and services" incurred on behalf of Medicare beneficiaries participating in the NIH clinical trial of islet cell transplantation. The Centers for Medicare & Medicaid Service (CMS)' current reimbursement rate for human pancreatic islets reflects the routine costs including costs for immunosuppressive drugs, follow-up care, costs of the islet cell isolation for the clinical trial, and the pancreata that are procured for the transplants. It has been suggested that CMS allocate a lesser amount for the costs of such pancreata because the current rate structure results in a higher cost for obtaining all organs from a given donor, for all payers. However, reducing the reimbursement rate for human pancreatic islets will not adequately cover the costs incurred for Medicare beneficiaries, and would thereby violate the statutory requirement that Medicare costs not be shifted to other insurers. As a result, CMS has recommended that additional funding be provided to cover these costs at comparable rates for non-Medicare participants in the NIH clinical trial.

Question 5:

CMS Nursing Home project: Recently I have heard some questions about CMS's "star" rating system for nursing homes. How did this program develop, and what input did nursing homes provide in developing the criteria?

Answer: Like Secretary Sebelius, I am committed to assuring the quality of care, transparency, and accountability in nursing homes. Consulting with a panel of experts from academia, patient advocacy and nursing home provider groups, CMS developed a rating system for nursing homes. Specifically, in December 2008, CMS launched the Five-Star Quality Rating System to help consumers and caregivers to more easily compare and decide between different nursing homes. Data, upon which the Five Star is based, has been publicly available on Nursing Home Compare since 2002. Nursing Home Compare represents an important information source for beneficiaries and their families when making as critical a decision about where to receive care.

It is my understanding that CMS intends to increase the usefulness of the CMS Nursing Home Compare website to consumers, family members, and the general public. We can continue to make strides in improving measurement, reporting, and ultimately the quality of care in America's nursing homes. If confirmed as Deputy Secretary, I look forward to working with you to identify areas of further transparency and improvement.

Questions from Senator Snowe

Question 1:

The Medicare Rural Hospital Flexibility Program (MRHFP) establishes a new designation for limited-service hospitals called critical access hospitals (CAH) to assist small rural hospitals having financial difficulty. CAHs are distinguished by several features including distance to nearest hospital, average daily census and operating margin. Hospitals that may quality for CAH status tend to have lower volume and report poorer operating margins than other rural hospitals. Furthermore, research has shown that that the mileage requirements significantly impact the number of potential CAHs. One study suggested that only one of out nine of the hospitals that might be eligible if certified by the state as "necessary providers" regardless of distance to the nearest hospital meet the mileage criterion. The Medicare Rural Hospital Flexibility Program is designed to prevent small, isolated hospitals from closing and thus to ensure continued access to care for rural residents. However, given the number of potentially needy hospitals that are excluded by the mileage requirement participation will clearly hinge on the flexibility *of the program* and the ability of states to determine "necessary providers."

Given that many rural areas are difficult to navigate due to weather, road conditions or speed limits, it seems that a mere assessment of the number of miles between two hospitals is an inadequate picture of the delays that an individual may face when trying to access health care. For instance, a patient needing to travel 15 miles to the nearest hospital on a road with a 20mph speed limit would find access to that hospital restricted. Under such conditions, should these factors be taken into account? Are there alternatives that we should consider – for instance, a calculation of the time that it takes to travel whether than just a mileage count.

Answer: The Department of Health and Human Services' ability to certify hospitals as "Critical Access Hospitals" has enabled hundreds of rural hospitals to remain in operation. As a result, rural communities across the nation have access to a nearby hospital, and, without this program, millions of rural residents would have to travel great distances to receive vital care. We should continue to find ways to strengthen rural hospitals and, in turn, rural communities.

Under the program's current requirements, a Critical Access Hospital must be at least 35 miles from another hospital (or 15 miles from another hospital in mountainous terrain or areas with secondary roads). While, because Critical Access Hospitals are exempt from Medicare's prospective payment systems, I believe we should be cautious about relaxing this mileage requirement, I also understand that access is about more than just distance.

If confirmed, I pledge to undertake a review of the Critical Access Hospital program, working with the leadership of the Centers for Medicare and Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA). I also look forward to working with you and your colleagues in Congress in the effort to ensure our nation's rural hospitals are as strong as possible, and to address any specific issues of limited hospital access in accordance with our legislative and regulatory requirements.

Question 2:

As we are all aware, the shortage of health care workers in rural areas is due to several reasons including: an aging workforce population; difficulty in retention and recruitment of workers; lack of educational and training opportunities; high vacancy and turnover rates; lack of opportunities for career advancement; financial concerns including lower pay and benefits; and increased work load demand.

Rural health care workforce shortages have a negative impact on health care quality across the board from primary care— to emergency care – to tertiary care, through reduced health care access and increased stress on providers. Shortages not only contribute to higher costs by raising compensation levels to reflect increased demand but also by increasing the use of overtime pay and expensive temporary personnel. As I am sure you are aware from your work on primary care issues in rural Tennessee, having to travel long distances to reach health care facilities— especially to tertiary care hospitals—and scarcity of a variety of specialists discourage providers from practicing in remote rural locations.

One of the critical issues that we need to understand better is whether increasing the size of rural generalist residency training programs will yield an increase in rural providers that justifies the expense? And secondary to that, is whether the National Health Service Corp is more cost effective in producing rural physicians than simply expanding residency training programs— particularly only 2 percent of medical school graduates are choosing primary care and when primary care slots are increasingly being filled by foreign medical graduates?

Answer: There is no question that our country faces a shortage of primary care providers in rural areas, including both doctors and nurses. I agree that we need to learn more about the most effective and efficient ways to attract providers to rural areas. The questions you raise will be critical as we work to ensure that all Americans have access to primary care providers – a fundamental component of the effort to reform the healthcare system to expand coverage, improve quality, and reduce costs.

While primary care providers are important from the perspective of improving access, we also know that a strong primary care presence is associated with higher health care quality and lower health care costs. As you well know, there are a number of avenues to attract, train, and retain primary care providers, including traditional medical school programs and the National Health Services Corps.

Within these programs, we can address the current shortage by providing more scholarship and loan repayment support. We also have to revamp our payment systems to dramatically increase reimbursement for primary care services and primary care providers.

Follow up: Can generalist physicians be fiscally rewarded enough to practice in adequate numbers in small and remote rural towns? Alternatively, are resources better directed to increasing the supply of allied health professionals in these communities? What does that mean for standards of care?

Answer: As your question suggests, it is critically important that we determine the most appropriate vehicles for ensuring access to providers in rural areas. Allied health professionals, physicians' assistants, and advanced practice nurses could play an important role in delivering care in rural and frontier areas. It will be important to thoroughly explore this issue as we work to expand health insurance coverage and improve the quality of care in the system.

In addition, we also need to improve primary care practice by helping small and solo group practices, especially those in rural areas, to afford health IT systems and support personnel who can handle care coordination and case management – services that we know will both alleviate the burden on providers and improve the health outcomes for patients.

Question 3:

Experts will tell you that as many as one in four doctor's-office visits are "social calls," and nearly half of emergency room visits are for care that could have been handled in a nonemergency setting. These are surely factors that drive health care costs up. However, the real truth about health care costs is that 20 percent of patients account for 80 percent of spending, and that 20 percent is made up mostly of the chronically ill. These patients are often dealing with multiple conditions— such as diabetes, heart disease, and high blood pressure— and more than half of the money we devote to caring for them is spent when they are in the hospital. Clearly, one place where we can see an inordinate amount of savings is pushing the focus of care from tertiary settings to primary care and preventing that initial hospitalization.

I have heard for years from Medicare beneficiaries who recognize the value of periodic exams and they are perplexed why an annual exam isn't a covered benefit. I appreciate that under the Medicare Modernization Act we in fact finally saw the institution of a 'Welcome to Medicare' exam, but isn't there substantial evidence of the benefit of an annual physical and consultation in older Americans?

And wouldn't such a benefit – with substantial reimbursement linked to performance of recommended preventive and management actions – be a step we could take to see some timely progress in preventing unnecessary hospitalizations and managing chronic diseases better? And couldn't this provide a framework for more innovation in care?

Answer: I share the President's and the Secretary's firm belief that, in order to reform our health care system, we need to shift its focus away from paying for services when someone is sick and toward promoting wellness through greater prevention and care management. Medicare should lead in this transformation. In 2003, Congress expanded Medicare to cover an initial physical exam for all newly eligible Medicare beneficiaries. Under current law, the program does not pay for annual exams. I agree that expanded access to preventive services will reduce long-term costs. In the context of health reform, the Administration and Congress should work together to address Medicare's benefit shortfalls as well as to expand primary and preventive care to all Americans. We should also seek ways to create greater incentives, through performance measures, for the health care system to improve the quality of our care in the context of expanded primary care. If confirmed, I pledge to make available all of the resources of the Department to further these critically important goals.

Question 4:

In all the discussion regarding bundling of payments, it seems that some pundits underestimate the problems inherent in such a payment strategy. You have some experience working in primary health care centers in rural America which could *provide some insight into the potential difficulties that allocation of payments will create.* Others have recognized how the bundling of payments could create market restructuring far beyond that which is necessary to achieve care coordination. The discussion of *Accountable Care Organizations* (ACOs) is thought-provoking. This is the sort of activity which some managed care organizations do very effectively...but *what level of restructuring* is really required in order to achieve the objectives? Is this the first step to a broad vertical consolidation of health care providers?

There have been some promising suggestions of using incentives to spur a more coordinated care network...and perhaps more creativity there could allow us to avoid conflicts between providers on issues such as payment allocation.

For example, another strategy might be a pooling of incentives – into "group-level quality reporting and payment" coalitions of providers and hospitals, which would tie each provider's performance to that of other providers caring for the patient. It would appear that such an approach might also achieve care coordination, though not imposing the arbitrary payment cap which bundled payments offer. Are there other alternatives, or ways to avoid some of the negative consequences so many are concerned about?

Answer: Many researchers have noted that coordinated care entities have the potential to improve quality and provide appropriate incentives for care delivery. The Administration's FY 2010 budget builds on these findings and includes a demonstration payment reform proposal for Accountable Care Organizations in order to study the ways that health care entities can work together more efficiently to provide the best care for patients, avoiding the fragmented care that is often delivered today.

In a demonstration setting, I anticipate that different models of care coordination will be tested to determine alternatives that achieve the underlying objectives we support – patient-centric care that renders high-quality outcomes without duplication. The goal of any reformed payment system should be flexibility to encourage a variety of approaches that further these objectives. As we test these ideas in a demonstration, I am willing to explore alternative approaches that have the potential to accomplish the same objectives.

Question 5:

Under the President's budget, home health agencies are facing cuts of $37 billion over ten years. This is based on MedPAC's belief that home health agencies have been paid significantly more than their cost of providing the services in recent years, with profit margins of 16 percent.

I am highly concerned about the impact this will have on rural providers, which have a much different cost structure than urban and suburban providers. As you know from governing a rural state, rural agencies are at a disadvantage in terms of offering better wages and benefits. They don't have the same patient volume to absorb cuts. Additionally, the long distances that home health workers must travel between patients imposes higher labor costs per patient encounter, while making them susceptible to spikes in gas prices, which were sky-high only a year ago.

In recent years, Maine has lost 30 percent of home health providers. Far from having excessive profit margins, 43 percent of our home health agencies are in the red. Yet under the President's proposal, home health agencies in my state would stand to lose $2.6 million in the coming year alone. Cuts of this magnitude could have a devastating impact on the ability to deliver services in rural areas.

In addition to considering the differences between rural and urban areas when restructuring payments, I note that there are lingering issues of fraud and abuse within home health. The Government Accountability Office has recently documented practices such as overstating a beneficiary's condition to get higher payments as well as kickbacks and billing for services not rendered.

Given the demands the "Baby Boomer" generation will be placing on our health care system in just a few short years, will we have the health care infrastructure in place – especially in rural areas -- to meet this need if cuts of this magnitude are adopted? How can we better account for the differences in cost-structure when looking at reforming home health payments?

Answer: MedPAC, the Government Accountability Office (GAO), and others have raised concerns about the dramatic growth in Medicare payments to home health agencies, the very high margins these agencies earn from Medicare, and outright fraud that is occurring in certain parts of the country (e.g., south Florida). I believe the President's FY 2010 budget proposal represents a balanced approach that will help ensure Medicare pays the appropriate amount for home health care while preserving access to this very important benefit. One of Medicare's challenges is ensuring that payments promote efficiency and are commensurate with the need to maintain provider access for beneficiaries in all areas of the country. If confirmed, I look forward to working together to enact comprehensive health reform, and I welcome your input on how to best promote greater efficiency in the Medicare program.

Follow up: Clearly we must ensure that health care dollars are spent in the most appropriate and efficient manner. In light of this GAO report, what steps do you plan to take to reduce fraud and abuse in home health?

Answer: This Administration takes fraud very seriously. In the Administration's FY 2010 Budget Request, new resources will be targeted to fighting fraud in the Medicare program and ensuring that taxpayer dollars are spent appropriately.

As an example of the Department's ongoing efforts to address this issue, I understand that the Centers for Medicare & Medicaid Services (CMS) and HHS have a targeted demonstration underway to fight waste, fraud, and abuse by home health suppliers in the Dade County, Florida area. Last fall, CMS initiated efforts to address potential waste by suspending payments to 10 home health agencies.

In addition to suspending payments, I understand that CMS is working to implement extensive pre- and post-payment review of claims submitted by ordering/referring physicians; validate claims submitted by physicians who order a high number of certain items or services by sending follow-up letters to these physicians; verify the relationship between physicians who order a large number of home health services and the beneficiaries for whom they ordered those services; and identify and visit high-risk beneficiaries to ensure they are appropriately receiving the services for which Medicare is being billed.

If confirmed, I look forward to working with President Obama, Secretary Sebelius, and Congress to ensure that HHS programs are managed well, and to aggressively pursue waste, fraud, and abuse at the Department.

Question 6:

While we at last enjoy a universal prescription drug benefit in Medicare, the program remains fraught with problems. Even last November, as my staff attempted to obtain plan options for a couple of very common medications – but received blank screens in response from the Plan Finder on the web. Then the system's Compare Plans function didn't work at all. Finally, beneficiaries receive a listing of suggested plans – with no mention that the first plans listed – typically are lowest cost because they don't cover all one's medications! This situation is completely unacceptable. Beneficiaries must see a selection and enrollment process which serves their needs.

Last year Senator Rockefeller joined with me to author the Medicare Beneficiary Protection Act – to both address private plan marketing abuses and to improve the process of beneficiary enrollment and plan oversight. Working with Senator Baucus and Grassley, we saw agreement on some provisions on marketing abuses, but much was left undone – beginning with changing an enrollment period which is a "holiday affair" – could there be worse timing than November 15 to New Year's Eve?

Considering those actions you could take as Secretary without additional legislative authority, what would be your plan to see that beneficiaries see a Part D benefit more responsive to their needs?

Answer: While we should applaud the many successes of the Medicare Prescription Drug benefit in expanding access to Medicare prescription drugs, there are many improvements that can and should be made. I understand that the Centers for Medicare and Medicaid Services (CMS) recently issued a revised "Call Letter" to strengthen its oversight of the program. CMS announced that it will no longer allow Part D drug plans to manipulate prescription drug cost-sharing amounts. It will also require Part D plans to report and market their benefit offerings in standardized formats so beneficiaries can better understand their options. These changes will help simplify the benefit and reduce the opportunity for marketing abuses.

I believe we can take additional steps to strengthen the Part D benefit and to make it more responsive to the needs of beneficiaries. If confirmed as Deputy Secretary, I will work with Secretary Sebelius, leadership at CMS, and the rest of the Department to determine whether it is necessary to develop new regulations or other measures to strengthen CMS's ability to eliminate marketing abuses, simplify enrollment, and improve beneficiary education tools such as Medicare.gov. I look forward to working with you and your colleagues on these and other options for strengthening the Part D program.