FINANCE COMMITTEE QUESTIONS FOR THE RECORD

United States Senate
Committee on Finance

Hearing on
Confirmation of Gov. Kathleen Sebelius to be
Secretary of Health and Human Services
April 2, 2009

Questions from Chairman Baucus

Question 1:

I believe that we need to act to reform our health care system this year. There are enormous consequences for inaction on families, businesses, and federal and state governments. Do you share my sense of urgency about the need to reform our health care system?

> **Answer:** Absolutely. Comprehensive reform is needed to drive down costs, improve quality, cover all Americans, and prioritize prevention. Now is the time to achieve it. While some suggest that in this recession, we can no longer afford to invest in our nation's health system, the truth is that we can't afford not to. Premiums have doubled in the last eight years, and families and businesses are struggling to afford health care. As we face deep economic challenges, the number of uninsured is growing. Lowering health care cost growth is crucial to our long-term economic viability. The President supports reforms that will lower costs, improve quality and cover all Americans, and so do I.

Question 2:

As Secretary, are you prepared to help the Finance Committee move legislation – through technical support, identifying additional system savings, and helping us coordinate with other entities within the administration focused on reform?

> **Answer:** Yes. If confirmed, I would be fully committed to working closely with Congress and using all of the available resources at HHS to facilitate the development of comprehensive health reform legislation.

Question 3:

The President's budget includes a number of policies to improve the health care delivery system. Among these proposals are ideas that would change the financial incentives in the Medicare program from paying providers based on the "volume" of care, toward rewarding providers who offer high-quality, evidenced-based care.

In addition, the President's budget includes new incentives that encourage providers to better coordinate patient care, through mechanisms like bundling payments for hospital and post-acute services. Do you agree that it is a top priority to reform the health care delivery system? What steps would you take to improve quality and patient care, while also reducing costs to the health care system?

Answer: We have an outdated system of health delivery, a population of over 45 million uninsured individuals, which results in cost shifting, and a lack of investment in prevention and chronic care management. Medicare and Medicaid have performed as well if not better than many private insurers on cost and quality. Their growth rates are often comparable to and their payment rates lower than those of the private sector. At the same time, they need improvements to emphasize quality and primary care. A number of proposals to do so are in the budget. One of our top priorities is to modernize these programs to make them leaders in value-based purchasing and quality.

Question 4:

How do you see HHS and the newly created White House Office on Health Reform working together to accomplish health care reform? What role do you see the Centers for Medicare and Medicaid Services playing? In the structure you envision, what are the key offices within the Department that we will be working with to get health care reform enacted into law this year?

Answer: The President has made health reform a priority, and HHS will work arm in arm with the White House Office in achieving this goal. HHS will bring to the task a full set of tools essential to achieve reform. It will produce cost and coverage estimates, conduct studies on various problems and solutions, and lend its expertise to the policy development. It will also lead by example, especially at the Centers for Medicare and Medicaid Services. Shifting its payment policies to focus on quality rather than just quantity and to emphasize primary care and prevention will not just help beneficiaries and taxpayers; it will set a benchmark that private plans will likely follow. In addition, virtually every other agency will contribute, from the Centers for Disease Control and Prevention helping to design a 21st century prevention system to the Health Resources and Services Administration ensuring that access to care in rural areas is improved. The entire Department will be involved in both helping to design a reform plan and implementing it once enacted.

Question 5:

My goal is to move legislation through the Committee process in June. Beginning at the end of April, we will hold Member roundtables and walk-through specific proposals related to delivery system reforms, coverage, and revenues. Will the Administration be ready and willing to engage with us in that timeframe? Do you plan to engage the Office of the Actuary at CMS in order to help with estimating the cost of the proposals we are discussing?

Answer: Yes. HHS has already started developing the data, analyses, case studies, and other information that will be useful in designing policies to make health care affordable, high-quality and accessible for all Americans. This includes engaging the Office of the Actuary along with other analysts to help estimate the cost of proposals.

Question 6:

I was very pleased with the important down payment included in the President's budget for health care reform. However, more funding will be needed. I encourage the administration to dig down deeper within the health care system to find savings. Are there any potential offsets you see that were not included in the budget? Are you willing to work with us to identify, develop and estimate the costs or savings associated with different policies moving forward?

Answer: As you are aware, the President proposed over $316 billion in Medicare and Medicaid savings toward a reserve fund for health care reform in his budget blueprint for FY 2010. The President has said that, while the budget policies are significant, additional savings and revenues measures will likely be necessary. He has expressed a willingness to look at all serious ideas on improving efficiency, accountability, and shared responsibility in health care. If confirmed as Secretary, I pledge to bring the full resources of the Department of Health and Human Services to assist you and your colleagues as you develop your health reform proposals, including the analytic expertise of CMS's Office of the Actuary.

Question 7:

Some have proposed that the U.S. adopt a goal of reducing or eliminating poverty. What are your thoughts about setting such a goal? What programs administered by HHS do you think can play key roles in reducing poverty generally, and particularly among children? What is the role of TANF in addressing the needs of disadvantaged families with children? Is cash welfare performing its function adequately as a "safety net" for needy families? What is the federal government's role – and the role of TANF and child care block grants specifically – in helping states make investments in young, economically disadvantaged children?

Answer: Like President Obama, I am deeply committed to finding ways to reduce poverty in America. While the current economic crisis makes poverty reduction more daunting, I believe there are critical steps we can take to help families weather this economic storm and be positioned to take advantage of the coming recovery. If confirmed as Secretary of HHS, I look forward to the opportunity to coordinate our programs, in collaboration with our state, local, and community partners, to help families overcome poverty. As you note, the TANF program is a critical element of the safety net, and effective implementation of the American Recovery and Reinvestment Act provisions relating to TANF will be an immediate priority for me. Moreover, child care is an essential work support for low-income parents, and I look forward to finding ways to ensure that all families have access to high-quality child care.

Question 8:

Last year, Senator Grassley and I worked together, along with other members of this committee, to pass the "Fostering Connections and Increasing Adoptions Act." Implementation of that bill will require your immediate attention. Are you prepared to begin the implementation of this landmark piece of legislation? How should we interpret the constant rate of entries into foster care? What policies can reduce entries into foster care?

Answer: I applaud your leadership and vision in enacting the Fostering Connections and Increasing Adoptions Act. If I am confirmed, implementing this landmark legislation will be a high priority for me, and for my team at HHS. Consistent with the goals of safety, permanency, and well-being, it will be vital to invest in up-front services to strengthen families and avoid foster care placements where possible. These early services will need to link closely with family and other community-based supports for vulnerable families.

Question 9:

Do you see the need for the development of age-specific and culturally appropriate approaches to prevention of abuse and neglect and/or prevention of entry to foster care? What should HHS' role be in developing such approaches and/or tailoring existing programs to improve age-specific, developmentally, and culturally appropriate services? How do you see HHS' role in addressing parental "risk factors"? Are risk factors most appropriately addressed in child welfare policy or in other ways – for example, income security or via broader based mental health, substance abuse, and domestic violence related services?

Answer: If confirmed as Secretary of HHS, I intend to look closely at evidence-based approaches for preventing abuse and neglect and/or foster care placement. Parental "risk factors" should be addressed through both the broader-based approaches you mentioned and child welfare policy. It would seem very reasonable to examine tailored strategies that have proven effective in particular settings. HHS has an important role to play in promoting public health, including mental health, and in working with state, local, and tribal partners to provide direct services that support individual at-risk families.

Question 10:

Once confirmed what are your plans to address the health care delivery and health disparities that currently exist in Indian Country? What are your plans to address IHS's internal funding disparities?

Answer: The federal government has a trust responsibility to provide for the health and well-being of American Indian and Alaska Native tribes. The federal government also has a responsibility to consult with tribes on a government-to-government basis on matters that impact tribes.

If I am confirmed, the President and I plan to consult with tribes on health care delivery as well as health reform to ensure that the trust responsibility is honored and that tribes have input on and access to any new options, and that these new options do not adversely impact IHS and tribal health programs.

Some of the biggest challenges to eliminating the health disparities in Indian Country include improving access to care in rural, remote sites with few healthcare providers; ensuring collaboration and communication between IHS and mainstream healthcare providers; recruiting and retaining healthcare providers; addressing woefully inadequate funding for Indian health; and ensuring that healthcare in any system is culturally appropriate for the target population.

The President has committed to tackling these problems. While increased funding alone will not solve these problems, it is a critical first step. The President has provided increased funding in the Recovery Act as well as the FY 2010 budget. If confirmed, I will work with Congress, the President, and the IHS Director-designate, Dr. Yvette Roubideaux, to reduce the annual IHS funding shortfalls and reauthorize the Indian Health Care Improvement Act so that we can tackle more aggressively the underlying factors that have led to higher rates of diabetes, suicide, substance abuse, and other health threats. In addition, the Recovery Act and Children's Health Insurance Program reauthorization reduced cost sharing and targeted outreach to low-income Native Americans served by Medicaid and CHIP. The Recovery Act also included a major investment in the health workforce training programs, including those that encourage more Native Americans to become health professionals. While there is considerable work to be done, the Administration is off to a good start and, if confirmed, I look forward to contributing to this effort.

<u>Question 11</u>:

An estimated 80 percent of heart disease, stroke and Type-2 diabetes can be prevented if Americans stopped smoking, adopted healthy diets and became more physically active. The President outlined eight principles for health care reform in the Budget including an investment in prevention and wellness. Can you elaborate further on what kinds of investments Congress should consider?

Answer: Wellness and prevention are urgent priorities. This century's epidemic is chronic disease: over 70 percent of costs and deaths result from it. Yet, we spend only one to three percent of our $2.6 trillion health system on prevention.

President Obama has committed to expanding clinical and community-based prevention to shift our health care system from an "acute care" system to one that prioritizes health promotion and disease prevention activities. As part of his health reform agenda, the President established the coverage of evidence-based prevention services as an objective of a reformed health system.

He also advocated for the historic $1 billion investment in the Recovery Act, most of which will be used for community-based proven prevention policies. If confirmed, I will work with the President and Congress to make a greater focus on prevention a key cornerstone of health reform.

Question 12:

I am curious to know more about the proposal to create a Federal-State Partnership. The Budget says that OMB will try to extract savings from means-tested programs like Medicaid through the Partnership, and I would like to know more about your plan. Please tell the Committee as much as you can about this new proposal.

Answer: This partnership is proposed as part of the President's broader initiative to improve program integrity and ensure that every taxpayer dollar is well spent. The budget includes a significant increase for Medicare anti-fraud efforts as well as a proposal to work with states to improve the accuracy of payments in Medicaid. Given the Federal-State partnership in administering Medicaid, this initiative can only be successful if states are engaged. If confirmed, I look forward to working with you on details of this and other policies to make our health system more efficiency and fair.

Question 13:

Governor Sebelius, you recently filed amended returns reporting $7,040 in additional taxes in connection with your nomination to be Secretary of HHS. As Chairman of the Finance Committee, I take tax compliance very seriously and I am pleased that you have remedied your tax issues. I do not think your tax issues were intentional and I believe your amended returns should settle the matter. Please describe the changes you made on your amended returns and why they were necessary.

Answer: In preparation for my confirmation process as the nominee for Secretary of the Department of Health and Human Services, my husband and I hired a Certified Public Accountant to conduct a thorough review of our tax returns for 2005, 2006 and 2007. That evaluation revealed unintentional errors, which we immediately corrected by filing amended returns.

Charitable contributions: For charitable contributions in excess of $250, taxpayers must have an acknowledgment letter from the charitable organization in order to take a tax deduction. Out of 49 charitable contributions we made in these three years, there were three for which we could not locate our acknowledgement letter. The amended returns eliminated these deductions.

Interest: In July of 2006, my husband and I sold our home for an amount less than the outstanding balance on our mortgage. We continued paying off the loan, including interest we mistakenly believed continued to be deductible mortgage interest. Another loan for home improvements was treated similarly. These errors were corrected in our amended returns.

Business expenses: In reviewing our taxes, we discovered we had insufficient documentation required to claim some of our tax deductions for business expenses. While the amended returns reflect these changes, they did not affect the amount of taxes owed because we were subject to the Alternative Minimum Tax.

Questions from Senator Grassley

Question 1:

Some suggest that health care reform efforts should include the development of a Federal Health Board. This Board would be a quasi-governmental agency comprised of unaccountable, unelected experts who would be in charge of making decisions that would affect the entire nation.

a. Are you supportive of an entity such as this with power and little accountability to the public?

b. How would you ensure accountability if such an entity was developed?

Answer to 1(a) and (b): One of the biggest cost drivers in our health care system is the wide variance in procedures. You can live in one part of Los Angeles and get one therapy for a disease and live in another part and get a less effective, more costly therapy for the same disease. Aligning our system toward what works will both improve quality and help address the problem of skyrocketing costs. That is why I believe it is important that we have a process to promote best practices that is protected from politics and micromanagement.

There are many ways to go about doing this. Some like Senator Baucus promote an independent council to assist in advancing best practices. Others like Senators Conrad and Gregg prefer a commission as a way to make the difficult policy decisions regarding health programs. If confirmed, I look forward to working with Members of Congress on developing this and other ideas about how to make the health system more effective and better for patients.

Question 2:

Parallels have been repeatedly drawn between Great Britain's National Institute for Health and Clinical Excellence (NICE) and the development of a Federal Health Board as part of comprehensive health care reform here in the United States. A recent article in the New York Times notes that the NICE has placed an approximate $22,750 price tag for every six months of quality of life for a patient.

a. Do you think it's appropriate for the United States government be in the business of determining the value of a person's life?

Answer: We should be in the business of ensuring a health care system that promotes quality of care. As you know, we have a uniquely American health system. We have world-class doctors, nurses and hospitals as well as researchers and innovators who are developing treatments and cures for some of the most challenging diseases. We also have problems in the health system that are urgent and must be addressed through health reform. The President aims to build on what is best in the system while improving affordable, high-quality choices for all Americans.

Obviously, he has not suggested that we adopt the British system. If confirmed, I look forward to working with you on crafting a uniquely American solution to the health system crisis.

b. What steps will you take as HHS Secretary to ensure the protection of individual choice and freedom when it comes to health care decisions which should be made between the patient and physician?

Answer: Currently, too many Americans find their choices of doctors and treatments dictated by their ability to afford care. And today, insurance companies make decisions all the time to not cover care, which ends up restricting patient choice. Last year, half of all Americans skimped on medical care because of cost, according to a recent survey. One of the best ways to protect choice and freedom when it comes to health care is to make it affordable. The President has proposed a number of policies toward this goal and, if confirmed, I will work with you on achieving this top priority. Providing coverage to all Americans will also mean more choice for those who do not have coverage today. For those who already have coverage and are satisfied with it, the President has made it clear he believes they should be able to keep it.

Question 3:

As a result of the stimulus package, the Department of Health and Human Services has been charged with developing security, privacy, and interoperability standards for electronic medical records. As HHS Secretary, how will you seek to ensure and protect the privacy of personal health information?

Answer: It is absolutely critical that we ensure the privacy and security of patients' medical information. Only if we gain the trust of consumers will we ensure an effective system. It is also important that as we seek to facilitate the adoption of interoperable health information technology (HIT), we do not create financial incentives for providers to refer patients inappropriately or excessively. At the same time, we must be mindful of the very real complexities and challenges faced by the providers and others in the health care system who will utilize electronic health records systems. The best way to prevent problems from occurring is to move forward with a transparent process – to maintain a dialogue with all affected stakeholders. That way we can better understand and work to minimize the potential burdens on providers while we ensure that patients' information is confidential and secure, and that HIT facilitates the appropriate sharing of information that can improve quality of care and save lives.

Question 4:

Members of Congress are offered a range of private plans to choose from during each annual enrollment period. These plans range from Health Savings Accounts (HSA) coupled with a High Deductible Plan to more costly "first-dollar" coverage. Given President Obama's desire to give everyone "coverage like Members of Congress", shouldn't any reform proposal offer the same range of options instead of a "one-size-fits-all" standard plan?

Answer: The President and I believe in the principle of choice. We want to give Americans a choice of which health insurance option works for them. The President's campaign plan proposed a National Health Insurance Exchange that offers a public plan option alongside private insurance options. Coverage in the Exchange would be accessible, reliable, and meaningful and designed to promote competition on cost and quality, not cream-skimming and risk selection. He will work with Congress on this and other elements of the plan.

Question 5:

During the campaign, President Obama often pointed to the health system that Members of Congress use, the Federal Employees Health Benefit Program (FEHB), as a model for expanding health insurance coverage. As you probably recall, this is a pretty efficient system of competing private plans. But there is no public plan managed by the federal government – and for good reason. Given the success of the FEHB model, when crafting a broader health reform proposal, do you believe it is necessary to add a public plan option that would undermine the success of competing private plans?

Answer: We believe in the principle of choice and ensuring the private market works. The President wants to make health care affordable for families and businesses. We want to give Americans a choice of which health insurance option works for them. While the President discussed proposals to ensure that Americans had benefits as good as Members of Congress, his campaign plan also proposed a public option alongside private insurance options in a National Health Insurance Exchange. He recognizes the importance of giving the American people this choice, which will also challenge private insurers to compete on cost and quality, not cream-skimming and risk selection. At the same time, he recognizes the importance of a level playing field between plans and ensuring that private insurance plans are not disadvantaged. The President is open to good ideas from both sides of the aisle, and he will work with Congress on this and other elements of the plan.

Question 6:

Do you believe comparative effectiveness research should take into account the cost of a treatment or procedure, or should it focus solely on the clinical effectiveness?

Answer: A vital component of a high-functioning health care system is the empowerment of providers and patients with timely, rigorous, and relevant information on treatment options. Comparative effectiveness research assesses the relative strengths of different treatment options – critical information to improving quality and outcomes. Congress did not limit this research when authorizing it in both the Medicare Modernization Act and the American Recovery and Reinvestment Act. If confirmed, I will work to ensure that the research is high-quality and is used to enhance decision making and inform choices by patients and providers.

Question 7:

In other government agencies and within the Medicare program at times, at times there has been substantial delay in the time between private sector innovation and federal approval for implementation and use for new treatments. For example, it may take up to 5 years for the Federal government to approve new medications or devices. Some have raised concerns that the public may be further delayed access to new technologies for another several years while the Federal government performs comparative effectiveness trials. This in turn could have a negative impact on patient care. As Secretary of HHS, what approach would you take to ensure appropriate and timely access to new technologies generally and what steps would you intend to take to ensure that comparative effectiveness research does not have a negative affect on appropriate access to innovative technologies?

Answer: The President agrees with you on the importance of accelerating high-quality research to treat and cure debilitating and deadly diseases. This is why he supported the $10 billion increase in funding for the National Institutes of Health in the Recovery Act and further increases in cancer research funding in his budget. The Recovery Act also included $1.1 billion for comparative effectiveness research. These investments will speed the rate of discovery and adoption of best practices in the health system, not slow them down.

Question 8:

Some have suggested that health reform should include a "play or pay" mandate on American businesses, where businesses would be forced to either offer coverage or pay a penalty. A 2007 paper published by the National Bureau of Economic Research concluded that a "pay or play" mandate would cause more that 220,000 Americans to lose their jobs. Given the economic challenges businesses are facing in today's economic climate, what concerns to do you have, if any, that such a requirement is the equivalent of a new tax on businesses that are unable to afford health coverage today and that such a requirement may lead to increased unemployment, and if you share this concern how would you intend to approach the issue?

Answer: Our existing, costly health system is already a major job killer. It is a top concern for businesses across the board, and they have been leading advocates for reforming the system to make it affordable and accessible for all.

The President's campaign plan emphasized shared responsibility. This means that individuals have a responsibility to focus on health and prevention; the government has a responsibility to increase access and improve affordability; insurance companies have a responsibility to ensure no discrimination; and businesses have a responsibility to provide coverage or pay for it. The health care system cannot be reformed without each participant contributing to change. During the campaign, the President proposed a pay-or-play system that excluded small businesses; he recognized that small businesses are the engine of job growth and that most large businesses are currently offering coverage. In fact, over 98 percent of large employers already offer health insurance, so nothing would change for them – except that health costs would come down as system improvements kick in.

We are also committed to working with the American public and with Congress on this and other issues related to health reform. The President wants an open discussion about health reform and is open to all serious options.

Question 9:

Do you support an individual or employer mandate to purchase health coverage as part of health care reform, and if so, how would you believe such a mandate should be enforced?

Answer: As noted in my answer to the previous question, the President's campaign plan emphasized shared responsibility, including the responsibility of employers and individuals. The health care system cannot be reformed without each participant's contribution to change. We are committed to working with the American public and with Congress on how to specify policies and balance priorities.

Question 10:

According to the Dartmouth Atlas Project and others, studies have shown that increased spending on health care does not necessarily increase health or improve outcomes and in many cases results in poorer quality care and worse outcomes. Over-utilization of services is certainly a problem within the system. One prominent reason for overutilization, particularly of expensive imaging techniques, is the practice of defensive medicine. Additionally, the cost of medical malpractice protection has risen dramatically for the provider, some regions of the country have difficulty retaining physicians due to high rates of lawsuits, and physicians have dramatically decreased the amount of charitable care provided because of liability concerns.

a. In your opinion, does medical liability and defensive medicine adversely impact the health care system?

Answer: Independent and objective studies have consistently found that malpractice costs explain only a small part of medical costs. However, clearly some doctors are facing exorbitant premiums, and I believe we all need to work together to look for creative solutions.

b. What steps would you take as HHS Secretary to reduce the burden of cost imposed on the health care system by this problem while protecting individual rights?

Answer: The most important goal is to improve quality and patient safety to prevent medical mistakes from happening in the first place. This can be done in a number of ways. One such way is implementing the Recovery Act's investment in health information technology that can alert doctors when patients have allergies or drug contra-indications. Another is to requiring transparency about health care quality through reporting requirements. I think we should work to improve outcomes for patients without being doctrinaire about solutions to this problem, and I look forward to working with you.

Question 11:

Experts agree that up to 75% of current government health care spending is for diseases such as diabetes, certain cancers, chronic lung diseases, hypertension, preterm births, etc, that are largely preventable by healthier lifestyle choices such as diet, exercise, and smoking cessation. What specific measures do you believe the government should take in educating or assisting the public to adopt health lifestyle practices?

Answer: I agree the government should take a leadership role in educating the public to adopt healthy lifestyle practices. HHS develops and uses a variety of health communication strategies that deliver culturally appropriate and effective health promotion messages.

These interventions include paid advertising, media advocacy, public relations, health promotion activities, and campaigns that target specific audiences through innovative channels. For example, the *Screen for Life: National Colorectal Cancer Action Campaign* educates and informs men and women aged 50 years and older about the importance of having regular colorectal cancer screening tests.

Although chronic diseases are among the most common and costly of all health problems, they are also among the most preventable. Chronic disease prevention, to be most effective, must occur in multiple sectors and across individuals' entire life spans. Prevention encompasses health promotion activities that encourage healthy living and limit the initial onset of chronic diseases. Prevention also embraces early detection efforts, such as screening at-risk populations, as well as strategies for appropriate management of existing diseases and related complications.

To reduce chronic disease across the nation, we must rethink our health care system. It is essential that we have a coordinated, strategic prevention approach that promotes healthy behaviors, expands early detection and diagnosis of disease, educates people of every age, and eliminates health disparities.

Strategies are needed to facilitate and support individual responsibility and behavior change at schools and workplaces and in faith-, community-, and medical-based settings, such as:

- School-based strategies that foster environments and instruction that promote healthy eating, daily physical activity, sun protection, and the avoidance of tobacco, alcohol, and illicit drugs.

- Smoking cessation strategies, such as improved access to quit lines, improved insurance coverage of smoking cessation services, and greater involvement of health providers and health care systems in the routine delivery of cessation advice and services to patients who want to quit smoking.

- Better training and education of health care professionals to close the gap in time between discovering effective prevention tools and strategies and applying these tools in medical practice.

- More population-based case management programs to which doctors can refer patients once a condition has been detected (e.g., more diabetes clinics, hypertension management programs, tobacco quit lines).

Policy and environmental changes can affect large segments of the population simultaneously. Adopting healthy behaviors is easier if we establish supportive community norms and adopt a philosophy that embraces health in all policies and settings. We must promote proven social, environmental, policy, and systems approaches that support healthy living for individuals, families, and communities, such as promoting low-fat and high-fruit-and-vegetable menus in schools and more sidewalks and playgrounds.

Promising research findings are relevant only when they reach the people they are designed to serve. Key scientific advances must be applied and evaluated, reflected in state and local health policies, and widely adopted as community practices across the country. We should:

- Support community-based prevention research to identify the causes of health inequities and the best ways to provide access to high-quality preventive care and clinical services.

- Accelerate translation of scientific findings into community, workplace, and school practices to protect the health of people where they live, work, learn, and play.

- Apply scientific approaches to social marketing, health education, and consumer research in the design of effective communication strategies to inform and influence individual and community decisions on health.

Health inequities are reflected in differences in length of life; quality of life; rates of disease, disability, and death; severity of disease; and access to treatment. To ensure health equity, we should target social determinants of health, improve access to effective screening tools, and support early childhood education among other initiatives.
A skilled, diverse, and dynamic public and private health workforce and network of partners is crucial to promote health and prevent chronic disease at the national, state, and local levels.

Question 12:

As you know, many areas of the US are experiencing severe health care provider shortages. Many rural areas of the US in particular are facing primary care physician shortages. One reason that is cited for these shortages is the low reimbursement rates of Medicare and Medicaid. As Secretary, what will you do to ensure access to care and services for Medicare and Medicaid patients particularly in rural areas of the country?

Answer: Ensuring that all Americans have access to quality health care is a priority for President Obama, and I support this mission. Many have told me that access to primary care providers is becoming increasingly difficult for Medicare and Medicaid beneficiaries, in particular those living in rural areas. We should focus our efforts on attracting medical students into the field of primary care and look at ways to encourage primary care practitioners to work in rural areas.

We should address the primary care workforce shortage on a number of fronts. First, we need to expand support for workforce training programs, including Title VII, Title VIII, and National Health Service Corps programs, which incentivize students to pursue careers in the primary care health professions. The Recovery Act roughly doubled funding for the National Health Service Corps. Second, we should tackle payment reform in the Medicare program to ensure that primary care providers are paid fairly and appropriately for the important interventions and care coordination services.

Finally, we should take steps to support the actual practice of primary care, which could include assistance with adopting health IT or implementing disease management and care coordination programs. I look forward to working with you in the context of health reform to reorient our health care system toward primary care and prevention.

Question 13:

Rural health care is a major concern for many states, Iowa included. A one-size-fits-all approach in any health care discussion often leaves rural patients and clinics behind. Can you discuss how your vision of health care reform would address this concern?

Answer: Rural Americans face special challenges. Geographic access is limited, insurance options are few, and chronic disease is more prevalent. As such, health reform is particularly important to rural health care. Under the President's campaign plan, Americans could keep their health plan or have a choice through a National Health Insurance Exchange. This choice would be particularly welcome in rural areas. In addition, the plan would improve the performance of the delivery system, rewarding quality, promoting integrated care, and emphasizing primary care. This would benefit the many rural doctors, hospitals, and other providers that already offer such care but are not paid for it. Moreover, health reform will bring a new focus on wellness and prevention to rural areas, helping to stem the chronic disease epidemic that is straining the system. I look forward to working with you to achieve this goal.

Question 14:

There is a strong case to be made for compensating physicians, in part, on a pay-for-performance basis rather than strictly in a fee-for-service system. In your opinion, what kinds of quality measures should be developed and used to assess the quality of care and, as Secretary, how would you intend to guide the system for the development, approval and use of appropriate quality measures?

Answer: It is important for us to tap into the vast resources of agencies such as AHRQ as well as provider organizations to collaboratively develop quality guidelines to ensure that our health care system works for all Americans. I know that medical societies are doing extremely important work in developing peer-reviewed guidelines that improve quality. Equally important is the ability to maintain flexibility to address a dynamic practice environment with constant innovations and improvement in care. I look forward to working with Congress to pursue these goals.

Question 15:

In the past, some have strongly supported mechanisms to reduce prescription drug costs such as allowing states to purchase prescription medications wholesale and allowing individuals and pharmacies to purchase medications internationally. Unfortunately, former HHS Secretaries, including Secretary Shalala and Thompson did not provide the required certification in order for a drug importation program to be implemented. Will you support an importation program, and if so, how will you assure appropriate implementation that ensures public safety as well as providing access to lower cost prescription drugs?

Answer: There are number of options to lower the cost of drugs. We need to examine all options from expanding the use of generic drugs to providing greater flexibility to negotiate lower-priced drugs when appropriate, to reimportation of drugs from developed nations that have strict safety measures like the United States. That said, the recent incidents involving heparin and other consumer products has highlighted the potential challenges that must be addressed before we import drugs so we can be assured they are safe and effective. The President's FY 2010 budget includes new resources to plan for the safe reimportation of drugs, and I look forward to working with the Congress to implement such policies.

Question 16:

Even though the Congressional Budget Office (CBO) has concluded that giving Health and Human Services (HHS) the power to negotiate drug prices under Medicare Part D would result in little to no savings, many still promote this issue as a means to lower Part D costs. Some experts have suggested that the reason CBO did not find savings is because the legislation they analyzed prevented the Secretary from creating formularies or limiting access to pharmacies. Would you support a proposal for negotiations that would significantly reduce the number of drugs covered under Part D and force some seniors to use mail-order pharmacies? Under what conditions would you favor Secretarial negotiation in Part D and, as Secretary, how would you plant to exercise this authority?

Answer: Giving the Secretary the flexibility to negotiate with drug manufacturers would allow us to see what works best to save money both for Medicare beneficiaries and the taxpayer. While CBO says that it may not reduce drug prices, not all experts hold this view. Many states have used similar authority. In fact, the prices paid for the same drugs under state Medicaid programs for dual-eligible beneficiaries were lower than Medicare pays today.

Repealing the non-interference clause is intended to grant the HHS Secretary greater flexibility in ensuring affordable drug prices. It does not mean creating a one-size-fits-all Medicare drug plan for all Medicare beneficiaries.

Yet, there may be some lessons the Medicare program can learn from the VA, state Medicaid programs, and private-sector purchasing strategies, such as ways to promote lower-cost generics when medically appropriate. Working together, I believe we can improve Medicare Part D to adopt best practices, without creating a one-size-fits-all drug benefit.

Question 17:

One of the areas under the purview of Health and Human Services is the Medicare Advantage program. Each year the Centers for Medicare and Medicaid Services (CMS) is in charge of updating how much Medicare Advantage plans will be paid. This is done through something called the "45 Day Notice". This is a very important notice that helps plans determine their bids for the coming year. This year's "45 Day Notice" faces some extraordinary circumstances that may call for extraordinary action on your part. This year's proposed Medicare Advantage rates are calculated as if the 21 percent cut to physician payments will go into effect next year. We all know that's not going to happen. The President included a "physician fix" in his Budget, and the House and Senate have both included it in their budget resolutions. If CMS doesn't make the same assumption for the 2010 Medicare Advantage update it will likely result in drastically increased premiums and reduced benefits for 11 million enrollees. CMS is set to make the final announcement of the 2010 rate update for Medicare Advantage plans on April 6th. With access for all these beneficiaries on the line would you be willing to work to address this very big problem?

Answer: My understanding is that the annual update to Medicare Advantage payment rates is required and specified by law and that the law requires the agency to include the current-law 21-percent cut in physician fees for 2010. This spillover effect of the projected physician cuts on 2010 Medicare Advantage rates underscores the need for a long-term solution to the Medicare physician payment system. I pledge to work with you and all members of the Finance Committee to develop solutions that ensure that Medicare beneficiaries enrolled in both the traditional fee-for-service program and Medicare Advantage continue to have access to all necessary services.

Question 18:

As the Governor of a rural state, I hope you share my commitment to making sure people in rural areas have access to the same health care services as people in big cities. This is a particularly important issue in the Medicare Advantage program, where people living in urban areas often have more options and benefits than rural beneficiaries. In the President's 2010 Budget, the Administration proposes cutting more than $170 billion from payments to Medicare Advantage plans. There are close to 11 million Medicare Advantage beneficiaries across the country – more than 60,000 in Iowa and more than 40,000 in your home state of Kansas. The Congressional Budget Office has concluded that significant cuts to Medicare Advantage will force plans out of the program and jeopardize coverage for millions of Americans. This could be particularly bad in rural areas. The Administration is considering some drastic changes to the Medicare Advantage program. As we discuss changes to this program, can I count on you to work with me, so that beneficiaries in rural areas still have access to the same high-quality plans and services as people in urban areas?

Answer: As a Governor of a state with many rural communities, I understand the importance of ensuring access to high quality care for individuals living in rural areas of the country. And I also understand the critical need to improve rural health care services.

However, given the need to address the long-term financial stability of the program, I am also very concerned about the 14 percent overpayments currently paid to Medicare Advantage plans under the existing payment methodology. I believe there are a number of ways we can go about leveling the playing field between the two programs while ensuring beneficiaries retain access to critical Medicare benefits. I look forward to working with Congress to meet this goal, if I am confirmed as Secretary.

Question 19:

Waste, fraud and abuse in federal health programs has long been an issue. It is estimated that up to $120 billion a year or more in federal health care spending is lost to waste, fraud and abuse. Much has been done in the past, both administratively and legislatively, to curb waste, fraud and abuse, but much still needs to be done. Will addressing waste, fraud and abuse in federal health programs be a priority for you, and as HHS Secretary, what concrete steps do you propose to do in this regard?

Answer: We should have zero tolerance for fraud in the Medicare and Medicaid programs, and, if I am confirmed as Secretary, I will make it a top priority to manage these programs well and pursue fraud, waste, and abuse aggressively.

I understand that Congress has recently given CMS and HHS additional resources to combat waste, fraud and abuse. If confirmed, I will work to ensure these additional resources are allocated as effectively as possible. I look forward to working together with Congress to fight fraud so that the American people have confidence in the appropriate and transparent use of their tax dollars.

Question 20:

I have been looking into nonprofit hospitals and the charity care and community benefit they provide in return for the billions of dollars in benefits they receive under the tax code," Grassley said. The recently enacted stimulus bill amends the Social Security Act to provide incentive payments to hospitals that use electronic health records. The amount of a payment to a hospital is determined in part by a hospital's share of charges related to charity care. The more charity care provided, then the more payment received. I am concerned whether CMS is able to implement this payment policy in an accurate and consistent manner. CMS collects data on the uncompensated care that hospitals provide through Medicare cost reports. Unfortunately, this data is of limited use because of shortcomings to the collection instrument. MedPAC has pointed out numerous shortcomings with the collection instrument known as the Medicare cost report worksheet S-10 and has made recommendations on making improvements. The IRS has extensively studied the definitions of charity care and uncompensated care. The agency recently implemented new reporting requirements for non-profit hospitals.
I believe that CMS must coordinate with IRS and MedPAC to ensure consistency in reporting of uncompensated care and charity care. It also would eliminate a burden on hospitals that otherwise might be facing different definitions of uncompensated care and charity care when dealing with the IRS or CMS.

a. As HHS Secretary, what would you do to ensure that CMS is collecting accurate data on uncompensated and charity care that non-profit hospitals provide?

b. Would the steps you take include requiring CMS to coordinate with the IRS and MedPAC and develop a single, uniform definition of uncompensated care and charity care?

Answer: Implementing the historic $19 billion investment in Health Information Technology (HIT) authorized by the American Recovery and Reinvestment Act is a top priority for the Department. This involves ensuring that we have appropriate data to calculate the incentive payments authorized by this legislation.

It is my understanding that CMS has been working with the IRS, MedPAC and others for a number of years in order to try to clarify definitions of uncompensated care and charity care, and to further refine the Medicare cost report. CMS has indicated that these discussions have been very productive and fully expects its collaboration with IRS and MedPAC to continue into the future. Further, I understand that CMS will issue any revised definitions and changes to the cost report via the rulemaking process in order to benefit from public input on these issues. I pledge to work with you and your staff to ensure your concerns are addressed in future measures of charity care.

Question 21:

The role of physician-owned hospitals has been a longstanding issue in the Committee. Physician owners have a conflict of interest in referring their patients to these facilities. The best interests of the patient should come first and not the financial interests of the physician owners. The Finance Committee has convened several hearings about the safety of these facilities. If a facility holds itself out as a hospital, it must be prepared for foreseeable complications and not just rely on picking up the phone and calling 911. I am also concerned about the ability of community hospitals to survive if physician-owned hospitals cherry-pick the more profitable patients and leave community hospitals with the less profitable patients.

a. As the Governor of a state with physician-owned facilities, what have you done to address such issues?

b. As HHS Secretary, what would you do to address such issues?

Answer: As Governor of Kansas, I am very familiar with many of the issues surrounding physician-owned facilities. Under current federal law, referrals to entities in which the referring physician (or an immediate family member) has a financial interest are prohibited for many types of services, including hospital services, by the physician self-referral statute, which is enforced by HHS. The Administration recognizes the critical importance of protecting the integrity of the Medicare program. If confirmed as Secretary, I will ensure that program integrity protections, including effective oversight of the physician self-referral law, continue to be a high priority for HHS. The President's budget included additional measures to curb specialty hospitals, and I look forward to working with you to enact this legislation.

Question 22:

In your view, should the employee exclusion of employer-sponsored health insurance be examined in the context of health care reform, and if so, how would you work with congress on this important policy issue? In your view, should tax incentives be considered as a means of addressing health care reform, and if so, how would you work with Congress to implement such incentives?

Answer: The President believes health reform should build upon the existing employer-based health care system, through which the majority of Americans receive their health care. The tax exclusion contributes to sustaining this system. That said, he recognizes that many members of Congress have views on that subject. He has stated that he would consider this among other sources of financing if that is what it takes to cover all Americans.

The President has supported well-targeted tax incentives in health care and other areas. On the campaign trail, he suggested a small business tax credit for health insurance, since these firms face the highest premiums and need the most help. We will work with Congress on this proposal as well as other ideas on how to finance a sustainable health system and ensure that individuals and small businesses can afford coverage.

Question 23:

Many policy-makers, including Senator Hillary Clinton and advisors to President Obama, have suggested limiting the amount of health insurance that is excluded from an employee's taxable income. The Congressional Budget Office (CBO) has supported this proposal as an effective way to lower the overall cost of health care in the United States. Moreover, the revenue created by this policy change could be used to help the uninsured purchase coverage with tax credits. I'd like to hear what you think about using this type of tax reform to lower the cost of health care and expand access to services and whether you would pursue these changes.

Again, the President believes health reform should build upon the existing employer-based health care system, and the current tax exclusion contributes to sustaining this system. Recognizing that many members of Congress have views on this subject, the President has stated that he would consider this among other sources of financing if that is what it takes to cover all Americans.

Question 24:

Congress passed a new section 1937 in Title XIX which allows States to provide benefit packages to Medicaid beneficiaries that differ from coverage defined in the state's approved state plan through enrollment in approved benchmark or benchmark-equivalent coverage, such as procured health plans or employer sponsored insurance plans. This morning, April 2, 2009, CMS delayed the regulation implementing this provision. Several states, including Kansas under your stewardship, have implemented a Medicaid plan under section 1937. Do you think there is anything Kansas did in implementing their plan that was inconsistent with that Medicaid statute? As HHS Secretary, will you continue to support state initiatives under section 1937 to provide individualized health care coverage that best meets the needs of their Medicaid population?

Answer: As you noted, CMS issued a second final regulation on April 2, 2009 that temporarily delays the effective date of the final rule implementing state flexibility for Medicaid benefit packages. Delaying the rule does not impact any state plans that have already been approved under the statutory benchmark benefit provision in section 1937. The approval of Kansas and other state plans to implement benchmark benefit packages is not affected by the absence (or delay in the effective date) of agency regulations.

If confirmed as Secretary, I look forward to working with you and other members of Congress to support state initiatives to provide quality health care coverage that best meets the needs of the Medicaid population.

Question 25:

The Administration recently chose to reconsider the regulation implementing the statute under the Deficit Reduction Act. Do you expect the Administration to reissue a regulation implementing the statute consistent with the Congressional intent that states have flexibility to implement cost-sharing in Medicaid?

Answer: On March 24, 2009, CMS issued a second final rule that temporarily delays the effective date of the November 25, 2008 final rule implementing sections of the Deficit Reduction Act of 2005 that allowed states the option to impose premium and cost sharing requirements on certain Medicaid recipients. CMS is soliciting comments on the impact of certain provisions of the American Recovery and Reinvestment Act of 2009 on the rule, including an ARRA provision that prohibits Medicaid and CHIP from imposing enrollment fees, premiums, or similar charges on American Indians and Alaska Natives for services provided directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization.

A delay in the effective date and providing a comment period will ensure that the final rule takes into account public comments and conforms to the recently enacted legislation. Additionally, it allows sufficient time to review all of the policies set forth in the November 25, 2008 final rule.

Question 26:

In December, CMS issued a final Medicaid rule on auditing and reporting on the disproportionate share of hospital payments. The rule became effective in January. Will you commit to continuing its implementation on schedule?

Answer: On December 18, 2008, CMS issued a final rule setting forth the data elements necessary to comply with statutory requirements related to auditing and reporting of disproportionate share hospital (DSH) payments under State Medicaid programs.

The law requires States to report additional information about their DSH programs, and requires States to have their DSH programs independently audited and to submit the independent certified audit annually to the Secretary. As a governor, I understand the critical importance of proper oversight of Medicaid funds and, if confirmed as Secretary, I commit to work with you to ensure the timely implementation of the DSH rule and the overall integrity of the Medicaid program.

Question 27:

The Medicaid statute requires states to reimburse prescription drugs in Medicaid by the average manufacturer price. The regulation implementing the statute was prevented from going into effect by a federal court. While maintaining compliance with the injunction on the reglation as previously issued, do you think CMS should withdraw the regulation and try to more accurately follow the statute?

Answer: I understand that stakeholders have many concerns about this regulation. If confirmed as Secretary, I look forward to working with you to better understand those concerns and explore potential solutions.

Question 28:

As you well know from your time as a state governor, long term care in Medicaid is a growing financial burden on states. Senator Kerry and I have introduced a bill, the Empowered at Home Act, which we believe make great strides to keep people who provide home and community based services as a legitimate alternative to institutional care. What do you think the Administration should do to increase the use of home and community based services in Medicaid?

Answer: I share your concern about the escalating costs of long-term care and understand the burden these costs place on state budgets. It is important to address the institutional bias in Medicaid and empower individuals to self-direct their care, while also ensuring their care is provided in the most cost-effective setting. Home and community-based care services (HCBS) enable Medicaid to provide services in the most integrated setting appropriate to a person's needs.

A study recently published in *Health Affairs* has demonstrated that the expansion of home and community-based services reduces institutional spending and produces savings over the longer term, a promising finding as states contemplate expansions of these programs. This study further confirms that the tools Congress provided in this area are key ingredients to relieve states of the financial burden for long-term care and also provide quality long-term care to Medicaid beneficiaries. Congressional action to implement Medicaid state plan options for HCBS and self-directed care along with the Money Follows the Person Rebalancing Demonstration have made alternatives to institutional care more of a reality.

Kansas has been aggressive at pursuing waivers that allow our citizens to live in the least-restrictive setting. If confirmed as Secretary, I look forward to working with you to continue the existing partnership the Administration has had with Congress and the States on moving this important issue forward.

Question 29:

The previous Administration issued several Medicaid regulations (rehabilitation services, school-based services, hospital reimbursement) that sought to improve accountability in Medicaid. Those regulations are under moratoria pending further review. Do you believe that those areas need increased scrutiny even if the specific regulations in question may not have been the most appropriate way to address the issues?

Answer: On February 17, 2009, President Obama signed into law the American Recovery and Reinvestment Act, which further extended the moratoria on certain Medicaid regulations through June 30, 2009 in addition to placing a new moratorium on the Medicaid hospital outpatient rule. With this delay, the Administration will have an opportunity to give the regulations a more appropriate and thoughtful review to ensure they are in the best interest of the Medicaid program. Medicaid is a lifeline for our nation's most vulnerable patients, and if confirmed as Secretary, I am committed to working with you to strengthen the Medicaid program to ensure that it is viable for many years to come.

Question 30:

CMS recently issued guidance to states on the enhanced Medicaid funding provisions included in the American Recovery and Reinvestment Act and some of it addresses the rules placed on states' eligibility for this additional money. As a governor, I'm sure you appreciate the need to provide states with a certain amount of flexibility in managing their Medicaid program.

a. Are there aspects of the current guidance (specifically the interpretation of procedures) that would restrict state's ability to manage their programs as efficiently as possible and hinder their ability to protect the integrity of the program?

b. The purpose of the increased Medicaid funds as I understood it was to provide some fiscal relief to states. I know where you sit effects where you stand, but do you think HHS is allowing states to appropriately access needed funds?

Answer: President Obama is committed to transparency and accountability on how all American Recovery and Reinvestment Act (ARRA) funds are disseminated and spent, including the increased Federal Medical Assistance Percentage (FMAP) funds. Consistent with those principles, CMS has provided guidance to states on the statutory requirements associated with accepting ARRA's FMAP funds; this guidance has been provided through all state calls, individual state calls, and written guidance documents and letters. CMS has also disseminated information on ARRA through the web site, the quarterly state budget call letter, and a fact sheet describing the methodology for determining the amount of additional Medicaid funding made available to states.

The guidance and grant award letters to states are clear that as a condition of accepting these increased FMAP funds, states must comply with all ARRA eligibility requirements for the increased FMAP, including maintaining Medicaid eligibility levels, methodologies, and procedures. CMS is working diligently with each of the states to ensure they can meet this and other ARRA requirements. Additionally, States are required to report to CMS on an ongoing basis the use of the increased FMAP funds. CMS is committed to ensuring that states can understand and meet the requirements spelled out in ARRA.

ARRA provides $87 billion in the form of a temporary increase to the FMAP and spending caps for the territories. Thus far, $23.5 billion in increased FMAP funds were made available to states for the first, second, and third quarters of FY 2009. For territories, $94 million in additional funding is available for FY 2009 under the increased spending cap. President Obama is committed to making sure these funds are helping keep state Medicaid programs financially viable while helping states avoid drastic cost saving measures.

Question 31:

As Secretary, what leadership would you exhibit to ensure that clinical trials are free of commercial bias? Would you support transparency initiatives to help illuminate potential conflicts of interest in the medical and scientific communities?

Answer: Maintaining objectivity in the conduct and reporting of clinical trials is critical to protecting the health and safety of the public. This includes the conduct of clinical trials supported by NIH. Ensuring objectivity in the conduct of these trials and the other NIH-supported research is critical to preserving the public's trust. Only with the public's trust can NIH continue to support the search for new knowledge in the prevention, treatment, and cure of human diseases and conditions.

I recognize that effective oversight and management of the extramural community's financial conflicts of interest necessitates a commitment from institutions and their investigators to complete disclosure, appropriate review, and robust management of identified conflicts.

NIH is responsible for overseeing institutional compliance with the federal regulation (42 CFR Part 50 Subpart F) and has demonstrated a commitment to financial conflict of interest (FCOI) oversight activities and continues to make these activities an agency priority. Over the past year, NIH conducted a comprehensive review of its system of oversight and compliance with the federal regulation for the purpose of ensuring that a vigorous and effective oversight system is in place. As a result, NIH has enhanced existing oversight activities and has initiated many new activities, all designed to monitor and promote grantee compliance.

If confirmed as Secretary, I will ensure that NIH and the other relevant health agencies enhance these efforts, including by moving forward quickly with the issuance of the pending ANPRM to seek broad public input on the current policy.

One approach to enhancing the assurance of openness in the conduct and reporting of research supported by the NIH is to promote enhanced transparency in the disclosure of financial interest of investigators, particularly when these interests may present apparent conflicts of interest.

Currently the timing, nature, and content of these disclosures are determined by the institutions addressing identified FCOI of investigators. I support efforts to enhance consistency and perhaps broaden these and other disclosures to enhance transparency in these matters. Accordingly, I would welcome the opportunity to work with you and other members of Congress to consider legislation and other actions to achieve this goal.

Question 32:

What steps would you propose CMS take to support states' efforts to combat fraud and abuse in Medicaid?

Answer: We should have zero tolerance for fraud in CMS programs, and, if I am confirmed as Secretary, I will make it a top priority to help states pursue fraud, waste, and abuse in the Medicaid program aggressively. In fact, Congress established the Medicaid Integrity Program in Section 6034 of the Deficit Reduction Act (DRA) of 2005 to address provider fraud in Medicaid. Congress's establishment of this program dramatically increased the federal government's role and responsibilities in combating Medicaid provider fraud, waste, and abuse, once the sole purview of the states. I understand that Congress has recently given CMS and HHS new funding through the Health Care Fraud and Abuse Control program to reduce fraud in HHS programs; the FY 2009 discretionary appropriation for CMS includes $13 million in new funds for program integrity activities within the Medicaid and Children's Health Insurance Program.

If confirmed, I intend to work with states and the Congress to employ aggressive fraud-fighting tools to the fullest degree possible. I look forward to working together with the states and Congress to fight fraud so that the American people have confidence in the appropriate and transparent use of their federal and state tax dollars.

Question 33:

Will you support the efforts of CMS and the IG as well as qui tam whistleblowers to use the False Claims Act to suppress fraud against Medicare?

Answer: If I am confirmed as Secretary, I will make it a top priority to manage the Medicare program well and to pursue fraud, waste, and abuse aggressively.

I will vigorously support important fraud-fighting authorities, including the False Claims Act, the Anti-Kickback Act, the Stark law, and other federal laws that are used to investigate, prosecute, and suppress fraud in Medicare and Medicaid.

Question 34:

To what extent will you make fighting fraud and abuse a priority for the Department? How will you continue Secretary Leavitt's efforts to maintain and strengthen the Department's relationship with the DOJ and FBI to ensure that appropriated funds for fraud and abuse investigations are used effectively?

Answer: We should not tolerate fraud, and, if I am confirmed as Secretary, I will make it a top priority to manage HHS programs well and pursue fraud, waste, and abuse aggressively.

I understand that Congress has recently given CMS and HHS new authorities and funding through the Health Care Fraud and Abuse Control program to reduce fraud in our programs. If confirmed, I will work to ensure that all of these new tools are employed aggressively and to the fullest degree possible with our partners at the Department of Justice, Federal Bureau of Investigations, and Office of Inspector General. I look forward to working together with our partners to fight fraud so that the American people have confidence in the appropriate and transparent use of their tax dollars.)

Question 35:

When CMS revamped its Special Focus Facility program for poorly performing nursing homes in 2004, it promised to initiate progressive enforcement actions and to remove homes that failed to show improvement within 18 months, but several years later, some poorly performing nursing homes have been in the program for more than 36 months. What steps will you take to improve oversight of poorly performing nursing homes?

Answer: Oversight of poorly performing providers that participate in Medicare and Medicaid is an issue I take very seriously. The Special Focus Facility (SFF) program was created to identify nursing homes that were consistently providing poor quality of care, yet were periodically instituting enough improvement that they would pass one survey only to fail the next for many of the same problems as before. Such facilities with a "yo-yo" compliance history rarely addressed underlying systemic problems that were giving rise to repeated cycles of serious deficiencies.

CMS employs a policy of progressive enforcement, which means that any nursing home, not just those identified as an SFF, that reveals a pattern of persistent poor quality is subject to increasingly stringent enforcement action. If problems continue, the severity of penalties increases over time, ranging from civil monetary penalties, denial of payment for new admissions and, ultimately, removal from participation in the Medicare and/or Medicaid program.

CMS began releasing the names of facilities designated as a Special Focus Facility in 2007 and identifies them on its Nursing Home Compare website, giving consumers and their families seeking long-term health care services important information when choosing a nursing home.

If confirmed as Secretary, I will continue to support efforts to ensure the quality and safety of beneficiaries receiving care in America's nursing homes. I appreciate your ongoing interest in this issue, and I look forward to working with you to improve the quality of care in the nation's nursing homes.

Question 36:

As part of the Food and Drug Administration Amendments Act (FDAAA), Congress gave FDA and CMS the authority to develop a system, now referred to as the "Sentinel Initiative," that is linking the vast claims data from the Medicare Part D program to other data sources such as Medicare Parts A and B, and Medicaid to create a post-market drug safety assessment project. This historic new initiative strengthens the FDA's ability to monitor the performance of a product throughout its entire life cycle, thus enhancing the protection and promotion of public health. 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: The cooperative project between CMS and FDA is currently well underway. CMS has already linked the Medicare Part D data with the other Medicare Parts A and B data, and is currently in the process of adding Medicaid data. CMS and FDA are proceeding with post-market surveillance activities. FDA will use the results of these activities to inform their safety and effectiveness oversight efforts. I believe that these efforts should continue, and I look forward to working with you and your staff to strengthen HHS's current efforts.

Question 37:

Because my home state of Iowa has a history of high-quality, low-cost care, the federal government pays Medicare Advantage plans about $762 per member per month to deliver Medicare services. Some lower-quality, higher cost states, receive close to $1000 per member per month, which means states are being rewarded for their inefficiency.

a. Do you agree that enacting "across-the-board" cuts to Medicare Advantage funding, without taking into account existing payment inequities, would just perpetuate the practice of penalizing low-cost high-quality states, while rewarding lower-quality higher-cost states?

b. As Secretary, how would you intend to guide policy development and implementation in Medicare Advantage to accommodate these geographic differences in the cost of Medicare services while maintaining access to Medicare Advantage plans across the country for beneficiaries who desire such coverage?

Answer: As a governor of a state with historically low-cost care, I understand that there are some geographic disparities in the way Medicare reimburses for patient care.

However, given the need to ensure Medicare is on stable financial footing, I am concerned about the 14 percent overpayments currently paid to Medicare Advantage plans under the existing payment methodology. I believe there are a number of ways we can go about leveling the playing field between the two programs, and realign payment incentives in Medicare to reward quality care and health outcomes while protecting beneficiary access to critical benefits. If confirmed as Secretary, I look forward to working with Congress on these issues.

Question 38:

While you take your orders from the President of the United States, you will have a lot of discretion at the Department to implement policies related to the health of women and unborn children. Do you have any intention to alter abortion policies while you're in office, including any plan to increase the ability of anyone to terminate her pregnancy?

Answer: In over two decades of service as a public official in Kansas, I have never recommended altering the laws regarding abortion. Congress has the power to make laws, and my job, if I am confirmed as Secretary, will be to implement them within the parameters of the courts' interpretation.

Reproductive rights issues have been extensively debated in Congress and litigated in the courts, and I do not foresee a situation where related regulatory action would be taken absent congressional or court action. As Secretary, I will focus on common ground on this issue and will work with Congress to leverage the assets of the Department to reduce unintended pregnancies.

Question 39:

You vetoed legislation in Kansas that bans partial birth abortions. The Congress passed, and President Bush signed into law, a ban on this heinous procedure in 2003. The Supreme Court upheld the law in 2007. Will you, as Secretary, also fully uphold the law and not water down in any way the national partial birth abortion ban?

Answer: Kansas law has prohibited late-term abortion since 1992 and "partial birth" abortion since 1998. I vetoed the 2008 bill because it raised very serious medical privacy concerns. If confirmed as Secretary of Health and Human Services, my job will be to implement and uphold the law as passed by Congress and interpreted by the courts, and I am fully committed to doing that.

Question 40:

Do you agree with the federal law that states that partial birth abortions are "a gruesome and inhumane procedure that is never medically necessary and should be prohibited."? Please explain.

Answer: I oppose *all* post-viability abortions except in cases where they are medically necessary. I believe determinations about when a procedure is medically necessary should be made by qualified health professionals, in accordance with the law. While I understand there is some disagreement over whether the specific procedure you mentioned is ever medically necessary, as you know, Congress has banned the procedure except in cases where the life of the mother is endangered, and, as Secretary, if confirmed, my job will be to enforce the law.

Question 41:

How do you plan to reduce abortions in this country?

Answer: I believe the best way to reduce abortions in this country is by reducing the number of unintended pregnancies. We can work together to increase pregnancy prevention efforts, including expanded access to contraception; support pregnant women and new mothers; and encourage adoption with incentives and financial support. In addition, I share the President's support for age-appropriate education to encourage abstinence and to reduce the risks associated with sexual activity.

As Governor of Kansas, I supported and worked to implement policies to prevent unwanted pregnancies, provide quality medical care for pregnant women, and promote adoption as an alternative to abortion. During my tenure in office, funding for adoption support increased by over $5 million. In 2006, I signed legislation to double the state adoption tax credit and provided finding for pregnancy maintenance efforts. Last year, I signed a bill that expanded the pool of people eligible to conduct adoption home assessments. In part as a result of these efforts, the number of abortions in Kansas decreased by over 10 percent between 2002 and 2008, and the number of teen pregnancies declined over that same period.

If confirmed, I look forward to working with the President and members of Congress in both parties to focus on aspects of this issue where we can find agreement, and to using the tools and programs within the Department in ways that will reduce the numbers of unintended pregnancies and abortions in this country.

Question 42:

Do you believe that the TANF block grant was a fundament element in the 1996 welfare reform bill? H.R. 1, the American Recovery and Reinvestment Act of 2009 included provisions that would give states additional federal resources, at an 80% match for additional families added to the caseload. Do you believe that it is appropriate to introduce matching funds to what has been a block grant for over 13 years?

Answer: I strongly believe in welfare reform that is based on work and responsibility, and creation of the TANF block grant program was a central feature of the landmark 1996 federal welfare reform legislation. I also believe that Congress was correct in recognizing that states would need additional resources to address increasing demands for services for low-income families during this economic crisis. If confirmed as Secretary of HHS, I look forward to working with our state partners to implement the new TANF Emergency Fund created by Congress in ARRA.

Question 43:

Do you believe that 80% is an appropriate match for the federal government to reimburse states for the cost of additional families on welfare? If, so please explain why 80% is an appropriate match. If not, what is the appropriate match, if any?

Answer: In creating the new TANF Emergency Fund, Congress provided that states would be reimbursed for 80% of their increased TANF spending in three categories: (1) assistance, (2) one-time assistance, and (3) subsidized employment. Each state may receive Emergency Fund payments of up to 50% of its Family Assistance Grant. In crafting the Emergency Fund, I believe Congress sought to create a funding mechanism that would allow states to respond to the needs of families in this economic crisis while ensuring that TANF remains focused on promoting work and responsibility.

Question 44:

How would you respond to critics who argue that establishing a matching funding stream within TANF erodes the block grant and undermines welfare reform?

Answer: In my experience as Governor, I learned that effective welfare reform requires focusing on work and responsibility while ensuring that families have the support they need to succeed on the job and at home. The TANF provisions in ARRA preserve work participation requirements for states, as well as time limits and work requirements for participating adults. States also retain the flexibility to design effective strategies for supporting low-income working families. As a result, I do not believe the ARRA provisions will undermine welfare reform.

Question 45:

H.R. 1 included a provision that creates an "Emergency TANF fund" to provide additional resources to states based on increases to their caseload. Do you believe that creating this Emergency TANF fund is better policy that improving upon the existing Contingency Fund, which was designed to address state need in an economic crisis? Please explain the rationale behind your answer.

Answer: States will continue to be able to access resources through the Contingency Fund first established in the federal welfare reform law in 1996. The TANF Emergency Fund, created by Congress in ARRA, makes additional funds available to states that are increasing their TANF expenditures in response to the economic crisis. I support this approach.

Question 46:

States will continue to be able to access resources through the Contingency Fund first established in the federal welfare reform law in 1996. The TANF Emergency Fund, created by Congress in ARRA, makes additional funds available to states that are increasing their TANF expenditures in response to the economic crisis. How do you respond to critics of this provision who characterize it as rewarding states who increase their caseload, thereby undermining a basic principle of welfare reform?

Answer: I believe that effective welfare reform is based on the principles of work and responsibility. During this economic crisis, as unemployment rises, more families will need assistance to weather these hard times, and states are already reporting increased demands for services from low-income families. In crafting the TANF Emergency Fund, Congress created a mechanism whereby a limited amount of federal funds will be available to states that are increasing their TANF expenditures in response to increasing demands for assistance during the economic crisis. I believe the mechanism is clearly defined, and, as a result, will not undermine the principles of welfare reform.

Question 47:

H.R. 1 included a provision which allows states to get caseload reduction credit for caseload in FY 07 and 08, instead of in 09, 10, and 11.

a. Do you agree that this means that states will be able to get a greater case load reduction credit for those years?

Answer: In ARRA, Congress permits each sate the option of calculating its caseload reduction credit by using either the previous fiscal year or the base year for the new Emergency Fund (FY07 or FY08). The impact of the credit will depend upon the option selected by each state.

b. Do you agree that means that a state's target participation rate will be lower for those years that it might have been otherwise?

Answer: For some states, the ARRA caseload reduction credit will result in a lower work participation rate than would have been the case prior to the changes enacted in ARRA. It is important to recognize that, even in those situations, many states will be engaging lager numbers of adults in work activities, as the lower work participation rates will be applied to much larger caseloads.

c. Do you agree that means that states will not have engage as many able bodied adults in meaningful work, work-related or educational activities in order to meet their target participation rate?

Answer: This is not necessarily the case. First, the precise impact of the new caseload reduction credit on each state will depend upon characteristics of that state's caseload, as well as the specific options selected by the state. In addition, as noted above, many states may be engaging larger numbers of adults in work activities, as lower work participation rates will be applied to much larger caseloads.

d. Do you think it is appropriate in tough economic times, to loosen requirements for states to provide training and other work related assistance for families?

Answer: I believe we must do all we can to help Americans find work and stay employed. In this economic crisis, as unemployment rises, it will be increasingly challenging for low-income families receiving TANF to find steady employment. I believe that states should be encouraged to work with families to provide supports during this downturn and position those families to be ready to take advantage of the recovery when it begins. Appropriate training, work experience, and child care may provide families with the kind of assistance they can use in this economic environment.

<u>Question 48</u>:

The Emergency Fund in H.R. 1 sunsets at the end of FY 2010. The participation rate changes in H.R. 1 sunsets at the end of FY 2011.

a. Why do you believe it is important for these provisions to end?

Answer: ARRA is intended is to provide an immediate and time-limited response to the current economic crisis, and the TANF provisions are part of that larger strategy.

b. What assurances can you provide that your agency will not push to extend these provisions after the sunset date?

Answer: I believe it is premature to consider future steps in this area before we even begin implementing the TANF provisions of ARRA. However, I remain strongly committed to implementing TANF in a manner that reinforces the principles of work and responsibility, and consistent with the immediate and time-limited objectives of the Recovery Act.

Question 49:

The TANF provisions reauthorized in the Deficit Reduction Act of 2005 will expire at the end of FY 2010. This means that the Congress will have reauthorize welfare next year or face another series of TANF extensions. Describe how you intend to work with Members of the Committee and the congress in developing a bipartisan plan for TANF reauthorization?

Answer: If confirmed as Secretary of HHS, it will always be my priority to craft bipartisan solutions to the issues and challenges within the purview of the Department. With that in mind, I look forward to working with Congress in a bipartisan manner to reauthorize TANF in manner that reinforces the principles of work and responsibility.

Question 50:

As you know, TANF reauthorization was very difficult to achieve. In 2002, Chairman Baucus produced a bill that was never considered by the Democratic Congress. In 2004, I produced a bill that was filibustered by the Democrats. There were 12 extensions of TANF before the reauthorization was finally enacted. What are the lessons learned from the last reauthorization effort and how you intend to ensure that meaningful welfare reform is enacted in the 111th Congress?

Answer: If confirmed as Secretary of HHS, I intend to work with members of both parties to highlight the need for bipartisan TANF reauthorization that reinforces the principles of work and responsibility. In particular, I would seek the advice of the Chairman and Ranking Member of the Finance Committee in considering strategies for the Administration to pursue.

Question 51:

According to analysis, prepared by the Congressional Research Service (CRS) based on the FY 2006 TANF National Data Files, of the 2.0 million TANF families, less than half represent what is typically considered a "welfare family" -- one with an unemployed adult recipient. The so-called "child only" families receiving welfare are now nearly the same size as families with a work-eligible adult. CRS notes that this is very different from the past. For example, in 1994, 75% of all families receiving welfare were families with an unemployed adult recipient. Describe how you plan to address the changing demographics of the welfare caseload.

Answer: The growth of "child-only" cases is a very important development in TANF caseload trends over the past 13 years. If confirmed as Secretary of HHS, I would welcome the opportunity to work with experts both in and out of the Department to examine these trends more carefully and to understand the policy implications of those changes.

Question 52:

How do you plan to improve the integration of services for low income people?

Answer: When seeking assistance, low-income families too often face a myriad of conflicting and confusing program rules. To address these kinds of issues, there needs to be closer coordination between federal agencies, Congressional committees, and implementing agencies at the state/local level. As Secretary of HHS, I will work closely with leaders of HHS programs, as well as other Cabinet departments, to examine potential strategies for promoting integration of programs.

Question 53:

Describe how you plan to address the jurisdictional barriers presented when attempting to integrate services such as food stamps, welfare and the Workforce Investment Act which are authorized by separate Congressional committees.

Answer: As you note, the varying rules that exist today for multiple low-income programs can be traced to statutory differences that relate to separate Congressional committees of jurisdiction. If confirmed as Secretary of HHS, I would seek to work closely with committee leadership to address these issues and would welcome your advice about the most effective way to do so.

Question 54:

What level of mandatory child care funding will the Department be proposing as part of a welfare reform reauthorization proposal?

Answer: It is premature to discuss details of the Administration's welfare reform reauthorization proposal. However, I strongly believe in welfare reform based on the principles of work and responsibility. In my experience as Governor, a critical element of successful welfare reform was to provide work supports, such as child care, that enable families to succeed on the job and at home. If confirmed, I look forward to keep you informed as the Administration develops proposals in this area, and to working with Congress to enact meaningful welfare reform.

Question 55:

Do you believe it is appropriate to condition the receipt of new child care funds on a state's ability to meet a vigorous target participation rate or a state's willingness to engage clients in 40 hours of work or work related activities?

Answer: It is premature to discuss details of the Administration's welfare reform reauthorization proposal. However, I strongly believe in welfare reform based on the principles of work and responsibility. In my experience as governor, a critical element of successful welfare reform was to provide work supports, such as child care, that enable families to succeed on the job and at home. If confirmed, I look forward to keep you informed as the Administration develops proposals in this area, and to working with Congress to enact meaningful welfare reform.

Question 56:

Should states be exempted from their match for the receipt of federal child care funds?

Answer: It is premature to discuss details of the Administration's welfare reform reauthorization proposal. However, I strongly believe in welfare reform based on the principles of work and responsibility. In my experience as governor, a critical element of successful welfare reform was to provide work supports, such as child care, that enable families to succeed on the job and at home. With respect to changes in financing requirements generally, it will be critical to ensure that adequate resources are available to serve needy families.

Question 57:

As you know, crowd out occurs when families either give up or do not take private coverage in order to participate in a public plan. Current regulations require that states much have a plan to address crowd out in their CHIP program. How do you intend to ensure that states are implementing appropriate procedures to minimize crowd out in CHIP.

Answer: I share the goal of minimizing crowd out so that scarce federal and state dollars are used to cover as many uninsured children as possible rather than to replace private insurance. As you note, all states are required to have a plan in place to address crowd out in CHIP, and, if confirmed as Secretary, I would enforce that requirement. I would also expect states expanding coverage to more moderate-income levels—where crowd out is a larger concern—to regularly monitor and evaluate the extent to which crowd out occurs, and, if necessary, to take additional steps to minimize employers dropping coverage or workers opting out of affordable coverage. I would also be mindful, however, of the fact that we are now are in a situation where many children are losing access to employer-based coverage because of our nation's economic problems, not because of crowd out, nd any actions taken to stem crowd out should not penalize children who are losing their coverage because of factors outside of the family's control.

Question 58:

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. This law was based largely upon the successes of other qui tam statutes—such as the False Claims Act. Recent court decisions have held that the Medicare Secondary Payer 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 for mismarked patent filings.

In that brief, the Justice Department expressly stated that Congress has enacted several qui tam provisions most notably, the MSP statute. 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.

a. Gov. Sebelius, do you believe that the MSP statute is a qui tam statute?

Answer: It is my understanding that multiple courts have considered in recent years whether the Medicare Secondary Payer (MSP) private cause of action is a qui tam provision and all have ruled that it is not. I am not in a position to second-guess this body of precedent, but I can commit to you that, if confirmed, I will carefully examine the issue in consultation the Department of Justice.

b. 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 construe the MSP statue as containing a qui tam mechanism. I commit that I will carefully examine the issue in consultation with the Department of Justice; however, I would not be in a position to adopt the use of the MSP statute as a qui tam mechanism unilaterally.

c. 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: Yes -- the Medicare Secondary Payer statute is designed to (1) ensure that Medicare avoids making payments for which it is not obligated, and (2) recover payments that should have been made by primary payers. It is not necessary to read a qui tam provision into the current statute for the Medicare program to recover payments that should have been made by primary payers. The MSP statute's private right of action merely provides one of several available mechanisms through which Medicare can recover payments that should have been made by primary payers.

<u>Question 59</u>:

In 1996, Congress enacted the Health Insurance Portability and Accountability Act (HIPAA), in part, to provide better stewardship of the Medicare program. Until then, the Centers for Medicare and Medicaid Services (CMS) had traditionally delegated most of the responsibility for safeguarding the Medicare program to the claims administration contractors. With HIPAA's enactment, CMS had the authority to contract with program safeguard contractors (PSC) to combat fraud, waste and abuse.
Last fall, CMS announced that the work of its PSCs and Drug Integrity Contractors (MEDIC) would be transitioned to the new Zone Program Integrity Contractors (ZPIC) to enhance its program integrity efforts to prevent Medicare and Medicaid fraud, waste and abuse.

a. As Secretary, how will you guide HHS to ensure that CMS has appropriate oversight in place to ensure that the ZPICs are effectively and efficiently carrying out its program integrity responsibilities?

b. Under your leadership, how will CMS be evaluating the success of the ZPICs in identifying and preventing potential Medicare and Medicaid fraud, waste and abuse?

Answer: It is my understanding that CMS is in the process of transitioning work to the new Zone Program Integrity Contractors (ZPIC), whose responsibilities will include working to prevent fraud, waste, and abuse in Parts A, B, C and D of the Medicare program, including durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); as well as home health and hospice. As this transition progresses, I believe the ZPICs will prove to be a more efficient and effective way to conduct program integrity activities due to their ability to look across multiple payment types. In order to accomplish this, CMS is transitioning from 18 PSC task orders to just 7 ZPICs, which will allow all stakeholders, including law enforcement, to go to just one contractor (previously stakeholders would have had to go to as many as four contractors for the same information).

The new ZPIC jurisdictions are aligned with the Medicare Administrative Contractors (MACs), which integrated Medicare Part A and B claims-processing activities under a new single contractor, as well as the CMS field offices. This will promote enhanced cooperation, allowing each to assist in monitoring each other's performance and effectiveness. Since they will be under a single task order for all claim types, I am confident that each ZPIC will foster a better, more comprehensive look at fraud over an entire region for elements such as a common owner, beneficiary, provider, or supplier, which may signal the misuse of resources.

If confirmed as Secretary of HHS, I will ensure that CMS remains focused on the evaluation of the performance of all Medicare contractors. I believe that having clearly defined performance metrics will be critical in determining the efficacy, productivity, and effectiveness of the ZPICs. If confirmed, under my leadership, CMS will aggressively look at outcomes in terms of total overall impact to the Medicare program. Such actions will include reviewing interagency coordination and education to limit programmatic vulnerabilities; improving the timeliness of responses to requests (both law enforcement and hotline) in high-fraud areas of the country; evaluating the quality of information provided to CMS; and taking administrative actions to evaluate ZPIC success.

Question 60:

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.

Quality Improvement Organizations (QIOs) are tasked with a wide range of functions. I am concerned about the inherent conflict of interest posed by these organizations having to conduct beneficiary protection functions such as investigating complaints of poor quality by providers and at the same time providing quality improvement technical assistance to these same providers. Also, no one knows if QIOs actually improve health care quality despite that fact that they receive over $300 million a year in federal funding. Furthermore, my oversight and investigations staff have discovered numerous instances of questionable activities in the governance of these organizations.

a. **As Secretary, what steps would you take to address the inherent conflicts of interest with the duties assigned to QIOs?**

b. **What steps would you take to ensure that the taxpayers are getting their money's worth from the QIO program and there is adequate accountability by QIOs?**

c. **Finally, what steps would you take to ensure that there is adequate oversight over QIOs by HHS?**

d. **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?**

e. **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: Quality Improvement Organizations (QIOs) are an important part of the Administration's ongoing efforts to improve the quality of care furnished to people with Medicare. As you know, QIOs work with consumers, physicians, hospitals, and other caregivers to refine health care delivery systems to make sure patients get the right care at the right time, particularly among underserved populations. QIOs also investigate beneficiary complaints about quality of care.

If confirmed as Secretary, I will ensure that CMS holds all Medicare contractors accountable, including the QIOs. I understand that QIOs that did not meet CMS evaluation criteria for the 8th Statement of Work (SOW) had to recompete for the 9th SOW core contracts. In addition, for the 9th SOW, CMS will be conducting quarterly evaluations of each QIO. At the eighteen and twenty-eight month evaluation periods, CMS has the authority to terminate a QIO contract if the QIO is not meeting the evaluation criteria. Also as part of the 9th SOW, CMS built an information management system that is designed to improve oversight of the program and help the Agency monitor how QIOs are performing on themes and progressing on evaluation criteria.

With regard to QIOs and conflicts of interest, I understand that CMS currently has policies in place that address potential conflicts of interest by QIO contractors and that the QIO contract has been modified to include CMS guidelines regarding conflicts of interest. With that said, if confirmed as Secretary, I am committed to working with Congress to continue this oversight of QIOs and to ensure that they contribute to critical delivery system reforms.

Question 61:

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.

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

b. 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: I share your commitment to assuring the quality of care, transparency, and accountability in nursing homes. Over the course of your career beginning with your chairmanship of the Senate Special Committee on Aging in the late 1990s and continuing with your role on the Finance Committee, you have shined a bright light on serious deficiencies in the quality of care provided by poorly performing nursing homes.

You have also demonstrated the need for strengthened federal oversight of nursing home survey and certification.

If confirmed as Secretary, I will continue to support efforts to ensure the quality and safety of beneficiaries receiving care in America's nursing homes, and I look forward to working with you to make even greater strides in this area.

In December 2008, CMS launched the Five-Star Quality Rating System on its Nursing Home Compare website, which provides quality ratings for each of the nation's 15,800 nursing homes that participate in Medicare or Medicaid. CMS created the Five-Star Quality Rating System to assist consumers, their families, and caregivers in comparing nursing homes more easily and in identifying areas about which they may want to ask questions. Facilities are assigned star ratings based on health inspection surveys, staffing information, and quality of care measures.

If confirmed as Secretary, I pledge to work with you and your colleagues to advance HHS's quality initiative to improve the quality and safety of our nursing home care.

Question 62:

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.

The FDA has expressed interest in conducting a greater number of inspections of foreign establishments that manufacture drugs and medical devices for the US market.

a. What would be the most important steps for FDA to take when increasing its foreign inspections?

Answer: The most important steps FDA can take in this area pertain to the smart use of inspectional resources. First, FDA should expand its efforts to apply a risk-based approach when determining where and when to conduct inspections. Second, as appropriate, FDA should establish dedicated inspectorates for the products it regulates. Inspectors who focus on a particular category of product, whether it be foods or drugs, will develop the necessary expertise to conduct quality inspections more quickly and be more effective at detecting and addressing problems.

Third, FDA should work closely with trusted foreign governments to more effectively use the information they gather through their own inspections or through other channels to better target FDA's inspectional resources.

b. Since resources have been an issue for the agency, what steps would you take as Secretary to ensure that FDA has the resources it needs to improve its oversight of foreign establishments manufacturing drugs and medical devices for the U.S. market?

Answer: An important responsibility of the FDA is to ensure that foreign facilities manufacture high-quality FDA-approved drugs and devices for the U.S. market. I look forward to working with the President and Congress to provide FDA with the resources it needs to meet its oversight responsibilities.

Question 63:

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." What steps would you take to make sure GAO's recommendation is implemented?

Answer: Under the Federal Food, Drug, and Cosmetic Act, the first step in this process is for FDA to order manufacturers of preamendment class III devices for which no final regulation has been issued requiring the submission of PMAs to submit to the agency a summary of any information known or otherwise available to them about those devices. If confirmed, I would ask for a status update on this important first step.

Question 64:

A few months ago, the FDA finalized its guidance on the dissemination of scientific literature on off-label uses of drugs and devices to physicians by drug and device sales representatives. I strongly advocate the dissemination of more information to doctors and their patients about the safety and effectiveness of drugs and devices to inform medical decisions. However, I have serious concerns about FDA's guidance in light of studies and editorials on "ghostwriting" and manipulation of data by the drug industry and my own findings regarding the lack of or limited transparency in the financial relationships between the drug and device industries and physicians.

In 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA), which included a provision, Section 401, allowing drug and device manufacturers to distribute scientific literature and other medical information on new or off-label uses under certain conditions. The manufacturer was required to submit a supplemental new drug application for the off-label use or obtain an exemption from the requirement from the Secretary of the Department of Health and Human Services. Section 401, however, expired in September 2006, and in February 2008, the FDA proposed draft guidance on its views regarding distribution of scientific literature to physicians by drug and device manufacturers.

The guidance was finalized on January 13, 2009. As a result of this guidance, what the FDA once considered evidence of unlawful marketing or misbranding or adulteration of a drug or device the Agency now seems to consider appropriate dissemination of information. In fact, the final guidance specifically states that "if a manufacturer follows the recommendations of…this guidance and there is no unlawful promotion of the product, FDA does not intend to use the distribution of such medical and scientific information as evidence of an intent by the manufacturer that the product be used for an unapproved use." But an intent of manufacturers in distributing such scientific literature would be to encourage or "promote" an unapproved use.

a. What is the basis for FDA's issuance of guidance on this matter?

Answer: FDA based its guidance on an opinion about the sunsetting of an applicable federal law related to the distribution of medical and scientific information.

b. What is your position on FDA's new guidance?

Answer: If confirmed, I will closely examine the new guidance, and work with the new FDA commissioner to determine how best to proceed.

c. What steps will you take to ensure that this guidance is not used to circumvent the FDA approval process by allowing manufacturers to go directly to physicians about off-label uses for which they might otherwise have sought approval.

Answer: If confirmed, I will work with the new FDA commissioner to ensure that the law is upheld with respect to off-label uses.

d. How will you ensure appropriate oversight by the FDA, especially with no requirement that manufacturers submit copies of the literature being disseminated as a result of the sunset of the statutory provision?

Answer: If confirmed, I will instruct the new FDA commissioner to provide appropriate oversight or to advise me if new authorities are needed to provide that oversight.

Question 65:

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: An important public health role of FDA is to oversee the promotion of drugs and devices. False or misleading promotional materials can lead to misinformed decisions by patients and practitioners regarding the selection and use of medical products. I am interested in hearing any thoughts and 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 direct the appropriate oversight of promotional materials.

Question 66:

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.

Senator Edward Kennedy and I introduced the Drug and Device Accountability Act (DADAA) in July 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 registration and 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.

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

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

Question 67:

Each year, billions of dollars flow from pharmaceutical and medical device companies to practicing physicians. These transfers may take such various forms as consulting agreements, funding for research or a night out on the town. There're mountains of evidence to suggest that these relationships can have an affect on physician practice – on what drugs a doctor prescribes, or what device a surgeon implants. Currently, in all but a few states, people have no way of knowing what financial relationships might be affecting their doctor. Physicians have no way of knowing what relationships might be affecting journal authors or opinion leaders. Universities have no way of knowing if medical faculty members are adhering to disclosure rules required by NHI regulations. Many of my recent investigations have confirmed that all of this is the case. That's why I, along with Senator Kohl, 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.

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.

a. If confirmed, will you direct NIH, FDA, and others to take conflicts of interest seriously in federal grants and drug trials?

Answer: If confirmed, I will ensure that all HHS departments and agencies take conflicts of interest seriously, and that the public interest is always put first. However, I do believe that it is important to distinguish between "interests" and "conflicts." We want our scientists to have interests. We want them to share information and collaborate, including with the private sector, to challenge each other's ideas and advocate for their own ideas. We do not want, nor is it in the nation's interest, to create a world where university and government scientists are completely isolated from industry scientists.

A major component of avoiding conflicts – academic ties, financial ties, institutional biases – is to insist 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 those conflicts that arise from legitimate interests, and we prohibit interests that do not further the scientific mission of NIH and its grantee institutions.

b. 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: I support the principle of transparency in the relationship between practicing physicians and drug and device companies. I understand that some states have been moving in this direction.

I would like to hear from physicians and the industry about their perspective on these efforts before deciding whether federal legislation is appropriate at this time.

Question 68:

For years, I've been an advocate of whistleblowers. Too often, federal whistleblowers sacrfice 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.

a. What steps would you take as 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: Whistleblower protections are critically important so that problems within agencies can be brought to light. If confirmed, I will demand that whistleblower issues be addressed through the Department-wide effort on scientific integrity. Each agency should have a clear process for investigating concerns and protecting the rights of whistleblowers.

b. 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: Congress has an important oversight role, and I support HHS cooperation with Congressional investigations. Of course, my goal is for concerns about agency function to be handled appropriately by the agencies themselves in the first instance. Each agency must have a credible process for listening to and investigating concerns raised by any and all employees, and each agency should make this process accessible to its employees. In addition, the agency has an OIG that can review complaints by anyone in the Department.

Question 69:

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 would like to emphasize that NIH believes that it is vital to maintain objectivity in research and takes its responsibility to provide oversight of extramural investigators' conflicts of interest very seriously. NIH is committed to its financial conflict of interest oversight activities and continues to be at the forefront of an initiative to reexamine the existing regulation to facilitate regulatory compliance and effective oversight. To that end, NIH on behalf of the Department and PHS developed an Advanced Notice of Proposed Rulemaking (ANPRM) to initiate a carefully considered, open dialogue with all affected parties on the complex issues surrounding financial conflicts of interest (FCOI). Thus, the ANPRM will invite public comments on possible revision of the FCOI regulation.

The ANPRM was designed to elicit comments on some of the most controversial issues and in areas where there may be inherent weakness in the existing regulation. The ANPRM is organized into the following six areas:

1. Expanding the scope of the regulation and disclosure of interests (including questions addressing a new requirement for grantees to provide details regarding the nature of financial conflicts of interest and how they are managed, reduced, or eliminated)
2. Definition of "significant financial interest"
3. Identification and Management of Conflicts by Institutions
4. Assuring Institutional Compliance
5. Requiring Institution to provide additional information to the PHS
6. Institutional Conflict of Interest (institutional conflict of interest is an area of increasing concerning that currently is not addressed by the Federal regulations)

I support NIH's efforts and agree that it is time to reevaluate the existing FCOI regulation to assure that PHS supported research is conducted without bias.

<u>Question 70</u>:

The NIH has submitted an Advanced Notice of Proposed Rulemaking (ANPR) to seek public comment on changes to their conflict of interest policy. Please provide a date for when this ANPR will be released.

Answer: I will take immediate steps to ensure that the Department completes its review of the ANPRM expeditiously so that it can be forwarded to the Office of Management and Budget. I will also recommend that OMB move swiftly to post it in the Federal Register.

Question 71:

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: When an institution fails to comply with the terms and conditions of an award and does not demonstrate compliance with the federal regulations, Departmental regulations (45 CFR 74.61 and 74.62, and in 92.43) and policy provide NIH the authority to impose a range of enforcement actions, depending on the severity and duration of the non-compliance. NIH will undertake any such action in accordance with applicable statutes, regulations, and policies. NIH generally will afford the grantee an opportunity to correct the deficiencies before taking enforcement action unless public health or welfare concerns require immediate action. However, even if a grantee is taking corrective action, NIH may take proactive action to protect the federal government's interest, including placing special conditions on awards or precluding the grantee from obtaining future awards for a specified period, or may take action designed to prevent future non-compliance, such as closer monitoring.

This may entail imposing special reporting requirements on all NIH grant awards made to the institution subject to the provisions of 42 CFR Part 50, Subpart F. NIH may also consider suspending the grant until the institution demonstrates that it has achieved compliance with the regulation, specifically 42 CFR Part 50.605(g)(2), pending corrective action, or may terminate the grant for cause.

The introduction of bias in the conduct of NIH-supported research is untenable, and NIH 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 and also imposed institution-wide special reporting requirements to address weaknesses in the institution's administrative process to identify and manage, reduce, or eliminate conflicting interests at an institution. NIH does not take such actions lightly and will not hesitate to take similar enforcement actions when warranted.

Question 72:

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 do to strengthen human subject research protection in clinical trials?

Answer: OHRP actually evaluates every allegation of non-compliance it receives, to determine whether it provides credible evidence of non-compliance that is within OHRP's jurisdiction. In every instance where there appears to be such evidence, OHRP opens a compliance case and fully investigates.

While the number of compliance cases does not end up being very large – maybe 10 to 15 cases each year – I am advised that reflects the number of complaints being made to OHRP. OHRP also opens a handful of not-for-cause reviews of institutions each year.

It is certainly true that there is much room for improving protections for research subjects, and the goal of doing so is an important one. One specific change could be to revise the regulations to give OHRP specific authority to institute compliance actions against so-called "independent" or "private" IRBs. These entities, which are usually for-profit, appear to be taking a greater and greater role in reviewing and approving clinical trials.

Question 73:

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: The Accreditation Council for Continuing Medical Education (ACCME) has the primary responsibility for identifying, developing, and promoting the standards for quality continuing medical education (CME) utilized by physicians in their maintenance of competence and incorporation of new knowledge to improve quality medical care for patients and their communities.
The ACCME fulfills its mission through a voluntary self-regulated system for accrediting CME providers and a peer-review process responsive to changes in medical education and the health care delivery system. NIH does not grant CMEs directly, but does fund conferences that may have sessions that are accredited for CMEs by other organizations in line with ACCME guidelines. These grantees must abide by the NIH rules governing management of conflicts of interest. The ACCME approves the educational content and reviews the potential for real or perceived conflicts of interest for granted CMEs.

Question 74:

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 Director 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: 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.

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 75:

The new Obama Administration has placed emphasis on implementing health information technology (HIT) systems and the Congress recently provided about $20 billion for HIT under the American Recovery and Reinvestment Act.

a. Please describe whether or not there a system in place for health care professionals to report to HHS or other government entity problems or concerns and make recommendations regarding HIT systems being implemented in their hospitals or other treatment facilities? If not, would you consider establishing such a system?

Answer: To ensure that we maximize the potential of a fully interoperable health IT infrastructure, both patients and healthcare providers must trust it and be committed to using the system. One important factor in this is ensuring that they are active participants in its development so that it reflects their needs and input. The Policy and Standards Committees established by the Recovery Act are both important vehicles for providing this type of input, as are the Regional Extension Centers and the Research Center that must be established under the Act. I would welcome any additional thoughts and suggestions you have to ensure that the input of healthcare professionals is adequately represented in the development and implementation of the nationwide health IT infrastructure.

Question 76:

What oversight exists to ensure that individuals and/or institutions are adopting new health care technologies responsibly?

Answer: A key federal role in the development of a nationwide health IT infrastructure is ensuring that systems are fully interoperable and can talk to each other and that patient privacy is assured. The Recovery Act gives HHS tools to help accomplish these goals. The standards and certification process established in the Recovery Act will help assure providers that the electronic medical record systems they purchase are indeed interoperable, while spurring innovation and competition as vendors develop products that meet these standards and the needs of providers in the system. In addition, the introduction of payment incentives in 2011 will encourage providers to purchase and utilize systems that allow them to meaningfully use health IT.

Question 77:

Recently, I received a number of concerns regarding a specific HIT system, the Computer Physicians Order Entry (CPOE) device, which is used during the administration of medical care to patients. In particular, questions have been raised about the adoption, regulation and testing of CPOE. Please explain how these devices are regulated and by whom? Who assesses whether or not a CPOE device is effective and which devices are adopted? Is there surveillance of adverse outcomes of care that may be associated with the use of these devices? If not, why not?

Answer: FDA can regulate products, including computer software, when they meet the definition of a medical device, and some CPOE systems may be medical devices. The increasing complexity of more recent CPOE versions and their use by physicians to make clinical decisions may require additional oversight by the agency. If confirmed, I look forward to looking into this important issue in more detail to ensure that patient safety and provider confidence in these products are assured.

Question 78:

Governor Sebelius, as a result of the vetting process you have gone through as a nominee, you filed amended federal income tax returns for years 2005, 2006, and 2007. As part of the review process undertaken by the Finance Committee, you responded to a March 31, 2009, letter from Chairman Baucus and myself discussing this situation. Both letters are attached. Please discuss how and when you decided you needed to have your tax returns reviewed, how and when you determined that amended returns needed to be filed, and describe the specific changes that needed to be made.

Answer: In early March of this year, in preparation for my confirmation process as the nominee for Secretary of the Department of Health and Human Services, my husband and I hired a Certified Public Accountant to conduct a thorough review of our tax returns for 2005, 2006 and 2007. That evaluation revealed unintentional errors, which we immediately corrected by filing amended returns.

Interest: In July of 2006, we sold our home for an amount less than the outstanding balance on our mortgage. We continued paying off the loan, including interest we mistakenly believed continued to be deductible mortgage interest. Another loan for home improvements was treated similarly. Although the proceeds of the loans are traceable to home acquisition and home improvements, the loan was not secured by a principal residence. On our amended returns, loan interest is no longer deducted.

Business expenses: We eliminated deductions for businesses expenses, including meals and entertainment which should have been classified as gifts and others for which we had incomplete documentation, such as business purpose or relationship of those entertained. We also eliminated deductions for a home computer, a national newspaper subscription, club dues and a trip we concluded had been personal in nature. While the amended returns reflect these changes, they did not affect the amount of taxes owed because we were subject to the Alternative Minimum Tax.

Charitable contributions: For charitable contributions in excess of $250, taxpayers must have an acknowledgment letter from the charitable organization in order to take a tax deduction. Out of 49 charitable contributions we made in these three years, there were three for which we could not locate our acknowledgment letter. The amended returns eliminated these deductions.

Question 79:

Given that you are a state governor and that your husband is a Federal judge, it is expected that most business expenses would be reimbursable by your respective employers. Please describe how both of you came to incur business expenses that it was appropriate to deduct on your federal income tax return that you were not reimbursed for by your employers.

Answer: As Governor, I incurred employee business expenses for staff luncheons, business lunches and dinners, and travel for business meetings that were related to my occupation but not necessarily related to my duties as Governor of Kansas. In my judgment, these expenses were not eligible for reimbursement from the State of Kansas. Kansas law delegates decisions about reimbursable expenses to the Governor. During this time period, I did incur expenses that were reimbursed by the State of Kansas.

My husband incurred employee business expenses that were not reimbursable by his employer, including travel to association meetings, association dues, staff gifts, and meals and entertainment expenses for business purposes, but unrelated to the official business of the court. As a federal judge, my husband regularly incurs expenses which have been reimbursed by the Federal District Court.

Question 80:

Last week, the Secretary of state indicated that the troubles on the border between the United States and Mexico related to drug cartels was partially the fault of the United States for insufficient law enforcement and a need for a better job in addressing the demand for drugs. The demand side portion of our efforts on drugs abuse is within the Department of Health and Human Services and specifically The Substance Abuse and Mental Health Services Administration "SAMHSA". As the Secretary of the US Department of Health and Human Services, how would you work with "SAMHSA" to address this problem that the Secretary of State referred to in front of both Mexican and United States press especially since there were no funds available for substance abuse in the stimulus package?

Answer: The Department of Health and Human Services through the Substance Abuse and Mental Health Services Administration (SAMHSA) has been focusing on reducing the demand for drugs with some success, yet, according to the National Survey on Drug Use and Health (NSDUH) in 2007, an estimated 19.9 million Americans aged 12 or older, approximately 8 percent of the total population aged 12 or older, used drugs in the past month at the time of the survey. This is a slight reduction from 2006 (8.3 percent). The devastating cost – to affected individuals, their families and friends, the businesses where they work, the health budgets of state and local health departments, and the budgets of state and local prisons in which many affected individuals are maintained – was estimated at over $100 billion per year.

To address this, the Department provides funding through the Substance Abuse Prevention and Treatment Block Grant and discretionary grants to all 50 States, the District of Columbia and U.S. Territories for prevention and treatment services. Total spending by SAMHSA on substance abuse prevention and treatment is nearly $2.4 billion.

While many of our past and future efforts will be focused on the border, demand for drugs is a national problem. While there has been some success in decreasing drug use, especially among those aged 12 to 17, much more must be done. To provide a coordinated federal response, we should continue to work with the Office of National Drug Control Policy (ONDCP), the Department of Justice, Department of Transportation, and other agencies.

The primary place individuals go when they need help is their family physician, suggesting we should continue to work on the integration of substance abuse prevention and treatment into primary health care. An example of that is the Screening, Brief Intervention, and Referral to Treatment program. We should also continue to work on criminal justice programs with the Department of Justice, and to focus our efforts on areas of need, using Access to Recovery grants and Treatment Capacity Expansion grants.

Finally, we must continuously evaluate the success of programs to help states and local communities implement best practices in both prevention and treatment. These best practices are on the SAMHSA website under the National Registry of Evidence-based Programs and Practices. More needs to be done in this area, and, if confirmed, I will be dedicated to making sure that is done.

Questions from Senator Rockefeller

Question 1:

Governor Sebelius, in your testimony, you referenced a heart-breaking scenario of three women all fighting breast cancer. Despite the advances in the treatment of breast cancer, only one of the three women survived. Pre-existing condition exclusions by insurance companies prevented the other two women from getting the care they needed, despite the fact that they had health insurance – and, as a result, they died. I have held hearings over the last week on the dishonest practices of insurance companies, and I am the author of legislation to eliminate pre-existing condition exclusions in every market.

Isn't it long past time to enact meaningful insurance market reforms that take decisions out of the hands of dishonest insurance companies so that people can get the life-saving care they need?

> **Answer:** The President supports policies that keep health insurance companies honest and promote competition on cost and quality rather than enrolling the healthiest and lowest-cost individuals. A National Health Insurance Exchange that offers a choice of private plans and a public plan option is one way of achieving this. The President has also called for an end to the practice of denying coverage to people with pre-existing conditions. I look forward to working with Congress to ensure that all Americans can obtain the coverage they need.

Question 2:

Governor Sebelius, I was thrilled to learn that during your time as Health Insurance Commissioner, you served as a commissioner on President Clinton's Advisory Commission on Consumer Protection and Health Care Quality. We must improve quality in order to achieve better patient outcomes. However, I fear that the lack of coordination among all the different entities involved with federal quality efforts will make improving quality a difficult task. As Secretary of HHS, you would have some authority to help define and streamline health care quality improvement efforts, particularly for Medicare, Medicaid, and CHIP.

Do you agree that there needs to be more direction and coordination of quality improvement efforts among the various agencies under the HHS umbrella?

> **Answer:** Yes. If confirmed, I will ensure that the agencies, along with their leadership, understand that we can no longer treat quality as an afterthought. A comprehensive strategy implemented across the Department – and ideally across all Federal health programs – is a central pillar of moving toward a high-performing health system.

Do you also agree the process for testing, improving, and implementing quality improvement strategies in Medicare is not clearly defined today, nor is it efficient?

> **Answer:** Medicare's ability to advance quality improvement strategies can and should be improved. If confirmed, I will bring my experience as an insurance commissioner and Governor to the task of developing and implementing such strategies. And I will ensure that the Administrator of the Centers for Medicare and Medicaid Services – and other key agencies – have the same priority.

And lastly, do you agree this problem also exists more broadly across all federal agencies – including the VA and Department of Labor – and that we should consider a more permanent role for a Quality Interagency Coordinating Commission similar to what was established temporarily under the Clinton Administration?

> **Answer:** I agree that we need to improve quality across our public – and private – insurance programs. Our health care providers are the best in the world, but operate in a flawed and fragmented system. Ending gaps in coverage, expanding health information, integrating quality measures into payment systems, and advancing research on what works will improve the health system's performance. Leadership to prioritize quality of care comes from the President, who emphasized this during the campaign and reiterated it in his budget. If confirmed, I will work with the White House Office of Health Reform and other departments to promote patient safety and support our providers' efforts to improve quality.

<u>Question 3</u>:

Governor Sebelius, while the new CHIP law will provide states with federal support to expand coverage for an additional 4 million children, almost 5 million will remain uninsured. As we put together the CHIP bill, I worked closely with a number of my colleagues to ensure that it would not only expand health coverage for children, but that it would also improve the quality of care that children receive. A recent study published in the October 11, 2007, New England Journal of Medicine found that fewer than half of America's children – regardless of family income or insurance status – receive the right care in the right amount at the right time. I hope you agree with me that implementation of the quality provisions of the new CHIP law should be a priority.

How can we work together to build on the new CHIP law to ensure that health reform provides coverage for every child that meets their unique healthcare needs?

> **Answer:** CHIPRA's quality initiatives provide an important and exciting opportunity to assess and improve health care quality for America's children; I agree with you that implementation of these initiatives must be a high priority. As President Obama said when he signed CHIPRA into law, the bill's coverage expansion provides a down payment on ensuring every American has access to health care.

Similarly, CHIPRA's quality initiative provides a platform for us to be able to measure and improve health services to assure that all children receive the best possible care, regardless of where they live or their racial or ethnic background. I am very appreciative of you and your Congressional colleagues' forward thinking in this area and, if confirmed as HHS Secretary, I look forward to working with you and other members of Congress with an interest in these provisions to ensure the timely and smooth implementation of the quality initiative.

What can you tell us about plans at HHS to move forward on the provisions including in the CHIP law requiring the development, dissemination and implementation of pediatric quality measures in CHIP and Medicaid?

Answer: With respect to implementation of the quality provisions, HHS is currently reviewing measures now available and in use by State Medicaid and CHIP programs to prepare for a January 1, 2010 release of a core set of child health measures that address the quality and stability of children's coverage, as called for in CHIPRA. Recognizing how important this issue is to families, children's advocates, State leaders, providers and employers, HHS will consult with leaders in children's health and health care quality and will be creating a federal advisory group that will include representatives from many sectors and provide a forum for public participation. Another critical component of the quality initiative will be a tight linkage between the use of electronic health records and quality assessment so that new scientific advances are easily translated into improved health and health care for children. Officials from both the Agency for Health Care Research and Quality and CMS are working together on implementation of all of the components of the quality initiative.

<u>Question 4</u>:

Governor Sebelius, I was encouraged to see that during your confirmation hearing before the HELP Committee, you stated your support for a public health care plan. I believe that access to a public plan is key to bringing transparency, stability, and affordable, meaningful health coverage to every American. The Senate Commerce Committee, which I chair, has held two investigation and oversight hearings into UnitedHealth Care and the lack of transparency in the health insurance market that resulted in providers being underpaid and patients overpaying for their out of network treatment. This is unacceptable.

In your experience, does the current private health insurance market do an adequate job of providing affordable health insurance to our most vulnerable, for example those with chronic conditions? Shouldn't we have a public plan option that competes with private plans?

Answer: The current system has clearly failed to provide Americans with affordable health insurance. No further evidence is needed than the 45 million uninsured – and millions more who are under-insured. Having public plan option is one means toward improving choice and affordability.

The President's campaign plan proposed a public option alongside private insurance options in a National Health Insurance Exchange. This choice will challenge private insurers to compete on cost and quality, not cream-skimming and risk selection. At the same time, he recognizes the importance of a level playing field between plans and ensuring that private insurance plans are not disadvantaged. He will work with Congress on this and other elements of comprehensive reform.

Question 5:

One of my greatest concerns with our current health care system is how we provide care to individuals who are dually eligible for Medicare and Medicaid. Most dual enrollees are very low-income individuals with substantial health needs: 77% have annual income below $10,000 and over half are in fair or poor health, twice the rate among others in Medicare. Currently, the care for dual eligibles is poorly coordinated between Medicare and Medicaid – leaving one of the country's sickest populations terribly vulnerable.

If you are confirmed, how do you intend to improve quality and coordination of health care for dual eligibles?

Answer: As a Governor in a state with higher-than-average enrollment of dual eligibles, I am well aware of the health and financial challenges faced by this vulnerable population. Medicaid often chases Medicare to ensure that these beneficiaries get the care they need. Medicare, in turn, has its legislative limits on what it will pay for, especially with regard to long-term care. If confirmed, I will explore all administrative options to improve quality and coordination of care for the health as well as the long-term care needs of dual eligibles. I also look forward to working with you on any legislative solutions that meet our shared goals of quality and coordination.

Question 6:

Governor Sebelius, research out of Dartmouth shows great variation between hospitals in what is spent on care during the last year of life, but no evidence of better outcomes or satisfaction with greater spending. I've worked to promote advance care planning between patients and their physicians, including advance directives, so physicians know what their patients want at the end of life.

Governor, what do you think are some of the most important components of quality end-of-life care, and what are some of the things the health care system can do to improve it?

Answer: We need physicians and other health care professionals to be educated about and sensitive to the physical, emotional, and spiritual needs of patients and their families at the end of life. They should be prepared to explain the patient's options to them and support them through their decisions. Advance directives are a key component of end-of-life care, and we need to do more to promote their use. We also need to support hospice and palliative care, which includes promoting a greater understanding of pain and the best means of addressing it.

Question 7:

Governor Sebelius, I firmly believe that long-term care needs to be part of overall health care reform. The main coverage for long-term care in America is Medicaid, which means people have to spend down meager savings to the level of impoverishment to qualify for help. Additionally, we must provide greater opportunities for people to receive care in their homes and communities, instead of institutions.

Governor, why should long-term care be a part of health reform?

Answer: I would welcome it if Congress decides to address the gaps and financing challenges of long-term care in health reform. As a Governor, I know first hand the challenges of our fragmented long-term care system. States through Medicaid are a major source of financing of nursing home care as well as home and community-based services. Protecting vulnerable seniors and people with disabilities, improving the quality of care, and promoting consumer choices are high priorities for me as Governor, and will continue to be if I am confirmed as Secretary. Regardless, as Secretary, I would use the tools and resources across the Department – from Medicaid waivers to the community-support programs at the Administration on Aging to research at the National Institute on Aging – to improve the long-term care system.

Question 8:

Last fall, Congress passed a bipartisan bill that I was pleased to work on with Chairman Baucus and Senator Grassley called the Fostering Connections and Increasing Adoptions Act. HHS will need to implement this historic legislation to increase adoptions and allow states the option to help grandparents raising their grandchildren by guardianship.

- **Adoption and child welfare don't dominate the news, but having a safe permanent home is essential for a child's healthy development and future. We hope to work with you on strong implementation. I would appreciate hearing you views on adoption and child welfare issues.**

  Answer: I applaud your steadfast leadership on the issue of child welfare reform and advocacy, and I appreciate your central role in passing the Fostering Connections and Increasing Adoptions Act. I recognize that the Department of Health and Human Services has a special responsibility to our most vulnerable people, and that children who suffer abuse and neglect deserve our attention even if their plight does not dominate the news.

  If confirmed, I look forward to working with you to identify other opportunities to improve outcomes for children served by the child welfare system, and to increase adoptions so that more children receive the benefit of a safe, loving, and permanent home.

Question 9:

My strong view is that child care is an important issue for *all* working families, not just those parents on welfare. I am aware that some groups are prompting the creation of a separate in distinct office on Early Learning and Child Care, and I think it makes good sense.

Can you share your views on child care, and how you can work to highlight the issues of quality care as part of the Administration's birth to 5 initiative?

Answer: As a working mother of two sons, I have experienced first-hand the challenge of finding high-quality child care, and I know that quality requires investment in staff, curriculum, and other proven ingredients of success. As Governor of Kansas, I formed an Early Learning Council that has worked to coordinate various federal, state, and private sources of early childhood funding and to make quality a focus of all our investments in early care.

If confirmed as Secretary of HHS, I would work to improve the effectiveness of federal early childhood programs and to advance the President's comprehensive Zero-to-Five Initiative that will help ensure we are investing in our country's greatest resource – young children.

Question 10:

Would you consider a change in the agency to highlight the importance of child care?

Answer: If confirmed as Secretary of HHS, I will conduct appropriate reviews of the organizational structures of various HHS components to ensure that they are well-suited to meet our goals with respect to child care. Toward that end, I would be pleased to have your input.

Question 11:

Do you share my conviction that we must find a way to coordinate child care, Head Start and pre-K programs?

Answer: As a governor, I learned that collaboration between child care, Head Start, and education agencies is essential to achieving our objectives with respect to young children and their families. If confirmed as Secretary of HHS, I plan to work closely with Secretary Duncan to coordinate early childhood programs within HHS and the Department of Education.

Question 12:

I appreciate Senator Obama's support in the 110th Congress for child support enforcement, and the investments in the Recovery package to support investments in child support for the next 2 years.

What are your views on child support enforcement and improving its effectiveness?

Answer: I am pleased that the Recovery Act reversed the Bush Administration's policy prohibiting states from receiving a federal match when they reinvest their performance incentives in state child support programs. Looking forward, I believe it will be very important to focus not only on continuing performance improvements in the child support enforcement system, but also on strengthening the ability of non-custodial parents to support their children. As you know, President Obama strongly supports Responsible Fatherhood initiatives and investing in the economic futures of young parents. If confirmed, I look forward to helping the President promote that agenda.

Question from Senator Kerry

Question 1:

On March 5th I sent a letter, with several of my colleagues, to CDC Acting Director Besser regarding delay in proposing a regulation to remove HIV from the list of communicable diseases of public health significance to finally end the HIV ban. I have yet to hear back. When you are confirmed would you make this issue a priority and follow-up on the delay in promulgating a regulation? I hope that we can work together to finally end this discriminatory ban and I look forward to the response from the Administration.

Answer: I am aware that the global health legislation – the President's Emergency Plan For AIDS Relief (PEPFAR) bill – did repeal the ban on HIV-positive travelers to the U.S. If I am confirmed as Secretary, I will work to repeal this ban as quickly as possible to comply with the law. In addition, I will ensure that your staff receives regular updates on the status of this effort.

Questions from Senator Lincoln

Thank you so much, Governor Sebelius, for your testimony at today's hearing. Below are a few follow up questions that address issues of particular importance to me. I appreciate your attention to the questions and look forward to working with you on these and other health and human services issues upon your confirmation.

Question 1:

I have long supported the concept of chronic care management and coordination, especially for older adults with multiple chronic conditions including dementia. This approach to care involves multiple players beyond the primary physician, such as physician assistants, nurses and nurse practitioners, social workers, pharmacists, rehabilitation therapists, direct care workers, caregivers, and so many more. I have been working with the Finance Committee for many years on this issue and will soon reintroduce my bill with a fresh new name – the *RE-Aligning Care Act* – which stands for *Reaching Elders with Assessment and Chronic Care Management and Coordination*. This legislation would provide assessments and care coordination to Medicare beneficiaries in the fee-for-service program with multiple chronic conditions, including those with dementia.

How can we best work with you to redesign the health and social care delivery systems to meaningfully incorporate chronic care management and coordination, especially for our most vulnerable populations, ensure that the various professionals and paraprofessionals involved in these systems are available and have the proper training to care for aging Americans, and that these systems involve patients and caregivers to the greatest extent possible?

> **Answer:** There are a number of initiatives that can ensure effective coordination of care for patients with multiple chronic conditions, several of which have received funding through the American Recovery and Reinvestment Act. First, the creation of an interoperable health information technology system will allow improved communication across providers. Second, health training programs will build a 21st-century health workforce capable of meeting the needs of our aging population. Third, comparative effectiveness research will provide patients and providers with information on what works best to treat diseases. And fourth, prevention and disease management will keep our populations healthier, longer. If confirmed, I look forward to working with you to build on this investment to achieve the goal of high-quality care for patients with multiple chronic conditions.

Question 2:

Senator Hatch and I have been working for many years to pass the *Elder Justice Act*. This landmark legislation is the first comprehensive federal effort to address and prevent elder abuse, neglect and exploitation. We have legislation that addresses child abuse and domestic violence, but no comprehensive national strategy to combat elder abuse. The Elder Justice Act represents a consensus agreement developed by the Elder Justice Coalition, a national coalition of 558 members, including 230 organizations, dedicated to eliminating elder abuse, neglect, and exploitation in America. In the 110th Congress, this bill had co-sponsorship from 30 Senators and has passed through this committee unanimously several times. We have great hopes for this bill becoming law this year as vulnerable elders at risk for physical, emotional, and financial harm can no longer wait for Congress to decide if this is a priority. One of the strengths of this bill is that it acknowledges we have incredible expertise among a number of HHS agencies to address this issue, such as the Administration on Aging, CMS, and HRSA, as well as other departments such as the Department of Justice. Like other bills that address complex issues, the challenge this bill presents is the need for coordination and collaboration across agencies and departments, not only on elder mistreatment issues, but on a variety of other health and human service problems Americans face. We look forward to working with you and your staff to resolve some of the concerns that have surfaced within the Department on this bill.

How will you work to improve interagency collaboration within HHS and with other Departments, especially when legislation requires that agencies work together to address social problems that are beyond the jurisdiction of a single agency?

Answer: I applaud your tireless efforts to call attention to, and to propose concrete solutions to address, the deeply troubling issue of elder abuse, neglect, and exploitation. Our seniors deserve honor and respect, not abuse and neglect.

The challenge of finding creative and effective mechanisms to bring disparate agencies together to maximize impact is significant. As a governor, my recipe for addressing these coordination issues has been to demand that all state government employees, regardless of their agency affiliations, focus upon achieving measurable results for our citizens. If confirmed as Secretary, I would bring together federal agencies to focus on quantifiable results for the people we are serving.

Question 3:

As the Senate Finance Committee worked diligently on the Children's Health Insurance Reauthorization Act, I worked closely with a number of my colleagues to ensure that it would not only expand health coverage for children, but that it would also improve the quality of care that children receive. A recent study by Dr. Rita Mangione-Smith, published in the October 11, 2007 New England Journal of Medicine, found that fewer than half of America's children – regardless of family income or insurance status – receive the right care in the right amount at the right time. I hope you agree with me that implementation of this provision to improve the quality of care that children receive under the CHIPRA bill should be a priority.

What can you tell the me and my Senate Finance Committee colleagues about plans at HHS to move forward on the CHIPRA provisions for developing, disseminating and implementing pediatric quality measures in CHIP and Medicaid?

Answer: CHIPRA's quality initiatives provide an important and exciting opportunity to assess and improve health care quality for America's children, and I agree that implementation of these initiatives must be a high priority. HHS is currently reviewing measures currently available and in use by state Medicaid and CHIP programs to prepare for a January 1, 2010 release of a core set of child health measures that address the quality and stability of children's coverage, as called for in CHIPRA. Recognizing how important this issue is to families, children's advocates, state leaders, providers, and employers, HHS will consult with leaders in children's health and health care quality and will create a federal advisory group that will include representatives from many sectors and provide a forum for public participation. Another critical component of the quality initiative will be a tight linkage between the use of electronic health records and quality assessment so that new scientific advances are easily translated into improved health and health care for children. The ultimate goal of these efforts is to be able to measure and improve care, and to assure that all children receive the best possible care regardless of where they live or their racial/ethnic background.

Question 4:

As you are aware, chronic conditions, such as diabetes, are on the rise and are driving up health care costs. Currently, 23.6 million Americans, or 7.8 percent of the population, have diabetes. One out of every 10 health care dollars is spent on diabetes and its complications. My home state of Arkansas has been disproportionately affected by this disease, however, the epidemic spans all parts of the country and people of all ages. The U.S. Preventive Services Task Force (USPSTF) recommends screening for diabetes only after there is evidence of hypertension. The Task Force also does not screen for pre-diabetes, even though an estimated 70% of Medicare beneficiaries and 57 million Americans have pre-diabetes.

Given that Type II diabetes in many cases is preventable, how can we move health care providers and systems to embrace methods for earlier detection and screen for pre-diabetes to reduce the incidence of the deadly and costly disease?

Answer: I share your concern about the nation's diabetes epidemic and its disproportionate effect on states like Arkansas. Based on the 2007 Behavioral Risk Factor Surveillance System, 184,000 Arkansan adults had been diagnosed with diabetes, a doubling of the state's diagnosed population since 1995.

Before adults develop Type II diabetes, most have a condition known as pre-diabetes where blood glucose (sugar) is elevated, but not yet high enough to be diabetes. Obesity increases the risk for many diseases and health conditions, including Type II diabetes, coronary heart disease, hypertension, stroke, and some cancers. The relationship between obesity and Type II diabetes is remarkable – approximately 80% of American adults with diabetes are overweight or obese.

Identifying people with pre-diabetes and delivering interventions to prevent the development of Type II diabetes may be the most promising strategy available today for achieving cost-savings from a concentrated effort to prevent diabetes. For example, the Diabetes Prevention Program (DPP), a large-scale research trial in which participants were screened for pre-diabetes, showed that a structured lifestyle intervention program that helps individuals with pre-diabetes lose 5-7% of their existing body through regular physical activity, caloric reduction, and behavioral support could reduce over half of new cases of Type II diabetes.

Chronic diseases share risk factors. Many interventions, both clinical and behavioral, can address multiple diseases. Often, it is the interventions outside the medical system that provide the most benefit for the least cost. Implementing such evidence-based strategies that prevent the further development of chronic conditions to all who need them is a health and economic imperative. If confirmed, I look forward to working with you to promote early detection and prevention strategies in the effort to reduce cases of Type II diabetes and other chronic diseases.

Question 5:

Approximately 26 million American adults have chronic kidney disease (CKD) and millions of others have related health conditions that place them are at increased risk for CKD. Education and early detection methods have been widely demonstrated to help prevent the progression of CKD to kidney failure, the result of which would save thousands of lives and billions of taxpayer dollars. Last year, Congress acknowledged the important role of kidney disease education and awareness by adopting provisions in the Medicare Improvements for Patients and Providers Act of 2008 that incorporate kidney disease education services into Medicare, which was a bill that I introduced, and by requiring the Secretary of HHS to establish pilot projects to increase awareness, screening and surveillance of CKD.

As Secretary of HHS and in light of the MIPPA provisions, will you commit to making CKD awareness and early detection a priority? How would you utilize the resources of HHS to maximize the effectiveness of this important program?

Answer: I recognize the burdens of chronic kidney disease and the opportunities that early detection provides. I also recognize the importance of marshalling the Agency's resources in CMS, NIH, CDC, HRSA, and elsewhere to take on this challenge.

Chronic kidney disease (CKD) is a public health threat in the United States, with increasing prevalence, high costs, and poor outcomes. A more widespread effort to promote prevention, early detection, evaluation, and management of chronic kidney disease and antecedent conditions could prevent complications of decreased kidney function, slow the progression of kidney disease to kidney failure, and reduce cardiovascular disease risk. In March 2009, an expert panel convened by CDC to identify comprehensive public health strategies to address CKD published its recommendations in the American Journal of Kidney Disease. I look forward to working with federal, state, and local governmental and private organizations to carry out these recommendations.

In addition, CDC continues to engage with professional and public partners in the development of effective strategies for prevention and progression of chronic kidney disease. If confirmed, I look forward to discussions on how to enhance some of the current chronic kidney disease activities underway at the CDC and other operating divisions.

Question from Senator Wyden

Question 1:

One of the pressing issues in heath care and for families is the issue of long term care. Demographics are catching up with us and public funding for long term care is inadequate. Medicaid has historically underfunded the costs of nursing home care and given the budget crunch States are now in, we can expect that to continue. Most Americans have not saved enough or cannot save enough to cover the costs of long term care. What role do you see for long term care as part of health reform? What approaches do you think should be taken to fund long term care needs and make sure seniors and their families have access to appropriate services as they age and needs change?

Answer: As a governor, I know first hand the challenges of our fragmented long-term care system. States, through Medicaid, are a major source of financing of nursing home care as well as home and community-based services. Protecting vulnerable seniors and people with disabilities, ensuring quality of care, and promoting consumer choices are high priorities for me as Governor, and will continue to be if I am confirmed as Secretary. If Congress decides to address the gaps and financing challenges of long-term care in health reform, I would work with you to ensure the policies meet their goals and are consistent with the President's agenda. Regardless, as Secretary, I would use the tools and resources across the Department – from Medicaid waivers to the community support programs at the Administration on Aging to research at the National Institute on Aging – to improve the long-term care system.

Questions from Senator Stabenow

Question 1:

As you know, there is a tremendous backlog of generic drug applications which is costing consumers billions of dollars in lost savings. Additionally, the FDA is also supposed to be reviewing citizen petitions at a much faster rate, thanks to language I included in the FDA reauthorization in the last Congress.

Unfortunately, I am very concerned that the Office of General Drugs remains underfunded, meaning consumers and businesses will lose access to safe, affordable generic medicines. I am sure as a Governor, you appreciated increased use of generics to hold down costs in Kansas's Medicaid program.

As Secretary, will you work to increase appropriations to fund ODG to provide the Office with the necessary resources to review applications and to eliminate the backlog of citizen petitions?

> **Answer:** Generic drugs play a critical role in keeping medicines affordable. To fulfill their role, Americans must have access to them as soon as the law permits, and they must be as safe and effective as the brand name drug. If confirmed, I will work hard to ensure the Office of Generic Drugs has adequate resources to review applications and citizen petitions in a timely manner and to carry out those reviews with the most up-to-date science.

Question 2:

I was very excited that wiring our nation's health care system, something I have worked on for years with Senator Snowe, was part of the economic recovery package. The ARRA includes over $20 billion for health IT, much of which is included in incentives to reward providers for demonstrating a meaningful use of certified electronic health record technology.

But recent studies on the readiness of the health system have me troubled. Earlier this week, the *New England Journal of Medicine* published a study finding that only 1.5% of U.S. hospitals have a comprehensive electronic-records system and an additional 7.6% have a basic system. Computerized provider-order entry for medications has been implemented in only 17% of hospitals. Larger hospitals, those located in urban areas, and teaching hospitals were more likely to have electronic-records systems.

This follows on the Robert Wood Johnson Foundation's national survey of physicians that only 4 percent of physicians have a fully functional electronic health record system while an additional 13 percent of physicians have a basic electronic health record system.

I believe the incentives in the recovery package will help drive implementation but a lot must be done in educating providers about what system may work best for their needs and how they practice. Additionally, not all providers are eligible for incentive payments because there simply wasn't enough money, meaning parts of the health care system still need to be brought in.

As Secretary, would you support initiatives to drive implementation? What role do you see for health IT in healthcare reform legislation? How will you utilize the resources at HHS, including the National Coordinator for Health IT, as well as perhaps working with your colleagues in the Cabinet to ensure the alignment of federal health IT initiatives?

> **Answer:** A nationwide interoperable health IT infrastructure is a fundamental building block for broader health reform. A key federal role is ensuring that systems are interoperable, and that patient privacy is assured. The Recovery Act gives HHS tools to help accomplish this. The standards and certification process established in the Recovery Act will assure providers that the electronic medical record systems they purchase are indeed interoperable, while spurring innovation and competition as vendors develop products that meet these standards and the needs of providers. In addition, the grant and loan programs, the establishment of Regional Extension Centers, and the role of the National Coordinator for Health IT in coordinating the activities of HHS with other federal agencies are all critical components of the successful implementation of the Recovery Act.

Question 3:

As we begin to consider a health reform effort that expands on our current system by enrolling the previously uninsured into private insurance or subsidized insurance products, it is worth considering the challenges safety net providers will face in this new environment.

For example, your local community health center is likely engaged in providing high quality primary care to a medically underserved population that may have a high incidence of chronic disease as well as other barriers to care aside from insurance status. This health center may have outcomes that match or surpass its local private sector peers, and yet its bargaining power in dealing with large national insurers may be non-existent.

How can we ensure this local health center and other safety net providers get paid adequately for its services as its proportion of privately insured patients grows?

> **Answer:** Health centers and other safety-net providers currently have and, under health reform, will continue to have a critical role in delivering high-quality care to vulnerable populations. The need for their provision of comprehensive, culturally sensitive care in underserved communities will not diminish as more people gain coverage. In fact, I anticipate that health plans will seek to include safety net provider in their networks to manage the care of the newly insured people living in the areas that they serve.

Already, these providers have complemented their public support with insurance funding from Medicaid and private plans. If confirmed, I look forward to working with you in developing a health reform plan that supports high-quality safety-net providers.

Question 4:

Over the last Congress, several moratoria were imposed Medicaid regulations that, in my view, represented a back door effort to make billions of dollars in Medicaid budget cuts – without input from the Senate Finance Committee. The highly controversial rules covered everything from provider taxes to graduate medical education. I was very surprised by regulations on case management and rehabilitative services rules that would have jeopardized community-based services for millions of people with disabilities, individuals with serious mental illnesses, and children in the foster care system. Congress spent a great amount of time and capital trying to reign in these regulations.

As a Governor, you know full well the importance of Medicaid and how these regulations would have impact the care that a State could deliver. How did the regulations impact your state, and do you think such drastic changes should have been done by regulation without congressional input? Can you provide the Committee with your thoughts on how Medicaid can be improved to work better for the millions of Americans—women with children, seniors, people with disabilities—who rely on this vital program for coverage?

Answer: As you know, the Recovery Act extended the moratoria on the Medicaid regulations through June 30, 2009 and placed a new moratorium on the Medicaid hospital outpatient rule. HHS is taking a close look at all regulations as part of a regulation review process, and will closely examine each of these regulations as part of that effort. With this delay, the Administration will have an opportunity to give the regulations a more appropriate and thoughtful review to ensure they are in the best interest of the Medicaid program. As Governor, I realized that these regulations would have impacted my state and would have been felt most acutely by low-income children and people with disabilities, as well as our safety net providers. Medicaid is a lifeline for our nation's most vulnerable citizens, including people with disabilities, individuals with mental illnesses, and low-income pregnant women and children. I am committed to working with you to strengthen the Medicaid program to make sure that it is viable for many years to come, and I look forward to sharing with you ideas about how to proceed.

Question 5:

Since 1969, non-emergency medical transportation (NEMT) has long been a required service in Medicaid by regulation because it is essential in assuring many beneficiaries access to medically necessary health services that are statutorily required.

In 2005 the Deficit Reduction Act (DRA) made substantial changes to the Medicaid program, including allowing the States greater flexibility in benefit package design at Section 6044--commonly referred to as 'benchmark plans'.

There is nothing in Section 6044 or in the legislative history of the Act to suggest that the Congressional intent was to modify the original and current regulations requiring transportation to medically necessary services.

However, on December 3, 2008, the Administration published the final rule allowing States to drop NEMT in their benchmark plans. The regulation was initially scheduled to take effect Feburary 2, 2009; however, the Obama Administration delayed the effective date. It is critical that the NEMT regulation not be overlooked. The NEMT benefit is an essential service, and it is important that the States continue to provide this benefit to all beneficiaries that need transportation including those in benchmark plans.

What is your position on this regulation and whether it should go forward or be reversed? What are your thoughts on codifying the original NEMT regulation?

> **Answer:** HHS recently issued a second final regulation that would temporarily delay the effective date of this final rule until December 31, 2009. A delay in the effective date and a reopening of the comment period can help ensure that the final rule takes into account public comments and conforms to recently enacted legislation. HHS will consider comments on the rule through May 5, 2009. Additionally, the delay allows for sufficient time to review all of the policies set forth in the December 3, 2008 final rule, including the non-emergency medical transportation provision.
>
> If confirmed as Secretary, I look forward to working with you and other members of Congress to ensure that Medicaid beneficiaries have access to medically necessary health care services.

<u>Question 6</u>:

Even before the recent economic downturn, programs that provide critical cancer screening and treatment services to underserved populations were stretched thin. For example, the National Breast and Cervical Cancer Early Detection Program, which provides breast and cervical cancer screening to low income and uninsured women - and provides a gateway to affordable cancer treatment through Medicaid - is only able to screen fewer than one in five eligible women. The successful WISEWOMAN program builds off of the breast cancer program and provides women with heart screenings as well as heart disease is often misdiagnosed in women. Unfortunately, WISEWOMAN is unavailable in many states.

Now that we are in the midst of an economic recession, demand for these services is rising and money is tight. However, the recovery package we passed earlier this year invested billions in health care services for underserved populations, including $1 billion for prevention services.

As Secretary of HHS, have you considered using the recovery funding to aid states for critical health services such as WISEWOMAN and the breast and cervical cancer program? How would you build on these successful community health programs to improve prevention, research, and treatment for women and all Americans?

Answer: Thank you for support of the WISEWOMAN and the National Breast and Cervical Cancer Early Detection Programs. They serve as critical components of the health system by targeting screening and follow-up services to high-risk and under-served populations. These programs provide proven and effective public health strategies that should be considered as part of a reformed health system.

With regard to expansion, the WISEWOMAN program is a scalable program that has had success in preventing chronic disease in a cost-effective manner. The WISEWOMAN program also serves as a prime example of a comprehensive program that links clinical and community interventions that are able to effectively address multiple chronic disease risk factors while targeting high risk-populations. I am hopeful that these issues can be addressed in the context of health reform.

It is my understanding that HHS is currently formulating a program and an accompanying spend-plan for the wellness money provided in the Recovery Act. No final decisions have been made, but the program is likely to address the link between clinical and community interventions and will seek to address more than one risk factor (as the WISEWOMAN program does) with the affected populations. If confirmed, I look forward to working with you and other members of Congress to build on the strategies employed by the WISEWOMAN program.

Question 7:

As you know, the NIH has been starved for resources under the prior Administration. Yet, even under these circumstances, NIH placed a high priority – as did Congress in the most recent NIH Reauthorization – on funding translational research programs, research that is focused on accelerating the development of actual treatments and cures for so many life threatening diseases.

For example, one such disease that I have been working with family organizations on is Spinal Muscular Atrophy, the leading genetic killer of infants under age 2. SMA was chosen by NIH for an accelerated translational research project – known as the SMA Project – because the scientific research on SMA is so far along and holds real promise in the near-term to develop actual treatments. This program is now at a crossroads because it needs additional resources to help conduct actual clinical trials on potential treatments.

As we look to hopefully invest more resources in the NIH, can we count on you and the new Administration to focus resources on these initiatives to help bring them across the finish line to actual treatments?

Answer: After a five year doubling initiated in the Clinton Administration, NIH has been essentially flat-funded since 2003. This has produced a 17% loss of "buying power" since 2003, and an acute fall in the success rates for grant applicants, now as low as 10% for many NIH Institutes. In addition, researchers have to wait longer for their first award and usually have to apply multiple times. For example, the average age when a researcher gets a first, coveted RO1 used to be 39. Today it is 43. A plan to achieve sustained growth of the NIH budget is much needed so that "feast or famine" can be avoided. President Obama's pledge to increase funding for basic science research will enable the U.S. to regain its leadership in the area of biomedical research, expand training opportunities for the next generation of scientists, and stimulate local economies to create jobs.

With respect to SMA Research over the past three years, NIH has funded SMA Research at the following levels: 2007 ($10.5M), 2008 ($9.6M), and 2009 ($9.9M). Notably, NINDS, NICHD, NHGRI and other parts of NIH all contribute expertise toward SMA Research, which includes disease mechanisms, preclinical/translational therapy development, clinical trials, and early detection/genetic testing issues.

As you note, one initiative, the SMA Project, is an aggressive translational program to develop drugs and test them in the laboratory. The Project has two patents on compounds that show promise and is evaluating the safety of the most promising drug candidates, with the goal of a human clinical trial beginning in 2010. If confirmed, I look forward to working with you to ensure that NIH and the research it funds receive adequate support.

Question 8:

I would like to bring to your attention a critical health care matter in my state. The issue relates to the Medicare Disproportionate Share (DSH) formula and its impact on an acute care hospital in Michigan. Metro Health Hospital provides a unique ventilator service to vulnerable Medicaid patients, including veterans, in Michigan and surrounding states. Patients from all over the country can come to Metro for this unique ventilator care.

The Medicare DSH calculation is based in part on the number of Medicaid patients that a hospital serves. Virtually every patient in the Metro ventilator unit is a Medicaid beneficiary. Since 1985, Metro has counted these patients as Medicaid patients in the Medicare DSH calculation, and its claims have been paid under the Medicare program.

CMS has taken the position that any Medicaid patient who is enrolled in the Medicare program cannot be counted as a Medicaid patient for DSH purposes. I understand this is not correct. While these patients may be enrolled in the Medicare program, they are not being paid for by Medicare, generally because they have exhausted their Medicare coverage. The primary payer for these patients is Medicaid.

CMS has now engaged Metro Health Hospital in a multi-year reimbursement dispute that has greatly strained the hospital's resources and places at risk the delivery of acute care in Michigan. To preserve critical services to our most vulnerable patients, I hope you will work with me to address this matter.

Will you work with me to fully examine this problem - that greatly strains the ability to deliver critical services to ventilator-dependent patients -- by exercising any available administrative flexibility? Will you work with your team at HHS to review existing policies in light of this issue so that we can work together on beneficial legislative solution to restore the former DSH calculation for these services?

> **Answer:** I recognize there are concerns about how CMS calculates Medicare DSH payments. Some of these concerns stem from the statutory requirements, and some from CMS's regulations. We must ensure that the Medicare DSH program fulfills its goal of supporting true safety-net providers. If confirmed, I pledge to carefully review this issue and keep you informed of my findings.

<u>Question 9</u>:

The 2006 Tax Relief and Health Care Act required the establishment of a physician quality reporting system, including an incentive payment for eligible professionals who satisfactorily report data on quality measures for covered services furnished to Medicare beneficiaries during the second half of 2007. CMS named this program the Physician Quality Reporting Initiative (PQRI). This program has been authorized through CY 2010.

Many concerns remain over the accuracy of how CMS captures quality measures reporting information and how this information is shared with PQRI participants through timely and meaningful feedback reports.

What is HHS planning for developing timely and effective educational and outreach programs to train Medicare carriers to assist in clearly informing physicians of the requirements that must be met to successfully participate in PQRI?

Timely, accurate and confidential feedback reports at the individual level allow the physician or their practice to take actionable steps to improve quality at the point of care. The agency's *PQRI 2007 Reporting Experience Report* mentions that CMS faces certain practical "limitations" that make it difficult to develop more frequent feedback reports. What are your plans for carefully exploring these limitations and determining the necessary next steps to overcome them?

CMS has communicated that the PQRI program is an important first step toward establishing a value-based purchasing program for physicians and other health care professionals. Many have cautioned against expanding the PQRI until its many glitches are rectified. What are the views of the new Administration regarding the PQRI program? Do you envision a Medicare value-based purchasing system based on the PQRI program?

Answer: The President and I both believe that Medicare's payment systems need to be reformed to promote greater value and accountability for high-quality outcomes. Congress authorized CMS to take some initial steps through the PQRI program, which provides incentive payments to physicians that agree to submit certain data. My understanding is that there have been some issues with the implementation of this program and that further steps need to be taken to ensure that providers may submit data and receive their incentive payments in a more transparent manner. I am concerned about the operational challenges associated with this program, and I intend to carefully review this program as well as all of CMS's on-going efforts to promote greater quality. The PQRI program is currently authorized through 2010, and, if confirmed, I look forward to working with you to build upon this program and improve its implementation to ensure that Medicare has every possible tool to improve the quality of care.

Question 10:

Please describe your vision for the FDA and the NIH, and how the Agency and the Institute can hasten access to safe and efficacious breakthrough therapies for the millions of Americans living with un-treated or under-treated diseases.

Answer: As I noted in my testimony before the Senate HELP Committee, As Americans focus more on prevention and leading healthier lifestyles, HHS must live up to its responsibility to protect the public from health risks. It is a core responsibility of HHS, through the FDA, to ensure the food we eat and the medications we take are safe. Unfortunately, there is growing concern that the FDA may no longer have the confidence of the public and Congress. If confirmed as Secretary, I will work to restore trust in the FDA as the leading science-based regulatory agency in the world.

Under FDA's Critical Path initiative, the agency is working with academia and industry to develop important scientific tools to facilitate and expedite the development and production of safer, more effective medical products. These tests and tools include those used to predict whether a product candidate will be safe and effective, to assess how prototypes interact with the human body, and to guide the manufacturer in choosing an appropriate dose and regimen or device size and/or placement. For example, FDA is working proactively with stakeholders to reduce the obstacles for developing an artificial pancreas to treat diabetes.

FDA also has a number of programs that can hasten access to safe and efficacious breakthrough therapies for millions of Americans living with un-treated or under-treated diseases. Two such programs – fast track and accelerated approval – are used routinely to hasten approvals of new treatments where there is an absence of available treatment.

With respect to the National Institutes of Health (NIH), as important as it is to protect people by regulating drugs, it is equally important that we support efforts to discover new drugs and treatments that can prevent, treat, and cure disease. The National Institutes of Health (NIH) provides that critical support.

The mission of NIH is science in pursuit of knowledge about the nature and behavior of living systems, and the application of that knowledge to extend healthy life, combat illness, and ease the burden of disability. If confirmed, I will work to strengthen NIH, with leadership that focuses on the dual objectives of addressing the health care challenges of our people and maintaining America's economic edge through innovation.

Recognizing the urgent public health need for new, safe, and effective treatments, the agency has launched many key programs and initiatives focused on moving scientific discoveries through the pipeline to the marketplace. Through these and other efforts aimed at solving problems that block the flow of the drug-development pipeline, NIH will continue to identify impediments to drug and treatment development and implement strategies and programs to facilitate the rapid translation of breakthrough discoveries into treatments in the marketplace.

Question 11:

All Americans are concerned about access to needed medical care, but there is a less well-known issue facing many Americans – diagnosis with a disease or disorder for which adequate treatments do not exist. For example, only certain symptoms of Parkinson's disease can be treated and for a limited amount of time. Ultimately, the underlying disease continues to progress without any therapeutic interventions to slow or stop its disabling march. There are currently no treatments to slow or stop progression of Alzheimer's as well. How will you ensure that discovery, market, and access to safe, effective, new, breakthrough treatments is hastened?

Answer: FDA has been at the forefront in developing new biomarkers and in aiding manufacturers in integrating these biomarkers into their drug discovery and development processes. The use of validated biomarkers can help manufacturers identify potentially successful treatments earlier and demonstrate that they are safe and effective more quickly and at lower cost. In addition, FDA has hired a Genomics coordinator to foster the creation and use of genomic tools in medical product development. The agency is also developing a regulation on expanded access to investigational new drugs that will clarify mechanisms for patients seeking access to breakthrough treatments while they are still under development. If confirmed, I look forward to working with you on this critical issue.

Question 12:

The number of Americans stricken with serious and life-threatening diseases stands at an all-time high, and the number of Americans facing chronic life-threatening conditions without adequate treatments, such as Alzheimer's and Parkinson's disease, is expected to increase exponentially in the years ahead. Despite vast advances in basic understanding of the root causes of disease brought about by a doubling of biomedical research funding in recent years, a pipeline problem exists that is stifling innovation and denying patients access to the treatments they need. Recent studies confirm that the number of new medical therapies reaching the marketplace is the lowest in decades.

How would the Department of Health and Human Services, including the National Institutes of Health and the FDA, address this urgent need?

Answer: FDA would play three important roles in this effort. First, the agency would bring national focus to current product development issues, serving as a hub for problem identification and information exchange. Second, the agency would serve as the catalyst to initiate projects and collaborations to help modernize the drug, biologic, and device development programs through the Critical Path initiative. Third, the agency would encourage the use of new Critical Path tools by accepting the results of these new tools as proof that a medical product is safe and effective.

The NIH would complement these efforts through a number of key programs and initiatives focused on moving scientific discoveries through the pipeline to the marketplace. Through these and other efforts aimed at solving problems that block the flow of the drug-development pipeline, NIH will continue to identify impediments to drug and treatment development and implement strategies and programs to facilitate the rapid translation of breakthrough discoveries into treatments in the marketplace.

Question 13:

Over time, expanded regulatory responsibilities for drugs, medical devices, and food, without accompanied financial resources have put the FDA mission of promoting and protecting the public health at risk. The dire straits of the agency's scientific infrastructure have been documented by both the Institute of Medicine and FDA's own Science Advisory Board. As Secretary, how do you envision the Department supporting and equipping the FDA to make sound scientific regulatory decisions in an increasingly complex and rapidly evolving marketplace?

Answer: The FDA's mission is to protect the public's health by ensuring the safety of drugs, devices, and our nation's food supply, and, if confirmed, I will take this responsibility very seriously. We all know that the FDA has not performed as well as it should in recent years, whether we look at recent food safety outbreaks, unsafe drugs such as Vioxx being pulled off the market, or intentional adulteration of products such as the melamine contaminated pet foods and infant formula.

The President and I are committed to strengthening the FDA by bringing in new leadership, devoting additional resources to the agency, and taking a close look at how we do business at the FDA. Whether we are focused on the drug side or the food side, we need to do a better job identifying potential problems on the front end and preventing those problems from occurring, even as we step up and improve our oversight and enforcement on the back end.

If confirmed, I look forward to working with you to restore public trust in the FDA as the leading science-based regulatory agency in the world, and to address additional challenges with respect to the safety of our nation's food supply.

Questions from Senator Menendez

Question 1:

As we discussed in our meeting, I championed the Patient Navigator program when I was a member of the House. This program is incredibly important to me and as I continue to fight for full funding, I hope I can count on your support. While this program is based on proven models and had broad bipartisan support, the past administration didn't make it a priority until the heavy lifting had already been done in Congress. As a result, we only began receiving funding 2 years ago, so our authorization will expire before our original 5-year demonstration project can be completed.

Will you be a partner in extending the authorization and fully funding the program so that patients across the country can see the benefit that navigators offer in helping them understand our complex health care system?

Answer: The Patient Navigator Program is a key component of HRSA's efforts to increase access to health care for underserved populations, particularly those with chronic diseases. Although it is my understanding that the agency has only been able to fund six grantees, it is already clear that the program has great potential to link important services, such as coordinating care with health centers. The Administration supports continuing funding for the current grantees so that the Department can complete the analysis of the demonstration as required by the Congress. If confirmed, I look forward to working with you to extend the authorization.

Question 2:

One of the big issues for New Jersey hospitals is CMS' proposal to apply a statewide neutrality adjustment to the rural and imputed floor wage index. While it sounds technical, the bottom line is that a system that originally protected urban hospitals from unfair Medicare reimbursement rates is now pitting New Jersey hospital against New Jersey hospital for funding. I am beginning to see that this is having severe adverse financial consequences for our hospitals.

Senator Lautenberg and I are working closely on this issue—will you agree to work with us on this issue? I am really worried about the long term affect that this will have on my state's hospitals who are already being forced to close their doors at an incredible rate.

Answer: It is my understanding that the Balanced Budget Act of 1997 (BBA) established the rural floor by requiring that the wage index for a hospital in an urban area of a state cannot be less than the area wage index determined for that state's rural area. In order to compensate for the increased wage indices of urban hospitals receiving the rural floor, CMS applied a nationwide budget neutrality adjustment to account for additional payments to these hospitals.

Beginning in FY 2006, CMS temporarily adopted an "imputed" floor measure by establishing a wage index floor for those states that did not have rural hospitals. This was also funded through a nationwide budget neutrality adjustment.

My understanding of this issue is that the policy to apply a statewide budget neutrality adjustment rather than a nationwide adjustment was intended to better address issues of inequity associated with the application of nationwide budget neutrality for the rural and imputed floor. The concern, as I understand it, was that the rural and imputed floor policy was creating a benefit for a minority of states that was funded by a majority of states, including states that are overwhelmingly rural in character. I greatly appreciate your bringing this issue to my intention, and, if confirmed, I will carefully review CMS's hospital wage index to ensure that they are equitable to all hospital providers.

Question 3:

Postpartum depression is one of the most common and frequently undiagnosed conditions associated with childbirth. In the United States alone, approximately 400,000 to 800,000 women are suffering from postpartum depression each year. I believe we need to we need to increase research and education on this condition, and provide support services to women suffering from postpartum depression and psychosis. And I have a bill to do just that: the MOTHERS Act, which just passed in the House of Representatives and is now pending in the HELP Committee. This issue is incredibly important to me and to my constituents in New Jersey

Do you support additional research and outreach on PPD? Additional services for women and families?

Will you work with me on this important legislation?

Answer: I would be happy to work with you on the development of appropriate legislation. And I agree that more can be done to enhance our understanding of and outreach to affected women and health care providers on post-partum depression.

Post-partum depression is critical and common problem, with one in seven women experiencing depression around the time of pregnancy and with approximately 50 percent having depression both during pregnancy and the post-partum period. Among women who have complications of any kind during pregnancy, about one in four will have post-partum depression. CDC is conducting important research to understand the predictors and co-morbidities associated with post-partum depression. This research has found that:

- Women who have delivered twins or higher-order multiples are more likely to experience post-partum depression.
- Women with post-partum depression are more likely to report difficulties during their pregnancy, including physical abuse and partner-related stress.

- Post-partum depression has important implications for the health of women and their families. For example, women who experience post-partum depression are 1.8 times more likely to relapse on smoking than those who are not depressed. Similarly both pre-pregnancy and gestational diabetes are associated with post-partum depression.
- Post-partum depression has short- and long-term impacts on child development.

Furthermore, states are using data from CDC's Pregnancy Risk Assessment Monitoring System (PRAMS) to estimate the prevalence of self-reported post-partum depression (SRPPD) and identify trends in and risk factors for self-reported post-partum depression. PRAMS data can also be used to monitor progress toward meeting the Healthy People 2010 developmental objective 16-5c to reduce post-partum complications, including post-partum depression. I look forward to working collaboratively with you on this serious problem.

Question 4:

In 2007, then Senator Barack Obama introduced the Genomics and Personalized Medicine Act and said, "genomics has the potential to revolutionize the practice of medicine, but despite significant scientific advances, very few genomics-based tests or treatments have reached consumers." Under former Secretary Leavitt, who established the Personalized Health Care Initiative within the Immediate Office of the Secretary, the U.S. Department of Health and Human Services stated that "personalized medicine will improve the safety, quality and effectiveness of healthcare for every patient in the United States."

How do you believe personalized medicine can be utilized most effectively in the context of fundamental health reform?

Answer: Health care reform will include improvements in access to medical services, the use of preventive interventions, and the quality of care. Some of these changes can be achieved through administrative improvements notably in reimbursement policies, and quality measurement. However, health care reform will also include changes in the way care is delivered – especially changes that take advantage of scientific discovery and value-enhancing technology. If we are to achieve higher quality care for all Americans at a sustainable cost, we must look to those changes that improve the "productivity" of health care in the same way that we see quality gains traveling hand-in-hand with lower costs in other sectors throughout our economy.

Personalized medicine seeks to use advances in knowledge about genetic factors and biological mechanisms of disease coupled with unique considerations of an individual's patient care needs to make health care more safe and effective. As a result of these contributions to improvement in the quality of care, personalized medicine represents a key strategy of health care reform. The potential application of this new knowledge, especially when supported through the use of health information technology in the patient care setting, presents the opportunity for transformational change.

Today, it is common for a medical product to be fully effective for only about 60 percent of those who use it. As the medical community is now learning, this in part reflects biological variation among individuals that affects the clinical response to medical interventions. In the past, they have not had the tools or knowledge to understand those differences. In the future, when doctors can truly prescribe "the right treatment, to the right person, at the right time," we will have a new level of precision and effectiveness that will provide the knowledge-driven power that is necessary to achieve our highest goals in health care reform – including more effective disease prevention and early disease detection.

Question 5:

What specific role will HHS play in collaborating with other relevant federal departments and agencies, as well as key scientific research institutions, counselors, hospitals and doctors, to examine the many different aspects of personalized medicine?

Answer: The HHS initiative places as a high priority the engagement of patient and provider groups, researchers, innovators, and other federal stakeholders to advance and accelerate personalized medicine. In two annual reports, HHS has inventoried efforts in federal programs, examined leading efforts in the private and academic sectors, and sought to help bring about common understandings of the opportunities, barriers and pathways for progress. HHS has also identified significant policy issues that will require broad public input. By its nature as a potentially transformational use of medical knowledge and technologies, personalized medicine will encounter challenging, cross-cutting issues, including the incorporation of new genomic knowledge into medical practice; data ownership and sharing; regulation of medical products and laboratories; coverage and reimbursement policies; development of medical evidence; ethical uses of patient information; and maintenance of public trust. Coordination across the Department and collaboration with stakeholders throughout the health care sector and the public will be crucial in realizing the benefits of personalized medicine.

Questions from Senator Hatch

Question 1:

The Congressional Budget Office (CBO) released its estimate predicting that President Obama's budget will produce $9.3 trillion worth of red ink over 2010-2019. That averages out to our deficit increasing by a trillion dollars every year for the next 10 years. That's $2.3 trillion worse than the administration predicted in its budget at the beginning of this year.

In 2009 alone, we have spent more than $200 billion in health care spending between CHIP and the Stimulus along with an additional $200 billion in the Omnibus. The President's budget has proposed a $600 billion reserve fund as an *initial down payment* on health care reform. Experts estimate health care reform to cost anywhere between $1.5 trillion to $2 trillion over 10 years in addition to the more than $2 trillion we are already spending every year.

How would you propose to finance health care reform in a fiscally responsible manner?

> **Answer:** The President believes we can't afford not to reform our health care system. The crushing costs of health care are making it harder for families to make ends meet, and they're making it harder for businesses to compete in the 21st century. In the last eight years, premiums have nearly doubled. And, health costs are a major cause of our long-run fiscal deficit.
>
> Modernizing our health care system and ensuring affordable coverage will require an up-front federal investment. The President's budget includes policies to help offset this investment. Moreover, health reform, along with the Recovery Act investments, will yield long-run cost savings for both taxpayers and the federal government. Our goal is to fix our broken system in a fair and fiscally responsible manner, covering all Americans and lowering the long-run growth of health care.

Question 2:

As part of the American Recovery and Reinvestment Act of 2009, the NIH has received new funds for Fiscal Years 2009 and 2010. The NIH has designated at least $200 million for a new initiative called NIH Challenge Grants in Health and Science Research. Under this initiative, the NIH has listed *Integrating Cost-Effectiveness Analysis into Clinical Research*.

This initiative calls for the inclusion of rigorous cost-effectiveness analysis in the design and testing of new and innovative interventions as well as existing interventions with demonstrated effectiveness. This data will be used to provide information to guide future policies that support the allocation of health resources for the treatment of acute and chronic diseases.

Governor, to me this seems contradictory to what was stated in the President's budget for comparative effectiveness research that "the findings can thereby enhance medical decision-making by patients and their physicians." I take that to mean that the comparative effectiveness research is intended to be used solely to review clinical effectiveness, and <u>not</u> for making treatment and coverage decisions. Can you explain this discrepancy?

> **Answer:** Producing timely, rigorous, and relevant information on treatment options will lead to empowered decision-making for patients and providers. That's why comparative effectiveness research is supported by businesses, providers, and members of Congress from both parties. This research has nothing to do with government dictating choices. As stipulated in law, this research will not be used for coverage decisions by Medicare.

<u>Question 3</u>:

Governor, as I am sure you know, last year the HELP Committee approved a bill to encourage development of lower-cost, follow-on biologic products, a bill which carefully balanced a new, abbreviated approval pathway with incentives for development of the innovator products that will, essentially, be copied. Chairman Kennedy, then-Senator Clinton, Senator Enzi and I worked very closely to develop this consensus legislation, consulting closely with all interested parties, including your agency and the FDA. We tried very hard to base the bill on the best available science. The Committee approved the bill without any objection.

I have two questions. First, are you willing to work with us as this issue moves forward this year? And second, don't you agree that science should be our guide in developing this legislation?

> **Answer:** If confirmed, I am anxious to work with you and the professionals at HHS and FDA to address this important issue. It is time that we bring competition to the biologic drug market and allow for an expedited approval process for these important medications, while providing appropriate incentives for development and innovation. Increasing access to affordable medicines is critical both to consumers and to our broad efforts to reduce the cost of health care.
>
> With respect to your second question, I agree that science should drive the decisions made by HHS in this and other areas, and both the President and I are committed to returning this basic tenet to the work of the Department.

Question 4:

As you may know, I have authored and will introduce, once again, the bipartisan Elder Justice Act with my colleague Senator Blanche Lincoln. This legislation was prompted by the need for a more coordinated and comprehensive federal response to elder abuse, neglect and exploitation. The previous Administration did not support this bill on grounds where Senator Lincoln and I simply disagreed with them. When President Obama served in the Senate, he was a cosponsor of this bill and his current chief of staff, Rahm Emanuel, was the author of the bill in the House.

Will you conduct an early review of this bill and work with us to achieve the kind of consensus that will allow us to better respond to this growing national problem?

Answer: If confirmed, I would welcome the opportunity to review this legislation, and to work with you, Senator Lincoln, and others in Congress to improve our response to elder abuse and neglect.

Question 5:

Medical malpractice insurance costs and defensive medicine have had a serious impact on our nation's total health care costs and health care delivery system. Sadly, there is no national consensus on the problem or the solution. Some states have been harder hit than others by the recent economic crisis; additionally, neurosurgeons, obstetricians, orthopedic surgeons have all been disproportionately affected by high liability premiums. Your home state of Kansas has a $250,000 limit on non-economic damage awards. Kansas also is one of only a small number of states that has a patient compensation fund that covers excess awards and helps stabilize the medical liability insurance market. Can you comment on this and do you believe there a place for medical liability reform in health care reform?

Answer: The most important goal is to improve quality for consumers. I support improving health care quality and patient safety and preventing medical mistakes from happening in the first place. This can be done in a number of ways, including by investing in health information technology that can alert doctors when patients have allergies or drug contra-indications and by requiring transparency about health care quality through reporting requirements. I think we should work to improve outcomes for patients without being doctrinaire about solutions to this problem, and I look forward to working with you if confirmed.

Question 6:

I am interested in your thoughts on President Obama's proposal on payment bundling for post-acute care services. The President has proposed bundling all of the post-acute payment and gives hospitals the responsibility to distribute these payments.

To me, this is very ambitious undertaking – I believe it makes more sense to study this issue through a pilot or demonstration program before implementing national policy. How will the hospital determine where the patient will go? There are several choices -- nursing homes, rehab hospitals, long-term care hospitals and home health care if a patient goes back home after being discharged from the hospital.

In Utah, we have many rural communities around the state and, as a result, there may be limited post-acute settings in many of our small towns. How will bundling affect both hospitals and post-acute providers where there are limited places for patients to go after they are discharged from the hospital? I am worried about the impact this bundling proposal could have on patients and providers in rural and medically underserved areas.

Therefore, I highly recommend that you bring in stakeholders such as hospitals and post-acute providers before moving forward with bundling. I hope you agree.

> **Answer:** It is my understanding that the Medicare program currently covers post-acute care services in a variety of settings and often pays different reimbursement rates to post-acute care providers treating similar patients. The intent behind the President's budget proposal is to improve incentives for providers to deliver the right mix of services to beneficiaries at the right time. It is also intended to create greater incentives for providers to manage patients during the entire episode of care.
>
> Having said that, I can assure you that the President is very mindful of ensuring that beneficiaries have adequate access to post-acute care services–particularly beneficiaries residing in rural and medically underserved areas. I am very interested in your views on this subject, and look forward to working with you and others in Congress on this policy if confirmed.

Question 7:

A constituent in my state, who practices medicine at a rural freestanding cancer center, recently brought to my attention an issue I would ask you to look into once you are confirmed and assume your duties as the new Secretary of the Department of Health and Human Services. The issue pertains to significant proposed cuts in Medicare payment for treatments using high dose rate brachytherapy (HDR), which is one of the more cost-effective and less invasive cancer treatments available to Medicare beneficiaries.

HDR brachytherapy is an outpatient procedure that delivers a custom-designed radiation into the tumor site. It is most frequently used to treat cancers of the breast, head and neck, lung, and prostate. And is one of the more effective and more common treatments for gynecological cancers.

The rule *(Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; Final Rule; CMS-1403-FC)* proposed substantial reductions to the 2009 interim relative value units (RVUs) for new HDR brachytherapy procedure codes. I am informed by a number of physicians in my state and medical specialty societies that there are significant questions as to the accuracy of the data CMS used to determine the value of direct practice expense inputs, which encompass equipment, supply and non-physician labor costs associated with these cancer treatments. The end result, which is troubling by itself, is that payments for these important cancer treatments will in some cases be reduced by nearly half.

I would urge you to consider directing the Centers for Medicare and Medicaid Services (CMS) to delay the implementation of the 2009 interim relative value units (RVUs) for high dose rate (HDR) brachytherapy procedures 77785, 77786 and 77787 and crosswalk current 2008 RVUs effective January 1, 2009 until more accurate practice expense data is collected to base future RVUs for HDR brachytherapy procedure codes.

These extreme reductions in RVUs and 2009 payments will cause freestanding cancer centers of excellence that perform HDR brachytherapy cancer treatments exclusively, to abandon this cancer treatment and negatively impact access for Medicare beneficiaries. Alternatively, freestanding cancer centers may necessarily offer more costly treatments (e.g. Intensity Modulated Radiation Therapy) or more invasive treatments (e.g. radical surgery).

Background

In the 2009 final rule, CMS established three (3) new procedure codes for HDR brachytherapy 77785, 77786 and 77787 effective January 1, 2009 with interim RVUs of 5.16, 15.47 and 22.99 respectively. At the same time, the four (4) current HDR brachytherapy codes 77781-77784 will be deleted on January 1st with 2008 RVUs of 14.97, 19.99, 27.38 and 40.41.

The Joint HDR Brachytherapy Working Group has reviewed the direct practice expense inputs for the interim 2009 HDR brachytherapy codes and has concerns regarding equipment, supply and nonphysician labor costs associated with these cancer treatments. The practice expense inputs for the new HDR brachytherapy procedure codes have been significantly reduced causing 2009 payment decreases in excess of 46%.

HDR Brachytherapy

Iridium-192 is used medically in brachytherapy to treat various types of cancer. Brachytherapy is a form of radiotherapy whereby a radioactive source is brought close to the target tissue, via a natural or created channel. High dose rate brachytherapy is an outpatient procedure that uses an automated remote afterloading device to place a radioactive source into the tumor site. The source is precisely maneuvered by the afterloader device through a series of timed positions in order to deliver a custom-designed radiation dose pattern, then the radioactive source is retracted. This procedure is very effective at providing localized radiation to the tumor site while minimizing the patient's whole-body radiation dose. HDR brachytherapy is cost-effective and has a very favorable side effect profile. Like any brachytherapy, HDR can be used for almost any localized tumor but is most frequently applied to breast, head and neck, lung, prostate and gynecological cancers.

Practice Expense Inputs

In the 2009 final rule, CMS presumes a 5-year useful life for the Iridium-192 renewable source (equipment code ER060). This is incorrect. The Iridium-192 renewable source is typically replaced every 70-90-days or 4-5 times per year depending upon treatment load and case complexity. The $45,326 annual cost of the renewable source should be assigned a useful life of one (1) year. The current assumption of a 5-year useful life is significantly decreasing the renewable source costs associated with HDR brachytherapy.

In addition, Work Group members have identified several types of medical equipment that have not been included in the practice expense inputs for HDR codes 77785-77787, including:

- **Well Chamber with Calibration**
- **Radiation Wall Monitor**
- **HDR Connect Set of Tubes (not associated with per patient catheter use)**
- **Pulse Oximeter**
- **Vital Measures**
- **Prostate Brachytherapy Mattress (CPT 77787 only)**

Answer: I understand the concerns you have about the payment reduction for the high-dose rate (HDR) brachytherapy service used in treatment of prostate cancer for 2009.

The HDR brachytherapy services, including the one used to treat prostate cancer, were redefined by the American Medical Association's Current Procedural Terminology editorial panel for 2009. This new code series was discussed in the 2009 physician fee schedule final rule that was published in the Federal Register on November 19, 2008. The reduction in physician payment for each of these HDR services was a direct result of the redefinition of these services.

While I understand that CMS does not have the authority to delay implementing the 2009 rates, CMS is working with the practicing physicians and the relevant specialty societies to explore options to address these issues for 2010 and beyond. If confirmed, I will closely monitor CMS's payment policies for these services to ensure that they are appropriate.

Question 8:

There are only approximately 50 freestanding children's acute care hospitals in the nation, and their unique mission should -- in my view -- be facilitated. In the Department's annual review of the Inpatient Prospective Payment System (IPPS), I encourage you to remove children's hospitals from the satellite hospital and hospital within hospital restrictions. Children's hospitals simply do not present the same payment manipulation risks as other exempt facilities; if you believe differently, I would very much like an explanation.

Answer: Children's hospitals are exempt from the Medicare hospital inpatient prospective payment system (IPPS) and are paid based on reasonable costs subject to a limit. This payment methodology is generally more favorable than the IPPS for patients who are eligible for Medicare.

It is my understanding that current law does not permit children's hospitals (and certain other PPS-exempt hospitals) to be units of existing IPPS hospitals. The hospital within hospital and satellite rules are designed to ensure that PPS-exempt hospitals are separate and distinct entities from IPPS hospitals so that there is no inappropriate incentive to move patients from one part of the hospital to another solely for the purpose of receiving a higher Medicare payment.

If confirmed, I would be happy to work with you to address any unintended consequences of Medicare's treatment of children's hospitals on access to care.

Question 9:

Research indicates that one in 17 older persons is abused, neglected and/or financially exploited, overwhelmingly by their own children, grandchildren and other relatives, yet the federal government provides virtually no funding to address this growing issue. This situation, despite 30 years of Congressional hearings on the horrors of elder abuse, is in sharp contrast to the billions of dollars provided for services for other victims of crime and family violence. It is also in light of the fact that not only are seniors our fastest growing population group, but also the fact that abuse undoubtedly costs Medicaid and Medicare many, many millions of dollars annually. Do you support HHS at long last beginning to aggressively address elder abuse, through leadership, research, training, public awareness, and most importantly, through providing states with critically needed funding for adult protective services programs, which are the front line responders to elder abuse victims?

Answer: Our seniors deserve honor and respect, not abuse and neglect. I applaud your leadership on this very important issue, and agree that it has received too little attention. If confirmed as Secretary of HHS, I would welcome the opportunity to work with Congress and with my colleagues at HHS to design and implement effective strategies for reducing the abuse, neglect, and exploitation of seniors.

Question 10:

Governor Sebelius, as you may know, last year the Congress passed legislation to delay implementation of the Medicare DMEPOS competitive bidding program because there was a high likelihood that it could cause significant disruption of access and care for beneficiaries, including people with diabetes, and put thousands of small medical supply companies out of business. Although problems with the program have yet to be rectified, CMS has indicated its intention to move forward with the implementation of the competitive bid program over the course of the coming year.

Can I ask you to look into this program, and given the great concerns that exist with the competitive bidding model, as well as the holistic approach you will be bringing to health care reform in 2009, consider putting the program "on ice" until a safe and cost effective approach is put forward as part of broader health care reform?

Answer: If confirmed as Secretary, I pledge to ensure that all of Medicare's requirements are implemented in a transparent manner that ensures beneficiaries have access to all medically necessary goods and services. I will listen to concerns of all stakeholders, and work to ensure those concerns are addressed.

The Administration extended the comment period for CMS's recent competitive bidding rule to ensure that all stakeholders have an opportunity to review CMS's proposed policies. If confirmed, I will ensure the comments are reviewed very carefully in order to implement the policies fairly.

While we test new models of payment reform, we need to remain aware that Medicare is the largest payer for health care goods and services, and Medicare's actions have a tremendous impact on the health care economy. This purchasing power should never be taken lightly. We should seek ways for Medicare to lead the way to a reformed health care system while preserving access and protecting against up unnecessary disruptions to local health care economies.

Question 11:

Governor Sebelius, would you agree that one of the more serious contributors to the over-utilization of health care services (and therefore one of the more serious contributors to rising and unnecessary costs) is the incentive which some health care providers have to refer patients for services in which the referring provider has a financial interest or for which the referring provider can otherwise benefit financially? If this is the case, would you be committed as Secretary of HHS to eliminate financial incentives from referrals so that the best interests of patients would be put first?

Answer: The President and I support the bipartisan work of Chairman Baucus and Senator Grassley in this area. In addition, the President's budget includes a proposal to expand the current moratorium on physician-owned hospitals to ensure that community hospitals' roles are not undermined.

Question 12:

Governor Sebelius, twenty-six million American adults have chronic kidney disease (CKD) and millions of others have related health conditions that place them are at increased risk for CKD. It has been widely demonstrated that education and early detection can help prevent the progression of kidney disease to kidney failure, the result of which would save both thousands of lives and billions of taxpayer dollars.

Last year, Congress acknowledged the important role of kidney disease education and awareness by adopting provisions in the Medicare Improvements for Patients and Providers Act of 2008 that incorporate kidney disease education services into Medicare and by requiring the Secretary of HHS to establish pilot projects to increase awareness, screening and surveillance of CKD.

As Secretary of HHS, will you commit to making CKD awareness and early detection a priority? How would you utilize the resources of HHS to maximize the effectiveness of this important program?

Answer: I recognize the burdens of chronic kidney disease and the opportunities that early detection provides. I also recognize the importance of marshalling the Agency's resources in CMS, NIH, CDC, HRSA, and elsewhere to take on this challenge.

Chronic kidney disease (CKD) is a public health threat in the United States, with increasing prevalence, high costs, and poor outcomes. A more widespread effort to promote prevention, early detection, evaluation, and management of chronic kidney disease and antecedent conditions could prevent complications of decreased kidney function, slow the progression of kidney disease to kidney failure, and reduce cardiovascular disease risk. In March 2009, an expert panel convened by CDC to identify comprehensive public health strategies to address CKD published its recommendations in the American Journal of Kidney Disease. I look forward to working with federal, state, and local governmental and private organizations to carry out these recommendations.

In addition, CDC continues to engage with professional and public partners in the development of effective strategies for prevention and progression of chronic kidney disease. If confirmed, I look forward to discussions on how to enhance some of the current chronic kidney disease activities underway at the CDC and other operating divisions.

Question 13:

The Centers for Medicare & Medicaid Services (CMS) instituted a new program called "Five Star" in December, 2008. The program was designed to create a rating system for nursing homes that would assist consumers in choosing a nursing home. My understanding is that the program was not tested prior to implementation.

I am also informed that the stakeholders were not brought in for any meaningful discussions to provide comments on any draft proposal, nor did this go through the rulemaking process.

I have heard a lot about the fact that the data upon which the rating system is built, is flawed and out of date. There are apparently unintended consequences where HUD has raised questions about whether some 1 star or 2 star facilities can qualify for HUD loans.

Apparently the program is based upon a "bell shaped curve" such that only a small number of facilities can receive a 5 star rating, even if they otherwise have no citations and have an exemplary record of patient care.

In addition, I understand that hospitals may be reluctant to place patients in a 1 or 2 star facility. In rural Utah, the choices may be few and far between. And these 1 or 2 star facilities may in fact be very good. This can create anxiety for consumers as well as nursing homes which are given the low rating.

You also have a program which may well be a breeding ground for lawsuits. Trial attorneys looking to make some money may troll around looking at 1 or 2 star facilities and find fault which may not otherwise exist in an effort to find a basis for a lawsuit.

We hear a lot about transparency but our agencies should be transparent too. While the bugs in the program are being worked out, will you consider suspending the program so that consumers are not misled and providers will not be unfairly penalized?

> **Answer:** I share your commitment to assuring the quality of care, transparency, and accountability in nursing homes. In December 2008, CMS launched the Five-Star Quality Rating System on its Nursing Home Compare website, which assigns quality ratings to each of the nation's 15,800 nursing homes that participate in Medicare or Medicaid based on health inspection surveys, staffing information, and quality of care measures. CMS created the Five-Star Quality Rating System to assist consumers, their families, and caregivers in comparing nursing homes more easily and in identifying areas about which they may want to ask questions. Data, upon which the Five Star is based, has been publicly available on Nursing Home Compare since 2002.
>
> No rating system can address all of the important and individualized considerations that should go into a decision about which nursing home may be best for a particular person. Consumers should use the website as one tool, together with other sources of information, including geographic considerations, an in-person visit to the nursing home, and consultation with state or local organizations, such as local advocacy groups and the State Ombudsman program. Nevertheless, 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. This new rating system is rooted in the tradition of the OBRA'87 nursing home reform law and quality improvement campaigns such as the Advancing Excellence in America's Nursing Homes, a collaborative coalition of consumers, health care providers, labor, and nursing home professionals. We can continue to make strides in improving measurement, reporting, and ultimately the quality of care in America's nursing homes. If confirmed as Secretary, I look forward to working with you to identify areas of further transparency and improvement.

Question 14:

Some in this Congress want to eliminate the use of arbitration to resolve disputes between nursing homes and patients. I happen to oppose eliminating arbitration as an option. A decrease in arbitration will result in a corresponding increase in litigation, and that would increase costs and prolong disputes. Ultimately, eliminating arbitration as an option would force providers to spend more resources fighting lawsuits rather than caring for patients. In particular, I am concerned about the impact on Medicaid funding that removing arbitration might have by adding costs at a time when states are concerned about dwindling funds for health care. Do you believe arbitration should remain in place?

Answer: Currently, under Medicare, whether to have a pre-dispute arbitration agreement is a decision between the resident and the nursing home. Under Medicaid, state law governs whether or not such arbitration agreements are permitted subject to where federal regulations may be implicated. Under both programs, however, there may be consequences when facilities attempt to enforce these agreements in a way that violates federal requirements. I appreciate your concern about the cost and quality of long-term care, and, if confirmed, I intend to monitor this issue closely.

Question 15:

Congress included a device identification (UDI)-related provision in the Food and Drug Administration Amendments Act of 2007 (H.R. 3580). Specifically, section 226 of the legislation requires the Secretary of Health and Human Services to promulgate regulations establishing a UDI system for medical devices requiring the label of devices to bear a unique identifier. UDI will strengthen the ability of the FDA and manufacturers to monitor adverse events related to medical devices and create a common vocabulary for reporting and enhance tracking abilities. It is also essential to maximizing the value of electronic health records (EHRs). EHRs will require that data standards, including those for medical devices, are in place and used by all institutions to transfer information. Having a UDI for medical devices is a basic requirement that must be in place before automated identification systems are fully effective. A common vocabulary for medical devices is necessary for healthcare providers to be able to effectively document devices in patient records. Because of all these important patient safety issues, it is important the department issue the proposed rule as soon as possible. What is the status of the proposed rule?

Answer: FDA considers this proposed rule to be a priority. It is my understanding that the agency is reviewing the public comments it received during its February 12, 2009 public meeting on developing a unique device identification system. If confirmed, I would be happy to keep you informed on the status of the proposed rule.

Question 16:

Governor, the Centers for Medicare & Medicaid Services (CMS) Office of the Actuary (OACT) recently released its national health care estimates for 2007. Their findings report a historic slowdown in prescription drug spending growth. Prescription drugs are now among the slowest growing categories of health care spending, even though in recent years we added prescription drug insurance for millions of seniors and disabled persons. CMS also just released its national health care projections for 2008 through 2018. Since last year, OACT has reduced its 2008-2016 cumulative projection for prescription drug spending by 14 percent, or $515 billion. All this has happened without new government initiatives to control costs. What are the lessons of this historic slowdown for cost containment throughout the health care system? As HHS Secretary, would you agree this data is critical as we shape any sort of health reform efforts related to drug coverage?

Answer: I agree that the findings in the 2007 National Health Expenditures Report are important. As the CMS Office of the Actuary noted in its national health care estimates released this spring, the deceleration in 2007 drug expenditures results from a number of factors. This slower price growth was driven by both the increased use of generics and the introduction and continuation of generic drug discount programs by large retail chain stores. Additionally, the report noted that the loss of patent exclusivity for several major blockbuster medications in 2006 and 2007 contributed to increased use of generic drugs and slower growth in total drug spending in 2007. Despite the slow-down in prescription drug spending growth, I believe that Congress and the Administration can continue to reduce prescription drug costs. If confirmed, I look forward to working with you and your colleagues toward that end.

Question 17:

I'm also concerned about providing Medicaid managed care plans with access government-provided rebates while also allowing then to restrict access to medicines (through utilization management tools and other limitation on access). Do you think it's fair to allow these private plans access to government-mandated rebates while also allowing them to impose access restrictions that are otherwise not permitted in the fee-for-service context? Do you think this could have a negative impact on Medicaid beneficiaries?

Answer: President Obama's FY 2010 budget blueprint has identified changes in the Medicaid drug rebate program as a key way to achieve health care savings while improving the quality and efficiency of health care, and without negatively affecting the care Americans receive.

The budget blueprint proposes to bring down the drug costs of Medicaid by increasing the Medicaid drug rebate for brand-name drugs from 15.1 percent to 22.1 percent of the Average Manufacturer Price, applying the additional rebate to new drug formulations. As you highlight, the blueprint also proposes to reduce drug costs in Medicaid for the federal government by allowing states to collect rebates on drugs provided through Medicaid managed care plans.

If confirmed as Secretary, I look forward to working with you and other members of Congress to promote cost-effective purchase and delivery of prescription drugs for Medicaid beneficiaries.

Question 18:

Governor, almost two out of three Medicare beneficiaries have more than one chronic condition they cope with every day. That often means taking multiple medications from a variety of providers. Helping these patients stay on top of their treatment could both improve their health and lower costs to Medicare in the long term. Currently, the Medication Therapy Management program created as part of Medicare Part D is limited to a small number of beneficiaries, though many others could benefit. Also, the quality and level of engagement with the patients getting these services varies quite a bit because of the limited guidance provided to plans. As HHS Secretary, what would be your plan to enhance these services, identify beneficiaries who could benefit, and improve the quality of services provided?

Governor, about 20 percent of the Medicare population has five or more chronic conditions and accounts for more than two-thirds of Medicare spending. Many of the most common chronic conditions – high blood pressure, diabetes, heart disease, and dyslipidemia -- are manageable with adherence to prescribed medication and behavioral changes. Reduced disability, fewer hospitalizations, and lower overall costs are associated with improvements in patient adherence to medicines. Unfortunately, research shows that levels of patient adherence are surprisingly low, and many patients do not adhere to prescribed treatment sufficiently to receive the expected clinical benefit. Given the prevalence of chronic conditions among Medicare beneficiaries, and the benefits of engaging patients more actively in their own care, what are your thoughts about how to measure and reward health plans and providers for efforts to improve patient adherence to the treatments their doctors' recommend?

Answer: I share your concern about the importance of medication treatment management (MTM) in Part D. CMS has just announced in its 2010 Call Letter – the guidance document that CMS releases every year to alert plans to new program requirements in the upcoming program year – a series of new MTM requirements for the Part D program. CMS recently conducted a program-wide review of the existing MTM protocols used by plans and has developed the new requirements based on the best clinical practices observed across all plans.

Moving forward, I believe that it is important to continue to review the MTM programs that plans are implementing in Part D, and shape CMS' future policies on the practices that show the most evidence of meeting the needs of the program's most vulnerable beneficiaries.

Ensuring that Medicare beneficiaries receive and benefit from high-quality care is complicated by the fact that many beneficiaries have multiple chronic conditions and care is commonly delivered by different providers making multiple treatment plans. Furthermore, patient self-management in the elderly population is often complicated by cognitive impairment and general frailty. These complexities make care coordination all the more important.

The Administration recognizes the importance of coordination across the health care system, and has included proposals in the President's FY 2010 budget blueprint to promote such efforts. If confirmed as Secretary, I will encourage continued efforts to coordinate care, especially for beneficiaries with chronic conditions, and examine ways to improve our outreach to and education of Medicare beneficiaries. These efforts will include strengthening Medicare Part D's MTM programs.

Question 19:

Governor, I applaud the Administration's historic commitment to cure cancer in our lifetime – which highlights the critical importance of medical advances. As you know, outcomes in major areas, like cardiovascular disease and cancer, have improved dramatically in recent years – despite growing problems in how we organize and finance care. Now we need to set a goal of innovating our way to a better, more efficient health system that sustains and expands these advances – particularly for medical conditions like Alzheimer's and Parkinson's disease. Achieving medical advances against these conditions is a key part of a better, more sustainable health care system and a more productive society. Governor, do you agree that promoting medical advances is important and should be one of the goals of broader health care reform?

Answer: I absolutely believe that as we reform our health care system, we can ensure America's leadership in medical advances. Indeed, the United States health care system is home to many of the preeminent researchers and research institutions in the world. A key to providing a high-quality health care system to all Americans is ensuring that we continue to develop medical advances that will improve the treatment of diseases. One path toward that end is to reform our health care system to make medical advances more affordable and accessible to all Americans.

Question 20:

Medical imaging is an important tool to diagnose and treat diseases. Further, GAO found in 2007 CMS data that Medicare physician expenditures related to imaging actually declined by 12.7 percent and that that utilization of advanced medical imaging services was flattening. With this information, how can we move forward with the notion that imaging reimbursement should be further dramatically reduced?

Answer: GAO found that the reduction in expenditures for imaging services in 2007 was primarily due to the reduction in payment for imaging services as a result of implementation of the Deficit Reduction Act (DRA) payment rate reductions. However, GAO found that the per beneficiary use of the tests subject to the DRA payment rate reductions increased 7.4 percent, almost four times faster than the 2.0 percent rate of growth in the utilization of imaging test not subject to the DRA payment rate reductions. While GAO's findings suggest that overall beneficiary access to imaging services was maintained under the DRA payment rate reductions, concerns remain about these utilization growth rates for imaging services. The President's budget proposes to authorize private-sector management tools for imaging services. If confirmed as HHS Secretary, I will continue to work with the Congress on imaging payment reforms and closely monitor the effects of imaging payment reforms on beneficiary access to quality imaging services.

Question 21:

How do you believe Radiology Benefit Managers can be implemented in a system like Medicare which has no experience with prior-authorization? Additionally, what overhead costs do you envision will be placed upon the agency? I fear that these overhead costs could limit care provided to Medicare beneficiaries.

Answer: Prior authorization is a technique used by private-sector insurance companies to eliminate payments for medically unnecessary services. Under radiology benefit management (RBM) programs used by the private sector, a physician or supplier seeks authorization, prior to furnishing the imaging service, for payment for a specific imaging service ordered by a physician. RBM decisions are based on criteria they develop based on recommended guidelines for clinical practice, including guidelines developed by medical specialty societies. Both the Congressional Budget Office and the CMS Office of the Actuary have estimated Medicare savings from the use of the RBMs. If confirmed, I look forward to working with you and your colleagues to ensure that patients have appropriate access to these services.

Question 22:

MedPAC has also suggested that the equipment utilization rate be increased to 90 percent (45 hours a week). This means that essentially, medical imaging equipment would be assumed to be in use 90 percent of the time that an office is open as opposed to the current 50 percent (25 hours a week) assumption. MedPAC acknowledged in its report that it lacks the necessary data required by law to support this change. My concern is that these recommendations could be based on questionable estimates by MedPAC and would lead to additional cuts in reimbursement for these life-saving and cost saving services without sufficient data and analysis. Therefore, I urge you to make sure that first, CMS is using sound policy before moving forward on such a proposal. I worry about the possibility of implementing such a policy, especially if there isn't sufficient data and analysis to support it. Could you please sure your thoughts with me on this important matter?

Answer: This question relates to the formula used to determine payment amounts for certain services under the Medicare physician fee schedule. The formula involves a factor for equipment utilization rate. A higher utilization rate would result in lower Medicare payment rate.

In a recent report, MedPAC indicated that its preferred approach is to set a normative standard for expensive imaging equipment that is based on a level of use that Medicare wants to encourage. In other words, MedPAC believes that Medicare should adopt a standard that would discourage providers from purchasing expensive machines unless they could use them at full capacity. MedPAC recommended that Congress direct the Secretary to use a standard of 90 percent (45 hours a week). The MedPAC recommendation is based on their analysis of data from two surveys, one of which was sponsored by MedPAC. I agree that Medicare policies need to be based on sound analysis, consistent with current statutory requirements, and conducted with full opportunity for public notice and comment. If confirmed as HHS Secretary, I will carefully consider MedPAC's recommendation.

Question 23:

Governor Sebelius, about ten years ago, the government funded entity that oversees organ donations and distributions, UNOS proposed to move the allocation of donated livers from a state to a regional system. That proposal was dropped due to significant and substantive opposition from states like my own. Just a few days after the start of this new Administration, UNOS revived this proposal and could move as early as this June to give it final approval. I have serious reservations about the substance and the timing of this proposal and am very much opposed to it going into effect – is this something you would be willing to take a look at for me?

Answer: Organ donation is an essential, life-saving gift from one person to another, and in order to maintain the public's trust in the program, distribution must handled judiciously. If I am confirmed, I will be glad to review this proposal.

Question 24:

The American Recovery and Reinvestment Act contains numerous provisions to foster the adoption of health information technology, as well as new privacy provisions that upgrade the existing HIPAA privacy rules. Is it your sense that the grant and loan funding should be made available not only for the adoption of health information technology, but also for health care providers to modify their existing systems to comply with the privacy provisions? For example, retail pharmacies already use electronic health records for their patients. The privacy provisions, especially the accounting of disclosures requirement, will require them to make significant and costly modifications to these existing systems.

Answer: It is very important that providers who currently employ electronic medical records have the support and technical assistance they need to implement the health IT legislation included in the Recovery Act, including the privacy provisions. HHS is currently engaging across the department, with other agencies in the federal government, and with outside groups to ensure we get this right. One important tool is the Regional Extension Centers program included in the Recovery Act. This program can support the efforts of providers not only to adopt health IT, but also to upgrade, use, and maintain their systems.

Questions from Senator Kyl

Question 1:

Can you describe your position on abortion? Did you ever veto any pro-life legislation during your tenure as Governor?

Answer: I am personally opposed to abortion, and my faith teaches me that all life is sacred. Throughout my career as a public official I have tried to reduce unwanted pregnancies, and thus curtail the need for abortion. In Kansas, the abortion rate dropped over 10 percent during my administration. I also signed into law bills to support adoption.

Adoption funding increased over $2 million during my time as Governor, and I signed into law the Pregnancy Maintenance Initiative to help those experiencing unwanted pregnancies. I also recently signed into law a measure requiring that women seeking abortions are given the opportunity to see an ultrasound.

Most of the abortion-related bills I vetoed as Governor threatened the constitutional rights or medical privacy of women. Some sought to provide people other than a woman's doctor access to her medical records. Like most Americans, I strongly believe the privacy of medical records must be protected. In addition, I vetoed two bills that attempted to put specific regulations on abortion facilities without applying those same standards to all outpatient surgical centers. I favored treating all outpatient surgical centers equally.

Question 2:

There has been a lot of attention concerning your relationship with George Tiller, a doctor who has performed late term abortions in Kansas. Can you describe your relationship with Mr. Tiller? Has he ever contributed to your campaign or has your PAC ever received money from Mr. Tiller or a PAC related to Mr. Tiller? Have you ever hosted Mr. Tiller at an event during your tenure as Governor of Kansas?

Answer: I have been familiar with Dr. Tiller for many years because he lives and works in Kansas. Dr. Tiller, like many Kansans, contributed to my campaign for Insurance Commissioner. I received $12,450 over an eight-year period (1994-2001), which represented 1% of my total contributions during that time. Since that time, I have received no donations from Dr. Tiller or any PAC related to him.

Throughout the course of my career, I have donated a lunch, dinner, or reception to non-profit organizations at their annual auctions. I did so every year as Insurance Commissioner and have done so every year as Governor. In 2006, I donated a reception at Cedar Crest to the Greater Kansas City Women's Political Caucus for their annual fundraiser, the Torch Dinner. Dr. Tiller bid on and won that auction item.

As a result, an afternoon event lasting approximately one hour was held at Cedar Crest, with Dr. Tiller and his staff in attendance. All costs were reimbursed to the state.

Question 3:

Will you assure us that you will never support the rationing of health care as a part of health care reform?

Answer: No one is proposing the rationing of health care as part of health reform. In fact, health reform is needed to prevent the rationing by income and pre-existing conditions that is rampant in the system today. One way to prevent arbitrary health care decisions is to empower providers and patients with high-quality information. Comparative effectiveness is about gathering and sharing information on what's most effective; it has nothing to do with government dictating choices or rationing care.

Question 4:

Will you assure us that HHS, federal health care programs, and any new entity will not use comparative effectiveness research to ration care?

Answer: I will assure you that the President and I will work to expand Americans' access to high-quality health care, not restrict it. The best way to do this is to make health care affordable since the system now rations care by ability to pay. At the same time, it is imperative that we both learn what works and design our policies to empower providers and patients to use it. Comparative effectiveness research is one component of building a high-quality, value-oriented health system. It is not about government rationing.

Question 5:

Will you assure us that you will protect patients' choice of the optimal therapies for their condition or disease?

Answer: Improving the evidence base through support for basic, applied, and comparative effectiveness research will improve patients' choice of optimal therapies. The President has made such research a high priority, and has already invested in it through the Recovery Act's $10 billion for the National Institutes of Health and $1.1 billion for comparative effectiveness research. His budget supplements this with funding to find a cure for cancer. Empowering patients and providers with this type of information is a key component of a high-quality, affordable health care system.

Question 6:

Do you believe that the term 'comparative effectiveness' includes cost-effectiveness analyses? Should treatments be allocated based on such analysis?

Answer: The term 'comparative effectiveness' means an overall comparison of treatment options. The goal of such research is to improve the database of information available to a patient and his or her provider so they can make informed decisions about care. The goal is to empower patients and providers with the best information on protocols, procedures, and other relevant issues, not to enable the federal government to dictate broad coverage decisions.

Question 7:

Is it the Administration's intent that comparative effectiveness research be used to help make coverage and reimbursement decisions?

Answer: In keeping with the provisions of a 2003 law, comparative effectiveness research will be used to allow patients and their providers to make the best, most informed decision possible as to which treatment is best. As specified in the law, Medicare cannot make coverage decisions based on this research.

Question 8:

The American Recovery and Reinvestment Act of 2009 (P.L. 111-5) included a rule of construction which stated that "nothing in this section shall be construed to permit the [Federal Coordinating] Council to mandate coverage, reimbursement, or other policies for any public or private payer." While the council's recommendations may not be payment or coverage mandates, isn't it true that nothing prohibits the Centers for Medicare or Medicaid Services or private insurers from using the council's recommendations to make coverage determinations and set reimbursement rates?

Answer: Comparative effectiveness will help consumers and providers make informed health care decisions based on effectiveness and appropriateness of treatments. The information gleaned from comparative effectiveness research will not be used for coverage decisions for Medicare, as dictated by a 2003 law.

Question 9:

In *Critical: What We Can Do about the Health Care Crisis*, Tom Daschle recommends the establishment of a Federal Health Board that would "promote 'high value' medical care by recommending coverage of those drugs and procedures backed by solid evidence. It would exert influence by ranking services and therapies by their health and cost impacts," (172). Do you support this recommendation?

Answer: One of the biggest cost drivers in our health care system is the wide variance in procedures. You can live in one part of Los Angeles and get one therapy for a disease and live in another part and get a less effective, more costly therapy for the same disease. Aligning our system toward what works will both improve quality and help address the problem of skyrocketing costs. I do agree with Senator Daschle – and Senator Baucus, among others – that promoting best practices should be protected from politics and micromanagement

There are many ways to go about doing this, and, if confirmed, I look forward to working with Members of Congress on this and other ideas on how to make the health system more effective and better for patients.

Question 10:

Additionally, in *Critical*, Tom Daschle conveys his support for comparative effectiveness research and a Federal Health Board, concluding that the combination works well in other countries. Please consider his quote below:

"In other countries, national health boards have helped ensure quality and rein in costs in the face of these challenges. In Great Britain, for example, the National Institute for Health and Clinical Excellence (NICE), which is part of the National Health Service, is the single entity responsible for providing guidance on the use of new and existing drugs, treatments, and procedures… NICE also weighs economic evidence or how well the medicine or treatment works in relation to how much it costs," (127).

a. Do you believe that comparative effectiveness research should be used to help rein in costs?

Answer: The goal of comparative effectiveness research is to inform provider and patient decision-making to promote high-value health care. When authorizing comparative effectiveness research in both the Medicare Modernization Act and the American Recovery and Reinvestment Act, Congress did not impose any limits on it. If confirmed, I will work to ensure that the research is high-quality, and that it is used to enhance decision making and inform choices by patients and providers.

b. Do you believe that the U.S. should weigh economic evidence or how well the medicine or treatment works in relation to how much it costs?

Answer: The goal of comparative effectiveness is for providers and patients to compare different treatment options, not to enable the federal government to dictate decisions about care. Indeed, Medicare is prohibited from using such research for coverage decisions.

Question 11

The National Institutes of Health released a list of research topic areas, one of which is entitled "Integrating Cost-Effectiveness Analysis into Clinical Research." The description reads "this initiative calls for the inclusion of rigorous cost-effectiveness analysis in the design and testing of new and innovative interventions… Cost effectiveness research will provide accurate and objective information to guide future policies that support the allocation of health resources for the treatment of acute and chronic diseases."

a. Do you support this research topic and description?

Answer: Providing information on treatments through rigorous research forms the cornerstone of empowered decision-making for patients and providers. This is a central part of a high-quality health care system. As stipulated in law, this research will not be used for coverage decisions by Medicare.

b. As HHS Secretary, would you stop cost-effectiveness projects such as the one listed above?

Answer: A vital component of a high-functioning health care system is the empowerment of providers and patients with timely, rigorous, and relevant information on treatment options. Congress did not limit this research when authorizing it in both the Medicare Modernization Act and the American Recovery and Reinvestment Act. If confirmed, I will work to ensure that the research is high-quality and is used to inform the decisions of patients and providers.

c. Please consider the following patient example. Patient A takes the antipsychotic, Risperdal. Comparative effectiveness research shows that another antipsychotic, Haldol, is just as effective and cheaper. Medicare decides to cover what the research determines is most effective, Haldol. Unfortunately, Patient A has a history of experiencing very bad side effects when taking Haldol.

Should Medicare use the data obtained by comparative effectiveness research to limit its coverage to Haldol?

Answer: The funding of research on the impact of different treatment options is intended to empower providers and patients, not to deny coverage of needed drugs by Medicare. As stipulated in law, this research will not be used for coverage decisions by Medicare.

d. Should Medicare alter the physician's reimbursement if he prescribed the non-approved Risperdal instead of Haldol?

Answer: Congress sets most of the rules for Medicare, and it does not allow withholding of reimbursement to doctors based on the particular drugs they prescribe.

Question 12:

Would you support a pro-patient firewall that prohibits the use of comparative effectiveness research to make cost-based coverage determinations?

Answer: As stipulated in a 2003 law, comparative effectiveness research will not be used for coverage decisions by Medicare.

Question 13:

Do you believe that a public plan option is necessary to ensure that every American is insured?

Answer: The President's campaign plan proposed a public option alongside private insurance options in a National Health Insurance Exchange. He recognizes the importance of giving the American people this choice, which would also challenge private insurers to compete on cost and quality, not cream-skimming and risk selection. At the same time, he recognizes the importance of maintaining a level playing field between plans and ensuring that private insurance plans are not disadvantaged. The public plan option should pay providers competitive rates, and the private plan options should be barred from cherry-picking the healthiest enrollees. The Administration will work with Congress on this and other elements of comprehensive reform, and, if confirmed, I look forward to contributing to that effort.

Question 14:

Do you support eliminating or capping the existing employer-provided health care exclusion to help offset the cost of comprehensive health care reform?

Answer: The President believes health reform should build upon the existing employer-based health care system, through which the majority of Americans receive their health care. The tax exclusion contributes to sustaining this system. That said, he recognizes that many members of Congress have views on that subject. He has stated that he would consider all serious proposals, if that is what it takes to cover all Americans.

Question 15:

In his book *Critical,* Tom Daschle recommends that "the next president should act immediately to capitalize on the goodwill that greets any incoming administration. If that means attaching a health care plan to the federal budget, so be it. This issue is too important," (196-197). Can you assure us that your top priority—and the Administration's— is a bipartisan health reform bill, and as a result, you will reject the use of budget reconciliation?

Answer: The President has been clear that he hopes that we can turn the page to a new era of bipartisan cooperation in Washington. The commitment to bipartisanship extends to health reform. This will be one of the largest undertakings of this Congress, and we hope to find common ground. There are many tools available and none of those tools, including reconciliation, should be taken off the table. The White House -- and I, if confirmed -- look forward to working with Congress to achieve a bipartisan solution to the health system crisis.

Question 16:

As you know, the Secretary bears the responsibility of distributing LIHEAP contingency funds. Will you take into account high cooling costs that warm weather states experience in the summer months when distributing LIHEAP contingency funding?

Answer: President Obama and I strongly support the goals of the LIHEAP program and believe it is critical to help low-income families who are struggling to meet their energy needs for heating and cooling. The President's budget includes a new proposal for creating a trigger to release emergency funds in the event of increasing energy prices and would supplement the existing contingency fund that provides support to states in emergency situations. If confirmed, I would be anxious to work with Congress to consider the President's proposal, and would welcome other ideas for improving ways to meet the energy burdens faced by low-income families across our country.

a. **Will you attempt to conserve the contingency funds so that there is adequate money left to distribute to warm weather states in the summer months?**

Answer: I strongly support the LIHEAP program and, if confirmed, will exercise discretion to deploy the contingency fund in a manner consistent with both the law and needs of low-income people across our country.

Question 17:

To encourage an equitable distribution of contingency money, would you support a 50-50 split of contingency funds between hot and cold weather states?

Answer: As I mentioned in my answer to the previous question, I strongly support the LIHEAP program and, if confirmed, will exercise discretion to deploy the contingency fund in a manner consistent with both the law and needs of low-income people across our country.

Question 18:

In 2007, a House bill, the "CHAMP Act," set MA payments equal to 100 percent of traditional Medicare. In a letter to former Rep. McCrery, the CBO Director—now OMB Director, Peter Orszag—outlined the bill's effect on MA enrollment, benefits, and plan participation.

The CHAMP Act would "result in a significant decrease in enrollment in MA plans" by approximately 6.2 million beneficiaries in 2012. The change to the benchmarks would be "significant enough to affect enrollment in almost every area of the country, including both urban and rural areas." "Some areas would lose all or nearly all of their plans." And for those beneficiaries fortunate enough to maintain access to a MA plan, "plans would be forced to increase cost-sharing" and "would probably also need to modify their benefit packages and increase premiums as well."

Since CBO establishes a direct correlation between significantly reducing MA plan payments and millions of seniors losing their health coverage, will you oppose such payment reductions as HHS Secretary?

Answer: Medicare Advantage plans are paid on average at least 14 percent more for health care than costs incurred under traditional Medicare for the same patient. These overpayments force all seniors and people with disabilities to pay higher premiums and threaten the long-term solvency of the program. While enrollees in these plans receive enhanced benefits, they are provided very inefficiently. For each $1 in extra benefits, the federal government spends $3. I share the President's view that we need to reduce these excessive subsidies. The President's budget proposes to alter the way Medicare pays Medicare Advantage plans through a competitive bidding mechanism, which we believe will save more than $175 billion over the next 10 years. If confirmed, I will work to ensure that Medicare pays fairly and protects access across the program.

Question 19:

The President's Fiscal Year 2010 budget includes a competitive bidding proposal that saves $176.6 billion over ten years. In order for the Administration to estimate the projected budgetary impact of its proposal, it must have set the benchmark at a particular rate. Does the Administration's estimate rely on setting the benchmark to 100 percent (or lower) of Medicare fee-for-service? And, if so, do you support the Administration's proposal?

Answer: The FY 2010 President's Budget proposes to replace the current-law benchmark calculation with one set by actual Medicare Advantage bids. MedPAC has estimated that, on average, Medicare currently pays Medicare Advantage plans 14 percent more than it pays local fee-for-service costs. Under the budget proposal, the benchmark in a given local service area would be set based upon the average of all plans' bids for that area. The budget's savings estimates are based upon actual bids that CMS has received by Medicare Advantage plans. In some areas of the country, plans' actual bids are below 100 percent of fee-for-service costs. The savings estimate presented in the President's budget does not limit the benchmarks to 100 percent of local fee-for-service costs. We expect that in some areas the benchmarks would be above fee-for-service and in some areas they would be below, due to the bidding behavior of plans. The President has made reforming Medicare's payments to Medicare Advantage plans a priority. If confirmed as HHS Secretary, I pledge to thoughtfully consider the concerns you and some of your colleagues have raised as the Administration works with Congress to address this issue.

Question 20:

Physicians face a 21 percent payment cut January 1, 2010. Congress acts each year to prevent scheduled payment cuts, but short-term fixes have exacerbated the long-term problems associated with the sustainable growth rate (SGR) formula. As you may know, the cost of physician-administered drugs is included in the SGR, even though these drugs are not 'physician services.' This leads to an inaccurate calculation of Medicare spending on physician and practitioner services. As HHS Secretary, will you administratively remove Part B drugs from the SGR formula?

Answer: As part of health care reform, the Administration supports comprehensive, fiscally responsible reforms to the physician payment formula. The President and I believe Medicare and the country need to move toward a system in which doctors face stronger incentives to provide high-quality care rather than simply more care. We also believe that Medicare's payment system should support more primary care. A 21 percent cut in physician payments is simply unsustainable. If confirmed, I look forward to working with you to improve the Medicare payment system to promote broader reform goals as we address changes to the SGR.

Questions from Senator Crapo

Question 1:

Governor, I know that you are all too familiar with the unique struggles that many rural states face with regard to access to quality health care. More than 50,000 seniors in my home state of Idaho, and more than 40,000 in Kansas, rely on the Medicare Advantage program to provide them with health insurance. When previous Congresses decided to cut payments to earlier versions of the Medicare Advantage programs, the result was that many seniors in rural states lost the insurance they had. Eventually, Congress had to intervene and increase the payment rates to rural communities in states like Idaho and Kansas to ensure that these seniors had access to a private health care option. As you know, the President's budget proposes nearly $200 billion in cuts to the Medicare Advantage program and a recent CMS announcement could result in additional cuts to these plans. Given past experiences with the program and the potential for these cuts, how will you, in your capacity as HHS Secretary, ensure that seniors in my state, and across America, won't lose their current health insurance and that we won't repeat mistakes of the past?

Answer: Rural communities face unique challenges. Provider access is often limited; hospitals are often a long trip away; and rural residents face different health challenges than their urban counterparts. For example, rural Americans tend to be older and more likely to suffer from chronic diseases like diabetes and congestive heart failure than urban seniors. If confirmed as HHS Secretary, I will make addressing the needs of rural Americans a high priority, by (1) ensuring greater access to physicians and health professionals in rural and underserved areas, (2) ensuring our rural hospitals and other providers are paid appropriately, and (3) ensuring Medicare promotes integrated and coordinate care delivery, especially in rural areas, so that chronic conditions are prevented or managed appropriately to improve health while reducing costs.

As we consider Medicare Advantage policy, we should keep in mind that the majority of plans in rural areas are so-called Private Fee-for-Service plans that do not provide the value-added services the Medicare Advantage program was intended to provide. Medicare should ensure that its payment policies promote value wherever possible. In addition, for too long, urban seniors have had access to generous health plan benefits, at the expense of rural seniors. Any change we make to Medicare Advantage going forward should make sure that all seniors—urban and rural—are treated equally. In addition to payment reforms, we also need to encourage Medicare Advantage plans to improve quality and coordinate care for all Medicare beneficiaries, in order to ensure that Medicare dollars are most appropriately spent.

Question 2:

Governor, as you know, the Administration's budget proposes to increase the Medicaid rebates drug manufacturers already pay to states and the federal government. My concern is that these proposed increases will cause cost-shifting to private payers – thereby increasing drug costs for employer-provided plans and other payers. The Congressional Budget Office (CBO) has noted that "although the Medicaid rebate program has lowered Medicaid's expenditures, it may have also increased the prices paid by other purchasers" by making it "more costly for drug manufacturers to offer price concessions to other purchasers if those concessions trigger the best-price provision." As a result, CBO found that the "large discounts offered by manufacturers have fallen substantially since the drug rebate program began." Given these concerns of further cost-shifting and increasing prescription drug costs for private payers, would you support an increase in Medicaid rebates as HHS Secretary?

Answer: The President has identified changes in the Medicaid rebates as a key way to achieve health care savings while improving the quality and efficiency of health care, and without negatively affecting the care Americans receive or shifting costs to other sectors. His budget proposes to bring down the drug costs of Medicaid by increasing the Medicaid drug rebate for brand-name drugs from 15.1 percent to 22.1 percent of the Average Manufacturer Price, applying the additional rebate to new drug formulations, and allowing states to collect rebates on drugs provided through Medicaid managed care organizations. This proposal is estimated to save the federal government a total of over $19.5 billion over the next 10 years. If confirmed as Secretary, I look forward to working with you and other members of Congress to promote cost-effective purchase and delivery of prescription drugs, and to monitor proposals like this to ensure they do not shift costs to other sectors.

Question 3:

Governor, as you know, last week, the Department of Health and Human Services named a 15-member panel to lead a $1.1 billion comparative effectiveness research program. While the prospect of comparative effectiveness research holds real value for patients, I'm very concerned that this could lead to centralized coverage decisions about who should and should not get access to medically beneficial care. We have seen this happen in other countries, such as the U.K., where patients with breast cancer, kidney cancer, Alzheimer's, and many other serious diseases are denied access to beneficial treatment options that are widely available in this country. Do you share these concerns? As Secretary, what steps do you plan to take to ensure this research achieves the goal articulated by President Obama – improving patient and provider decision-making – while avoiding these types of centralized access restrictions?

Answer: One of our priorities is to ensure a quality health care system, and quality care means people receive the care that is right for them. Improving the evidence base through support for basic, applied, and comparative effectiveness research will improve patients' choice of optimal therapies. Empowering patients and providers with this type of information is a key component of a high-quality, affordable health care system. Business groups, some provider groups, and bipartisan members of Congress support this effort because it will improve the performance of the health system. We must disseminate information on the best medical practice for people in a way that ensures effectiveness. I can assure you that the information gleaned from comparative effectiveness research will not be used for coverage decisions for Medicare, as dictated by a 2003 law.

Question 4:

Governor, I am concerned that, despite an increased focus on prevention and wellness within the health care reform debate, we as a nation have not given sufficient attention to men's health issues. In 2007, I introduced legislation to create an Office of Men's Health at the Department of Health and Human Services, to mirror the already-existing Office of Women's Health. Studies have shown that men are 100-percent less likely to visit the doctor than women. Even with improvements in medical technology, men continue to have a shorter life span than women and of the ten leading causes of death in our country, men lead women in all ten categories. Do you agree that men's health must be a national health care priority? As Secretary, how would you work to support the creation of an Office of Men's Health at HHS?

Answer: Like you, I am concerned about factors that contribute to a shorter life span among men, and I agree that we must work to better understand and address these and other health-related challenges facing men in this country. If confirmed, I look forward to working with you to consider the best mechanisms to help us make progress on this important issue, including the establishment of an Office of Men's Health.

Question 5:

Governor, I am concerned that the National Institutes of Health do not appear to be sufficiently prioritizing research that would develop imaging technologies for prostate cancer detection and treatment comparable to what women currently have for breast cancer detection. Women have mammograms, but men don't have a "manogram." A recent study funded by the National Cancer Institute at NIH showed no evidence of a survival benefit associated with aggressive screening for prostate cancer using the prostate specific antigen (PSA) test. As a two-time prostate cancer survivor, this is an issue that hits close to home for me. As Secretary, what actions would you recommend in an effort to support the development of and increase access to these types of imaging services for men?

Answer: If confirmed as Secretary, I will work closely with the National Cancer Institute Director to continue our aggressive research efforts to prevent and to diagnose prostate cancer at the very earliest stage of its initiation in the gland, to develop the technologies that will enable physicians to determine which prostate cancers require treatment and, of course, to continue to improve the therapies for the aggressive form of prostate cancer.

As reported earlier this month and as you noted, a recent National Cancer Institute (NCI) study determined that screening with the prostate-specific antigen (PSA) blood test, while capable of detecting the presence of prostate cancer, was not effective in reducing mortality. Physicians tell me that they have long recognized that prostate cancer can either occur in a form that is very slow-growing (and that, as a result, can be carefully observed rather than aggressively treated with surgery or radiation), or can occur in a form that is aggressive and life-threatening. It is clear that PSA alone is not enough to detect the aggressive forms of prostate cancer, or to enable men to actively protect their health. The challenge is to develop methods capable of distinguishing between the aggressive and non-aggressive forms of the disease.

NCI is actively researching other biomarkers -- substances that may be found in tumor tissue or released from a tumor into the blood or other body fluids -- that will distinguish between cancerous and benign conditions, and between slow-growing cancers and fast-growing, potentially lethal cancers. The identification of such biomarkers is a high priority in order to provide large population screening that is acceptable to men and at an affordable cost. Until such new tests have been discovered and validated in clinical trials, the PSA test remains an important screening test for men, and several methods of optimizing PSA tests are currently being studied.

As you state above, imaging science can play an important role in earlier diagnosis of prostate cancer, development of minimally invasive treatments, to help monitor men who elect active surveillance, and to improve quality of life in patients following treatment. Recognizing this opportunity, NCI continues to support the development of new technologies that will help us not only to diagnose prostate cancer earlier, but also to gain information about the characteristics of individual tumors, leading us to more effective treatments. In addition, NCI is combining cancer imaging methods with emerging technologies such as nanotechnology and proteomics to develop methods to identify cancers at an earlier stage.

I am confident that these efforts, on multiple fronts, will lead to the development of screening tests for prostate cancer that can be effective in identifying more aggressive forms of the disease in its early stages. I am also confident that advances in image-guided surgeries will enhance the treatment of prostate cancer and preserve quality of life for the men facing it. As you aptly point out, simply developing these new technologies for diagnosis and therapy is not enough. We must work hard to provide access and knowledge about optimal screening to all men. If confirmed, I look forward to working with you to promote and achieve these goals.

Question 6:

As you know, many hospitals around the country face an ongoing struggle to provide the best care to their communities despite financial, administrative and other challenges. How best do you think the Department of Health and Human Services can assist small regional and rural hospitals in paying for the cost of equipment and facility upgrades? Do you think the Department has a role in giving direct assistance to the community hospitals?

Answer: As a governor of a rural state, I fully appreciate the challenges that small, rural hospitals face in providing care and upgrading their facilities and equipment. I have heard many suggestions on ways we can improve the various programs administered by the Department of Health and Human Services to improve rural healthcare. If confirmed as Secretary, I will undertake a complete review of these programs, including those administered by the Health Resources and Services Administration (HRSA) and the Centers for Medicare and Medicaid Services (CMS). This review will include exploring ways to expand low-cost loans or grants to rural hospitals. The American Recovery and Reinvestment Act also provides crucial funding to provide greater financial incentives for hospitals to update their health information technology systems. Ensuring the successful implementation of this law, and its provision for rural hospitals, will be a top priority of mine. I look forward to discussing your other suggestion to ensure that all Americans, including those from rural areas, have access to the best possible and most efficient care.

Question 7:

Governor, as you know, ambulatory surgical centers (ASCs) are a critical point of access for important screening benefits and other nondiscretionary services such as diagnostic colonoscopies and cataract removal surgery. Patients save considerable money when they choose ASCs for their outpatient surgery. For example, Medicare beneficiary cost-sharing is 61 percent cheaper for cataract surgery and 57 percent cheaper for diagnostic colonoscopy than outpatient hospitals. However, ASCs have not received a payment update in six years and now CMS is using its administrative authority to further cut payments far below the current 59% of hospital outpatient departments for the identical services. What role do you think lower cost providers like ASCs have in Medicare and health care reform? Are you concerned that continuing to cut these providers – particularly when the patients save considerable money on their cost sharing -- could result in higher overall Medicare costs as patients would migrate to the more expensive setting?

Answer: Medicare's revised ambulatory surgical center (ASC) payment system is intended to encourage high-quality and efficient surgical care in the most appropriate outpatient setting for each Medicare beneficiary. As a result of this revised system, the number of ASCs and the number of surgical procedures performed in ASCs continue to grow, reflecting expanded access for Medicare beneficiaries to surgical procedures performed in this important setting.

It is my understanding that CMS implemented the revised ASC payment system as required by the law. The final ASC policies, proposed by the previous Administration, recognize that there are overlaps between services performed in hospital outpatient departments, physicians' offices, and ASCs, and attempted to avoid creating payment incentives that would favor one setting over another.

If confirmed as Secretary, I will closely monitor Medicare's payment systems for all providers, to ensure they promote the highest-quality care delivery for the most efficient cost.

Questions from Senator Roberts

Question 1:

Governor, in our recent meeting, we had a good discussion regarding comparative effectiveness research. In that meeting, I shared my concerns about the government using this research to deny coverage based on cost, leading to rationed health care. You said that you agreed with my concerns and that PROVIDERS, not the government, should make decisions on what is best for each patient. You further stated that current law does not allow the government to include cost analysis in its comparative effectiveness research, and does not allow CMS to use cost as a factor in making coverage decisions. However, I remain concerned that, in trying to cut costs, comparative effectiveness research will inevitably be used by policy-makers to create incentives that restrict coverage or discourage patient access to care. Would you agree that CER should NOT be used this way? And would you agree that, when CER is used by providers and patients, it can lead to better overall health care value?

If so, will you work with me on further protections to ensure CER is used appropriately to inform patient and doctor decisions and not misused to deny access to care?

> **Answer:** I agree with you that comparative effectiveness research can lead to better overall health care value. Others who agree are the business community, many provider and patient groups, and the President. This is why the investment in the Recovery Act is an important one. If confirmed, I will ensure that the current law prohibiting Medicare from denying coverage based on this information is implemented. I also look forward to working with Congress on the President's agenda to ensure that all Americans have to access to affordable, high-quality health care.

Question 2:

In a hearing last week before the House Labor-HHS Appropriations Subcommittee, acting National Institutes for Health Director Raynard S. Kington testified that his agency may use money from the economic stimulus law to fund grants for comparative effectiveness research that includes comparisons of the costs of the treatments involved. I am concerned about this I and believe it is not the legislative intent of the stimulus package. As HHS Secretary with ultimate responsibility for the agencies within HHS, do you believe comparative effectiveness research conducted by NIH should be focused on cost comparisons- or focused on clinical comparisons, as was the intent of the legislation?

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> **Answer:** A vital component of a high-functioning health care system is the empowerment of providers and patients with timely, rigorous, and relevant information on treatment options. Congress did not limit this research when authorizing it in both the Medicare Modernization Act and the American Recovery and Reinvestment Act. If confirmed, I will work to ensure that the research is high-quality and used to enhance decision-making and inform choices by patients and providers.

Question 3:

I'm told that the Administration may be considering invoking Least Costly Alternative authority, using Comparative Effectiveness Research to decide which test or treatment is the "least costly alternative" on average, and deny Medicare patients access to other options that would be better for them as individuals as determined by their doctor. We need to deal with Medicare spending, but not at the expense of patients who don't fit the statistical mean. As HHS Secretary, do you plan to pursue "least costly alternative"-type policies in Medicare? Will you work with me on alternative approaches that avoid denying patients access to appropriate therapeutic options?

Answer: Health care costs present a growing economic challenge in our system, so all serious proposals to reduce them should be considered. At the same time, ensuring quality coverage – for every patient – is a critical goal of the President's. The goal of efficiency must never come at the expense of quality, and the President's budget offers a number of proposals that enhance both.

Question 4:

The Centers for Disease Control reports that there were more than 120 million emergency visits in 2006. In addition, the Institutes of Medicine released three reports on the state of emergency care in the United States finding many problems including overcrowding, boarding, and appropriate emergency care for children.

What steps will you take to address adequate access and support for our nation's Emergency Departments?

Given that federal law requires Emergency Departments to care for everyone who asks to be seen, what is your plan for ensuring that the Emergency Department safety net has enough resources to provide care to all Americans who need it, especially in this time of financial crisis?

Answer: Emergency departments are a critical part of our health care infrastructure, and serve all Americans, regardless of ability to pay. One of the main reasons that emergency departments are struggling has to do with uninsurance and uncompensated care. As we move toward a system in which everyone is covered, much of the financial pressure on emergency departments will be relieved. That said, it will be critical to ensure that the financial incentives are aligned appropriately to assure that emergency departments remain available, without creating incentives to use emergency services in non-emergencies. This will create a win-win both for primary care and for emergency care.

Question 5:

Governor, CMS recently used its statutory authority to exempt several health care professionals from new requirements that they obtain accreditation, as well as obtain an annual $50,000 surety bond, in order to provide durable medical equipment to Medicare beneficiaries.

These requirements are designed to protect the Medicare program from fraud, as well as improve the quality of services provided to Medicare beneficiaries.

However, Congress exempted certain state-licensed health professionals from these new requirements, and gave CMS the discretion to exempt other professionals, recognizing that these new requirements would be duplicative and costly, and could reduce beneficiaries' access to these products and services.

For example, CMS has indicated that it believes that the combined costs of these new requirements will result in the loss of 25,000 durable medical equipments suppliers from Medicare. This is particularly a concern in rural areas.

However, I understand that CMS did not use its discretion to exempt pharmacists and pharmacies from these accreditation and surety bond requirements, even though they too are state-licensed health professionals.

I am particularly concerned that, without an exemption, the cumulative costs to retail pharmacies of complying with these requirements, which CMS estimates would be at least $2,500 per year per pharmacy, would reduce Medicare beneficiaries' access to durable medical equipment, especially diabetes testing supplies.

What are your views on whether pharmacists should be exempted from the accreditation and surety bond requirements? Would you consider reviewing CMS's decision not to exempt state-licensed pharmacists and pharmacies from them?

Answer: Fighting Medicare fraud and abuse should be one of CMS's top priorities. I understand that CMS has already taken a number of steps to address fraud and abuse in the durable medical equipment (DME) benefit. As you mentioned, DME accreditation and surety bond requirements are designed to protect the Medicare program and its beneficiaries from fraudulent DME suppliers, and to ensure that Medicare suppliers meet certain quality standards. It is my understanding that these requirements are mandated by statute. If confirmed as HHS Secretary, I pledge to ensure that efforts to contain fraud and abuse in the Medicare program do not unintentionally impede access to health care services.

Questions from Senator Ensign

Question 1:

Do you believe that abortion should be considered a "basic health care service?"

Answer: It's worth noting that the health reform plan the President proposed on the campaign trail outlined a National Health Insurance Exchange that was composed of several private plans, as well as a new public plan option that will have benefits consistent with those offered by typical employers. Most private plans do not cover abortion services except in limited instances, but do cover family planning, and Congress has limited the Federal Employee Health Benefit Plan to covering abortion services only in cases of rape or incest, or when the life of the mother is in danger. I support the model outlined by the President. Of course, Congress and the Administration will work together to define "basic health care services." If I am confirmed as Secretary, it will be my responsibility to follow the law, and that is what I will do.

Question 2:

What are your views on conscience clauses that protect providers who have moral and religious concerns with specific procedures?

Answer: Like the President, I have long supported well-crafted conscience clauses. At the same time I am committed to ensuring we are protecting women's health. This issue requires a careful balance between the rights of providers and the rights of the American people to get the care they need.

Question 3:

In your opinion, should Plan B be available to minors without a doctor's prescription or counsel?

Answer: My goal is to prevent the number of unintended pregnancies in this country and reduce the need for abortion. Politicians should not be making decisions – for women or any other citizen of this country – about what is safe or unsafe. As you know, the United States District Court in the Eastern District of New York remanded this matter to the FDA for reconsideration of its decision regarding appropriate age or point-of-sale restrictions on the over-the-counter status of Plan B. Doctors and scientists will provide us guidance on who can safely and appropriately use Plan B. At the same time, it is important to emphasize that this is a highly sensitive issue involving our families and our values. FDA scientists will address the safety issues, but parents need to teach their children to act responsibly.

Question 4:

The President's budget would income relate Medicare Part D prescription drug coverage. Senator Feinstein and I have introduced legislation (S. 677) to ensure that high-income seniors pay higher premiums than lower-income seniors for Medicare Part D. Can you provide me with assurances that the Administration will work with us on our proposal? Can you also provide me with data showing how many Medicare beneficiaries would be impacted by this proposal?

Answer: Medicare has been a success in part because it encourages all Medicare beneficiaries to participate, which keeps Medicare premiums affordable. However, Medicare costs are growing rapidly, and we must always seek prudent ways to use scarce resources as wisely as possible. As you know, the President's budget proposes to extend the same income relating policy for Part D premiums as currently required for Part B premiums. The policy will affect approximately 6 percent of the wealthiest seniors. The policy has been carefully crafted to ensure that all seniors receive a sufficient federal subsidy to encourage their participation. Continued widespread participation in Medicare will ensure premiums and total federal costs remain affordable. If confirmed, I will look forward to working with you and other members of Congress on this proposal.

Question 5:

The rising cost of health care and health insurance pose a serious threat to the future fiscal condition of the United States. As HHS Secretary, what specific cost-saving measures do you plan to endorse in order to make our entitlement programs more financially viable for the long-term, and in order to implement a health reform initiative? Don't you think we should resolve our current entitlement crisis before expanding existing public programs and increasing the potential debt our children and grandchildren will face?

Answer: The President believes we can't afford not to reform our health care system. Health care reform is critically important to our long-term economic health as families, businesses and our federal budget face skyrocketing health care costs. The crushing costs of health care are making it harder for families to make ends meet, and they're making it harder for businesses to compete in the 21st century. The President understands health reform and the economy are linked, and that is why he supported including important health care investments, like health information technology incentives, in the American Recovery and Reinvestment Act. But we can't address the rising costs of programs like Medicare and Medicaid unless we reform our health care system to cover everybody and lower costs.

Modernizing our health care system and ensuring affordable coverage will require an up-front federal investment. The savings and revenue proposals in the budget, along with the Recovery Act investments, will yield long-run cost savings for both taxpayers and the federal government. Our goal is to fix our broken system in a fair and fiscally responsible manner, covering all Americans while lowering the long-run growth of health care.

Question 6:

Some have indicated that a health reform package should allow individuals to choose a private plan or a government-run plan. Wouldn't a government-run plan mirror all of the problematic administered pricing problems in Medicare (like therapy caps and the sustainable growth rate formula)? Since government payments to doctors and hospitals are lower than private sector reimbursement rates, how much of the costs and growing liabilities of a public plan do you expect would be shifted to private carriers and the next generation of taxpayers?

Answer: The President's campaign plan proposed a public option alongside private insurance options in a National Health Insurance Exchange. He recognizes the importance of giving the American people this choice, which would also challenge private insurers to compete on cost and quality, not cream-skimming and risk selection. At the same time, he recognizes the importance of a level playing field between plans and ensuring that private insurance plans are not disadvantaged. The public plan option should pay providers competitive rates, and the private plan options should be barred from cherry-picking the healthiest enrollees. The Administration will work with Congress on this and other elements of comprehensive reform.

Question 7:

Approximately 12 million illegal immigrants live in the United States. Many of illegal immigrants do not have health insurance coverage and use hospital emergency rooms to obtain medical care. How do you envision illegal immigrants in the context of health reform?

Answer: The plan the President proposed during the campaign does not cover undocumented immigrants. Comprehensive immigration reform is ultimately the answer to the wide range of challenges posed by illegal immigration, including those related to the health care system. In the meantime, the President supports policies that ensure hospitals treat all individuals who are badly in need of care – regardless of their ability to pay or their immigration status. And he has been a long-time advocate for safety-net providers like community health centers that offer critical services like immunizations, prenatal care, and health screenings to so many, without regard to immigration status.

Question 8:

With the Administration's pursuit of broad-based health information technology, can you please explain to me and my colleagues what your commitment is to the pursuit of the administrative side of health information technology? Specifically, what are your views on pursuing savings through electronic processes for administration, such as claims status inquiry, claims remittance, and electronic payment?

Answer: While improving health care quality is a primary benefit of a nationwide interoperable health IT infrastructure, cost savings from reducing clinical redundancy and error, as well as from reducing greater administrative efficiencies, are fundamental goals that must be realized if we are truly going to reform our health care system. Electronic processes for the back-office functions of health care will help ease these burdens on physicians and other healthcare providers, freeing them to spend more time with patients.

Question 9:

One of the most controversial issues in health care reform is the use of comparative effectiveness to limit access to care based on costs. Unfortunately, despite language in the American Recovery and Reinvestment Act (ARRA) Conference Report, it appears that the National Institutes of Health recently issued a number of grants that are explicitly funding cost-effectiveness research. This includes a grant designed to use cost-effectiveness research to "guide future policies that support the allocation of health resources." That sounds to me like rationing, and I know it concerns members of this committee on both sides of the aisle. What is your view on conducting cost-effectiveness research to limit treatments, and will you instruct NIH to reconsider these grants so that they only consider clinical effectiveness as Congress instructed?

Answer: Comparative effectiveness will help patients and providers make informed health care decisions based on effectiveness and appropriateness of treatments. It is about empowering patients and providers with the best information. Business groups, some provider groups, and members of Congress in both parties support this effort because it will improve the performance of the health system. We must disseminate information on the best medical practice for people in a way that ensures effectiveness. Comparative effectiveness research is about spreading information on what's most effective; it has nothing to do with government's dictating choices.

Question 10:

The President's budget proposes increasing Medicaid rebates for prescription drugs paid by the drug companies to the Medicaid programs. How much of the prescription drug costs do you expect would be shifted to private carriers as a result of this proposal?

Answer: The President has identified changes in the Medicaid rebates as a priority area to achieve health care savings while improving the quality and efficiency of health care, without negatively affecting the care Americans receive or shifting costs to other sectors. His budget proposes to bring down the drug costs of Medicaid by increasing the Medicaid drug rebate for brand-name drugs from 15.1 percent to 22.1 percent of the Average Manufacturer Price, applying the additional rebate to new drug formulations, and allowing states to collect rebates on drugs provided through Medicaid managed care organizations. This proposal is estimated to save the federal government a total of over $19.5 billion over the next 10 years.

If confirmed as Secretary, I look forward to working with you and other members of Congress to promote cost effective purchase and delivery of prescription drugs.

Question 11:

In accordance with ARRA, 15 individuals were appointed to the Federal Coordinating Council for Comparative Effectiveness Research on March 19, 2009. Please provide a description of the selection process, including the role of the White House Office of Liaison, the Office of the Secretary, and the White House Office of Presidential Personnel. In addition, please provide information about the length of service for Council members and the process for replacing members.

Answer: The focus in developing the membership of the Council was to follow the statute, ensure that the Council had the expertise of clinicians, and ensure that the views of representatives of subpopulations were heard. The ARRA specified several offices/agencies to be represented on the Federal Coordinating Council, and those offices/agencies were asked to nominate a member of the Council. In particular, because of the concerns about the impact of comparative effectiveness research on subpopulations, the Office of the Secretary asked for nominees from the Office of Disabilities and the Office of Minority Health at HHS. Additional offices nominated members, but because of the limitations on the council numbers as specified by statute, they could not be accommodated. The White House Office of Liaison had no role regarding the Council; the Office of the Secretary informed the White House Office of Presidential Personnel of the Membership of the Council, but it took no action to determine the membership.

Question 12:

ARRA requires the Federal Coordinating Council for Comparative Effectiveness Research to submit a report to the President and Congress containing information describing current Federal activities on comparative effectiveness research and recommendations for such research by June 30, 2009. I would like the agenda for the public listening session that will be held on April 14, 2009. I would also like a monthly update on the Council's activities including a list of all participants in any decisions made by the Council.

Answer: The President and I believe comparative effectiveness research will improve the quality of care in our health care system, and, if confirmed, I look forward to working with you and other members of Congress on this topic. I aim to have a transparent process in place, and will share information with you and others on a regular basis.

Question 13:

Transparency is important in all aspects of healthcare reform. Please provide the names and affiliations of all individuals who have participated in the organization of the Council, including any registered lobbyists or individuals in non-profit advocacy organizations. Please provide a description of the process used in the formation of the Council including the role of each agency represented on the Council, the Office of Management and Budget, and the White House.

Answer: Only government officials participated in the formation of the Federal Coordinating Council. The law specifies that certain offices/agencies are to be represented on the Council, and those offices/agencies were contacted to designate a representative. In addition, other offices made recommendations, some of which were accepted by the Office of the Secretary. In particular, the Office of the Secretary asked for representatives from SAMHSA, the Office of Disabilities, and the Office of Minority Health in order to ensure that both subpopulations and people with expertise in mental health were represented on the Council.

Question 14:

Section 804 of ARRA provides the following rule of construction:

> **"(g) RULES OF CONSTRUCTION-**
> **(1) COVERAGE- Nothing in this section shall be construed to permit the Council to mandate coverage, reimbursement, or other policies for any public or private payer.**
> **(2) REPORTS AND RECOMMENDATIONS- None of the reports submitted under this section or recommendations made by the Council shall be construed as mandates or clinical guidelines for payment, coverage, or treatment."**
>
> **How will the Council work to abide by this rule of construction and how will it work to preserve and protect the patient-doctor relationship? I am particularly concerned about how the Centers for Medicare and Medicaid Services may use the work of the Council to impact provider payments, especially given that one of the Council members is from the Centers for Medicare Management. Please describe how you will maintain a wall of separation between the clinical aspects of comparative effectiveness and payment through governmental programs. It is important that voices outside of the Administration are heard in developing the strategic plan and research agenda for comparative effectiveness.**

Answer: The Federal Coordinating Council's purpose is to set research priorities and ensure that federal funding is coordinated so it can be most effective and avoid duplication of effort. The members of the Coordinating Council are mostly clinicians, and all are experts in policy or practice.

Comparative effectiveness research is about empowering patients and providers with the best information. It is not about government rationing. I can assure you that the information gleaned from comparative effectiveness research will not be used for coverage decisions for Medicare, as dictated by a 2003 law.

Question 15:

It is important that voices outside of the Administration are heard in developing the strategic plan and research agenda for comparative effectiveness. Will you invite the patient, consumer, and provider communities to participate in the development and drafting of the strategic plan and its implementation? Additionally, how do you plan to involve the patient, consumer, physician and provider communities in the development and dissemination of any recommendations made by the Council?

Answer: The President has embraced an open and transparent approach to governing, and that extends to implementing the Recovery Act's investment in comparative effectiveness research. Already, the Federal Coordinating Council created by the Recovery Act has scheduled a listening session to ensure that all voices are heard. The Act also charged the Institute of Medicine with soliciting stakeholder input. If confirmed as Secretary, I will ensure that these voices, along with others, are heard prior to developing recommendations and disseminating research.

Question 16:

The President's Fiscal Year 2010 Budget proposal indicates that comparative effectiveness research should be coupled with electronic health records. It also indicates that comparative effectiveness research "can form the basis for clinical decision support tools – distilling all available evidence on the outcomes of different treatment options into user-friendly pop-up alerts for physicians at the point of care." If this provision is carried out, will doctors have discretion to do what they think is best for their patients? In terms of enforcement, if a doctor provides care outside of the comparative effectiveness research/recommendations, do you think the doctor should be reimbursed?

Answer: Comparative effectiveness will help consumers and providers make informed health care decisions based on effectiveness and appropriateness of treatments. It is about disseminating information on what's most effective, so that physicians and patients can make the best decisions; it is not about dictating those decisions. Health information technology is one way that such information can be disseminated.

Questions from Senator Enzi

Question 1:

Although most people think of long term care as an issue for the elderly, the frightening truth is that a person could need long term care at any point in their life. How can we incentivize more people to buy long term care insurance?

Answer: Education and outreach are the cornerstones of informed decision-making in long-term care and financial planning. Too few people are aware of their risks and options. As a former insurance commissioner, I also know that we need to promote high-quality long-term care insurance. I look forward to working with Congress to ensure that the American people are able to make informed decisions regarding long term care insurance.

Question 2:

The demographics of long term care seem insurmountable. The Department of Health and Human Services says that people who reach age 65 will likely have a 40 percent chance of entering a nursing home. With 77 million baby boomers retiring over the next few years how can we finance provision of long term care without bankrupting our health care system?

Answer: Ensuring effective and efficient coordination of care for patients in long-term care facilities will help provide affordable, high-quality care without bankrupting our system. The President's budget includes Medicare proposals to better coordinate care across settings. Several policies to prevent the need for nursing home care in the first place have already received funding through the American Recovery and Reinvestment Act. First, the expansion of health information technology will prevent medical errors and duplicative tests and facilitate improvements in the quality of health care. Second, expanding the use of case management for chronic conditions such as asthma, diabetes, and congestive heart failure should reduce long-term care use and costs. Third, health training programs will build a 21st century health workforce capable of meeting the needs of our aging population. Finally, investing in research through the National Institutes of Health and comparative effectiveness research may yield information to better treat and cure conditions that require long-term care. If confirmed, I look forward to working with you on building on this investment to achieve the goal of high quality, efficient care for patients in long-term care facilities.

Question 3:

I support keeping people in their communities, rather than placing them in institutions. How do we ensure that long term care benefit packages accommodate home and community care and provide appropriate assistance to family caregivers?

Answer: Educating patients and family caregivers on the options available for care assistance is the key to empowering them to then choose the long-term care benefit package that works best for them. The President has outlined a series of principles he would like reforms to encapsulate, including the principle of choice. Empowering consumers to make informed decisions will spur long-term care plans and providers to provide an array of options from home and community care to institutionalized care, and to compete on quality and cost. If confirmed, I will also work to improve such choices in Medicaid.

Questions from Senator Cornyn

Question 1:

If confirmed as Secretary of the Department of Health and Human Services (HHS), you will oversee a department that loses billions and billions of dollars every year to waste, fraud, and abuse. Both Medicare and Medicaid are mainstays on the Government Accountability Office's list of "high-risk" programs. More than $60 billion is lost each year to Medicare fraud. 10.7 percent of Medicaid money—$32.7 billion—is spent improperly. That number may reach 40 percent in some states like New York. Medicare and Medicaid fraud drives up the cost of health care and also represents unacceptable mismanagement of taxpayer dollars. Our national debt was $6.3 trillion in January of this year, and the fiscal year 2010 Budget that the Senate is debating this week would triple that by fiscal year 2014. Getting fraud, waste, and abuse under control is one small step we must take in restoring fiscal responsibility here in Washington.

You have previously noted your desire to reduce fraud in government programs, and having introduced legislation on this in the past, I am keenly interested in helping you succeed in this. What specific plans do you have to make Medicare and Medicaid program integrity a priority? What steps will you take to transform HHS anti-fraud activities from a "pay and chase" methodology to one of "detect and prevent"? When can we expect you to implement these plans, if you are confirmed as Secretary of HHS?

Answer: We should have zero tolerance for fraud in the Medicare and Medicaid programs, and, if I am confirmed, I will make it a top priority to manage these programs well, and to pursue fraud, waste, and abuse aggressively. During my time as State Insurance Commission and Governor, I made fighting health care fraud and abuse one my top priorities, and I will continue that commitment if confirmed as Secretary of HHS.

I understand that Congress recently gave CMS and HHS new authorities to reduce fraud. If confirmed, I will work to ensure all of these new tools are employed aggressively and to the fullest degree possible. I will also identify areas where further Congress authorization is necessary to ensure that CMS and HHS have all the tools they need to effectively address this problem. If confirmed, I look forward to working with Congress to reduce inappropriate and fraudulent payments, so that Americans can have confidence that we are managing their tax dollars prudently.

Question 2:

During his Presidential election campaign, President Obama promised to "support legislation dictating that if you practice care in line with your medical societies' recommendations, you cannot be sued." He also said that he was "open to additional measures to curb malpractice suits and reduce the costs of malpractice insurance." I believe that any comprehensive health care legislation will have to include medical liability reform. Do you agree?

Answer: Independent and objective studies have consistently found that malpractice costs explain only a small part of medical costs. However, it is clear that some doctors are facing exorbitant premiums, and I believe we all need to work together to look for creative solutions. The most important goal is to improve quality for consumers.

I support improving health care quality and patient safety and preventing medical mistakes from happening in the first place. This can be done in a number of ways, including by investing in health information technology that can alert doctors when patients have allergies or drug contra-indications and by requiring transparency about health care quality through reporting requirements. I think we should work to improve outcomes for patients without being doctrinaire about solutions to this problem, and I look forward to working with you if confirmed.

Question 3:

Earlier this decade, Texas adopted strong reforms of the medical malpractice lawsuit system. These reforms capped non-economic damages in medical malpractice lawsuits. Plaintiffs can still recover any amount of actual, economic damages that they suffer, but the recovery for non-economic damages—such as pain and suffering or emotional distress—is strictly limited. This reform led to a decrease in insurance costs for Texas doctors, particularly those in high risk specialties such as obstetrics, orthopedic surgery, neurosurgery, pediatrics, and geriatrics. As a result, Texas patients gained access to more doctors and more care in these important areas of medicine. This effect has been the greatest in rural and underserved counties. For instance, twelve counties in Texas that had no obstetricians before medical liability reform have gained at least one obstetrician since the reform. Would you agree with me that improved access to qualified specialists is an important goal of health care reform, and that medical liability reform is a proven method of achieving that goal?

Answer: If confirmed as secretary, my goal will be to work to address this problem without being doctrinaire about solutions. While I share the President's concerns about caps on damages, I want to work with Congress to address the issue of exorbitant premiums faced by some doctors – in particular, certain specialists. When he was Senator, President Obama recommended an alternative dispute resolution mechanism for medical malpractice claims. These and other ideas should be considered.

Question 4a:

Part of our efforts during the health care reform debate will focus on transparency and empowering individuals to ensure that they have timely access to accurate, appropriate medical information. Moreover, as the federal government is called upon to significantly increase its investments in the National Institutes of Health (NIH) and other science agencies, it is important to increase the level of accountability. Where is our money being spent? How is it being spent? Who is spending it? What are we getting back for our money?

Answer: The National Institutes of Health (NIH) is the largest single engine for outstanding biomedical research in the country—and the world. From discoveries that make our nation's blood supply safe from HIV and hepatitis transmission to developing treatments that have vastly improved cancer survival rates among children to interventions that have helped reduce death from heart disease and stroke by more than 50 percent, research conducted and supported by NIH touches people's lives every day.

NIH supports scientists at more than 3,000 institutions in all 50 states and the U.S. territories, as well as researchers in more than 90 countries around the world. The core mission is to find new ways to help detect, treat, or prevent hundreds of diseases and conditions—from common diseases such as cancer and diabetes to extremely rare conditions. Part of NIH's mission is also to communicate research results broadly, so that they have a positive impact on people's health. It is well documented that investment at NIH reaps significant rewards, not only for the health of our citizens, but for the strength of our economy.

To determine which scientists--and which scientific ideas--to fund, NIH employs a peer review process that is the gold standard around the world. NIH relies on thousands of scientific experts to review research proposals to identify the best science to support, with the least amount of scientific burden. As a result of this process, in recent years alone, NIH has made significant discoveries across an incredibly wide range of diseases, conditions, and other health-related challenges. If confirmed, I look forward to working to supporting the work of NIH, and to promoting continued effectiveness, efficiency, and accountability in allocating NIH funding.

Question 4b:

HHS and NIH currently have in place a highly successful policy to ensure that manuscripts reporting on the results of NIH-funded research are made openly available to the public within 12 months of publication in a scientific journal, increasing patient and scientist knowledge about critical medical and health-related developments, speeding discovery and translation of research into treatments and cures, and effectively fostering public access to the results of this federally funded research to improve public health.

Given the importance and value of this policy to both advancing scientific discovery and fostering public health, would you support strengthening the policy by speeding access to these manuscripts by ensuring public access after a shortened, 6-month embargo period?

To ensure that these crucial public benefits are not limited to only that research conducted by the NIH, would you support an expansion of this public access policy to include research funded by the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, and other agencies within HHS?

Answer: The NIH Public Access Policy ensures that the public has access to the published results of NIH-funded research on PubMed Central to help advance science and improve public health. Through its Public Access Policy, NIH has made tens of thousands of NIH-supported papers publicly available on PMC, where they are heavily used. I am advised that on an average weekday, some 400,000 users retrieve over 650,000 articles. In total, PMC contains approximately 1.8 million articles, most of which are deposited by publishers who have been participating in PMC since 2000, and are not NIH-funded.

The NIH Public Access Policy's 12-month maximum delay period provides a window during which publishers can display and print any version of an NIH-supported paper exclusively, after which PubMed Central will make the author manuscript publicly available. The policy has other important publisher protections as well: the final published paper, as it appears in the journal, need never be posted to PMC. Also, NIH investigators may continue to charge any publisher-related expenses to their NIH Awards.

The 12-month maximum delay is set by statute, and it is likely that some publishers would like to leave it that way. However, certain publishers have stated publicly that they are able to sustain a profitable business model even when they make all their articles – not just the NIH-funded ones – openly available six months after publication. The shorter delay could make it possible for all Americans – scientists, clinicians, patients, and others to get greater benefit from the NIH investment. If confirmed, I look forward to working with you and other members of Congress to strike the right balance and to explore the option of expanding the public access policy to include all HHS-funded research.

<u>Question 5</u>:

America spends more than $2.4 trillion on health care every year—16.6 percent of our gross domestic product. On a per capita basis that is nearly twice what other industrialized nations spend. It concerns me that despite the fact that our health system already overspends by international standards, President Obama has proposed spending another $630 billion to radically overhaul the American health care system. At a time of unprecedented national debt and when the fiscal year 2010 Budget would add another $11 trillion to that debt, I believe we must focus on controlling health care costs.

Before spending more money and expanding public programs in our broken health care system, do you agree that it makes sense to focus on getting costs under control? How, specifically, do you plan to get those costs under control? Are there ways to do that other than comparative effectiveness research, which could deny patients access to lifesaving medical care?

Answer: The President believes we can't afford not to reform our health care system, and so do I. The crushing costs of health care are making it harder for families to make ends meet, and they're making it harder for businesses to compete in the 21st century. In the last eight years, premiums have nearly doubled. And, health costs are a major cause of our long-run fiscal deficit.

Modernizing our health care system and ensuring affordable coverage will require an up-front federal investment. The President's budget includes policies to help offset this investment. Moreover, health reform, along with the Recovery Act investments, will yield long-run cost savings for both taxpayers and the federal government. Our goal is to fix our broken system in a fair and fiscally responsible manner, covering all Americans and lowering the long-run growth of health care.

The President's health reform plan will reduce costs by creating a more efficient and higher-quality health care system that expands access to coverage to all Americans. It will make insurance cheaper by reducing cross-subsidization of the uninsured, and will reduce costs for drugs and other medical services. We expect we can reduce health care costs and premiums for families through the following improvements aimed at increasing the efficiency of the health care system:

- Expansion of health IT, which should reduce unnecessary spending in the system that results from preventable medical errors and duplicative tests and facilitate improvements in the quality of health care.

- Improving prevention of illness through wider use of vaccines, screening tests, and proven community-based programs.

- Expanding the use of case management for chronic conditions such as asthma, diabetes, and congestive heart failure. This should reduce hospitalization costs and save money.

Question 6:

Future generations of Americans will have to pay $36 trillion to keep commitments to provide health care benefits to American seniors in the Medicare program alone. Without reforms, the Medicaid program will spend at least $4.9 trillion over the next 10 years. If confirmed, you will work closely with the Office of Management and Budget Director Peter Orszag who said last year that the Medicare and Medicaid entitlement programs are "ultimately the nation's central long-term challenge in setting fiscal policy." What steps do you plan to take to address this challenge, if confirmed as HHS Secretary?

Answer: Everyone agrees that these programs face serious long-term financing problems that must be addressed. But the most serious challenge we face today is the skyrocketing costs in the health care system as a whole. Addressing the causes of the exponential, system-wide cost growth we have seen in recent years is the key to addressing Medicare and Medicaid's long-term financing challenges.

Medicare and Medicaid have performed as well as, if not better than, private insurers on cost. Their growth rates are comparable to, and payment rates are lower than, those of the private sector. That said, it is a top priority to modernize these programs to make them leaders in quality and efficiency – reforms that will ultimately reduce the growth of health care spending.

We must address existing policies that exacerbate the problem – for example, Medicare's current practice of paying private insurance companies an average of 14 percent more than it costs to treat the same beneficiaries under traditional Medicare. We must also modernize Medicare's fee-for-service payment systems to move away from the silo-ed approach to spending to one that focuses on prevention, care coordination, and overall quality improvement. Finally, we must ensure that every American has access to affordable healthcare, to reduce cost-shifting and to ensure that we manage chronic conditions early in an effort to avoid future costly care.

Question 7:

Texas has the largest percentage of uninsured individuals in the country – 5.9 million, which equates to 25 percent of the population. Texas health premiums have increased dramatically, at a rate that is third highest in the country. To address these issues, the Texas Health and Human Services Commission (THHSC) on April 16, 2008 submitted a Medicaid reform waiver request to the Centers for Medicare and Medicaid Services (CMS). The goal of the proposal is to reduce the number of uninsured in Texas by optimizing available Medicaid funds and encouraging a culture of insurance among Texas citizens. The Texas Medicaid reform proposal could potentially provide health coverage for uninsured Texas adults up to 200% of the federal poverty level.

Texas and many other states have taken significant steps to make the health care system work for their citizens. If confirmed as Secretary of HHS, you will lead the Administration's national health reform efforts. How do you plan to support existing State-based efforts to implement reforms that work best for their individual populations?

More specifically, will you direct staff at CMS to quickly engage in detailed negotiations with the THHSC, so that their waiver can be approved in a timely manner?

Answer: I share the President's strong commitment to health care reform and covering the uninsured, and we both believe a Medicaid reform demonstration is a useful and effective tool that states like Texas can use to provide health care coverage to uninsured citizens.

As we move forward on health reform, I believe we can learn from the creative ideas that many Medicaid reform waivers contain. The significance of these demonstration projects is underscored by the fact that they account for approximately 20 percent of program enrollment. That is an important impact on the lives of many Americans.

If confirmed as Secretary, I will direct CMS staff to work with Texas to make any adjustments necessary to the state's Medicaid reform proposal so that it can be considered in a timely manner.

Question 8:

Texas leads the nation in the number of uninsured, and therefore relies on federally qualified health centers (FQHCs) to offer health services to many underserved populations. HHS is responsible for awarding New Access Points funding to the FQHCs so that they are able to support new service delivery sites. In fiscal year 2009, Texas was not awarded funding for New Access Points for their FQHCs. If confirmed, what steps will you take to ensure that the criteria and standards taken into consideration in reviewing applications for New Access Points funding is equitable and reaches those who need it most?

Answer: If confirmed, I will ensure that Health Center New Access Points funding, which is allocated by the Health Resources and Services Administration, continues to be based on need. Currently, applications are evaluated by an Objective Review Committee based on documented need as well as the quality of the proposed service delivery plan. This includes the provision of services to the uninsured.

I am advised that a total of 16 New Access Point applications were recently received from Texas and 12 were funded – a success rate of 75 percent. On March 2, 2009, the Health Resources and Services Administration awarded 126 Health Center New Access Points, including the12 Health awarded to organizations in Texas:

Texas Tech University Health Sciences Center	Lubbock	TX	1,048,100
Matagorda Episcopal Health Outreach Program	Bay City	TX	1,300,000
Ellis County Coalition For Health Options	Waxahachie	TX	1,300,000
Houston Area Community Services, Inc.	Houston	TX	1,300,000
Health Opportunities for the People of East TX	Center	TX	1,300,000
Mt. Enterprise Community Health Center	Mt. Enterprise	TX	1,300,000
Planned Parenthood Center of El Paso	El Paso	TX	1,140,803
Motherland, Inc.	Houston	TX	1,300,000
Fort Worth Northside Community HC	Fort Worth	TX	1,250,000
Barrio Comprehensive Family Health Care	San Antonio	TX	1,300,000
Los Barrios Unidos Community Clinic	Dallas	TX	1,300,000
North Central Texas Community Health Care	Wichita Falls	TX	575,825

Question 9:

If confirmed, you will lead CMS, which is responsible for overseeing the survey and certification of new providers seeking to participate in the Medicare program. On May 21, 2007, CMS directed the Texas Department of State Health Services (DSHS) to stop conducting initial Medicare certification surveys until all "higher priority" work is completed. Practically, CMS guidance has meant that all state agencies must put Medicare initial surveys at a low priority level—regardless of the date on which the facility's request was received. CMS regional staff indicated to DSHS that they should not use state funds to conduct federal surveys. We are aware of a number of facilities were forced to close as a result of not receiving a timely survey. To date, there are 203 facilities in Texas that are waiting for their initial Medicare survey, of which 145 have been waiting for over 120 days. This bureaucratic mess has reduced access to care for Texas patients.

Over the past ten years, Texas has moved from sixth to third in the country for the number of senior citizens. Not only are these delays causing access to care issues, but these facilities are facing serious financial challenges to maintain operations without the ability to get reimbursed by Medicare. I have sent multiple letters to then Secretary Leavitt regarding my concern with the delays in Medicare certification.

If confirmed, will you develop a strategy to reduce the backlog of initial Medicare certification surveys? Will you ensure that CMS's allocation of federal funds to the states is appropriately allocated according to workload?

Answer: Securing quality care for Medicare beneficiaries, and all Americans, will be among my top priorities if confirmed. The Survey and Certification function is important to achieving this goal. In order to secure quality care and promote the health and safety of Medicare beneficiaries, the Centers for Medicare and Medicaid Services (CMS) requires that all facilities seeking participation in Medicare and Medicaid undergo an inspection when they initially enter the program, and on a regular basis thereafter. It is my understanding that, in the past, budgetary and resource shortfalls have limited the agency's ability to conduct surveys with ideal regularity.

If confirmed, and provided Congress fully enacts the key components of President Obama's Fiscal Year 2010 budget request, I will strive to secure the maximum impact from the available Survey and Certification dollars, working closely with the states to leverage available resources and to ensure the quality and safety of the entire health care delivery system.