

Questions for the Record from Chairman Wyden
Finance Committee Hearing for Xavier Becerra,
Nominee for HHS Secretary

February 24, 2021

Nursing Homes

The COVID-19 pandemic has taken an outsized toll on our nation's 1.3 million seniors living in nursing homes. As of early February, more than 160,000 long-term care workers and residents have died. While long-term care residents represent roughly 5% of the U.S. COVID-19 cases, they represent about one-third of total U.S. COVID-19 deaths.

Throughout the pandemic, nursing homes have faced chronic shortages of PPE, staffing, and testing. HHS has allocated roughly \$10 billion to nursing homes from the Provider Relief Fund, but with essential resources like staff and PPE in short supply for much of the last year, it is not clear whether those dollars have always translated to an improved response on the ground. Nursing homes where Black and Latino residents make up a higher percentage of their population have faced the worst outcomes. The failure to control the spread of the virus in communities across the country resulted in nursing homes in majority-minority communities bearing a disproportionate risk, compared to mostly white communities.

I've worked closely with Senator Casey over the last year to push and prod HHS to collect and make public information about COVID-19's impact on Medicare and Medicaid certified nursing homes. The weekly nursing home data required and posted by CMS has provided families, policymakers and health care experts with timely information about how COVID-19 is affecting nursing home residents and workers.

Broadly speaking, if confirmed as Secretary of HHS, will you support efforts to improve transparency relating to COVID-19 in nursing homes and address the disproportionate impacts of COVID-19 on nursing home residents of color?

And specifically in regard to vaccinations, will you support efforts to provide consumers and Congress facility-level data about the rate of COVID-19 vaccinations in nursing homes?

Answer: Thank you for your leadership on this important issue. If I am fortunate enough to be confirmed, it will be a top priority for the U.S. Department of Health and Human Services (HHS) to protect our most vulnerable Americans by addressing the disproportionate impact of the novel coronavirus of 2019 (COVID-19) pandemic on nursing home residents, especially people of color. As you and I have discussed, making data-driven decisions will be critical to addressing racial and ethnic health disparities not just at the nation's nursing homes but across the health care system. If confirmed, I will make transparency and data

collection regarding the impacts of COVID-19 and vaccination a priority because good data is essential to good policy.

Family Separation and Treatment of Unaccompanied Noncitizen Minors

Policies promoting the forced separation of children from their families at the border has led to serious trauma for noncitizen children and their families.

If confirmed, how do you plan to support the health and wellbeing of noncitizen children and ensure their safe and timely reunification with family members or sponsors?

Answer: If confirmed, I will ensure HHS is making the safety and well being of vulnerable children in the care and custody of the Office of Refugee Resettlement (ORR) a priority. Ensuring these children's safety and wellbeing is both our legal duty and our moral obligation – I take both seriously. Providing such care includes complying with all legally mandated services required by the terms of the *Flores* Settlement Agreement, the Homeland Security Act of 2002, and the Trafficking Victims Protection Reauthorization Act of 2008. As you know, HHS is required to release children to an appropriate sponsor without unnecessary delay. When a child enters ORR care, ORR aims to put every child safely in contact with their parents, guardians, or relatives as soon as possible. We are committed to continued improvement in the program's discharge rate.

Will you commit to providing Members of Congress timely updates and details on the changes the Office of Refugee and Resettlement makes to meet the physical and mental health needs of children its care at all placement types?

Answer: Yes.

Will you commit to soliciting the input of child welfare experts, in addition to comments from the general public before implementing significant policy changes?

Answer: Yes.

Lastly, will you commit to working with the Secretary of the Department of Homeland Security to uphold the Flores Settlement and the Trafficking Victims Protection Reauthorization Act?

Answer: Yes.

Senator Stabenow Question for the Record: Hearing to Consider the Nomination of Xavier Becerra, of California, to be Secretary of Health and Human Services

I'm a strong supporter of Medicare's home health benefit, and it's a really important option, particularly during the pandemic. What improvements and modernizations would you like to see made to the home health benefit?

Answer: As you mention, the Medicare home health benefit allows beneficiaries to receive care from their home, which is a much needed lifeline for our nation's seniors. I believe the home health benefit is necessary to ensuring quality health care. I also understand this issue personally. As I discussed briefly in our hearing, I was fortunate enough to care for my father at home, prior to his passing. I understand that in response to the COVID-19 Public Health Emergency, the Centers for Medicare & Medicaid Services provided flexibilities to home health agencies, giving them tools to help ensure beneficiaries maintain access to care. If confirmed, I will work with you and other Members of Congress to ensure that our nation's seniors are able to utilize home health care and to continue to improve the benefit.

Senator Maria Cantwell
Nomination of Attorney General Xavier Becerra to Secretary
U. S. Department of Health and Human Services
Questions for the Record
February 26, 2021

Lymphedema Treatment Act

Lymphedema is an incurable but treatable medical condition caused by injury, trauma or congenital defects. One of the most common causes of Lymphedema is cancer treatments that remove or damage lymph nodes and vessels, or cause blockages in the lymphatic system. The disease is effectively managed through prescription medical compression garments, which are highly specialized compression stockings, sleeves, gloves, and other items, all of which must be custom-fit by trained providers. In the case of more advanced disease or complex cases, these garments must be custom-made.

Medically necessary supplies such as these should be covered by insurance. Moreover, by not treating the condition with compression garments, patients are more likely to enter hospitals and doctors' offices during the current COVID-19 pandemic, which is not helpful to our efforts to combat the spread of the virus.

Unfortunately, Medicare does not currently provide coverage for lymphedema compression supplies, which must be replaced about every six months, because the Centers for Medicare and Medicaid Services (CMS) claim they do not fit into an existing benefit category.

I have been leading the effort in Congress to correct this problem and have sponsored the Lymphedema Treatment Act (LTA) to direct CMS to cover prescribed medical compression garments.

Question: If confirmed as Secretary, are you willing to endorse this legislation and recommend President Biden sign it into law if passed by the Congress, unless you are able to fix this administratively?

Answer: Thank you for your leadership on behalf of Lymphedema patients. I agree that we must ensure Medicare beneficiaries have access to medically necessary health care items and services. If confirmed, I will work with you to identify solutions to this issue.

Senator Benjamin L. Cardin
Senate Finance Committee
Questions for the Record

**Hearing to Consider the Anticipated Nomination of Attorney General Xavier Becerra
to be Secretary of Health and Human Services**

Medicaid and COVID-19

1. Last year, at the beginning of the COVID-19 pandemic, the country saw a dramatic decline in the utilization of healthcare services as individuals sought to limit their risk and exposure to contracting the coronavirus. Almost a year later, many states have lifted restrictions on medical procedures, begun re-opening schools, and relaxed other restrictions. As a result, utilization of non-urgent care has returned to or trended near normal utilization levels, pre-pandemic.

Capitated managed care is the dominant way in which states deliver services to Medicaid enrollees. States pay Medicaid managed care organizations (MCOs) a set per member per month payment for the Medicaid services specified in their contracts. During the pandemic, states were making payments to plans, but those payments were not necessarily flowing to providers where utilization had decreased. As a result, many Medicaid providers faced substantial losses in revenue, while many health insurers reported record earnings.

In the waning days of the Trump Administration, many states sought approval from CMS to implement a risk corridor financing mechanism for their respective Medicaid programs. This allowed states to recoup monies that were paid to Medicaid MCOs prior to the pandemic and the Public Health Emergency Declaration.

Now that utilization patterns in the Medicaid program are returning to normal, when would it be appropriate for CMS to review state risk corridor arrangements?

Answer: The COVID-19 public health emergency (PHE) disrupted all aspects of our lives, including our use of routine and urgent health services, presenting unique and unanticipated circumstances. Over the past year, there have been different patterns in health care utilization. If confirmed, I look forward to working with you to support state efforts to respond to COVID-19, including regarding payment to the managed care plans and providers to ensure Medicaid beneficiaries have continued access to care.

Questions for the Record

“Hearing to Consider the Nomination of Xavier Becerra, of California, to be Secretary of Health and Human Services”

Witnesses: Attorney General Xavier Becerra, Nominee to be Secretary of the Department of Health & Human Services

Finance Committee Hearing Date: February 24, 2021 at 2pm

Questions Submitted: February 26, 2021

From: Senator Brown

Child Abuse Fatalities

In my state, there have been a number of tragic child abuse related deaths, which is unacceptable. It is critical that we do more to support at risk children and families and ensure states have the resources to prevent these tragedies. Right now, the National Child Abuse and Neglect Data System (NCANDS) fails to capture the entire number of child abuse fatalities. Like almost every other aspect of the child welfare system child abuse deaths disproportionately affects Black families. The federal Commission to Eliminate Child Abuse and Neglect Fatalities recommended significant reforms, including increased funding to child welfare programs and the development of a standard definition of “child maltreatment fatality.”

Will you commit to working with Members of Congress to advocate for funding to ensure states and community partners have the resources to support families and prevent child abuse related deaths? Will you commit to incorporating the voices and lived experiences of young people and families to root out factors that lead to this tragedy having a disparate impact on Black families? If confirmed, what initial steps would you take to strengthen federal data systems and encourage cross agency collaboration to ensure policymakers and practitioners have the information necessary to prevent child abuse related fatalities?

Answer: Federal data systems are critically important to ensuring child safety and must be inclusive so that they capture all relevant information that states, policymakers, and practitioners need to prevent child abuse-related fatalities. Working with Congress to support states and community partners will be an important part of our broader efforts to reduce child abuse-related fatalities, including by strengthening federal data systems. President Biden has been unequivocal that equity issues will be and will remain at the forefront of his Administration. If confirmed, I will ensure that the experiences and perspectives of all children and families will inform my work.

Family First Implementation

COVID-19 has devastated state budgets, particularly systems that were already underfunded such as the child welfare system. As states like Ohio, work to implement provisions from the Family First Act, it is critical to ensure they have adequate and clear guidance and support to be successful under the new system.

Will you commit to providing states and child welfare providers with the tools, resources, and information necessary to implement Family First? Will you commit to working with county-administered child welfare systems in states like Ohio to promote equitable access to Family First support services across jurisdictions?

Answer: The Family First Prevention Services Act is an important law that seeks to transform child welfare services by increasing support for prevention services to strengthen families and keep children safely at home and in their communities with their parents, or other family members whenever possible. When children must come into foster care, the law seeks to limit the use of institutional care and encourage family-based placements. If confirmed, I commit to ensuring HHS takes every available step to support vulnerable children and families, and makes available needed guidance and technical assistance so that all states, including those with county-administered child welfare systems like Ohio, can effectively implement the law and ensure equitable access to needed services.

Social Determinants of Health

As was discussed during Wednesday's hearing, entities across the health care and political spectrum are increasingly focused on ways to address the social determinants of health. The Department of HHS – as both a payer and a policy driver – has many tools at its disposal to improve health and drive value by addressing social determinants.

If confirmed, how will you use federal payment policy – across Medicare and Medicaid and through the Center for Medicare & Medicaid Innovation (CMMI) – to address the social determinants of health, ensure our federal programs and models address health-related social needs of patients, and support upstream investments in the social determinants of health?

Answer: The COVID-19 pandemic has further exposed the disparities that exist in our society. I understand the CMS Innovation Center is currently testing the Accountable Health Communities Model, which evaluates whether systematically identifying and addressing the health-related social needs of Medicare and Medicaid beneficiaries through screening, referral, and community navigation services will impact health care costs and reduce health care utilization. In addition, if confirmed, I intend to take a department-wide approach to the advancement of equity, consistent with President Biden's charge to federal departments and agencies, and this would include examination of ways to address the social determinants of health.

COVID-19 Vaccine Disparities and Data

A recent Washington Post article gave examples of states that have managed the COVID vaccination process well, while others have had a more challenging time navigating the complex process. All states, however, have failed to distribute vaccines equitably – we are failing our communities of color.

Many states, including Ohio, are working to develop a vaccine appointment finder tool to increase resident participation and aid in the state's vaccination campaign. Some localities have made use of online platforms that help collect data on the root causes of vaccine hesitancy,

providing public health and community leaders with additional information on actions they can take to improve the vaccine distribution process, particularly for communities of color and underserved communities.

If confirmed, will you commit to getting states the complete set of data and information they need to populate their vaccine finder tools, and ensure states have the tools to build and leverage their platforms to accelerate the vaccine distribution process and reduce disparities in access to vaccine?

Answer: I am acutely aware of the disparities faced by communities of color and other underserved communities. If confirmed, I will ensure that we are partnering with states on data and vaccine information so that Americans, especially communities of color, can more easily access vaccination. I will also endeavor to work with states on other options for those who may not have access to a computer as well. It is critical that federal and state governments are closely coordinated and sharing information to best serve the needs of the American people.

Direct and Indirect Remuneration Fees

Community pharmacists are a critical player in our nation's health care workforce, extending essential services to underserved and disproportionately at-risk communities. Especially during the COVID-19 pandemic, pharmacists have been critical in our efforts to expand access to testing and vaccination services, including long-term care residents and other seniors and Part D beneficiaries.

Unfortunately, the rapid growth of pharmacy direct and indirect remuneration (DIR) fees continues to create uncertainty for the community pharmacies Ohioans rely on for essential services. The use of DIR fees in Medicare Part D has exploded over the past several years, threatening the financial viability of pharmacies across Ohio and the health of the patients they serve. The Centers for Medicare & Medicaid Services (CMS) has estimated that pharmacy DIR fee reform could result in saving Medicare beneficiaries between \$7.1 and \$9.2 billion in cost sharing burden over the next decade.

If confirmed, will you commit to working with Congress on solutions to address the explosion of DIR fees and support stability for community pharmacies, while ensuring quality and low costs for Medicare beneficiaries?

Answer: I agree that community pharmacists are critical to our nation's health care system. We must do all we can to ensure that Americans can access important health care services, including from local pharmacies in their communities. If confirmed, I look forward to working with Congress to ensure that community pharmacists have predictability.

Preventive/Primary Care/Screenings during COVID-19

COVID-19 has been a threat to our health in more ways than one. Not only has the virus stolen the lives of more than 500,000 Americans, it has drastically reduced other vital health care

services that are essential to keeping Americans healthy. COVID-19 has had a significant negative impact on primary care visits, childhood vaccination rates, and cancer screening rates.

The Centers for Disease Control and Prevention (CDC) issued a Morbidity and Mortality Weekly Report (MMWR) in September 2020 that found that “because of concerns about COVID-19, an estimated 41% of U.S. adults had delayed or avoided medical care including urgent or emergency care (12%) and routine care (32%). Avoidance of urgent or emergency care was more prevalent among unpaid caregivers for adults, persons with underlying medical conditions, Black adults, Hispanic adults, young adults, and persons with disabilities.”

It is essential that we both work to reduce the backlog in screenings and vaccinations and other primary health care services, and to better understand factors associated with medical care avoidance to – as the CDC MMWR says – “inform targeted care delivery approaches and communication efforts encouraging persons to safely seek timely routine, urgent, and emergency care.”

If confirmed, what will you do to ensure that we make up for the lost progress (as a result of the pandemic) in our rates of childhood vaccinations and cancer screening efforts, as well as in our work to reduce the prevalence and severity of other chronic conditions and to improve public health outcomes?

Answer: We know the COVID-19 pandemic caused Americans – adults and children – to delay routine care, including important preventive measures like vaccinations and cancer screenings. If confirmed, I look forward to working across the Department to address lost progress and the looming effects of unaddressed chronic conditions.

Medicare Advantage/Prior Authorization

Thank you for your commitment to working with me to equal the playing field between traditional Medicare and the Medicare Advantage program. I look forward to collaborating on this effort.

One area where we can create some parity lies in the prior authorization process. Last Congress, I introduced legislation with Senator Thune to establish an electronic prior authorization program in Medicare Advantage (MA) to better facilitate the prior authorization process in MA and improve the timeliness and efficacy of care delivery for beneficiaries and their providers. CMS has issued a notice of proposed rulemaking to establish similar programs in Medicaid, the Children’s Health Insurance Program (CHIP), and insurers operating qualified health plans on the federally-facilitated exchange under the Affordable Care Act (ACA). Beneficiaries and their providers should not have to jump through hoops in order to access medically necessary services.

If confirmed, will you work with Senator Thune and me to provide additional technical assistance on our legislation so that we can advance improved prior authorization processes that put the patient back at the center of care and reduce barrier to timely access to essential services?

Answer: I believe that ensuring Americans have timely access to health care is critical, and I agree with you that providers and individuals should not have to jump through unnecessary hoops for access to medically appropriate care. If confirmed, I look forward to working with you, Senator Thune, and other Members of Congress on these important issues.

Biosimilars

Thank you for your commitment to lowering the high cost of prescription drugs. The robust uptake of biosimilars represents an opportunity to increase competition in the prescription drug marketplace and reduce costs for patients and taxpayers. I'd like to work with you on ways to maximize the uptake of biosimilars as they enter the market to ensure competition and reduce patient out of pocket cost.

If confirmed, what additional steps should and will you take to build out a robust biosimilars market and ensure all patients who require treatment have immediate access to high quality, affordable biosimilar biologic medicines?

Answer: Competition in the market has helped control the growth in spending on prescription drugs. Biosimilars have a role to play in containing the cost of innovative yet expensive biologic treatments by creating competition. As Attorney General, I helped to promote competition by taking on a number of pharmaceutical companies that restricted competition through "pay-for-delay" schemes, which delayed putting a generic product on the market to compete with the brand-name product, therefore keeping the price of that brand-name product high. In addition, I sponsored a law in California that made it more difficult for pharmaceutical companies to enter into anti-competitive "pay-for-delay" agreements. If confirmed, I will continue to work on finding ways to lower drug costs and ensuring Americans have access to prescription drugs.

Antibiotic Resistance

From the CDC to the World Health Organization, public health experts consider antibiotic resistance to be one of the top threats to global health security. The threat posed by superbugs demands swift action and a robust response.

I urge you to commit to building on the National Action Plan for Combating Antibiotic-Resistance Bacteria (CARB) and follow through on coordinated, strategic actions to address antibiotic resistance.

What actions will you take, amidst and after this pandemic, to prioritize our nation's fight against antibiotic resistance in addition to building out our antibiotic stewardship programs and curbing the overuse of antibiotics?

Answer: It is clear that antimicrobial resistance (AMR) must be a top public health priority, not only for the United States but around the world. Even during this time, AMR remains a top CDC priority, and if confirmed, we will continue investing in key prevention strategies like early detection and containment, infection prevention, and ensuring the appropriate use of antibiotics

in the U.S. and around the world. I will also support efforts to develop new antibiotics to treat infections that are becoming untreatable.

**Senator Michael Bennet’s QFRs – Senate Finance Committee Hearing to Consider the
Nomination of Xavier Becerra, of California, to be Secretary of Health and Human
Services, February 24, 2021**

1. *Rural Health:* According to the Brookings Institute, rural communities had not yet recovered from the recession when COVID-19 hit. Farm workers and packing plant workers have experienced particular hardship over the past year. I recently finished a tour of all 64 counties in Colorado and I often visited with hospital leaders in the rural parts of the state. In the past 10 years, 135 rural hospitals have shut down, including 19 in 2020. I heard the same refrains throughout: that Medicare reimbursement wasn’t adequate, that they needed infrastructure support, and that they were afraid that one more thing could shut them down. I have worked with my colleagues, Senators Murkowski and Barrasso and many others, on legislation to support our rural providers and public health, often the bedrock of their communities.

Will you commit to working with me on rural health? What can you do to support rural hospitals and providers to ensure they can recover more quickly than they did in the last recession?

Answer: I believe it is HHS’s role to support programs and advance policies that promote access to high-quality care in rural and other underserved areas. If confirmed, I look forward to working with you and other Members of Congress to advance rural health through the work of the Health Resources and Services Administration, Centers for Medicare & Medicaid Services, and other parts of the Department, and to support efforts that put rural hospitals in a better financial position to deliver needed care in their communities.

2. *Surprise Medical Billing:* In December, Congress passed the No Surprises Act, which will end the practice of surprise billing. I think this was a major step to protect patients who were often taken advantage of in their most vulnerable state. I had been working on that effort for years with Senators Cassidy and Hassan and others on the committee, and I am grateful it was signed into law. Now you have the responsibility to implement the legislation before it goes into effect next year.

Can you highlight your thoughts on surprise billing and your commitment to implement the legislation over the next year should you be confirmed?

Answer: This law is important to so many. I want to thank you and your colleagues for the good work that went into getting this legislation enacted. If confirmed, I will work to ensure that this critical legislation is implemented effectively and in a timely manner. I look forward to working with you and other Members of Congress on this shared goal.

3. *Public Health Jobs:* In Colorado, the public health infrastructure has been underfunded by up to 40%. Our national public health infrastructure has been in a similar place. I believe that this underinvestment, on top of a total lack of leadership from the previous administration, is a huge reason why the response in the United States compared to other countries was so poor. The American Rescue Plan has a public health jobs program, which

looks very similar to the Health force proposal that I put together with Senator Gillibrand, and would provide 100,000 public health jobs to do everything from contact tracing to vaccine administration through and beyond the COVID-19 pandemic. This proposal would create jobs for people in the communities they serve, which I believe can make a massive difference to help reduce racial and ethnic disparities, which this pandemic has only highlighted.

Do you agree that public health workers should come from the local communities they serve? How can the Public Health Jobs program improve case in underserved, Black, Indigenous, and Latino communities?

Answer: I am deeply committed to bolstering the nation's public health infrastructure. Like you, I believe that equity must be central to all aspects of our COVID-19 response and how we prepare for future public health challenges. It is also important that our health workforce is representative of the communities they serve. As you know, the President's American Rescue Plan calls for 100,000 public health workers who will work in their local communities. The President has stated that these public health workers will perform critical near-term tasks, including vaccine outreach and contact tracing, and ultimately transition into long-term roles in low-income and underserved communities. If confirmed, I would look forward to the opportunity to work with you on this program and other initiatives to promote health equity and strengthen the country's public health workforce.

Will you work to ensure that the formula for the Public Health Jobs Program funding include a percentage of funding that would go directly to local public health agencies and not fully through the state health agencies?

Answer: If confirmed, I commit to work with you to ensure that support reaches local public health agencies.

4. *OPO Regulations:* Colorado is consistently among the top performing states for organ donation in the country: last year, in Colorado, 215 heroic organ donors saved a record setting 622 lives. This marked a 45% growth in the last five years. New organ procurement organization (OPO) performance regulations that the Trump Administration created were long awaited to reform the current organ donation and transplantation system. Unfortunately, the age only adjustment for organs transplanted metric could unintentionally place the Colorado OPOs in a lower, inappropriate tier due to the state's young population.

As the Centers for Medicare and Medicaid Services may review and update the OPO, will you work with me to ensure that such updates take into account Colorado's unique situation? For example, will you include a medical adjustment in the metric to take into account health characteristics that may affect the eligibility for donation, such as diabetes or hypertension?

Answer: I share your desire to ensure OPOs are held to high, fair standards using appropriate metrics that account for high-performing OPOs. If confirmed, I look forward to working with you to increase the organ supply and hold OPOs accountable for their performance.

5. *Equity in Policy Decisions:* Many of the efforts surrounding health equity address issues among the private sector among the health care industry, but often overlook bias among policy makers and their staff in both the Executive and Legislative Branch. Your nomination as the first Latino to lead HHS would be historic and provides you with a unique lens and prerogative to create lasting change in the agency.

Would you work to use all available tools to hire diverse staff specifically assigned to reviewing policy and communications (e.g., regulations, legislation, technical assistance for legislation, guidance, press releases, etc.) and, as appropriate, embed policy and feedback that would help reduce disparities among agencies and the industries they regulate under your purview?

Answer: I am committed to a diverse workforce within HHS including, but not limited to, policy and communications staff. I agree with Office of Personnel Management tenets that workforce diversity benefits organizations' ability to effectively serve our increasingly diverse nation and address disparities. A diverse workforce also can ignite innovation in policies, programs and processes. If confirmed, I will champion diversity, equity, and inclusion across HHS.

6. *Public Health Leader Safety:* Over the past year, public health leaders at local public health agencies (LPHA) in Colorado and across the country have experienced a great deal of stress responding to the pandemic, including threats to their personal lives and families. This has led to a significant amount of turnover, including 21 LPHA directors in Colorado alone leaving their posts.

Should you be confirmed, will you work with the Department of Justice to provide guidance to state, local, territorial, and tribal governments on how to best support LPHA and other health agency leaders, including their physical safety?

Answer: If confirmed, I commit to working to address the physical safety and behavioral health concerns of our nation's public health leaders and consulting with the Department of Justice, as appropriate, on these efforts.

Question from Senators Michael Bennet and Todd Young

7. *Antimicrobial Resistance:* Antibiotic resistance and the broken antibiotic marketplace complicate our response to public health emergencies, may lead to a public health crisis that is worse than the COVID-19 pandemic, and threaten the very foundation of modern medicine. It has been over 30 years, since the late 80s, since a new class of antibiotics has entered the market. Small biotech firms are keeping this industry alive, but in the past few years there have been a number of casualties and these companies have shuttered. Without better preparation and investment in novel antibiotics, some have projected up to 10 million deaths globally per year by 2030 if we don't invest now. Procedures including cancer chemotherapy, surgery, transplants, treatments of wounds and burns, and care of medically complex patients all rely upon safe and effective antibiotics.

We have developed legislation—the PASTEUR Act—to establish a subscription model for new, critically needed antibiotics. Under PASTEUR, the federal government would enter into contracts with antibiotic developers to provide set payments for new antibiotics that are delinked from the volume of antibiotics used. In exchange, they will provide a reliable supply of antibiotics. The PASTEUR Act would also provide support for antibiotic stewardship programs in health care facilities—which are proven to reduce inappropriate antibiotic use and improve patient outcomes.

Will you commit to working with us on legislation to prepare for the threat that resistant infections pose, including the PASTEUR Act, which both incents antibiotic development and supports the appropriate use of antibiotics?

Answer: It is clear that antimicrobial resistance (AMR) must be a top public health priority, not only for the United States but around the world. Even during this time, AMR remains a top CDC priority, and if confirmed, we will continue investing in key prevention strategies like early detection and containment, infection prevention, and ensuring the appropriate use of antibiotics. I agree that it is important to encourage the industry to develop innovative therapies that improve health outcomes. I also believe it is important to ensure access to and appropriate use of crucial therapies such as antibiotics. If confirmed, I am committed to working with you to achieve these important goals.

**Senator Mark R. Warner Questions for the Record for Nominee to be HHS
Secretary Xavier Becerra**

1. Question on Medicare Diabetes Prevention Program:

According to the Centers for Disease Control and Prevention (CDC), 88 million Americans – more than 1 in 3 – have prediabetes while another 34 million – just over 1 in 10 – have diabetes. Those rates hold true in my home state where over 631,000 Virginians suffer from diabetes. Fortunately, there is a proven and innovative CDC-recognized lifestyle change program to help prevent or delay type 2 diabetes, the National Diabetes Prevention Program (DPP).

In recent years Congress and CMS have recognized the benefits of this program for Medicare beneficiaries by ensuring patients have access to DPP. However, despite the increased demand and need for accessing health care virtually, current CMS rules do not ensure comprehensive access to virtual DPP. To address this gap, I introduced bipartisan legislation, the PREVENT DIABETES Act, with Senator Tim Scott. HHS has temporarily allowed individuals to access the DPP via a virtual platform during the COVID-19 pandemic, but this administrative change still excludes a number of providers and does not ensure long-term access to a virtual benefit. Our legislation will improve access to the program by ensuring individuals can access the DPP Expanded Model via virtual suppliers.

- As Secretary, will you work with CMS and Congress to ensure the DPP services can be offered to Medicare beneficiaries via a virtual platform?

Answer: Innovation is important to advancing the Administration's goals in health care, and the CMS Innovation Center is integral to the Administration's efforts to promote high-value care and encourage health care provider innovation, including virtual and digital health innovation. With respect to the Medicare Diabetes Prevention Program (MDPP) expanded model, I understand that CMS issued regulatory flexibilities in response to the COVID-19 pandemic, including waiving the limit on virtual sessions that can be provided by MDPP suppliers. If confirmed as Secretary, I commit to working with you on this and other models to reduce health disparities and prevent chronic diseases such as diabetes.

2. Question on Rural Health/Area Wage Index:

Over the past decade, well over 100 rural hospitals have closed, and over the past year, the COVID-19 pandemic has made this rural health care crisis significantly worse. It is no coincidence that the vast majority of these hospital closures have occurred in areas with the lowest Medicare Area Wage Index rates. To help solve this problem, I have previously introduced the Save Rural Hospitals Act of 2020 and plan to introduce similar legislation this year.

This legislation that would establish a reasonable national minimum Medicare Area Wage Index of 0.85, and as a result, would increase Medicare payments for rural hospitals in 22 states. The previous administration took several administrative steps to help solve the numerous problems with the Medicare Area Wage System, but much more needs to be done.

- If confirmed, would you pledge to work with Congress, and take additional administrative steps as needed, to support rural hospitals by addressing the problems in the Medicare Area Wage System?

Answer: The Biden Administration believes that all Americans should receive quality health care. Rural hospitals provide critical access to care in communities that have unique needs and challenges. While many requirements for Medicare payment to hospitals are defined in statute, I look forward to working with Congress to help rural hospitals serve their communities.

3. **Question on Health Data Privacy:**

I recently worked with Senator Blumenthal, as well as with Representatives Eshoo, Schakowsky, and Delbene to introduce the Public Health Emergency Privacy Act, which would set strong and enforceable privacy and data security rights for health information. After decades of data misuse, breaches, and privacy intrusions, Americans are reluctant to trust tech firms to protect their sensitive health information – according to a recent poll, more than half of Americans would not use a contact tracing app and similar tools from Google and Apple over privacy concerns.

Our health privacy laws have not kept pace with what Americans have come to expect for their sensitive health data; HIPAA was passed by Congress at a time when health data looked very different than it does today. Health data collected by health technology companies, apps, and other entities - whether for public health emergency purposes or in general - is not protected in the same way as health data collected by providers, exposing patients to potential harm.

The previous Administration recently released rules that would further reduce privacy protections and lead to an expanded role for third party apps and other entities not subject to health privacy laws. Strong protections created through the patient authorization process have been eroded, and apps are given the same right to access data as patients. These rules appear to be moving forward under the new Administration.

- Will you commit to curtailing data abuses by third parties who seek to monetize valuable health data as HHS secretary? How else do you plan to address this important issue and protect patient privacy?

Answer: As California Attorney General, I held several companies accountable for legal violations for not protecting patients' health information. Patients have a legal, enforceable right to request a copy of and access to their health information under the HIPAA Privacy Rule and may use a variety of means to do so. As technology has changed, so, too, have the ways in which that access can be provided. HHS is aware and sensitive to the importance of protecting patient privacy and continues to work collaboratively with partner agencies across the Executive Branch. If confirmed, I look forward to a collaborative relationship with Congress on this evolving issue.

- How will you ensure that companies with documented privacy lapses and anti-competitive behavior will not benefit from HHS's efforts to enable third-party access to sensitive and valuable health data?

Answer: The issue of data privacy and ensuring the security of valuable health data is constantly evolving. If confirmed, I commit to working with Congress on this important issue.

4. **Question on Telehealth:**

In recent years, I have worked with a bipartisan group of senators to advance common-sense telehealth reform in the Medicare program. Specifically, our previously introduced and soon-to-be reintroduced CONNECT for Health Act provides targeted reforms to the Social Security Act to ensure access to telehealth for Medicare beneficiaries. Telehealth use and popularity – including among the Medicare population – has increased significantly during the COVID-19 Public Health Emergency. However, these services will go away with the PHE. Now more than ever, we must work with the administration to support policies like those in CONNECT.

- What role do you see telehealth playing post-pandemic?
- Do you think Congress should restrict access to telehealth after the end of the PHE based on a patient’s geographic or physical location?
- How would you, as Secretary, work to ensure patients have the choice to access care via telehealth?

Answer: Telehealth is an important tool to improve health equity and improve access to health care. Health care should be accessible, no matter where you live. If confirmed, I will look at the telehealth flexibilities developed for the current public health emergency and determine how we can build on this work to improve health equity and improve access to health care.

5. **Pre-existing Conditions:**

To date, the COVID-19 pandemic has taken the lives of more than half a million Americans and infected millions more across our country. Those who have been infected with the diseases have suffered with the short-term health implications of the virus, but the long-term health impacts are still poorly understood. As a result, more Americans than ever will now have a pre-existing condition.

Junk insurance plans, such as short-term limited-duration plans and association health plans, are allowed to discriminate against people with pre-existing conditions, charge them more based on their health status, and rescind or deny coverage altogether. In the wake of the pandemic, it is critically important that the Administration move quickly and decisively to limit the availability of substandard insurance products that undercut the health and wellbeing of Americans.

- Will you commit to taking immediate action to reign in these harmful products and if so can you commit to working with me and my office on this issue?

Answer: Making sure that all Americans have access to quality, affordable health care is one of the Biden Administration’s top priorities. If confirmed, I will examine rules and other policies, to ensure that plans provide Americans access to the care that they need. I look forward to working with you and your office on this important issue.

6. **Question on Foster Youth**

Almost everyone living in the United States has had to make significant adjustments in the wake of the COVID-19 pandemic, but it has greatly worsened existing challenges for foster youth across the nation. Even before the public health emergency, only about half of youth aging out of the foster care system each year were anticipated to have some form of gainful employment by the age of 24. Studies show that foster youth have and will continue to feel the brunt of the pandemic's economic impact and the growing digital divide. A survey conducted by FosterClub found that 65% of transition-age foster youth who were employed before the pandemic lost their jobs by May 2020. According to a report conducted by iFoster, only about 5% of youth in foster care in rural settings and 21% of youth in foster care in urban settings have regular access to a computer. I am concerned that foster youth will continue to be harmed if changes are not made to strengthen support and resources. Therefore, I would appreciate a response to the following questions:

- In light of the challenges faced by foster youth during the pandemic, how would you use your role as HHS Secretary to support foster youth and ensure they receive the support and resources necessary to enter the workforce and accomplish their personal and professional goals?
- What specific steps do you plan to take to ensure stability for foster youth, both in the short-term and long-term, during the pandemic and its aftermath?

Answer: I share your concern that young people aging out of the foster care system too often lack access to stable housing, income, and other resources, and the pandemic has made these challenges even more pronounced. The Supporting Youth and Families Through the Pandemic Act, passed as part of the Consolidated Appropriations Act of 2021 contained critical provisions to prevent youth from aging out of foster care and to allow voluntary re-entry into foster care. It also contained expanded flexible funding that states may use to provide direct financial assistance or housing assistance, or to assist with other needs, whether that be purchasing food, cell phones and laptops, or gaining internet access. It is essential that states reach out to and listen to the diverse populations of youth with lived experience in the foster care system to guide their implementation of these provisions and to lay the groundwork for stronger supports for youth moving forward. I appreciate your thoughtful leadership on this issue, and, if confirmed, look forward to working with you on it.

7. **Question on Protections for Coal Workers**

As you well know, the U.S. passed a grim milestone last week: more than 500,000 Americans have died after contracting COVID-19. Coal miners living with coal workers' pneumoconiosis (black lung disease) are particularly at risk for suffering severe consequences of the disease. Many miners receive diagnostic, treatment, and rehabilitation services at black lung clinics funded through the Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA). Given that these clinics are under your authority, I would appreciate your response to the following questions.

- Do you believe that further guidance is needed to ensure that miners' treatment is not compromised during the pandemic and their needs are best served? If so, what step do you plan to take?

- Moving forward, what specific steps do you plan to take, in coordination with the Department of Labor, to ensure that coal miners receive the appropriate health screenings, preventive care, and treatment necessary for their wellbeing?

Answer: It is important to protect the most vulnerable in our communities, especially during a global pandemic. If confirmed, I will work across the federal government to ensure all people with chronic conditions are able to access the health care they need, and I will support robust oversight of HRSA's black lung clinic program.

Questions for the Record of Senator Sheldon Whitehouse
Nomination Hearing of Xavier Becerra for Secretary of Health and Human Services
February 25, 2021

Substance Use and Opioid Use Disorder Treatment

Access to evidence-based substance use disorder treatment including medication-assisted treatments (MAT) is limited in the U.S. due to restrictive federal laws and regulations. For example, providers are limited in the number of patients they can see and are required to obtain an additional “X-waiver” from the DEA to provide this type of treatment. In addition, people incarcerated in U.S. jails and prisons often are denied access to these effective treatments and the rate of overdose death for individuals who recently have reentered the community from incarceration is very high. My legislation the TREATS Act would provide providers with flexibility and improve access to MAT.

- Will you work with Congress to eliminate the X waiver and lift the patient caps that artificially limit how many patients providers can serve?

Answer: If confirmed, I will work with Congress to expand availability of and access to substance use disorder prevention, treatment, and recovery services. There are a number of measures that HHS can consider implementing. If confirmed, I will work with you toward these goals.

- Will you work with SAMHSA and the DEA to make permanent the current temporary waivers for methadone and buprenorphine that enable more stable patients to take home medications (allowing 14-28 days to be taken home) and enable buprenorphine induction to happen via telehealth?

Answer: I am committed to reducing barriers to medication-assisted treatment and will work with SAMHSA and the DEA to do so.

Behavioral Health IT

I authored a provision in the SUPPORT Act to create a CMMI demonstration program that furnishes financial incentives to help Community Mental Health Centers, psychiatric hospitals and other behavioral health providers obtain Electronic Health Record systems. The prior Administration did not implement the demonstration, which is critical to helping mental health and addiction treatment providers communicate with hospitals, primary care doctors and medical specialists through Health Information Exchanges (HIEs) and Health Information Technology (HIT).

- Will you commit to exploring ways to generate CMMI funding to implement this authorized demonstration?

Answer: Innovation is critically important to advancing goals in health care, and the CMS Innovation Center is integral to the Administration’s efforts to improve behavioral health. I know CMS is always looking for ways to incorporate payment incentives for improved behavioral

health into its models, and if confirmed as Secretary, I look forward to working with you to find ways to better support our nation's mental health and addiction treatment providers.

**Questions for the Record
Senator Maggie Hassan
Senate Finance Committee**

To: Xavier Becerra, Of California, To Be Secretary Of Health And Human Services

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1. **Gun Purchaser Safety Education**

The Gun Shop Project was started in New Hampshire as a suicide prevention program that encourages gun stores and firing ranges to display and distribute suicide prevention materials, as well as trains gun dealers on how to look for customers who may be in crisis or at risk for suicide.

Today, more than half of all gun stores in New Hampshire are disseminating materials about the risk of suicide, and the program has expanded to more than 21 states. The Gun Shop Project is a proven example of a successful partnership between gun owner groups and suicide prevention advocates.

The federal government can build on the success of the Gun Shop Project by providing funding for similar programs. A recent study that interviewed leaders from state-level and national-level Gun Shop Projects found that funding was the primary challenge to implementing these programs.

Do you support funding and support for public awareness campaigns that provide gun purchasers with safety information about the risks associated with guns, best practices for responsible gun storage, and suicide prevention information?

Answer: We certainly should be funding innovative and collaborative strategies for suicide prevention and reducing gun violence. Providing gun purchasers with safety information and information on suicide prevention seems like a commonsense way to help protect Americans, and if confirmed, I hope to work with you on this issue to keep people safe.

2. **Direct Distribution of COVID-19 vaccines to Health Centers**

As COVID-19 vaccination continues across the United States, the data is showing that people of color, people with low incomes or limited English proficiency, and people in rural areas are much less likely to get a vaccine. One way to address these disparities is to rely on the nation's system of Community Health Centers.

To date, many Health Centers are completely unable to receive vaccine allocations. Will you commit to working with states and providers to ensure that future vaccine distribution plans incorporate the inclusion of Community Health Centers?

Answer: Yes, if I am confirmed, I will aim to strengthen our community health center vaccination program to reduce barriers and increase access to the COVID-19 vaccine for people of color, people with low incomes or limited English proficiency, and hard-to-reach communities in rural areas.

3. **Grant Funding to Health Centers to support vaccine administration**

When Health Centers have access to COVID-19 vaccines, they will need financial support to administer the vaccine. Health Centers in my state estimate that it costs around

\$100 per dose to administer a vaccine. This reflects the cost of freezers, staff, supplies, and scheduling work. If confirmed, how will you work to provide Health Centers with the funding they need so they can be able to vaccinate our most vulnerable populations?

Answer: The Biden Administration's program to distribute vaccines directly to community health centers is intended to increase access to the COVID-19 vaccine. The health centers invited for participation in the initial phase of the program serve a significant number of vulnerable populations, including those experiencing homelessness, migrant/seasonal agricultural workers, residents of public housing, seniors, and those with limited English proficiency, and include at least one health center in each state or territory. In order to ensure that health centers have the support they need to succeed, if confirmed, I will work with HRSA to ensure each health center that is part of the program has the ability to participate, readiness to receive doses, and staff capacity to distribute vaccines.

4. **National Suicide Hotline**

For individuals in a mental health crisis, a law enforcement response, rather than a mental health response, can lead to negative outcomes, including jail or death. Last year, Congress unanimously passed the National Suicide Hotline Designation Act to provide a national, easy-to-remember 3 digit number, 9-8-8, for individuals in crisis to reach trained counselors 24/7. HHS will play a vital role in the success of the new, 3 digit dialing code, 9-8-8. Should you be confirmed, how will you work with the Substance Abuse and Mental Health Services Administration to ensure the public is aware of this service and improve the outcomes for individuals in crisis?

Answer: If confirmed, I will work closely with the Assistant Secretary for Mental Health and Substance Use and the Substance Abuse and Mental Health Services Administration and other federal partners to ensure the American people are aware of the availability of 988 once it becomes universally available across the country. We will work to improve outcomes for those in a mental health or suicidal crisis, this includes pursuing improvements in the crisis response infrastructure in order to reduce unnecessary police involvement. HHS will continue to work with the FCC, with VA, and with the Office of Emergency Medical Services in the Department of Transportation to implement 988.

5. **Strategic National Stockpile**

The COVID-19 pandemic has revealed vulnerabilities and shortfalls within our existing Strategic National Stockpile (SNS). Since then, the SNS has entered into short-term public-private partnership contracts to leverage the capabilities of the distribution industry to ensure a continuously replenishing inventory system. As SNS continues to reassess and restructure its operations, will you commit to working with Congress to improve our nation's preparedness for future shortages caused by pandemics and other national emergencies?

Answer: Yes, I will work with Congress to improve the SNS in order to increase our overall readiness for future public health emergencies.

6. **Substance Misuse**

You were among a bipartisan group of Attorneys General that sent a letter to former FDA Commissioner Hahn requesting an update on what actions the Food and Drug Administration has taken under the SUPPORT Act to address the nation's devastating opioid epidemic, and what actions are proposed for the future. If confirmed, how will you work with FDA and SAMHSA to better address the ongoing opioid crisis by improving efforts around prevention, including improvements to education and awareness campaigns and access to non-opioid therapies, and increasing access to medication-assisted treatment?

Answer: The opioid crisis demands a multifaceted approach to include prevention, intervention, treatment, and recovery support services. We will continue to fund training, educational resources and materials for providers, and technical assistance for professional organizations to support these efforts. And we will explore opportunities for additional education and awareness activities. Moreover, we will work with the FDA in their efforts to approve novel therapeutics and devices for the treatment of opioid use disorder.

7. **Perinatal Vaccinations**

Too many women – particularly women of color – in this country are dying. Greater attention and efforts are needed to ensure that women are receiving necessary preventive care during their pregnancies, including recommended immunizations that not only protect them but also protect their babies from vaccine preventable illness.

Senator Cassidy and I have introduced bipartisan legislation to help ensure that pregnant women have access to these vital services. If confirmed, will you work with us to improve maternal access to care and preventive services such as immunizations?

Answer: Thank you for your leadership on this important issue. If confirmed, I look forward to working with you and Senator Cassidy and others to improve maternal health in our country, including access to preventive services like immunizations and other recommended care.

8. **Access to items and services for vulnerable populations**

HHS and CMS have significant regulatory authority to ensure that that vulnerable populations have access to items and services. This is particularly true during the pandemic, in rural and underserved areas where individuals struggle to access care. What steps will you take to ensure that seniors and individuals experiencing disabilities are able to access health care services and essential equipment, particularly in rural areas?

Answer: Individuals dually eligible for Medicare and Medicaid, including seniors and people experiencing disabilities, are some of the most vulnerable Americans. Many of these individuals have complex health care needs with multiple chronic conditions. Medicare and Medicaid provide indispensable access to care for this vulnerable population. These programs have kept many families from losing hope, particularly in rural parts of the country. If confirmed,

I am prepared to work with you and your colleagues in Congress to strengthen these valuable programs and ensure vulnerable populations have access to the quality, affordable health care that they need.

U.S. Senate Committee on Finance
Full Committee Hearing: Nomination of Xavier Becerra for Secretary of Health and Human Services

Wednesday, February 24, 2020

Questions for the Record from Senator Elizabeth Warren

1. **OTC Hearing Aids:** In 2017, President Trump signed into law the *Over-the-Counter Hearing Aid Act*, a bill that I introduced with Senator Grassley, Senator Hassan, and Senator Isakson. The bill requires the FDA to categorize certain hearing aids as over the counter (OTC). Under law, the FDA was required to issue regulations regarding OTC hearing aid safety and manufacturing by August 18, 2020—but the agency failed to issue the rules on time. **As HHS Secretary, will you commit to ensuring that the FDA releases these statutorily required regulations as soon as possible?**

Answer: Thank you for your leadership on this issue. I commit that, if confirmed, I will support FDA in its work to ensure availability of over-the-counter hearing aids. I recognize this as a public health priority as hearing loss can have a negative effect on communication, relationships, and other important aspects of life.

2. **Drug Pricing Authorities:** The federal government has the power to step in and rectify the market failures that have allowed drug prices to skyrocket. Using its compulsory licensing authority, the federal government can use patented products without the permission of the patent holder. Codified at 28 U.S.C. § 1498, this authority allows the government to “manufacture, import, and use” products protected by active patents, as long as it provides patent holders with “reasonable and entire compensation for such use and manufacture.”¹ Meanwhile, using the march-in rights established under the Bayh-Dole Act,² the federal government can require the re-licensing of certain patents.³ Bayh-Dole gives federal contractors the right to exclusively manufacture and sell products developed with federal support. However, Bayh-Dole allowed the federal government to retain “nonexclusive, nontransferable, irrevocable, paid-up” licenses for products developed with government funds.⁴ In certain cases, such as when health or safety needs have not been reasonably satisfied by the original licensee, the federal government can “march-in” and direct other licensees to produce products. **As HHS Secretary, will you commit to conducting a review of the Department’s pre-existing executive authorities to determine how they can be used to lower the prices of critical drugs—like insulin and naloxone—that millions of Americans rely on?**

Answer: If I am fortunate to be confirmed, we will conduct a thorough review to identify and analyze the tools at our disposal to reduce the price of drugs and make treatments more affordable for the American people. President Biden has been clear that reducing costs is a top priority for this Administration.

3. **Nursing Homes and Private Equity Firms:** The National Bureau of Economic Research recently released a study showing that private equity (PE) ownership of nursing homes “increases the short-term mortality of Medicare patients by 10%, implying 20,150

lives lost due to PE ownership over [a] twelve-year sample period.” Meanwhile, PE-owned nursing homes also saw “declines in other measures of patient well-being, such as lower mobility, while taxpayer spending per patient episode increases by 11%.”⁵ **As HHS Secretary, will you commit to working with me and my colleagues to review, reduce, and mitigate the negative impacts of private equity ownership of health care facilities, including but not limited to nursing homes?**

Answer: I agree that we must ensure nursing homes provide high-quality care to their residents. Nursing homes’ first obligation should be to their patients, no matter what kind of ownership arrangements they have, and nursing homes participating in Medicare and Medicaid programs should meet required federal health and safety standards. If confirmed, I am committed to working with you and your colleagues to ensure nursing homes provide high-quality care to their residents.

4. **Assisted Living Facilities and Congregate Care Settings:** Congregate settings like nursing homes, assisted living facilities, and prisons and jails have been epicenters of the COVID-19 pandemic since the virus began to spread. My oversight has revealed the extent of these problems, and the gaps that are making outbreaks in these facilities so frequent and so severe. Assisted living facilities, for example, have high rates of COVID-19 infections, hospitalizations, and deaths, but report limited COVID-19 data when compared to more heavily regulated nursing homes.⁶ Meanwhile, federal correctional facilities and state and local prisons and jails are not required to report sufficient demographic data to adequately track the spread of COVID-19, and behavioral health facilities have limited resources to prevent outbreaks.⁷ **As HHS Secretary, will you commit to expanding COVID-19 demographic data collection at congregate care facilities, including but not limited to assisted living facilities, residential behavioral health facilities, and correctional facilities? After the pandemic subsides, will you commit to examining the regulations that currently apply to congregate care facilities to determine if more routine data collection and standards could improve patient safety?**

Answer: If confirmed, I am committed to expanding the scope of data collection in congregate settings, such as assisted living facilities and correctional facilities, in order to better track demographic and other relevant trends associated with the spread of COVID-19. If confirmed, I will work with various HHS agencies, including the CDC, as well as states, tribal, local, and territorial partners on ways to improve data collection and the quality of data in such settings.

5. **Supply Chain:** The United States is heavily dependent on foreign sources of pharmaceutical products such as active pharmaceutical ingredients (API) and their raw materials. Only 28% of facilities manufacturing APIs used in drugs and 47% of facilities manufacturing finished dosage forms of drugs for the U.S. market are located in the United States.⁸ The COVID-19 pandemic revealed the extent and the dangers of this overreliance, as materials needed for diagnostic testing, PPE, and other pharmaceutical products have been in chronically short supply, marring the nation’s response to the pandemic.⁹ An interruption to the supply of APIs and other pharmaceutical products could have severe public health and national security implications, and there is an urgent need for the Biden Administration to take action. **As HHS Secretary, what steps will you take to address this overreliance?**

How will you work alongside other federal agencies like the Department of Defense, the Food and Drug Administration, and other drug procuring agencies to create a unified federal response to this overreliance?

Answer: The global pandemic has highlighted the vulnerabilities of the global supply chain for many products. I am aware that BARDA has invested in and is working to expand pharmaceutical manufacturing in the United States for use in producing medicines needed during the COVID-19 response and future public health emergencies. This work will expand domestic manufacturing of raw materials and active pharmaceutical ingredients for drugs. If confirmed, I will continue to support ongoing efforts in this area, as well as support the department's work with the FDA and other federal agencies to expand domestic capacity for supplies needed in the ongoing COVID-19 response.

6. **Medication Abortion:** Last year, you led 21 Democratic Attorneys General in a letter to then HHS Secretary Alex Azar and FDA Commissioner Stephen Hahn, urging them to waive the Risk Evaluation and Mitigation Strategy (REMS), or use FDA enforcement discretion, to allow certified prescribers to use telehealth for Mifepristone, the prescription drug used to provide medication abortion care.¹⁰ As you noted in your letter, the REMS requirements on mifepristone create unnecessary delays for women who need access to time-sensitive health care and force them to travel unnecessarily during the COVID-19 public health emergency. Furthermore, your letter noted that mifepristone is extremely safe and effective. Mifepristone was approved by the FDA over twenty years ago and about three million women in the United States have used the drug.¹¹ On April 14, 2020, Senators Murray, Baldwin, and I sent a similar letter to then-Commissioner Hahn regarding the REMS imposed on mifepristone by the FDA and our concerns that FDA is not following the science by allowing these restrictions to remain in place.¹² However, we have not received a written response or staff briefing from FDA, which we requested. **Can you commit that the FDA will respond to our request within 30 days and will clarify what scientific evidence the FDA is currently using to justify that the REMS for mifepristone remains in place?**

Answer: Thank you for raising this important issue. I strongly believe women should not be put through unnecessary hurdles to receive access to health care. Further, I believe FDA should be empowered to make regulatory decisions based on the available science. If confirmed, it would be a priority to make sure the Congress is provided information when requested.

7. **Title X:** The Title X Family Planning Program (the Title X program) is the only federal program dedicated to providing family planning services to people with low incomes. In 2016, Title X supported nearly 4,000 health centers providing basic primary and preventive health care services—including contraception, Pap tests, breast exams, and STI and HIV testing—to more than 4 million Americans.¹³ But in 2019, the Trump Administration finalized a rule that gutted the Title X program, causing family planning providers in 34 states to leave the program and at least 1.5 million people to lose access to care.¹⁴ On January 28, 2021, President Biden issued a Presidential Memorandum on Protecting Women's Health at Home and Abroad, which directed HHS to “consider, as soon as practicable, whether to suspend, revise or rescind, or publish for notice and comment proposed rules, suspending, revising, or rescinding those regulations, consistent with applicable law, including the

Administrative Procedure Act.”¹⁵ I believe this review will make clear the numerous harms patients and community health faced as a result of the rule. For example, in Massachusetts, only one Title X grantee remains in the state.¹⁶ **Will you commit to complete the review of the Title X rule, as directed by President Biden, no later than March 29, 60 days after the president issued the presidential memorandum?**

Answer: If confirmed, it will be a priority to review the Title X regulation as quickly as possible.

8. **Child Care Assistance:** The COVID-19 pandemic has severely damaged the child care sector, with many providers struggling to keep their doors open and parents missing work or leaving the workforce altogether because of the lack of affordable care. Even before the pandemic, quality, affordable child care was much too difficult to find, despite extensive research showing that federal investment in child care and early childhood education pays off in increased earnings for families, higher levels of parental employment, and improved health development of children.¹⁷ The Child Care and Development Fund is the primary source of federal funding dedicated to helping low-income families afford child care. Yet national figures show that five out of six children who are eligible for help and who need that help aren’t receiving a subsidy. According to a GAO report, many states manage demand by setting their eligibility limits very low, preventing many families from being able to participate.¹⁸ **In administering the supplemental funds provided under the Child Care Development Block Grant (CCDBG) and other child care programs for COVID-19 relief, how will you promote the stabilizing the child care sector and sharing best practices between states?**

Answer: The COVID-19 pandemic has highlighted the many gaps in child care in this country. Important investments have been made, but even with these efforts, additional investments are necessary to stabilize the child care sector, which is why the Biden Administration has proposed additional funding for CCDBG as well as new child care stabilization grants for child care providers. If confirmed, I look forward to working with you on these efforts and appreciate your leadership on this important issue.

**Hearing on HHS Secretary Nominee Xavier Becerra
February 24, 2021
Questions for the Record**

Questions Submitted by Ranking Member Crapo

COVID-19 Pandemic

Question. I appreciate your comments throughout the nomination process regarding the importance of good data and following science in making decisions. As we approach the first anniversary of the COVID-19 pandemic lockdowns, many Americans are wondering how long they will have to endure the restrictions fighting the pandemic has required.

- How long do you anticipate that the COVID-19 Public Health Emergency will last, and what specific criteria would you and the other advisors to President Biden use to assess an appropriate public health response?

Answer: Americans' frustrations and exhaustion with this pandemic are understandable. We all want to get back to our lives, see our friends and families, be able to visit loved ones or go to work or school without fear of contracting or spreading the virus. We need to approach this crisis with urgency, and if we all do our part, we can finally end this pandemic. If confirmed, I would work closely with the medical doctors, scientists, and other public health experts at HHS to make determinations about the Public Health Emergency and would utilize the criteria set forth by experts to ensure that HHS's response to the pandemic is driven by the science and relies on the most recent data available, such as infection and mortality rates.

Question. How does the HHS Secretary fit into the larger Biden Administration COVID-19 response team structure?

Answer: As the head of the Department tasked with executing so much of the federal government's public health response to the pandemic, if confirmed as the HHS Secretary, I would lead the HHS COVID-19 response efforts – everything from ASPR's efforts to expand testing and diagnostics, to OASH's deployment of vaccinators and ongoing minority outreach efforts, to the development, procurement, and distribution of the vaccines – and work in close collaboration with the White House COVID-19 Coordinator and the White House COVID-19 Response Team. This is a whole-of-government effort, and if confirmed I am committed to ensuring HHS is leading the implementation of President Biden's National Strategy and executing the programs that deliver Americans the aid they need.

Question. What have you learned from your experience with the California COVID-19 response and how would you apply those lessons if you are confirmed as HHS Secretary?

Answer: This has been a dynamic and evolving virus, which has posed constant challenges for the American people. In my state, I took action as Attorney General early in the pandemic to keep Californians safe. I used my authority to protect workers from exposure to COVID-19, secure key safeguards for frontline health care workers' rights, take on fraudsters trying to take advantage of people during the pandemic, and stand up for homeowners trying to make their

mortgage payments during the downturn. I also worked with a Republican colleague from Louisiana, Attorney General Jeff Landry, to try to make COVID-19 treatments more available for the American people. I have seen the importance of working together – with urgency – to tackle this crisis, with the constant goal of protecting Americans.

Question. Congressional Democrats are moving swiftly to use budget reconciliation to advance President Biden’s \$1.9 trillion COVID-19 response plan. The planned increase in spending through reconciliation would trigger automatic spending reductions to Medicare and other programs.

- Considering that bipartisan support is needed for Congress to waive its budget rule to prevent those reductions, would it be more prudent for the Administration to work with Congress to negotiate another bipartisan COVID-19 relief bill?

Answer: I agree that we must work together to tackle this crisis. This pandemic is a threat to us all, and we have to find common ground to get the American people the help they need. Urgency is critical: the public needs help and they need it now. President Biden has been very clear that he agrees and believes bipartisan agreement on this front is achievable. If I am confirmed, I will commit to working with you to both address this crisis and strengthen our health care lifelines like Medicare.

Question. During the COVID-19 Public Health Emergency, HHS has provided flexibility to providers to better furnish care to patients, including through telehealth and access to innovative treatments. As we begin to consider the end of the pandemic, we must carefully evaluate our response to the pandemic, and implement appropriate reforms based on the data and lessons learned.

- Which policies do you believe have been most successful for patients and providers, and how would you work with Congress to make appropriate improvements to our federal health care programs?

Answer: Telehealth is an important tool to improve health equity and improve access to health care. Health care should be accessible, no matter where you live. If confirmed, I will look at the telehealth flexibilities developed for the current public health emergency and determine how we can build on this work to improve health equity and improve access to health care.

Question. It was reported on February 14, 2021 that Vice President Harris said, with respect to Covid-19 vaccinations and the state of preparedness when the Biden Administration began, that “There was no stockpile...of vaccines; there was not a national strategy or plan for vaccinations. We were leaving it to the states and local leaders to try and figure it out. And, so, in many ways we’re starting from scratch on something that’s been raging for almost an entire year.” Earlier, in a January 21, 2021 White House press briefing, medical adviser Dr. Anthony Fauci said during a White House press briefing that “We certainly are not starting from scratch because there is activity going on in the distribution.” Do you believe that Vice President Harris’s characterization that in many ways the Biden administration was starting from scratch

and there was not a national strategy or plan for vaccinations, or Dr. Fauci's characterization that the Biden administration was certainly not starting from scratch?

Answer: If I am fortunate to be confirmed, I promise I will work with you and your colleagues in the Senate, as well as my colleagues in the administration, to ensure our plans for addressing this crisis are collaborative and meet the needs of the moment. It is no secret that this crisis has carried on for far too long, in no small part because of deficiencies in our earlier federal response efforts, and as HHS Secretary, I would work to strengthen our efforts to increase vaccinations, expand testing, and ensure that there is a clear, strong, and well-executed federal plan to tackle COVID-19.

Medicare

Medicare Hospital Insurance Trust Fund Insolvency

Question. The most recent Medicare Trustees report projected that the Hospital Insurance (HI) trust fund would be officially bankrupt in 2026, at which time it would no longer be able to pay full benefits for our nation's seniors and the disabled. That report failed to include any analysis showing the fiscal impact of the COVID-19 pandemic on the trust fund. Earlier this month, the Congressional Budget Office (CBO) released its updated winter baseline. The new baseline takes into account increased tax revenue due to a stronger economic forecast. While CBO now also predicts that the HI trust fund will be insolvent in 2026, there is substantial uncertainty behind their projections. Given recent Medicare spending trends, it seems unlikely that the trust fund could remain solvent through 2025.

- Will you commit, if you are confirmed, to immediately direct the Centers for Medicare and Medicaid Services (CMS) Chief Actuary to provide an update to me, in writing, that shows the current status of the Medicare HI insolvency date that takes into account the fiscal impact of the COVID-19 pandemic?

Answer: If confirmed as Secretary, I can commit to you that we will work with you to give you and this Committee the information you need to make the right decisions with respect to Medicare.

Question. Congress has historically looked to reform and adjust Medicare payments to providers in order to extend the life of the HI trust fund. However, the last time Congress enacted significant Medicare savings the money was used to finance spending on the 2010 health care law.

- As a member of the House, you voted for the law that raided over \$700 billion from a financially strapped Medicare program and spent it. Now, a decade later, those savings are not available to protect Medicare. What policies do you now think Congress should consider to extend the life of the HI trust fund?

Answer: If confirmed, my team and I will be ready to sit down with you and other Members of Congress to discuss both short and long-term solutions to guarantee Medicare's future.

Question. Medicare is on a near-term path toward bankruptcy. The HI trust fund could be insolvent in anywhere from four to five years. Other than during the first few years of the Medicare program's existence, Congress has never allowed the HI trust fund to project less than four years of solvency without acting in order to minimize the impact on beneficiaries, health care providers and taxpayers.

- Given the looming fiscal crisis, how soon would you provide a comprehensive legislative proposal that extends the life of the HI trust fund?

Answer: If confirmed, my team and I will be ready to sit down with you to discuss short and long-term solutions to guarantee Medicare's future.

Prescription Drugs

Question. Modernizing the successful Medicare Part D program has been a feature of numerous recent proposals to address prescription drug issues from Republicans and Democrats, including a comprehensive bill that I introduced last Congress. The different proposals involve many of the same common elements, such as improving incentives to increase competition and establishing a cap on patient out-of-pocket spending. Making these improvements to a program that serves over 45 million beneficiaries would be a momentous, bipartisan accomplishment. Some, however, have suggested that Part D modernization is insufficient and that it should not happen without other major changes. While other changes may be worthy of debate, there have been few major reforms that have broad bipartisan support. Would you oppose legislating a Part D modernization that includes a first-time patient out-of-pocket cap on spending as a standalone policy?

Answer: If I am fortunate to be confirmed, we will conduct a thorough review to identify and analyze the tools at our disposal to reduce the price of drugs and make treatments more affordable for the American people. President Biden has been clear that reducing costs is a top priority for this Administration, and I hope we can work together on finding solutions.

Question. You have consistently advocated for the federal government to negotiate prescription drug prices in Medicare Part D. If confirmed as Secretary, you would be the one in charge of negotiating those prices. Barring some type of artificial price ceiling, the Congressional Budget Office has consistently maintained that the federal government would not be able to secure lower prices than those established through negotiation between private entities, unless the government used a national drug formulary list. Are you prepared to determine which prescription drugs over 45 million beneficiaries can access, knowing this would inherently involve denying medications that physicians prescribe as the best course of treatment for patients?

Answer: If I am fortunate to be confirmed, we will conduct a thorough review to identify and analyze the tools at our disposal to reduce the price of drugs and make treatments more affordable and accessible for the American people. President Biden has been clear that reducing costs is a top priority for this Administration, and I hope we can work together on finding solution.

Question. There is broad concern that establishing Medicare (or other) prescription drug payment amounts using foreign reference prices will harm patient access and stifle innovation. Do you support the use of foreign reference prices in Medicare? Do you view the use of a foreign reference price to set payment amounts as price setting or a form of negotiation?

Answer: If I am fortunate to be confirmed, we will conduct a thorough review to identify and analyze the tools at our disposal to reduce the price of drugs and make treatments more affordable and accessible for the American people. President Biden has been clear that reducing costs is a top priority for this Administration, and I hope we can work together on finding solution.

Other

Question. You have highlighted the settlement you secured with a large California hospital system related to the charge that it acquired hospitals and physician practices to unfairly increase market power and increase costs for consumers. The Medicare Payment Advisory Commission and other experts have determined that Medicare payment systems incentivize provider consolidation. Do you believe that some Medicare payment policies incent consolidation and increase costs for beneficiaries and the program?

Answer: Thank you for this question. This has been a significant focus of my tenure as Attorney General, and if I am confirmed, I will continue to focus on preventing consolidation that increases prices on consumers and patients. Like President Biden, I believe that all Americans should be able to access affordable health care, and part of that is identifying solutions to hospital over-consolidation. I hope I have the opportunity to work with you to tackle this issue and pursue solutions that strengthen our federal programs and protect patients and consumers.

Question. You have highlighted that you authored Medicare provisions included in the Affordable Care Act. Can you describe those policies and note those of which you are most proud?

Answer: As a member of the Ways and Means Committee for two decades, I have a lot of experience on Medicare legislation. I introduced legislation -- the Medicare Savings Programs Improvement Act of 2007 -- that expanded cost-sharing subsidies for low-income seniors who receive both Medicare and Medicaid benefits by increasing the amount of resources they could receive. Several of these provisions were included in the Medicare Improvements for Patients and Providers Act of 2008 and the Medicare Access and CHIP Reauthorization Act of 2015. I also championed provisions of the Medicare Improvements for Patients and Providers Act of 2008 that required physicians who perform imaging to be accredited and trained to ensure patient safety. I introduced legislation in 2007 to raise the cap on the benefits of patients receiving Medicare physical therapy, as well as the E-Centives Act of 2009, which provided incentives for Medicaid providers to implement electronic health records. A version of this legislation was included in the American Recovery and Reinvestment Act of 2009. I introduced the Medical Anesthesiology Teaching Funding Restoration Act of 2007 to improve anesthesiologists' teaching payments, and it passed in 2008. I helped draft the Improving Medicare Post-Acute

Care Transformation Act (IMPACT) of 2014, requiring the HHS Secretary to conduct research on the social determinants of health in Medicare's value-based programs, so we could use good data to improve outcomes and save costs. And as you mentioned, I worked on the Affordable Care Act which strengthened Medicare and lowered costs for seniors. As a member of the Ways and Means Committee and House leadership, I led successful discussions on the design of the health care exchanges and Medicare reimbursement payments. The ACA added years of solvency to the Medicare Trust Funds, closed the prescription drug “donut hole,” and provided free preventive care to all Medicare beneficiaries. I am proud of all this work to protect and strengthen health care for our seniors.

Question. The Affordable Care Act established the Center for Medicare and Medicaid Innovation (CMMI). There is significant bipartisan support for testing different ways to pay for services to figure out how patients can get better care at a lower cost. However, there is concern that Congress ceded too much authority to the executive branch by allowing CMMI to override statute, especially in Medicare, in the name of a payment change “test.”

- What are your views on the appropriate use of CMMI authority?
- If confirmed, will you commit to ensuring that CMS would not use CMMI to avoid working with Congress?
- Considering that many CMMI tests have run for an extended period of time without meeting the criteria for expansion, is there a length of time sufficient to determine if a model works?
- With CMMI having a large budget of \$10 billion for each decade and little accountability to Congress, what metrics would you use to determine whether CMMI is successful?

Answer: Innovation is critically important to advancing goals in health care. The CMS Innovation Center is integral to the Administration’s efforts to promote high-value care and encourage health care provider innovation. If confirmed as Secretary, I can commit to you that we will be wise stewards of CMMI funds and follow the evidence generated by Innovation Center models.

Question. HHS finalized a number of rules toward the end of the President Trump’s term that the Biden Administration is reviewing. While this is a routine practice for incoming Administrations, have you identified which rules you would continue, modify, or withdraw? Please respond specifically on:

- Most Favored Nation (MFN) Model (Interim Final Rule with Comment Period); and
- Fraud and Abuse: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees.

Answer: If I am fortunate to be confirmed, we will conduct a thorough review to identify and analyze the tools at our disposal to reduce the price of drugs and make treatments more affordable and accessible for the American people. President Biden has been clear that reducing costs is a top priority for this administration, and I hope we are able to work together on these issues.

Question. If confirmed, you would be integral to determining what goes into President Biden’s budget submissions to Congress. Prior Administrations of both parties have proposed specific policy changes that aim to improve Medicare, with many of those policies reducing baseline Medicare spending. Democrats characterized Trump Administration budget policies that would make payment system changes that bring efficiencies and reduce Medicare spending as “cuts” (even when the identical policy had been proposed by the Obama Administration). Do you view any budget policy proposal that reduces Medicare spending as a Medicare “cut”?

Answer: I believe that we must protect Medicare beneficiaries, being careful stewards of taxpayer dollars and the Medicare Trust Funds. I look forward to working with Congress to consider policies that would lower costs for seniors, and also enhance our ability to reduce waste, fraud, and abuse in these vital programs.

Question. There are concerns that the inclusion of calcimimetic medications in the Medicare End Stage Renal Disease (ESRD) bundled payment rate may harm beneficiaries’ access to these treatments. There are anecdotal reports that some patients have had to change or otherwise stop using a medicine that has worked for them in response to this payment policy change. How would you ensure that ESRD patients have access to calcimimetic treatments and monitor patient outcomes in this area?

Answer: I agree that it is important for Medicare beneficiaries, particularly vulnerable groups such as those beneficiaries with ESRD, to have access to medically necessary treatments such as calcimimetics. If confirmed, I will work to ensure that Medicare beneficiaries continue to have access to these treatments and that patient outcomes are not compromised.

Question. Numerous press reports indicate that the Department of Justice and the Federal Bureau of Investigation, in conjunction with the U.S. Attorney’s Office, have opened an investigation into the allegations that New York Governor Andrew Cuomo and his administration took actions that exacerbated the COVID-19 crisis in nursing home facilities, allegedly leading to increased fatalities. Will you commit to, if confirmed, fully cooperate with any investigation that examines whether the State of New York, Governor Cuomo himself, Governor Cuomo’s staff, or the Cuomo Coronavirus Task Force obstructed justice or violated federal guidance by pressuring nursing home facilities to accept patients who tested positive for COVID-19?

Answer: I am deeply committed to protecting our most vulnerable Americans by addressing the disproportionate impact of COVID-19 on our seniors and nursing home residents, but if I am fortunate enough to be confirmed, I will not have any role in the Department of Justice or Federal Bureau of Investigation decision making with respect to this matter. At HHS, we will follow the law and carry out our mission to protect people’s health care.

Private Insurance

Question. How would President Biden’s proposal to lower the Medicare eligibility age affect Medicare’s already precarious financial situation and would such a plan require raising taxes?

Answer: President Biden has proposed to allow Americans to enroll in Medicare at an earlier age using general revenue, not the Medicare Trust Funds. At the same time, this Administration knows the importance of lengthening the solvency of the HI Trust Fund because Medicare's current beneficiaries depend on it. I am committed to working with you and your colleagues on solutions both to extend the life of the Medicare HI Trust Fund and to expand health care coverage.

Question. Idaho has proposed or implemented several reforms in an attempt to diversify private insurance options so that consumers can choose a plan that best fits their needs and their budget. Several years ago, Idaho sought to combine Medicaid and private market innovation waivers to better coordinate insurance options and lower patient costs. Unfortunately, this approach was rejected because of overly-stringent statutory and regulatory requirements. Meanwhile, Idaho insurers have started offering renewable short-term, limited duration plans, which are less expensive than those offered on the exchange.

- I strongly support the right of states, as the primary regulators of the individual market, to adopt innovative solutions that benefit consumers. How do you view HHS's role in the individual market, and what reforms would you propose that could impact the types of plans offered to consumers?

Answer: Making sure that all Americans have access to quality, affordable health care is one of the Biden Administration's top priorities. If confirmed as Secretary of HHS, I will work to identify opportunities that ensure all Americans can access the care that they need and look forward to working with states to help improve health care for their residents.

Question. As states invest in their health systems and public health infrastructure, many could choose to address coverage gaps or alternative coverage options through Affordable Care Act Section 1332 waivers. Would you support states using these waivers to increase coverage in innovative ways of their own choosing? Are there policies that you consider inappropriate for a waiver?

Answer: I support innovative approaches to make sure that all Americans have access to quality, affordable health care, and I believe Section 1332 waivers can be one tool states can use to achieve such results. If confirmed as Secretary, I look forward to working with states to help improve health care for their residents.

Question. Do you support the use of existing enforcement mechanisms for Affordable Care Act subsidies? Should the federal government claw back funds if audits of an individual's income show that the individual is not eligible for the subsidy?

Answer: The Affordable Care Act gives millions of Americans access to quality, affordable health coverage. If confirmed, it will be my job to ensure that we are following and enforcing applicable laws and regulations.

Waste, Fraud and Abuse

Question. Careful stewardship of public resources is essential, both to maintaining our citizens' trust in their government, and to ensuring that government programs are effective. HHS is an enormous entity and prudent management of its agencies will require close scrutiny from its leadership. However, the loss of California's federal pandemic funding to fraudsters over the past year suggests that this careful scrutiny has not been a priority to you as Attorney General.

- What initiatives would you undertake to ensure careful stewardship of the trillion-plus dollars in annual spending that HHS oversees, ensuring that each dollar is spent consistently with the law and the intent of Congress?

Answer. At the California Department of Justice, our team has cracked down on Medicare and Medicaid fraud to protect these lifelines, recovering almost \$1 billion in just the last three years from defendants that defrauded California's State's Medicaid program with false claims for payment, and in 2020, we expanded the Bureau of Medi-Cal Fraud and Elder Abuse to its own division so we could better investigate and prosecute fraud. This has been a priority for me as Attorney General because it is critical we are being good stewards of taxpayer dollars and making sure our health programs are efficient. If I am confirmed as HHS Secretary, I would continue this focus and would like to work with you and the Congress to ensure strong oversight of federal programs and continue a bipartisan focus on reducing waste, fraud and abuse.

Question. On November 30, 2020, then Chairman of the Finance Committee Chuck Grassley sent a letter to the Office of the Inspector General of the Department of Labor seeking an investigation into California's Employment Development Department (EDD), with particular attention to fraud and the EDD's practice of mailing documents that contain individuals' social security numbers.

A November 23, 2020 letter to California Governor Gavin Newsom, with you as a carbon-copied recipient, from District Attorneys from various areas of the state who were on the California District Attorney's Statewide EDD Fraud Task Force requested a personal meeting and request for state officials to become involved in "halting what appears to be the most significant fraud on taxpayer funds in California history."

A December 3, 2020 Los Angeles Times article on the "tsunami" of prison unemployment fraud in California, which the article identified was fueling street crime, reported that "Multiple district attorneys interviewed by the Times said they are frustrated that state officials, including state Atty. Gen. Xavier Becerra, have not taken leadership in what some have described as the biggest taxpayer fraud in California history."

A January 28, 2021 Los Angeles Times article identified that state officials in California have "confirmed more than \$11 billion in fraud, and are investigating \$19 billion in other, suspicious claims for potential fraud." The magnitude of fraud in largely federally-financed unemployment programs in California—upward of \$30 fraudulent or suspicious payments and claims—is staggering, the largest fraud in California history, and widely reported for quite some time.

Despite all of this, since warning signals were sounded in at least late November of last year, a scan of the California Attorney General's press releases does not appear to identify any response to multiple calls for state officials to get involved in battling fraud. Instead, during the period

November 23, 2020 through February 25, 2021, there were at least 25 press releases directed at political activities by your office against the Trump administration.

Oversight and protection of federal taxpayer resources is a responsibility of federal government officials, including the Department of Health and Human Services (HHS). Any Secretary of HHS, which is responsible for an enormous amount of payments of federal taxpayer resources, must take fraud seriously and devote requisite resources to battle fraudsters. Money intended for unemployment insurance payments, or payments from HHS, that ends up in pockets of fraudsters is money that does not go to those truly in need.

Given that you were warned about unemployment insurance fraud, and asked to respond, at least by the end of November last year, please explain:

- a. When were you first asked to respond to California's massive unemployment fraud?
- b. Why multiple district attorneys interviewed by the Los Angeles times in late November or early December of last year reportedly identified their frustration over lack of action by state officials regarding unemployment compensation fraud and their assessment that you had "not taken leadership" in the face of the biggest taxpayer fraud in California's history?
- c. What actions did you take, and when, to combat unemployment compensation fraud in California (and please provide supporting documentation)?
- d. How many full-time equivalent hours of work in the California Attorney General's office were devoted to battling unemployment fraud relative to hours devoted to activities to battle the Trump administration during the period between November 23, 2020 and February 25, 2021?

Answer: At the California Department of Justice, we have made combating fraud a serious priority. When the department has been given primary authority combatting fraud such as in the Medicare and Medicaid program, we have cracked down on this fraud to protect these lifelines, recovering almost \$1 billion in just the last three years from defendants that defrauded California's State's Medicaid program with false claims for payment, and in 2020, we expanded the Bureau of Medi-Cal Fraud and Elder Abuse to its own division so we could better investigate and prosecute fraud. In regard to other programs, the California Department of Justice provides support to investigators in departments like the California Employment Development Department investigators when requested. In investigations where the California Department of Justice has found fraud in any public benefits program, we primarily refer those cases to district attorneys who carry out the vast majority of criminal prosecutions in California. If I am confirmed as HHS Secretary, I would continue this focus and would like to work with you and the Congress to ensure strong oversight of federal programs and continue a bipartisan focus on reducing waste, fraud and abuse.

Medicaid

Question. What would be your top Medicaid priorities?

Answer: The President has made clear his commitment to protecting and strengthening Medicaid so that this critical program can continue to provide life-saving access to care for millions of Americans. Medicaid will also continue to play an essential role in the Biden Administration's

response to the COVID-19 pandemic. If confirmed, I will work to ensure that people have access to quality and affordable care, and to ensure that Medicaid makes progress on addressing the major health care challenges facing our country, including maternal health.

Question. Data infrastructure in state Medicaid programs is extremely outdated. Historically, state Medicaid programs have attributed this to a lack of focus on improving data infrastructure among competing priorities. If confirmed, would you prioritize improved data systems at the state level to promote the sharing of data—such as claims, laboratory results, and eligibility information—between state systems and data sharing with the federal government?

Answer: Medicaid data is an important tool for improving health equity and access to health care. I believe we need better data because good data leads to good policy. If confirmed, I look forward to partnering with states to improve Medicaid data.

Question. You have highlighted the need to stop consolidation in California that gives hospitals unfair market power. I am interested in how this view may influence your position on the use of restrictive networks by insurance companies to drive down cost. For example, if a major hospital system chooses not to enter into a contract with any Medicaid managed care companies in a state, would you have HHS intervene at the federal level or leave that to the companies and state to resolve?

Answer: As Attorney General in California, I worked to tackle the issue of hospital consolidation. If confirmed, I will enforce the laws and regulations on the books and work to ensure that individuals have adequate access to affordable, quality health care.

Question. If confirmed, would you rescind Medicaid Section 1115 waivers that were approved in the prior administration? If so, could this create considerable disruption and prevent the adoption of waivers, given state Medicaid operations could be changed with each new Administration?

Answer: Medicaid is an important lifeline for many American families. Section 1115 demonstrations can be invaluable in allowing states to pursue innovative ideas through Medicaid. If confirmed, I will work to ensure that states' Medicaid section 1115 demonstrations promote the objectives of the Medicaid program and that these demonstrations are approved in accordance and compliance with the Medicaid statute.

Question. The pipeline for new drugs and therapeutics is changing rapidly and dramatically. Medicaid remains the primary payer for rare disease treatments, yet the Medicaid Drug Rebate Program (MDRP) has not evolved to keep up with new technologies, like cell and gene therapies. Should the MDRP be updated to ensure patients with rare diseases, including cancers and sickle-cell disease, can receive the treatments they need? How would you address affordability without causing innovators to reduce or eliminate investments in cell and gene therapies out of fear of government involvement?

Answer: Medicaid is a crucial lifeline for ensuring that Americans with low incomes, especially those with complex health care needs, have adequate access to quality health care, including

lifesaving therapies. We need to foster innovation in medical technology to encourage the development of new therapies. If confirmed, I look forward to working with you to ensure that Medicaid beneficiaries have access to those therapies.

Question. If confirmed, will you commit to allowing prescription drug value-based arrangements in Medicaid to expand flexibility and coverage of lifesaving treatments, especially for cell and gene therapies?

Answer: I believe that people should have timely access to lifesaving innovative therapies, including prescription drugs, biologics, devices, and other medical products such as cell and gene therapies. We need to foster innovation in medical technology to develop new lifesaving therapies. If confirmed, I look forward to working with you and other Members to find solutions to address the high cost of new therapies.

Question. In your role as Attorney General, how have you worked to ensure federal Medicaid funding does not go to non-citizens (a requirement under Medicaid) even as California allows non-citizens under 26 years old to be covered by its Medicaid program? How do you ensure accountability related to the bifurcated federal and state funding streams?

Answer: The law does not allow people with undocumented status in this country to receive federal Medicaid benefits except in very rare circumstances. If confirmed, it will be my job to make sure that the Department follows the law.

Miscellaneous

Question. The Secretary of Health and Human Services serves as a trustee on the Board of Trustees of the Federal Old-Age and Survivors trust fund and the Federal Disability Insurance trust fund. As a trustee, you would, if confirmed, have a role in helping to develop annual “trustee reports” on the financial condition of the trust funds. In 2017, allegations were made that a single public trustee for Social Security somehow forced insertion of assumptions into models used to project the future finances of Social Security that led to the “playing up the potential future insolvency of the program.” One piece of evidence to support the allegations was that the Chief Actuary for Social Security wrote a public statement of actuarial opinion containing some sort of public rebuke of questionable elements of the 2015 Social Security trustee report. The Chief Actuary’s Statement of Actuarial Opinion from the 2015 report is available on the Social Security Chief Actuary’s website (on pp. 256-257 of <https://www.ssa.gov/oact/TR/2015/tr2015.pdf>). Given that you will assist in developing trustee reports if confirmed, it is important to know that you have knowledge of and sound judgement regarding Social Security trust funds. Do you agree that the Statement of Actuarial Opinion of the 2015 trustee report represents a public rebuke of questionable elements of the trustee report—elements that represent assumptions used to project the future finances of Social Security to play up the potential future insolvency of the program?

Answer: If confirmed as Secretary, I can commit to you that we will work with you to give you and this committee the information you need to make the right decisions with respect to Medicare.

Question. In response to a questionnaire sent to you by the Senate Committee on Finance, you included the following: “I served on the Ways and Means Committee for two decades, where I focused on protecting and strengthening Medicare, Medicaid, and health care payments and program financing, and where, in 2015, I led efforts to successfully stave off roughly 20 percent cuts in Social Security Disability Insurance.” Republicans on the Finance Committee, led at the time by then-Chairman Hatch, worked with Republicans and Democrats in the House, and Obama administration officials, to put in place reforms to the Disability Insurance program at Social Security to make it better for beneficiaries and taxpayers. Unfortunately, Senate Democrats at the time took the position that nothing should be changed, aside from taking resources from the Old-Age and Survivors (“retirement”) trust fund and giving those resources to the Disability Trust Fund—something they referred to as a “clean reallocation.” The reforms that then-Chairman Hatch led from the Senate, and a reallocation of resources between trust funds, ultimately became law. None of those reforms privatized anything or cut benefits for anyone, aside from one change that was inserted by the Obama administration to cut benefits for certain upper-earners, and the reallocation ensured that Disability Insurance benefits did not have to be cut, which otherwise would have occurred. However, it is not clear the sense in which you “led” efforts in the House Ways and Means Committee to arrive at what became the reforms. Can you provide evidence of how you led the House efforts, such as legislation that you had sponsored that ultimately ended up in the Disability Insurance reform package?

Answer: As chairman of the House Democratic Caucus and Ranking Member of the House Ways and Means Subcommittee on Social Security, I was deeply committed in this effort to preventing cuts to Social Security, including introducing legislation, as part of this debate.

Question. During your tenure at the House Ways and Means Social Security Subcommittee, you said numerous times that “Social Security has not added one penny to our deficit and our debt.” I don’t believe that Social Security has contributed a great deal to deficits and debt, but to be honest with respect to government accounts of taxpayer resources, there have been contributions.

In his book title “Stress Test: Reflections on Financial Crises (Crown Publishers, New York, 2014), former Treasury Secretary Timothy Geithner wrote the following: “...I objected when Dan Pfeiffer wanted me to say Social Security didn’t contribute to the deficit, but it did contribute. Pfeiffer said the line was a ‘dog whistle’ to the left, a phrase I had never heard before. He had to explain that the phrase was code to the Democratic base, signaling that we intended to protect Social Security.”

- a. Do you agree with Secretary Geithner that Social Security has contributed to the deficit?
- b. When you repeatedly made public statements that “Social Security has not added one penny to our deficit and our debt,” were you being truthful, or sounding a “dog whistle” to the left as, according to Geithner, former Obama administration official Dan Pfeiffer characterizes such statements?

Answer. I am committed to protecting benefits for American seniors, and if I am confirmed as HHS Secretary, my commitment will extend to efforts to protect Medicare and seniors’ benefits, and I hope we can find common ground to work together on solutions to strengthen these lifelines.

Question. As Attorney General, you filed 122 lawsuits against the Trump Administration, with some of these lawsuits related to HHS programs. The sheer volume is indicative of how active states can be when they are philosophically opposed to the Administration in power. What impact would the threat of lawsuits or actual lawsuits filed by states against HHS have on how you would run the department?

Answer.

Answer: If I am confirmed as HHS Secretary, I will follow the law, and we will comply with the law when implementing the President's agenda and the laws passed by Congress.

Question. President Biden announced your nomination for HHS Secretary simultaneously with his nomination of Dr. Vivek Murthy as Surgeon General. Dr. Murthy has in the past identified gun violence as a public health issue. Do you agree with Dr. Murthy's opinion that gun violence is a health care issue, and if so, how would you use your position as HHS Secretary to address it?

Answer: The American Public Health Association lists gun violence as a public health issue. If I am confirmed as HHS Secretary, I will support ongoing peer-reviewed research efforts at CDC and NIH, and implement the President's agenda.

Question. The U.S. Supreme Court recently enjoined enforcement of California's restrictive rules on gatherings for religious ceremonies. Indeed, some in the public health community have said that California's extreme restrictions, including on gatherings, may have been counterproductive. How, as HHS Secretary, would you balance advocacy for public health with respect for Constitutionally-guaranteed liberties, including religious freedom?

Answer: As a person of faith myself, I believe deeply in religious freedom. It is a protection in our Constitution that makes the United States so unique and special. This pandemic continues to disrupt our daily lives and routines, and we need to be vigilant in mitigating the spread and protecting our fellow citizens. If confirmed as HHS Secretary, I will follow the law and Constitution in all our efforts to implement the President's agenda.

Senator Chuck Grassley's (IA) Questions for-the-Record
for Health & Human Services Secretary-Nominee Xavier Becerra
Submitted February 26, 2021

Questions

1. During the last two years as chairman of this committee, I've focused some of my oversight on what steps the Department of Health and Human Services has taken to detect and deter foreign threats to taxpayer-funded research. As part of my oversight, I've also worked to ensure that the Department's Office of National Security is given full, complete, and consistent access to all Intelligence Community information involving threats to the nation's healthcare, such as COVID-19. That office has gained access to some Intelligence Community elements but more must be done.

- a. Do you agree that China is a significant and consistent bad actor when it comes to stealing U.S. taxpayer-funded intellectual property and academic research? If so, what will you do to protect American work product from the communist Chinese government's theft and espionage activities? If not, why not?
- b. If confirmed, do you intend to work with the Intelligence Community to better understand the origins of COVID-19 and China's involvement? If not, why not?
- c. If confirmed, will you commit to briefing this Committee on those efforts?
- d. If confirmed, will you commit to updating me on the functions of the Office of National Security and how it's interacting within the Intelligence Community?

Answer: If confirmed, I look forward to working with the Committee to protect research from undue foreign influences. As the president has said, China is a serious competitor, and I am deeply concerned about China's record of stealing intellectual property and engaging in coercive and malign economic practices. If confirmed, I will work with my colleagues to protect American work products from these activities. and I also am committed to working with the intelligence community and other partners to understand the origins of COVID-19, and I will keep the committee apprised.

I recognize the critical role of scientific collaborations based on principles of scientific excellence, integrity, responsibility to the public, and fair competition in advancing its mission. The National Institutes of Health (NIH) has taken a number of steps to address these risks, including clarifying expectations around foreign affiliation disclosures, financial conflicts of interest, and research support from foreign governments. Protecting the integrity of science is a priority for me to ensure that U.S. institutions and the American public benefit from their investment in biomedical research. If confirmed, I will work closely with NIH in their efforts to protect research integrity.

2. Congress's ability to acquire information from Federal agencies is critical to its constitutional responsibility of conducting oversight of the executive branch. If you are confirmed, will you commit to providing thorough, complete, and timely responses to requests for information from members of this Committee, including requests from members of the Minority?

Answer: As I committed during Thursday's hearing, I will provide prompt responses in writing to requests from any members of this Committee.

3. Science tells us that an unborn child has many of the neural connections needed to feel pain, perhaps as early as eight weeks and most certainly by 20 weeks fetal age. Providing health care to unborn children and their mothers can help reduce infant mortality rates in low-income communities, research also suggests. Some States already offer prenatal care and other health services to unborn children through the Medicaid program. What is your view on whether unborn children should be entitled to Medicaid coverage, and do you believe that the federal government has a role to play in encouraging such coverage?

Answer: Medicaid is an important source of pre- and post-natal care, and if I am confirmed, I will work to ensure that pregnant people have access to quality health care that improves their own health and the health of their babies. I look forward to working with members of this Committee and Congress to expand access to affordable quality care including through the Medicaid program.

4. Last year, Senator Wyden and I released a report to colleagues exposing the extensive financial ties between manufacturers of opioids and opioid-related products and tax-exempt organizations. This investigation found that manufacturers made more than \$65 million in payments to a handful of tax-exempt organizations since 1997 to amplify their business interests. Would you agree that the Physician Payments Sunshine Act should be expanded to include these types of transactions so that the public is aware them?

Answer: As Attorney General, I have acted to combat the opioid crisis, including holding drug makers accountable. As California Attorney General, I worked to shine a light on the relationships between opioid companies and their consultants. The Open Payments Program established by your Physician Payments Sunshine Act promotes transparency and accountability by making information about certain financial relationships available to the public. If confirmed, I look forward to working with you on ways to promote transparency of the financial ties of opioid manufacturers.

5. In 2020, I cosponsored the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act and it was signed into law. The law extended the Drug Enforcement Administration's temporary scheduling order to proactively control deadly fentanyl analogues. Fentanyl-related overdose deaths continue to rise and sophisticated drug trafficking organizations manipulate dangerous substances to skirt the law, so this critical law placed fentanyl substances in Schedule I so that they can be better detected and criminals can be held accountable for their actions. The law sunsets in May of 2021. You as Attorney General of California signed a letter in December 2019 joining all 55 other state and territory attorneys general asking Congress to permanently codify a temporary emergency scheduling order keeping fentanyl-related substances classified as Schedule I drugs. If confirmed, do you support permanently codifying a temporary emergency scheduling order keeping fentanyl-related substances classified as Schedule I drugs?

Answer: I recognize that fentanyl and fentanyl analogues pose a significant danger, and are responsible for far too many deaths every year. I continue to believe that we should place sensible restrictions on these substances that pose harm. I am also cognizant of the vital role HHS plays in the scheduling process and the need to ensure that our actions are not inadvertently stifling the type of research that is needed to develop new drugs that can help address the opioid crisis in America. I commit that, if confirmed, I will work with you on legislation to ensure the appropriate scheduling of the fentanyl and fentanyl analogues that pose a danger.

6. In 2003, Congress added an outpatient prescription drug benefit to the Medicare program called Part D. We did it the right way for seniors and taxpayers by allowing the forces of free enterprise and competition to drive costs down and drive value up. Key to designing this program was ensuring there was competition, not government mandates – to drive innovation, curb costs, expand coverage, and improve outcomes. This is why we wrote the non-interference clause into the law. The non-interference provision expressly prohibits Medicare from: negotiating drug prices, setting drug prices, and establishing a one-size-fits-all list of covered drugs. That language doesn't prohibit Medicare from negotiating with drug makers. It prohibits the government from interfering in the negotiations that are actually happening. The Congressional Budget Office has repeatedly stated that repealing non-interference wouldn't save money unless there was a restrictive formulary, therefore restricting patient access to critical drugs. President Biden, then as a candidate for president, said he wanted to “allow Medicare to negotiate lower drug prices” and last Congress the U.S. House of Representatives passed legislation that sought to give the Department of Health and Human Services (HHS) Secretary “broad power to negotiate lower drug costs now.” As a member of Congress, you cosponsored legislation that would have enabled the Secretary of HHS the ability to negotiate with pharmaceutical manufacturers. Does the Secretary of HHS have the authority to circumvent the 2003 law to negotiate prescription drug prices in Medicare? If confirmed, does the Biden administration support changes to Medicare's non-interference clause to stifle the free market that includes amending or rescinding the non-interference clause provision?

Answer: Like President Biden, I believe we must do all we can to lower the costs of prescription drugs and make them more accessible for Americans. If confirmed, I look forward to working with Congress to build upon the goodwork you did in the Finance Committee on this important issue and finding ways to achieve these important goals.

7. I recently requested the CDC to publicly release its weekly formula – including the state-by-state pro-rata share for allocating vaccines to states, territories, and tribes. No matter where you live, Iowans and all Americans should have fair access to a vaccine. Iowans must have confidence we are receiving our fair share of vaccines. I appreciate the CDC routinely releasing state-by-state vaccine data for allocation, doses delivered, and administration. However, it is difficult to determine based on this data whether Iowa is receiving its fair share. This publicly reported data can also lag. Will the Biden administration commit to the CDC publicly releasing its state-by-state weekly pro-rata share of vaccine allocations?

Answer: If confirmed, I look forward to working with the Department to ensure there is transparent and equitable distribution of vaccine allocations.

8. In Iowa, grandmothers health plans have enabled many middle class Iowans to keep the health plans and doctors they like at a reasonable price since the Affordable Care Act was implemented. For example, over 56,000 Iowans are covered by grandmothers health plans. To put this in context, about 59,000 Iowans signed up for the federal health insurance exchange in 2021. Iowans have chosen health plans that meet their individual needs. Currently, grandmothers health plans' existence is determined by the Department of Health and Human Services (HHS) through the Centers for Medicare & Medicaid Services (CMS) annually through non-enforcement extensions. If confirmed, are you committed to maintaining these affordable, consumer-chosen health plan options for Iowans by extending the non-enforcement authority for grandmothers health plans annually? Or do you support actions to remove choice for Iowans requiring them to select a one-size-fits-all Obamacare plan?

Answer: Making sure that all Americans have access to quality, affordable health care is one of the Biden Administration's top priorities. If confirmed, I will examine rules and other policies to ensure all Americans can access the care that they need.

9. I support transparency in the 340B Drug Pricing Program. The previous administration finalized a 340B Drug Pricing Program Administrative Dispute Resolution regulation that went into effect in January 2021. This final rule sets forth the requirements and procedures for the 340B Program's administrative dispute resolution (ADR) process. The rule establishes a 340B Administrative Dispute Resolution Board to review claims. In addition, on December 30, 2020, the Department of Health and Human Services' Office of the General Counsel released an advisory opinion. If confirmed, are you committed to the continued implementation of the 340B Drug Pricing Program Administrative Dispute Resolution final rule and Office of General Counsel's advisory opinion? If confirmed, what other detailed steps will the Biden administration take to ensure transparency in the 340B Drug Pricing Program?

Answer: The 340B Drug Pricing Program is an indispensable program for our safety-net providers serving some of our neediest populations. If confirmed, I look forward to working with you and other Members of Congress to uphold the law and ensure this vital program is able to support vulnerable communities.

10. In 2017, I sponsored the Over the Counter Hearing Aid Act with Senator Warren, which was included in the FDA Reauthorization Act of 2017. It required the FDA to issue a regulation by August 2020 establishing the requirements for products in this category. This legislation was based on recommendations put forth by the Presidential Council of Advisors on Science and Technology and the National Academies of Science Engineering and Medicine to increase consumer access to hearing aid technology and decrease costs associated with hearing aids. The Food and Drug Administration has not completed rulemaking on this. If confirmed, will you work to prioritize rulemaking so consumers can access affordable help for hearing loss that Congress intended?

Answer: Thank you for your leadership on this issue. I commit that, if confirmed, I will support FDA in their work to ensure availability of over-the-counter hearing aids. I recognize this as a public health priority as hearing loss can have a negative effect on communication, relationships, and other important aspects of life.

11. A Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report found the use of telehealth increased 154% during the last week of March 2020 during the emergency of COVID-19 compared to the same period in 2019. We know the use of telehealth has continued throughout the COVID-19 pandemic. The Centers for Medicare & Medicaid Services (CMS) throughout the public health emergency authority has allowed more than 80 services to be furnished via telehealth. The data and response from patients and providers prove permitting telehealth services is a positive action to improve access and care. This last Congress, we provided permanent coverage for mental health telehealth visits under Medicare, which is helpful during the pandemic and will remain critical for many Americans afterwards. If confirmed, are you committed to working with Congress and in the executive branch to extend telehealth flexibilities in Medicare beyond the pandemic? Additionally, some providers, including community health centers, face regulatory barriers based on provider type or site of service. If confirmed, do you support removing telehealth barriers for certain providers?

Answer: Telehealth is an important tool to improve health equity and improve access to health care. Health care should be accessible, no matter where you live. If confirmed, I will look at the telehealth flexibilities developed for the current public health emergency and determine how we can build on this work to improve health equity and improve access to health care, including at community health centers.

12. If confirmed, does the Biden administration plan to change the state-federal partnership in response to the COVID-19 pandemic by placing conditions of participation, including specific public health mitigation efforts, on states in order to receive vaccine doses?

Answer: If confirmed, I would work within HHS to determine the best way to ensure transparent and equitable distribution of vaccine allocations.

13. If confirmed, does the Biden administration plan to change the state-federal partnership in response to the COVID-19 pandemic by placing conditions of participation, including specific public health mitigation efforts, on states in order to receive federal funding to respond to COVID-19?

Answer: If confirmed, I would work within HHS to determine the best way to ensure transparent and equitable distribution of COVID-19 relief funding.

14. I am a proud champion for greater transparency in government. This extends to the need for greater transparency in health care. I am the author of the Physician Payments Sunshine Act, which requires public disclosure of payments between drug companies and doctors and have introduced legislation to apply the same disclosure rules to nurse practitioners and physician assistants. In 2019, the Trump administration issued two major rules requiring price transparency for hospitals and health insurance companies. The rules took effect in January 2021. This effort shines a light on the health care industry that is all too often shrouded in secrecy. While Congress can build upon the rules, consumers can finally see sunshine in health care pricing. I have cosponsored legislation to codify the two health care price transparency rules. This transparency will bring more accountability and competition to the health care industry. If confirmed, do you

plan to maintain, modify, or rescind these health care transparency rules that give consumers the ability to compare prices online so they can make an informed choice about what's best for them and their families?

Answer: . If I am fortunate enough to be confirmed, I will ensure that the Department continues to take steps to improve price transparency, so consumers can look behind the curtain to understand how providers and insurers are operating.

15. As a direct result of the Affordable Care Act's one-size-fits-all approach, many Iowans have been priced out of health insurance. To rectify this, the Trump administration and Iowa Insurance Division enabled Iowans more choice and competition in the health care marketplace by enabling and expanding short-term limited-duration insurance (STLDI). This gives Iowans access to health insurance with consumer protections. If confirmed as Secretary of Health and Human Services, will you stifle competition and limit the health plan choices for Iowans? Specifically, will you modify or rescind the current regulations enabling Americans to purchase STLDIs?

Answer: Making sure that all Americans have access to quality, affordable health care is one of the Biden Administration's top priorities. If confirmed, I will examine rules and other policies to ensure that plans provide Americans access to the care that they need.

16. It is important to give people affordable options for health insurance. Small business owners, like Iowa farmers, want to be able to provide insurance for their employees. Association Health Plans are a way for these small businesses to band together to expand access to health insurance and drive down costs. I have introduced legislation and support efforts to expand the pathway to affordable and accessible health care remaining open to employees across America. Association Health Plans allow small businesses to join together to obtain affordable health insurance as though they were a single large employer. The coverage offered to association members is subject to the consumer protection requirements that apply to the nearly 160 million Americans who receive coverage from large employers. If confirmed, will you as Secretary of Health and Human Services modify or rescind current regulations enabling employers and employees access to Association Health Plans removing the ability to access affordable health insurance?

Answer: Making sure that all Americans have access to quality, affordable health care is one of the Biden Administration's top priorities. If confirmed as Secretary of HHS, I will examine all rules and policies to ensure all Americans can access the care that they need.

17. I support access to affordable health care coverage for all Iowans, regardless of their health status or pre-existing conditions. Americans want to be in control of their own health care. National, single-payer health systems do not allow that. The Affordable Care Act took options away from people and adopting a single-payer system will make that worse. A national, single-payer health system would eliminate private health insurance for nearly 200 million Americans and require middle-class Americans to pay much more in taxes. Single-payer health care would also dramatically increase government spending substantially, fail to meet patient needs quickly, reduce provider payments rates and reduce quality of care, and the government would have more

control over health care. It also threatens the benefits that current seniors on Medicare have paid into the system their entire working lives. If confirmed, do you intend to take administrative actions to implement the vision of a one-size-fits-all government-run health care scheme like single-payer? If so, please describe what authority you believe you have to take such actions?

Answer: President Biden has made it very clear that his goals for improving the American health care system begin with building on the successes of the Affordable Care Act, and I am committed to working toward that goal.

18. If confirmed, will you take actions as Secretary of Health and Human Services that stifles innovation and competition in health care?

Answer: Thank you for this question. I believe it is important to foster innovation and competition in our health care system. Americans should have access to health care services and products at an affordable price.

19. Throughout the pandemic, the Trump administration gave states through the Medicaid program more flexibility to continue to care for and protect individual Americans and communities at most risk. If confirmed, will you work throughout the public health emergency to maintain these flexibilities for states?

Answer: I agree that these emergency flexibilities have played an important role in enabling state Medicaid programs to respond effectively to the COVID-19 pandemic. If confirmed, I am prepared to work closely with state Medicaid programs to ensure that they have the flexibility they need to care for Medicaid beneficiaries throughout the public health emergency.

Cornyn

Vaccine Allocation

In order to streamline the distribution of COVID-19 vaccine from manufacturers to the States, the Trump administration created a pro rata formula that the Biden Administration has left in place. The formula requires federal administrators to run an automated algorithm in a program called Tiberius, which then calculates the division of vaccine doses nationwide based on the size of each state's adult population. While Texas has received the second-most vaccine doses in the country, an analysis of Centers for Disease Control and Prevention data has shown the State ranks near the bottom, 49 out of 50, when it comes to doses per 100,000.

The state population numbers used in the algorithm are derived from the U.S. Census Bureau's 2018 data. Texas is one of the youngest states in the nation, with 25.5% of the state population under 18 years old. With that said, Texas media has noted "[s]till, even when adjusted for adults only, Texas ranks 48th."

- What steps would you take as Secretary to ensure Texans receive an equitable share in future distributions?

Answer: If confirmed, I commit to working with the Department to ensure equitable distribution of vaccinations for states and local jurisdictions, including the state of Texas.

1115 Waivers

In January, CMS granted Texas a 10 year extension of its Medicaid 1115 waiver, providing critical funding and stability for the program and Medicaid providers. The extension carries forward many policies and programs *approved across two different Administrations* that ensure quality outcomes, transparency, and greater access to care. A one size fits all approach cannot meet the needs of a state as large and diverse as Texas, and the flexibility inherent in the 1115 waiver gives the state the authority to employ innovative solutions.

There are concerns that the Biden administration will seek to withdraw approval of waivers that were granted at the end of the Trump administration. It is a dangerous precedent for the first action of a new administration to undo the final actions of the previous administration as states will no longer be able to trust in their negotiations with CMS.

- Will you commit to maintaining Texas' waiver extension *as approved*?
- Will you pledge to work with Texas to ensure the stability of the healthcare safety net, which is heavily dependent on funding provided through the 1115 waiver?

Answer: Medicaid is an important lifeline for many Texans. Section 1115 demonstrations can be invaluable in allowing states to pursue innovative ideas through Medicaid. If confirmed as HHS Secretary, I would work to ensure that states' Medicaid section 1115 demonstrations promote the objectives of the Medicaid program and that these demonstrations are approved in accordance with and comply with the Medicaid statute.

Foreign Threats to Research

Mr. Becerra, in 2019, this committee held a hearing on foreign threats to taxpayer funded research after multiple reports of espionage by the People's Republic of China. We have seen attempts by foreign entities like North Korea to steal intellectual property related to COVID vaccine development and I continue to hear concerns from research institutions in Texas.

- Do you believe that NIH and other funders of public research should consider cybersecurity protocols that institutions have in place when evaluating applications for research grant funds?
- What additional initiatives are you considering to ensure taxpayer funded research is protected from foreign threats?

Answer: If confirmed, I look forward to working with the Committee to protect research from undue foreign influences. As the president has said, China is a serious competitor, and I am deeply concerned about China's record of stealing intellectual property and engaging in coercive and malign economic practices. If confirmed, I will work with my colleagues to protect American work products from these activities. I also am committed to working with the intelligence community and other partners to understand the origins of COVID-19, and I will keep the committee apprised.

I recognize the critical role of scientific collaborations based on principles of scientific excellence, integrity, responsibility to the public, and fair competition in advancing its mission. The National Institutes of Health (NIH) has taken a number of steps to address these risks, including clarifying expectations around foreign affiliation disclosures, financial conflicts of interest, and research support from foreign governments. Protecting the integrity of science is a priority for me to ensure that U.S. institutions and the American public benefit from their investment in biomedical research. If confirmed, I will work closely with NIH in their efforts to protect research integrity.

ESRD

I have heard that some Medicare beneficiaries with End Stage Renal Disease (ESRD) are being denied access to certain therapies following the inclusion of calcimimetic medicines in the ESRD bundled rate. For example, I've heard that some dialysis centers are requiring patients to change or stop using a medicine now that it is part of the bundled rate. It is extremely disturbing that dialysis patients, a group that is already impacted by significant disparities, would be taken off a treatment for economic reasons by the dialysis center.

- What will you do to ensure that ESRD patients will continue to have access their calcimimetic treatment and what will you do to monitor patient outcomes in this area?

Answer: I agree that it is important for Medicare beneficiaries, particularly vulnerable groups such as those beneficiaries with ESRD, to have access to medically necessary treatments such as calcimimetics. If confirmed, I will work to ensure that Medicare beneficiaries continue to have access to these treatments and that patient outcomes are not compromised.

400,000 Medicare beneficiaries are on dialysis, and those patients have not benefited from any meaningful innovation in their standard of care in decades. Over the last several years I have joined colleagues on both sides of the aisle and worked with CMS, the patient community, and innovators to encourage adoption of a new policy to spur innovation in medical technology for Medicare patients under the ESRD bundled payment system. CMS has made significant progress, having created the TPNIES add on payment for innovation in medical technology used in the provision of dialysis services. However, our work is not done. CMS should better align its metrics for innovation and clinical improvements over existing technologies with the lens FDA uses to evaluate such improvements and innovations. And CMS should also extend by another year the period of time during which the add-on payment can be made, having established an application and qualification process via rulemaking that essentially negates the first year of the add on payment window. I will again work with my colleagues on legislation to make these additional improvements to the work CMS has already done, and hope that you will commit to working with me to achieve full success on this policy for Medicare patients in whatever is the most expeditious and achievable path.

- Will you commit to working with Congress to implement these policies and bring long overdue innovation to this vulnerable group of patients?

Answer: I agree that it is important to foster innovation in medical technology that improves health care outcomes. If confirmed, I look forward to working with Congress to improve access to innovative technologies to Medicare ESRD beneficiaries.

Drug Pricing - Rebate Wall

We continue to see participants in the pharmaceutical supply chain, including some manufacturers and PBMs, engage in behaviors designed to foreclose competition. One form of potentially anticompetitive behavior is known as a “rebate wall” or “rebate trap” – a practice that, while serving as [Attorney General for California](#), you acknowledged can foreclose competition and raise prices for consumers. Rebate walls occur when a firm with dominant market share requires a payer to prevent patients from accessing new innovation by coupling volume-based discounts with retaliatory measures such as the clawback of rebates. Rebate walls are especially problematic in therapeutic areas such as the autoimmune market where established medicines control considerable market share (i.e. patient volume) and have FDA-approval for multiple indications.

- A [recent report](#) found that removing rebate walls could save patients more than \$6,000 for high-cost (\$70,000 list price) infused biologics. Do you agree that a rebate wall can be problematic for patients, especially when it forecloses patient access to new, innovative, and often times lower cost brand and biosimilar options?

- As Secretary of HHS, how would you engage with FTC, FDA, and other agencies to address anticompetitive rebate wall practices? For example, how would you build upon the FTC and FDA’s ongoing work to address competition issues in the biosimilars market, including rebate walls?

Answer: Like President Biden, I believe we must do all we can to lower the costs of prescription drugs and make them more accessible for Americans who depend on these medications. Competition in the market has helped control the growth in spending on prescription drugs and as California Attorney General I made it my mission to ensure that the marketplace worked better. I believe that biosimilars have a role to play in containing the cost of expensive therapies by creating competition. I am committed to reducing drug prices and ensuring Americans have access to the drugs that they need. If confirmed as Secretary of HHS, I look forward to working with you to find ways to achieve these important goals. I will also work across the government to address barriers to reducing drug prices.

Biosimilars

Biologic medicines treat some of the most serious conditions such as cancer, diabetes, and inflammatory diseases. Treating these conditions also represents a significant cost burden to the Medicare Part B program and the patients it serves. Biosimilar medicines are approved by FDA to be as safe and effective to previously approved reference biologic products that have gone off patent. This represents the opportunity for high-value competition with savings estimates up to \$100B over the next 5 years.

- What role do you see high-value, off-patent products like biosimilars playing in the Medicare program in helping to ease Medicare spending and reduce patient cost?
- Will you commit to explore demonstration programs through CMMI or other authorities that allow savings from biosimilar adoption to be reinvested in patients and the health care system?

Seniors are paying the high-cost of prescription drugs. I introduced the Increasing Access to Biosimilars Act (S. 4134 in the 116th Congress) to encourage competition through the use of lower-cost biosimilars. The Increasing Access to Biosimilars Act would establish a five-year, voluntary demonstration program to allow providers to share in the savings created by the use of biosimilars. Medicare savings would be guaranteed as the shared savings payments are only available when the biosimilar ASP is less than the reference biologic ASP.

- Would you work with my colleagues and me to advance a biosimilars shared savings demonstration and test ways to encourage more biosimilar adoption?

Answer for 1-3: We can all agree that the cost of prescription drugs are too high. Seniors should never have to choose between a meal and their medications. Biosimilars have a role to play in containing the cost of innovative yet expensive biologic treatments by creating competition. As Attorney General, I helped to promote competition by taking on a number of pharmaceutical companies who restricted competition through “pay-for-delay” schemes, which delayed putting a

generic product on the market to compete with the brand-name product, therefore keeping the price of that brand name product high. If confirmed, I will continue to work on finding ways to lower drug costs and ensuring Americans have access to prescription drugs. As Secretary, I look forward to hearing your ideas for innovative models to do just that, and I look forward to working with you on this important issue.

340B - Contract Pharmacies

- Do you agree that the 340B statute does not mention contract pharmacies or define any role for them in the 340B program, and – notwithstanding that – contract pharmacies have pursued ways to generate revenue from their 340B patients, ultimately at cost to the federal government?
- As HHS Secretary, how do you plan to address recent increases in diversion and duplicate discounting in the 340B program?
- In your December 2020 letter to Secretary Azar, you noted that “some manufacturers are illegally conditioning 340B pricing on the provision of claims data to an agent of the manufacturer with insufficient compliance under HIPAA.” Assuming HIPAA were satisfied, would you still consider a manufacturer conditioning 340B pricing on the provision of claims data to a third party to be illegal?

Answer: The 340B Drug Pricing Program is an indispensable program for our safety-net providers serving some of our neediest populations. If confirmed, I look forward to working with you and other Members of Congress to uphold the law and ensure this vital program is able to support vulnerable communities.

Unaccompanied Alien Children Program

Mr. Becerra, if confirmed as Secretary of Health and Human Services, you would be responsible for supervising the Office of Refugee Resettlement (ORR) and its Unaccompanied Alien Children program. We are currently seeing a huge increase in apprehensions of unaccompanied migrant children (or UACs) along the border, particularly in the Big Bend and Del Rio Border Patrol sectors, where encounters have increased by 141 and 122 percent, respectively.

Many if not most of these children will ultimately be referred to the ORR UAC Program. Under the Flores Settlement Agreement, these children must be placed in non-secure, state-licensed facilities or placed with a family member or other sponsor.

- What is your plan with respect to HHS’s contracts with state-licensed facilities? Would you ensure that HHS has sufficient capacity to house children until they can receive at least preliminary merits hearings in their cases?

I am concerned about releasing children to sponsors while they are in removal proceedings. To the extent that we’re releasing to family members, we need to be sure that they are here legally and that they will be responsible for ensuring that the child shows up to the court proceedings.

And we need to be very conscious of the costs that such placements impose on state and local governments—which are already shouldering significant costs related to the COVID pandemic.

Answer: I appreciate your attention to this issue and the opportunity to answer this question. A guiding child welfare principle driving ORR's mission, along with legal requirements, is that children's best interests are served when he or she can safely be released to their family. HHS will release children without unnecessary delay to the care of appropriate sponsors, who are responsible for ensuring that children appear for any proceeding for which the children are a party. When a child is scheduled for a hearing before an immigration court while the child is in ORR care and custody, ORR arranges to transport the child to their hearings. ORR funds a national network of legal service providers who may represent children or appear as friends of the court at any immigration hearing the child is scheduled to appear.

ORR consistently seeks to balance permanent licensed bed capacity needs with being a good steward of taxpayer funds by closely monitoring migration patterns and reviewing historical trends in order to project program needs expediently and as accurately as possible. If confirmed, I will do everything in my power to ensure the safety and wellbeing of these vulnerable children.

Center for Innovation in Advanced Development and Manufacturing

During the Obama Administration, HHS created the Center for Innovation in Advanced Development and Manufacturing (CIADM) program. This was a public private partnership model that was created back in 2012 specifically to help protect Americans from the impacts of bioterrorism, of pandemic influenza and of other epidemics.

In response to the COVID-19 pandemic, HHS activated two CIADMs, one in Maryland and one at Texas A&M, as part of its COVID-19 response to domestically produce COVID-19 vaccine candidates and therapeutics. These CIADMs are serving as domestic manufacturers for the next tranche of vaccine candidates expected to be reviewed by the FDA – J&J, AstraZeneca, and Novavax, and working around the clock to manufacture these promising vaccine candidates. The program has not been without challenges, but the foresight of the Obama Administration to create the program and the quick action by the Trump Administration to activate these CIADMs show that the CIADM program could be a model to strengthen our domestic manufacturing capacity, strengthening our vaccine and therapeutics supply chain and helping ensure we can end this pandemic and respond to future public health emergencies quickly.

- **Are you familiar with the CIADM program?**

Answer: I am familiar with the CIADM program, which helps to ensure a sustainable domestic medical countermeasure infrastructure.

- **Will you commit to building on the successes of the CIADM program? No program is perfect of course – but this program clearly is playing a vital role in ending the pandemic domestically and likely globally.**

Answer: If confirmed, I look forward to working with the Biomedical Advanced Research and Development Authority (BARDA) to expand innovative solutions and strengthen our domestic manufacturing capacity.

Medicare Program Integrity

I'm very concerned about the amount of Medicare funds lost to errors, waste, fraud, and abuse. Previously, CMS expressed the need to “elevate program integrity, unleash the power of modern private sector innovation, prevent rather than chase fraud waste and abuse through smart, proactive measures, and unburden our provider partners so they can do what they do best – put patients first.” Also, Congress included language in the Fiscal Year 2021 appropriations encouraging CMS “to consider pilot programs using AI-enabled documentation and coding technology to address CMS’ top program integrity priorities and reduce administrative burden.” I think we can do more to harness the expertise used in the private sector to benefit our Medicare beneficiaries and safeguard the Medicare Trust Fund. I hope this is an area of policy that we can work on together.

- **Will you commit to working with this committee to prioritize the use of artificial intelligence and other emerging technologies to bolster Medicare program integrity and protect the Medicare Trust Fund?**

Answer: As California Attorney General, I cracked down on health care fraud. Fighting fraud and abuse is important for maintaining a strong Medicare program. It is my understanding that CMS has taken steps to explore the possibilities of artificial intelligence for program integrity purposes. If confirmed, I will work with the committee to make sure that we are good stewards of the Medicare program and taxpayer dollars.

Children’s Health

As HHS Secretary, you will oversee a number of programs and agencies important to children from health coverage programs vital to children’s health such as Medicaid and the Children’s Health Insurance Program (CHIP) to programs responsible for training the pediatric health care workforce like the Children’s Hospital Graduate Medical Education Program (CHGME) to pediatric research initiatives at the National Institutes of Health.

- What are your priorities for child health if confirmed?

Answer: Programs such as Medicaid and the Children’s Health Insurance Program (CHIP) are crucial lifelines for ensuring that children have adequate access to quality health care. I had the great honor to help expand CHIP as a Member of the House of Representatives, and have voted in support of reauthorizing the Children’s Hospital Graduate Medical Education Program (CHGME) . If confirmed, I would work to ensure children are receiving necessary health care so they can grow and thrive. I would also look to better ensure access to oral health and vision care for children, both necessary for children to thrive in school. And let us not forget that improving child health begins with ensuring maternal health. I will work tirelessly to reduce maternal and infant mortality and morbidity, using the expertise and resources across the many HHS agencies

whose missions include ensuring child health. I look forward to working with Congress, and with state and local partners to make sure that we are improving child health.

Medicaid and CHIP are critical programs for children, providing coverage for over 40 million children. Medicaid is also the backbone of the pediatric health care system providing care across the continuum from screenings and preventive to highly specialized diagnoses and treatments.

- What are your plans to strengthen this safety net for children and the providers who care for them?

Answer: If confirmed, I would work to support and strengthen crucial programs such as Medicaid and CHIP to ensure that children have adequate access to quality health care. In particular, I would look to better ensure access to oral health and vision care for children, while working to reduce maternal and infant mortality and morbidity. In addition, I would work to ensure that the providers who care for our children receive the support and resources they need to deal with the COVID-19 crisis and to make sure our children have access to quality care from the get-go.

The pandemic is having a profound impact on children's health and the providers who care for them.

- What are your immediate plans to address the current crisis in the increasing number of children facing severe mental, emotional and behavioral health challenges due to social isolation and the serious impact of the pandemic on the health of their families and caregivers?

Answer: I am deeply concerned about the impact of the COVID-19 pandemic on the mental, emotional, and other behavioral health outcomes of our children and their families and caregivers. I agree this must be an urgent national priority. If confirmed, I commit to working on this issue. In particular, we must ensure that we are fully leveraging the Medicaid and CHIP programs to connect children to the behavioral health care they need to navigate this unprecedented time and available SAMHSA funding to support behavioral health.

- The pediatric health care safety net has been affected by the pandemic in different ways than the adult health care system, with less direct federal financial support because they are not eligible for Medicare funding streams. What are your plans to sustain a stable pediatric health care system now and beyond the pandemic?

Answer: Medicaid and CHIP are lifelines to children and help form the fabric of the pediatric health care safety net. Over 77 million individuals are enrolled in those programs, and about half are children. It is critical that we work to support our pediatric health care safety net and pediatric health care providers during the COVID-19 pandemic and beyond. If confirmed, I would make it a priority to provide necessary support to pediatric providers.

The Children's Hospital Graduate Medical Education Program (CHGME) provides significant support for the training of pediatricians and pediatric specialists. But unfortunately, the funding

for this program still lags far behind the Medicare GME program – funding only half of what Medicare GME provides per resident.

- What are your plans to address this gap in training support for our nation’s pediatric workforce?

Answer: If confirmed, I will work to focus attention and resources to bolster our nation’s health care workforce, including those who work with pediatric populations. HRSA’s Children’s Hospital Graduate Medical Education (CHGME) and Developmental-Behavioral Pediatrics programs are key pieces in the overall workforce landscape. If confirmed, I look forward to working with Congress to continue training a high-quality, skilled pediatric workforce to help increase access to these services.

During the pandemic telehealth has played a major role in providing access to care for Medicaid beneficiaries, including children.

- How will HHS support the continued use and enhancements needed under Medicaid to ensure telehealth continues to enable access to care for children?

Answer: Telehealth is an important tool to improve health equity and improve access to health care. Health care should be accessible, no matter where you live. Medicaid has made great strides in expanding services available through telehealth, including pediatric services, during the public health emergency. If confirmed, I will look at the telehealth flexibilities developed for the current public health emergency and determine how we can build on this work to improve health equity and improve access to health care.

As you know, pediatric health care is organized differently than adult health care. Pediatric care is more regionalized and often results in children, especially those with complex health needs, having to travel across state lines for care. Under Medicaid, this can be challenging for them and their providers with different policies state to state. The Advancing Care for Exceptional Kids (ACE Kids) Act passed in 2019 and effective next year, is one step in addressing these inconsistencies and getting much needed national data to inform care improvements.

- If confirmed, how would you approach these cross-state challenges that children with complex needs face when traveling for needed care?

Answer: Programs such as Medicaid and CHIP are crucial lifelines for ensuring that children have adequate access to quality health care, especially those with complex needs. I had the great honor to help expand CHIP as a Member of the House of Representatives. If confirmed, I will work to ensure children are receiving necessary health care so they can grow. I look forward to working with other departments across the Administration, Congress, and with state and local partners to make informed decisions that address the specific needs of children with complex medical conditions.

A major focus in health care among policy makers has been on pursuing delivery system reforms that improve quality and reduce costs. The federal government has traditionally focused more on

adult populations rather than the needs of children in these reforms. As a result, Medicaid for children still lags behind Medicare in supporting improvements in care and innovative payment models.

- What steps will you take to promote increased emphasis on these types of innovations in Medicaid targeting the unique needs of children?

Answer: If confirmed, I will work with Congress and state and local partners to spur and encourage innovation in these important programs. Innovative delivery system and payment models are vital to ensuring that Medicaid and CHIP are equipped to address emerging pediatric health issues and can continue to provide children with access to quality health care.

Supply Chain

- Regarding further distribution of personal protective equipment (PPE) and COVID-19 vaccines and ancillary products, how will government coordination with the private sector be managed? How will updates and information be communicated to the healthcare supply chain in a timely manner?

Answer: The global pandemic has highlighted the vulnerabilities of the health care supply chain for many products. In order to continue responding to the COVID-19 pandemic and better prepare the federal government to respond to any future public health emergencies, it is critical that HHS work to improve and expand health care supply chain capabilities. If confirmed, I'm committed to working in coordination with the private sector on this urgent matter.

- How does the new administration plan to coordinate with and leverage the expertise of the commercial healthcare supply chain to get product the last mile and get supplies into providers' hands across the care continuum?

Answer: Coordination across departments, agencies, and industries is key to ensure the adequacy of the health care supply chain. If confirmed, I'm committed to working on this urgent matter.

- Once the COVID-19 pandemic is under control, how do you anticipate partnering with the commercial supply chain to ensure that the country is ready for the next public health emergency? Have you considered solutions such as a "vendor managed inventory" solution to help guarantee that non-expired product could be available on demand?

Answer: As the nation begins to turn the corner on the COVID-19 pandemic, it will continue to be important to think ahead to the next public health emergency. If confirmed, I will work with Assistant Secretary of Preparedness and Response (ASPR) to ensure these efforts can increase the nation's ability to meet demand in future crises.

- How does the Biden administration intend to use the DPA authority and will the administration do so with thoughtful consideration of those with expertise in the

medical supply chain so the existing infrastructure and supply are augmented rather than duplicated?

Answer: If confirmed, I commit to working closely with members of this committee on efforts related to the COVID-19 response, including the use of DPA and its potential impacts.

Bundled Payments

The healthcare system needs to continue to innovate while maintaining high quality and improving patient outcomes. The CMS Innovation Center, or CMMI, has several innovative models underway, including the Bundled Payment for Care Improvement Advanced (BPCI-A), that uses bundled payments to improve care, foster provider collaboration and lower healthcare costs. We have hospitals and physician groups participating in bundled payments, and many see them as a way to drive the healthcare system towards better value and better patient outcomes. When utilized with patient outcomes (and protections) and measurable value in mind, CMMI can be used to test new models without disrupting the rest of the program while a model is being tested.

- What is your vision for CMMI, and how can leverage what we have learned to expand advanced payment models to meet Medicare transformation goals?

Answer: Innovation is critically important to advancing goals in health care. The CMS Innovation Center is integral to the Administration's efforts to accelerate promote value-based care and encourage health care provider innovation. If confirmed as Secretary, I can commit to you that we will follow the evidence generated by Innovation Center model tests when considering whether to expand a model.

The Medicare Advantage program is currently covering about 24 million seniors, including almost 2 million in Texas. A recent report shows that MA has a higher percentage of racial minorities than fee-for-service (32% in MA compared to 21% in FFS) and MA beneficiaries tend to be older (almost 52% are between 70-84 years of age). We also know that seniors would prefer to remain in their home and their community, and that some seniors have trouble accessing care.

- How can we leverage existing tools in the Medicare Advantage program, particularly in home-based care, to ensure that seniors get the care they need?

Answer: Medicare Advantage plays an important role in giving people access to care. I believe we have to take every approach we can in order to get people the health care they need at an affordable price. If confirmed as Secretary of HHS, I look forward to working with you and other members of Congress to achieve this important goal.

**UNITED STATES SENATE
SENATE COMMITTEE ON FINANCE**

Questions for the Record for Mr. Xavier Becerra, nominee to be the Secretary of Health and Human Services (HHS)

Senator Richard Burr

COVID-19

1. In order to mitigate the financial challenges hospitals faces as a result of the COVID-19 pandemic, certain third-party companies are able to offer hospitals cash advances for the Medicare segment of their business as is currently offered by these third-party companies for the hospital's commercial segment. These cash advances on Medicare claims may be utilized by hospitals accepting Medicare patients to offset their loss of revenue from elective procedures that are not being performed as a result of the COVID-19 pandemic. However, many hospitals believe that accepting a cash advance from a third-party to cover such losses is non-allowable under Medicare regulations.

Will you work with hospitals and third-party companies to provide clarity on all options available and allowed under the Medicare program for hospitals suffering from cash flow issues due to the COVID-19 pandemic?

Answer: During the pandemic, while some providers have experienced challenges with overcapacity, many other providers have faced financial setbacks related to billing disruption, the suspension of non-essential surgeries and procedures, and health care staff unable to work. As you know, Congress has provided financial relief to providers and suppliers through the Provider Relief Fund, Paycheck Protection Program, and the CMS Accelerated and Advance Payments Program, among other relief efforts. If confirmed, I will review federal requirements to determine if there are barriers to providers obtaining financial assistance.

2. Operation Warp Speed was created in March 2020 to accelerate the development of countermeasures for COVID. This public-private partnership with HHS and the Department of Defense is a historic example of American innovation. As of the end of January, five of the six Operation Warp Speed vaccine candidates have entered phase 3 clinical trials – two of which, Moderna and Pfizer, have received emergency use authorization (EUA) from the FDA as of February 25, 2021.

- a. Should you be confirmed, what will your role be in this extremely successful public-private partnership?
- b. What do you plan to change about the program?

Answer: I agree with the success of the Operation in its ability to accelerate the development and manufacturing of COVID-19 vaccine candidates. If confirmed, I would work with all key partners to understand how to best support the ongoing development and distribution of medical countermeasures for COVID-19.

FDA-CMS Coordination

3. We are in an exciting era of biomedical research and development, from which all generations of Americans stand to benefit. The development of new medical products is only half of the story, innovators must meet the FDA's gold standard of approval, then jump the hurdles of CMS's coverage and pricing decisions. This process can add time between when a medical product is approved by FDA and when a patient can use it. What opportunities do you see for FDA and CMS to work in parallel in order to be prepared for the next decade of novel medical products and reduce the time patients wait for CMS to make a decision on an FDA approved product?

Answer: I agree with the goal of expediting patient access to new medical products. I understand FDA and CMS have taken certain steps towards parallel review, and I will support appropriate measures to enable payors to make informed decisions earlier in the process.

Clinical Trials

4. Last year, I worked with Senator Cardin on legislation to improve access to clinical trials for Medicaid beneficiaries. This bill, the Clinical Treatment Act, was signed in to law late last year. Medicaid beneficiaries have historically been less likely to participate in clinical trials because they had to pay for the associated medical care as a part of the trial. When this law is implemented, routine care costs for individuals participating in clinical trials will be covered, providing them access to treatments that can save and improve their lives. Additionally, by having more Medicaid beneficiaries participate in clinical trials, we will broaden the base of clinical trial participants so we can bring cutting-edge treatments to more Americans.

If confirmed, it will be your responsibility to implement this new law. What steps will you take to ensure that Medicaid patients can quickly benefit from this new policy?

Answer: If confirmed, I will work to implement your newly-enacted legislation to broaden access to potentially lifesaving clinical trials for Medicaid beneficiaries. I look forward to working with you and states to implement the law and to ensuring that Medicaid beneficiaries who wish to participate in clinical trials have adequate access to the health care they need.

Medicaid

5. You may be aware that Georgia recently gained approval of a unique Medicaid Waiver that establishes a pathway for currently ineligible individuals to gain coverage by meeting Qualifying Hours and Activities. No currently enrolled Medicaid beneficiaries would be impacted by the program. Do you believe the state's "Georgia Pathways" waiver fulfills the purpose of Medicaid by providing coverage to currently uninsured individuals, and will you commit to keep an open mind about this Waiver and other state-led initiatives to innovate within their Medicaid programs that fits their individual state needs?

Answer: Section 1115 demonstrations can be invaluable in allowing states to pursue innovative ideas through Medicaid. If confirmed, I will work to ensure that states' Medicaid section 1115 demonstrations promote the objectives of the Medicaid program and that these demonstrations are approved in accordance with and comply with the Medicaid statute.

Transparency

6. Empowering consumers with health care price information so they can make informed health care decisions has long been a bipartisan priority. If confirmed as Secretary, are you committed to ensuring full implementation of the Department's Transparency in Coverage final rule?

Answer: . If I am fortunate enough to be confirmed, I will ensure that the Department continues to take steps to improve price transparency, so consumers can look behind the curtain to understand how providers and insurers are operating.

Foster Care

7. The Family First Prevention Services Act created a new federal category for settings that deliver trauma-informed treatment for foster children with serious emotional or behavioral issues in a residential setting, known as Qualified Residential Treatment Programs (QRTPs). QRTPs are one of the few residential settings that are eligible for Title IV-E reimbursement. Recently, however, the Centers for Medicare and Medicaid Services (CMS) indicated QRTPs with more than 16 beds may meet the definition of an Institutions for Mental Diseases (IMDs), preventing Medicaid reimbursement for care in these circumstances. This interpretation is not consistent with Congressional intent.

Do you believe that QRTPs should be exempted from the IMD payment exclusion, allowing children in foster care to have Medicaid coverage in these placements?

Answer: This is an important and complex question that I am committed to addressing quickly if I am confirmed by the U.S. Senate. I am similarly concerned that children in foster care receive necessary medical care without disruption. As such, I will work closely with the Centers for Medicare and Medicaid Services to resolve this issue, and will consider all available administrative and legislative vehicles to ensure that children in foster care receive the medical care that they need and to which they are entitled.

Senator Toomey

Question for the record for Attorney General Becerra

Hearing to Consider the Nomination of Xavier Becerra, of California, to be Secretary of Health and Human Services

Question #1

I find it deeply concerning that you supported the government's use of march-in rights in the case of remdesivir. Dr. Francis Collins has publicly testified that the National Institutes of Health (NIH) does not have the authority to use march-in rights to lower the cost of a drug. Further, I have strong concerns with the disincentives created for innovators once government has set the precedent that it will "march in" and steal their intellectual property on a whim. As follow up to my questions during the hearing:

1. Can you assure me that you will not use your authority as Secretary of HHS to abuse the Bayh-Dole statute by invoking this march-in authority – that has never been used by NIH – to punish companies when you don't like their prices?
2. Do you acknowledge that the administration does not have the legal authority to use march-in rights to lower drug prices?
3. Your letter to the Trump Administration seems to conflict with the original intent of Bayh-Dole. Do you acknowledge that the intent of the Bayh-Dole Act is to incentivize public-private partnership and investment in innovative products?

Answer: Like President Biden, I believe we must do all we can to lower the costs of prescription drugs and make them more accessible for Americans. If confirmed, I look forward to working with Congress to build upon the good work you did in the Finance Committee on this important issue. If confirmed, I look forward to working with Congress to find ways to achieve these important goals.

Question #2

Separately, I have concerns regarding the legality and appropriateness of tying Medicare reimbursement for certain drugs to the prices foreign countries pay. The most obvious issue is the downstream effect it will have on patient access to lifesaving medicines.

If confirmed, will you advocate for reviving the interim final rule establishing the Most Favored Nation Model or promulgate similar rulemaking that ties the price Medicare pays for certain drugs to prices paid in other countries?

Answer: President Biden is committed to lowering the price of prescription drugs. Like President Biden, I believe prescription drugs must be affordable and accessible for all Americans. If confirmed, I will work to strengthen Medicare and Medicaid, reduce the cost of health care and prescription drugs, and ensure we are accountable in spending resources wisely and effectively. You have my commitment to work with you and other Members of Congress on this issue.

Question #3

The Biden Administration is requesting \$20 billion for vaccinations. Just 59 days ago, Congress provided \$8.75 billion for vaccine-related expenses. \$3 billion has been made available to states,

but it has become incredibly difficult to know exactly how much money remains available and how much has been spent or obligated in granular detail.

My staff has requested certain documents from the Department of Health and Human Services commonly referred to by the previous administration as “weekly draw down reports.” These reports provide some insight into the allocation of federal funding and subsequent spending by the states. It is my understanding that these reports have been shared with other members of this chamber and are generally used for press inquiries.

Attorney General Becerra, prior to any vote on COVID-19 relief, it is important all members are given an opportunity to view these weekly draw down reports. If confirmed, will you commit to providing this information to Congress on a weekly basis?

Answer: If confirmed, I commit to providing transparent and timely review of information.

On Leveraging Virtual Health Technology and Telehealth to Expand Access to Care:

On Enhancing Telehealth Access:

Earlier this week, joined by Sen. Schatz and a bipartisan group of my Senate colleagues, I introduced the Telehealth Modernization Act, legislation aimed at increasing access to high-quality health care services, particularly for our nation's seniors, by codifying crucial flexibilities for telehealth coverage.

Long before the pandemic began, South Carolina had emerged as a leader in telehealth innovation, hosting one of just two federally recognized Telehealth Centers of Excellence in the nation. High-quality telehealth services and networks spearheaded by cutting-edge providers like the Medical University of South Carolina have transformed the Palmetto State's health care landscape. Unfortunately, however, for the majority of the state's roughly one million Medicare beneficiaries, outdated coverage restrictions have long inhibited access to telehealth services.

For years, rigid rules around patient location (geographic and site of service), eligible services and provider sites, and other components of care have created substantial barriers to telehealth utilization. In February 2020, for instance, just prior to the COVID-19 public health emergency (PHE), only 0.1% of Medicare fee-for-service (FFS) primary care visits were delivered via telehealth. In any given week before the PHE, an average of just 14,000 Medicare beneficiaries received a telehealth service.

Congress took decisive steps towards expanding telehealth access through the CHRONIC CARE Act, particularly for the roughly 36% of Medicare beneficiaries nationwide who have chosen to enroll in Medicare Advantage (MA) plans, more than three-quarters of which provided extra telehealth benefits, even before the pandemic struck. For South Carolina, however, MA penetration remained below 30% last year. For the 72% of SC's Medicare beneficiaries enrolled in FFS coverage, substantial restrictions have remained.

While these Medicare access gaps predated the pandemic, the spread of COVID-19 highlighted the urgency of updating telehealth coverage rules, prompting Congress to provide authority for pivotal emergency waivers designed to ensure safe access to care for seniors and other vulnerable populations. As the pandemic raged, Medicare beneficiaries turned to telehealth services to minimize viral exposure risk and receive medically necessary care in safe and accessible settings. In April 2020, more than two-fifths (43.5%) of Medicare FFS primary care visits were provided through telehealth, and from mid-March through early July of that year, more than 10.1 million beneficiaries accessed telehealth services.

Without congressional action, however, these emergency flexibilities will expire at the end of the PHE, creating an access cliff for tens of millions of Medicare beneficiaries, including many who have come to rely on telehealth for critically needed care.

1. Mr. Attorney General, if confirmed, can you commit to making the expansion of telehealth access, particularly for seniors and vulnerable populations, a priority for the Department of Health and Human Services?
2. The Telehealth Modernization Act would eliminate a number of outdated restrictions on Medicare coverage for telehealth services, including by removing geographic and originating site restrictions and ensuring that federally qualified health centers and rural health clinics can continue to serve as distant sites, even after the pandemic subsidies. Would you support these types of policy proposals as a means of expanding access to care?
3. Can you commit, if confirmed, to working with my office, Sen. Schatz's office, and the offices of other telehealth champions to ensure that the tens of millions of Medicare beneficiaries enrolled in FFS do not face a telehealth service coverage cliff when the public health emergency expires?
4. In the absence of the emergency waivers, what would you cite as some of the most significant barriers to telehealth access, particularly for seniors and those with serious health conditions, and what steps would you take as HHS Secretary, if confirmed, to address some of these barriers?
5. What role or roles do you see telehealth and other virtual health technologies in playing within the Administration's broader goal of combating health disparities?
6. I see our digital infrastructure as a powerful tool in addressing health disparities. If confirmed, how would you work with other federal agencies and officials to bolster broadband access and bridge the digital divide?

Answer: Telehealth is an incredibly important tool to improve health equity and improve access to health care. Health care should be accessible, no matter where you live. If confirmed, I will look at the telehealth flexibilities developed for the current public health emergency and determine how we can build on this work to improve health equity and improve access to health care. As you mentioned, access to broadband is critical to the expansion of access to telehealth services, and I look forward to working with you and other departments across the Administration, if confirmed, on this important issue.

On Improving the Medicare Diabetes Prevention Program (MDPP) Expanded Model:

The Medicare Diabetes Prevention Program (MDPP) Expanded Model (EM) leverages proven interventions to prevent the onset of type 2 diabetes in Medicare beneficiaries with prediabetes. In 2016, the Chief Actuary of CMS certified that “beneficiaries participating in diabetes prevention programs have achieved success with losing weight and reducing the incidence of diabetes” and that the expansion was “expected to reduce Medicare expenditures.” According to CMS, the program at the core of the expanded model “has been shown to reduce the incidence of diabetes by 71 percent in persons age 60 years or older.”

Unfortunately, the exclusion of innovative virtual suppliers from the MDPP EM has impeded the program's reach and created substantial access gaps, particularly for older Americans living in rural and underserved urban communities. *POLITICO* reported that only 202 beneficiaries had used the program in 2018, and an *American Journal of Managed Care* study published in June 2020 concluded that “inadequate MDPP access” stemmed in part from “severe

shortages” of suppliers, particularly in states with large populations of Medicare beneficiaries of color. The COVID-19 pandemic has highlighted and exacerbated these access barriers, but regulatory flexibilities remain limited.

In order to address these access gaps, last Congress, I partnered with Senator Warner in leading a number of letters to HHS and CMS leaders, urging them to take administrative action to enable the participation of CDC-recognized virtual suppliers in the MDPP EM. We also introduced the bipartisan, bicameral PREVENT DIABETES Act, which would accomplish the same goal legislatively. Unfortunately, virtual suppliers remain excluded from the program, and even the flexibilities provided for the pandemic emergency period have proven unable to improve access for beneficiaries in need.

The Biden Administration has cited combating health disparities as a key policy priority. According to the CDC, 13% of American adults have diabetes, including 26.8% of those aged 65 or older. Diabetes prevalence varies substantially by race/ethnicity, affecting 16.4% of Black adults, 14.9% of Asian adults, and 14.7% of Hispanic adults, versus 11.9% of White adults. Inclusion of virtual suppliers in MDPP could help to address these disparities and improve outcomes for older Americans across the board.

In your testimony, you also pointed to reducing health care costs as one of your primary aims in taking on this role, should you be confirmed. A 2018 study that focused specifically on the provision of DPP services through virtual providers found statistically significant evidence of reduced costs and utilization pattern changes for a Medicare population.

1. Mr. Attorney General, if confirmed, can you commit to working, in consultation with my office, Sen. Warner’s office, and other relevant federal officials, to enhance access to the Medicare Diabetes Prevention Program?
2. Can you commit to reviewing the robust evidence base and giving due consideration to the bipartisan and bicameral requests that I have led, in partnership with Sen. Warner and others, to secure the inclusion of CDC-recognized virtual suppliers in the MDPP EM?
3. Beyond the MDPP EM, what do you see CMMI’s role to be in terms of facilitating the demonstration and evaluation of virtual care solutions and digital health tools?
4. More broadly, can you speak to the Administration’s efforts to enable Medicare beneficiaries to leverage digital health tools for the prevention and treatment of disease? Are their limitations in your ability to expand access to these valuable resources for those that want to use them within Medicare?

Answer: Innovation is important to advancing goals in health care, and the CMS Innovation Center is integral to the Administration’s efforts to promote high-value care and encourage health care provider innovation, including virtual and digital health innovation. With respect to the Medicare Diabetes Prevention Program (MDPP) expanded model, I understand that CMS issued regulatory flexibilities in response to the COVID-19 pandemic, including waiving the limit on virtual sessions that can be provided by MDPP suppliers. If confirmed as Secretary, I commit to working with you on this and other models to reduce health disparities and prevent chronic diseases such as diabetes.

On Enhancing Access to Innovation:

As Co-Chair of the bipartisan, bicameral Personalized Medicine Caucus, I have long championed the potential for cutting-edge innovations like gene and cell therapies to transform the treatment landscape. In recent years, the pace of development on these fronts has accelerated, with a report from last Spring suggesting that more than 360 gene and cell therapies were in the United States' clinical pipeline, versus fewer than 300 just two years earlier. More than one-third of these therapies aim to treat rare diseases, providing cause for optimism to patients across the country, as 95% of the 7,000 known rare diseases currently lack an FDA-approved treatment option. Individuals with sickle cell disease, for instance, which affects an estimated 100,000 Americans, could feasibly see a cure on the horizon.

According to a 2019 statement by key FDA leaders, the agency anticipated, at that point, approving 10 to 20 new gene and cell therapies every year by 2025, in addition to receiving a projected 200 investigational new drug applications for gene and cell therapy candidates annually, beginning in 2020.

That said, even in the face of these potentially lifesaving developments, hurdles remain, even for gene and cell therapies that successfully gain FDA approval. A number of laws and regulations around Medicaid "best price," the Anti-Kickback Statute (AKS), and the Stark Law, among other relevant statutes, understandably failed to contemplate this new generation of gene and cell therapies, which have only recently begun to come to market.

1. A disproportionate share of the patients affected by the diseases most likely to be treated by the early waves of gene and cell therapies receive health care coverage through Medicare or Medicaid. With that in mind, would you agree that HHS should do all that it can to ensure access to FDA-approved cell and gene therapies when a doctor and a patient agree that it is the most appropriate treatment option?
2. The current Medicaid reimbursement structure was not designed with curative therapy payments in mind. For the roughly 100,000 Americans affected by SCD and other painful and debilitating conditions, these outdated rules risk delaying patient access and hinder Medicaid's ability to pay for innovative therapies based on their value. How will HHS overcome barriers in the current Medicaid reimbursement structure for cell and gene therapies, giving patients access to cures and not just treatments?
3. In December, HHS finalized the "Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS 2482-F)" rule, which took important steps towards ensuring that State Medicaid programs have the flexibility they need to hold manufacturers accountable for the performance of their therapies. Will HHS commit to implementing this rule and ensuring that patients have timely access to lifesaving cell and gene therapies?
4. If and when HHS implements this rule, barriers to value-based arrangements will remain, both within the federal health care programs and in the private sector. Can you commit, if confirmed, to work with my office to develop the additional legislative and regulatory

solutions needed to facilitate meaningful value-based arrangements for drugs, biologics, devices, and other innovative medical products?

Answer for 1-4: I believe that people should have timely access to lifesaving innovative therapies, including prescription drugs, biologics, devices, and other medical products. We need to foster innovation in medical technology to develop new lifesaving therapies. If confirmed, I look forward to working with you and other members to find solutions to address the high cost of new therapies.

5. The prior administration issued new AKS safe harbors to protect value-based arrangements among health care providers and other industry stakeholders, but value-based arrangements for drugs and biologics received no such protections, inhibiting the development of these types of agreements and jeopardizing patient access to innovation. Will you commit to developing a safe harbor that would help promote greater innovation in the pricing of drugs and biologics?

Answer: I look forward to working with the Office of Inspector General and the Department of Justice to explore whether a safe harbor would help promote access to beneficial innovation while also protecting against fraud and abuse.

Over the past decade, Congress and the FDA have worked together to develop a useful set of tools to “fast track” new drug and biologic discoveries through the FDA review process. These tools, known as “fast track,” “breakthrough,” and “regenerative medical advanced therapy designation,” have the potential to bring new treatments to patients faster, helping to confront some of the most serious medical challenges. For example, one rapidly emerging area of innovative discovery known as allogeneic “T-cell immunotherapy” for the treatment of cancerous tumors, blood cancers and autoimmune diseases, has benefited from these avenues through the FDA review process.

However, even after the FDA uses these tools to find said treatments clinically safe and effective, applicants must navigate a second component of the FDA review process, known as the “Chemistry, Manufacturing and Controls” or “CMC” process. This part of the process includes an on-site FDA inspection of manufacturing facilities, which must be completed before a new treatment can come to market.

Unfortunately, even before the pandemic, this stage in the review process had become considerably delayed, with immunotherapy products that have shown strong safety and efficacy in clinical studies being held up because of a lack of clarity and consistency from the agency on CMC requirements. I appreciate the challenges created by the pandemic, but these CMC delays existed before the pandemic, and without action, they will persist even after the pandemic subsides, imperiling patient access to lifesaving innovations.

1. Can you commit to resolving this issue when you arrive at the Department and to expediting the FDA’s CMC review process, as well as the requisite inspections, for these urgently needed fast-tracked therapies?

Answer: I commit to do everything I can to ensure that safe and effective therapies get to market as efficiently as possible. While FDA paused all on-site surveillance domestic inspections in March 2020 due to the COVID-19 pandemic, FDA investigators continued mission critical inspections and other activities to ensure FDA-regulated industries are meeting applicable FDA requirements. FDA also later began resuming surveillance inspections in July 2020. To date, FDA has not experienced a significant impact on its ability to take actions on drug and biologic applications.

FDA has also been employing other tools to evaluate facilities, as appropriate, such as requesting records and other information or reviewing trusted foreign regulator inspection records under existing Mutual Recognition Agreements. These tools have been, in many cases, successful to allow the Agency to take actions on applications in lieu of an inspection.

I will work with FDA to ensure the Agency uses every appropriate tool to get critical safe and effective therapies to market as efficiently as possible.

On Vaccines:

On Seniors' Access to Preventive Care:

While Medicare Part B covers a number of vaccines, including for influenza, pneumococcal, and hepatitis B, with no beneficiary cost-sharing, the majority of vaccines recommended for adults, including for older adults, are covered under Part D, where seniors can face substantial copays. While cost-sharing can serve as a useful and appropriate tool in other contexts, those rationales do not apply in the case of ACIP-recommended vaccinations, and studies have shown a direct correlation between cost-sharing and increased abandonment rates for vaccines.

As a number of my colleagues and I noted in a letter we sent to CMS on this subject last Summer, "A 2017 report by Avalere Health found between 47 and 72 percent of the 24 million Medicare beneficiaries with Part D coverage had some level of cost sharing for vaccines, ranging from \$35 to \$70 in 2015. Another study found that only 4 percent or less of Medicare Part D enrollees had access to vaccines with no cost sharing."

1. How can the Biden Administration address the issue of ensuring medically necessary preventive care for all populations?

Answer: Ensuring access to health care, including preventive care, for all populations is a top priority of the Biden Administration. If confirmed, I look forward to working with Congress to find ways to ensure preventive care, including recommended vaccination, is accessible for all populations, including Medicare beneficiaries.

On Health Care Coverage:

Many of my constituents have expressed concerns about your longstanding support for a single-payer health care system, which many of them see as an existential threat. In addition to eliminating employer-sponsored health plans and replacing them with one-size-fits-all public

coverage, legislation that you supported while in Congress would exact unprecedented payment cuts on health care providers, likely triggering hospital and practice closures, early physician retirements, and a decline in care quality and innovation.

Even before the pandemic began, Medicare paid just half of what private insurance reimbursed for the same hospital care. If SC's providers were to lose all commercially insured patients, confronted with a Medicare-only payer mix, many would be forced to close, particularly in rural areas, where close to one-third of the state's residents live.

These concerns are not merely hypothetical, as a survey of countries with single-payer systems shows. During the 2018-2019 flu season, for instance, one in every four patients in Britain had to wait more than four hours in the ER to get the care they needed. Even left-leaning sources in Britain acknowledge that rationing care had risen dramatically in the years leading up to the pandemic. This meant massive delays for cataract surgery, hip and knee replacements, arthritis treatments, and other high-demand procedures. Furthermore, in terms of medications, of the new cancer drugs launched between 2011 and 2018, 95% were available in the U.S., versus fewer than three-quarters in the U.K.

1. Mr. Attorney General, if confirmed, this role will provide you with a powerful podium to advocate for your policy preferences, and many of my constituents are worried that your support for government-run health care will inform the decisions you make, whether in terms of provider cuts, efforts to downsize Medicare Advantage, or any number of other proposals that could jeopardize access to care. What would you say to address these concerns, given your three decades of public support for government-run health care?
2. If confirmed, can you commit to working to bolster and enhance the employer-sponsored health care system that provides coverage to roughly 50% of all Americans?

Answer for 1&2: President Biden has made it very clear that his goals for improving the American health care system begin with building on the successes of the Affordable Care Act. If I am confirmed, I will work to implement his agenda, build on the Affordable Care Act, and expand coverage and reduce costs for all Americans.

3. Looking at the current coverage landscape, what are some of the innovations in commercial health care coverage and benefit design that you see as most compelling, promising, or worthy of replication? If confirmed, what would you do to promote, further publicize, or otherwise advance these innovative models?
4. Do you believe that employer wellness plans can or should play a role in driving positive health outcomes for Americans and lowering long-term health care costs?

Answer for 3&4: I believe that there can be many innovative strategies which can help improve health outcomes for Americans and lower long-term health care costs. If confirmed as Secretary of HHS, I look forward to reviewing the information we have available to determine what approaches are working well and where there might be opportunity for further innovation.

On Medicare Advantage:

A growing share of Medicare beneficiaries, rising from just one-quarter in 2010 to 36% in 2020, have chosen to enroll in Medicare Advantage (MA), which is managed by private insurers and has a 94% satisfaction rate. MA has enjoyed increasingly strong bipartisan backing, with 64 senators and 339 Members of the House signing on to a letter of support for the program last year.

MA plans cover an increasingly broad array of extra benefits, relative to the fee-for-service model. Of all MA plans, 88% cover hearing aids and 91% cover glasses and eye exams, while 92% include dental benefits and 96% have a fitness benefit.

1. Mr. Becerra, given the overwhelming bipartisan support and the additional benefits, as well as the growing competition in the MA market, what steps would you look to take, if confirmed, to continue increasing access to and education on MA options for seniors?

Answer: Medicare Advantage serves millions of Americans and is one important option for seniors. I believe that we have to take every approach we can in order to provide people access to quality health care. If confirmed as HHS Secretary, I look forward to working with Congress on this important issue.

On Religious Liberty and Conscience Protections:

Since long before I came to Congress, I have prioritized protections for religious liberty and freedom of conscience, one of our core constitutional rights. I have also been a committed defender of all human life, including the lives of the unborn. Your stated positions on a number of issues, including late-term abortion, life, conscience protections, and overreaching government policies that infringe on religious freedoms have raised significant concerns among many South Carolinians.

1. Prior to taking any actions with implications for people of faith, can you commit to consulting and engaging with religious liberty advocates, including those who disagree with your previously stated positions on the issues above?

Answer: As a person of faith, I certainly understand the importance of people's faith in their own lives, and I would always seek a range of views when making any decisions, if I am fortunate to be confirmed.

2. If confirmed, can you commit, through all of your actions as HHS Secretary, to uphold religious liberty and freedom of conscience for all Americans, including those with deeply held religious convictions and beliefs?

Answer: As a person of faith, I believe deeply in religious freedom. I was raised in a Catholic home, and we would get up early on Sunday mornings to go to mass. My faith is a big part of who I am today, and I'm grateful that we live in a country that recognized the right of all Americans to exercise their religion. It's part of what makes the United States so special. I am also proud that, in this nomination, I have the support of the Catholic Health Association and

other faith-based groups. If confirmed as HHS Secretary, in executing the President's agenda, I would certainly follow the law and Constitution in our efforts to protect people's health.

On Access to Home Infusion Therapy:

As the CDC and researchers across the world have noted, COVID-19 presents the most severe health risks to older individuals, as well as to those with underlying conditions, making the Medicare-covered population especially vulnerable to this disease. Unfortunately, Medicare beneficiaries in need of medical care or treatment for issues unrelated to the pandemic too often face a grueling decision, whereby they must choose between forgoing the services and medications they need by staying at home or, alternatively, seeking care in a hospital setting or physician's office.

However, many of these patients could viably receive their infused or injectable medications at home, relieving them of the risks associated with traveling to an institutional setting to receive their treatments.

1. Considering these ongoing challenges, can you commit to prioritizing policies that increase access to home infusion therapy for patients who want to receive their treatments at home?

Answer: I agree that we must ensure Medicare beneficiaries have access to quality health care services, including access to these services in the home. During the public health emergency, CMS has taken actions to expand flexibilities under Medicare so that health care services can be furnished to Medicare beneficiaries in the safety of their homes. If confirmed, I commit to working with you on making sure Medicare beneficiaries have access to the services and medications they need.

Questions for the Record

Hearing on the Nomination of Xavier Becerra

Senator Bill Cassidy

1. The CARES Act provides FDA with authority to expedite the facility inspections. Do you think that FDA should exercise this authority to address or prevent drug shortages, particularly as ramping up vaccine manufacturing capacity may mean redirecting activities and resources from manufacture of other drug products?

Answer: While the COVID-19 pandemic strained FDA's ability to perform traditional foreign inspections, as I understand it, the Agency has worked to improve inspection capabilities within the current public health environment. I agree that we must apply the lessons learned during this public health emergency to our work going forward.

2. How do you think that FDA can best regulate tobacco products?

Answer: Tobacco use is the single largest preventable cause of disease and death in the United States. Each year, more than 480,000 people in the United States die prematurely from diseases caused by cigarette smoking and exposure to secondhand tobacco smoke. As you know, FDA has comprehensive tools to protect the public from the harmful effects of tobacco use through science-based tobacco product regulation. If confirmed, I will ensure FDA effectively uses this authority in the interest of the public's health .

3. Do you support a product standard that would limit the level of nicotine in cigarettes or other tobacco products?

Answer: . If confirmed, I will engage in this conversation with FDA and other experts across the Department and will examine potential actions in this area.

4. Based on your reading of the statute and applicable regulations, what is the scope of FDA's regulatory authority over tobacco products and do you believe it extends to synthetic nicotine products?

Answer: This is a legal question that I have not personally examined but, if confirmed, this is a question that I intend to resolve through consultation with the attorneys and experts at HHS.

5. How do you think that implementation of the interoperability regulations fits into data exchange efforts surrounding COVID-19?

Answer: Interoperability has proven to be an important innovation in health care that has gained bipartisan support. I believe we need increased access to data because good data leads to good policy. If confirmed, I look forward to partnering with states.

6. Medicare is often slow to cover new technologies, even when they represent significant clinical improvements over the existing standard of care. This is even when we have committed significant federal resources to supporting a product through the research and development process as well as FDA review, like we did with the artificial pancreas. What do you think CMS can do to make sure that Medicare can cover these new technologies?
7. Do you support the Trump Administration's final rule creating a new, accelerated Medicare coverage pathway to ensure national coverage for breakthrough products?

Answer to Questions 6 and 7: I agree that it is important to foster innovation in medical technology, which has the potential to improve health care outcomes. If confirmed, I will work to ensure Medicare beneficiaries have access to medically necessary innovative technologies.

8. How do you think that HHS could discourage rebate traps or rebate walls?

Answer: Like President Biden, I believe we must do all we can to lower the costs of prescription drugs and make them more accessible for Americans who depend on these medications. I am committed to reducing drug prices and ensuring Americans have access to the drugs that they need. If confirmed as Secretary of HHS, I look forward to working with you to find ways to achieve these important goals. I will also work across the government to address barriers to reducing drug prices.

9. Given current events and the importance of animal research to address medical emergencies such as COVID-19, as well as research for practically every other area of disease, can you tell us what steps HHS and NIH plan to take to ensure that air transport of and access to animal models in the U.S. is assured?

Answer: Research conducted in and supported by the NIH is invaluable to advancing the biomedical sciences and human health. If confirmed, I look forward to working with NIH and others at HHS to further the essential work of the NIH.

Senator James Lankford Questions for the Record

Senate Finance Committee Hearing to Consider the Nomination of Xavier Becerra, of California, to be Secretary of Health and Human Services

February 24, 2021

1. The HHS contraceptive mandate, promulgated under the Obama administration, purported to offer cost-free birth control to all women. However, because of massive exemptions given to grandfathered corporate entities and even to the government's own plans for Medicare and the US military, 1/3 of all Americans were not even covered by the original mandate. Yet the federal government insisted that it could not find an alternate solution for the relatively small number of religious organizations with conscientious objections to paying for contraceptive coverage. One of these groups was the Little Sisters of the Poor, an order of Catholic nuns who care for the elderly poor who have nowhere else to go.

The losing attempt to force nuns to pay for birth control has now been to the Supreme Court three times and has lost a resoundingly three times. At oral argument in April of 2016, the Obama Administration admitted that it can find ways to accomplish a policy goal of fully covered contraception without conscripting nuns into the process.

Continuing this unnecessary fight is only be an affront to the First Amendment, but also a waste of valuable government resources and time. But you are leading one of the ongoing lawsuits to continue forcing the Little Sisters of the Poor to choose between shutting down their ministry to the elderly poor or violating their religious beliefs.

- a. **Will you commit that if confirmed, you will not re-impose the contraceptive mandate on religious ministries like the Little Sisters of the Poor?**

Answer: President Biden has committed to building on the Affordable Care Act to ensure that men and women have expanded access to health care. I strongly believe women should not be put through unnecessary hurdles to access to health care .

2. I am concerned about the increasing trend to medically transition children who have self-diagnosed gender dysphoria. This has led to children as young as nine being prescribed puberty blockers that have irreversible consequences such as permanent infertility. The vast majority of Americans do not believe that a nine-year-old child can consent to puberty blockers or that a thirteen-year-old girl can consent to a double mastectomy.

- a. **If confirmed, under your leadership, what steps will the Department take to ensure that children are not subjected to experimental hormone therapy with life-altering effects?**
- b. **Do you believe insurance must be required to pay for and doctors must be required to administer puberty-blocking drugs and sex-reassignment surgeries to children as young as 13?**
- c. **Do you agree that doctors and hospitals should have the right to refuse to participate in gender transition therapies and treatments due to medical, religious or moral convictions?**

Answer: If I am fortunate to be confirmed, I will rely on doctors and scientists to offer clear, scientific, fact-based information on issues like this because I believe medical decisions should be left to individuals and their health providers. As HHS Secretary, I will follow the law when it comes to regulating insurance and respecting constitutional freedoms.

3. As you may know, an Obama administration regulation change that took effect on January 11, 2017 expanded the non-discrimination clause of Title IV-E of the Social Security Act in a way that resulted in faith-based child placing agencies being faced with the dilemma of abandoning their religious beliefs and convictions or losing funding and possibly their licenses to operate.

HHS issued a notice of non-enforcement for the Obama-era rule. It subsequently announced and published its final rule (86 FR 2257) on nondiscrimination requirements in grants to allow faith-based child welfare organizations to operate in accordance with their faith.

If confirmed, will you commit to allowing faith-based organizations, specifically child welfare providers, to serve and partner with the federal government in accordance with their sincerely held religious beliefs?

Answer: I believe deeply in religious freedom. I am a person of deep faith myself. And faith-based organizations certainly have a role to play in our health care and human services mission. If I am fortunate enough to be confirmed, I will work with our faith-based partners to deliver health care to Americans who need it and respect our Constitution.

4. You have been asked a number of times over the past few days about the impact that Pharmacy Benefit Managers (PBMs) have on the pharmaceutical industry and drug prices. As you may be aware, the Trump Administration released a number of executive orders over the past few years intended to decrease drug prices. While many of those proposals have since been temporarily frozen, one proposal that we hoped would be seriously looked at was not able to cross the finish line. That is PBMs' use of Direct and Indirect Remunerated Fees, or DIR Fees.

Many Oklahoma pharmacists have talked to my office to share their frustration with the current DIR fees, specifically under Medicare Part D. Under the current policy these fees may not be charged at the time a claim is processed. When the PBMs and plan sponsors collect these fees, pharmacists are given almost no insight about why they were imposed. Also, it is virtually impossible for the pharmacy owner to assess his or her actual reimbursement rate at the outset of the plan year, the time of dispensing medication, or at the end of the contractual term.

This leaves pharmacies, particularly small and rural pharmacies, with little to no financial security based on the unknown level of fees they may be charged for simply doing their job and providing prescriptions to their customers, and has many times caused local pharmacies' doors to close. If we do not take a closer look at this, we may be nearing the end of many small, local pharmacies and the necessary services they provide their communities.

a. Will you commit to documenting the impact of DIR fees on pharmacies and to working with Congress toward viable solutions?'

Answer: Small and rural pharmacies are critical to our nation's health care system. We must do all we can to ensure that Americans can access important health care services, including from local pharmacies in their communities. If confirmed, I look forward to working with Congress to ensure that community pharmacists have predictability.

5. A little over a week ago, I sent a letter to the CDC asking that additional guidance be released for senior individuals who are isolated in long term care facilities, but have received both doses of the COVID-19 vaccine. Many people who are elderly or may be more vulnerable to COVID have seen the vaccine as the light at the end of the tunnel. With little clarity on what can change after their full vaccine dosage, many seniors are more confused and hopeless than ever.

- a. **Will you commit, if confirmed, to work with the CDC to ensure that such guidance is quickly released and that continued guidance be released as new updates occur?**

Answer: HHS and CDC stand committed to providing the best, most current data and scientific understanding available to protect the health, safety, and wellbeing of our communities. And, if confirmed, I will work to continue that effort and provide updated guidance as appropriate.

6. You have discussed transparency and accountability at great length when it comes to all areas of the current health care system. **What specific solutions are you looking at to provide transparency when it comes to health care costs and prescription drug costs?**

Answer: The American people are entitled to know what they're buying. And, like President Biden, I believe prescription drugs must be affordable and accessible for all Americans. I am committed to reducing drug prices and ensuring Americans have access to the drugs that they need.

7. If confirmed, you will have authority over the largest federal department by budget and some of our largest federal expenditures like Medicare and Medicaid. As I am sure you are aware, in September 2020, CBO predicted that if no changes were made, the Medicare Hospital Insurance Trust Fund would be insolvent in 2024.

- a. **How will you work to ensure the solvency of the Medicare trust funds without implementing additional financial stress on taxpayers?**

Answer: If confirmed, my team and I will be ready to sit down with you and other Members of Congress to discuss both short and long-term solutions to guarantee Medicare's future.

8. In 2019, the Senate Finance Committee considered a bipartisan amendment, of which I was a part, to reduce cost-sharing for seniors in Medicare Part D. Generic and biosimilar medicines can only provide significant savings for patients if they are covered on the appropriate Medicare Part D formulary tier.

- a. **Will you work with us to ensure Part D covers newly available generic and biosimilar medicines and ensure proper formulary tier coverage?**

b. **How will you work to encourage more use of generics and biosimilars in Part D?**

Answer: Competition in the market has helped control the growth in spending on prescription drugs. I believe that generic drugs and biosimilars have a role to play in containing the cost of innovative yet expensive therapies by creating competition. Like President Biden, I believe we must do all we can to lower the costs of prescription drugs and make them more accessible for Americans who depend on these medications for their health. If confirmed as Secretary of HHS, I look forward to working with Congress on these important issues.

9. During the pandemic telehealth has played a major role in providing access to care for both Medicaid beneficiaries, including children, and Medicare beneficiaries, including our nation's most vulnerable elderly individuals. **How will HHS support the continued use and enhancements needed under Medicaid and Medicare to ensure telehealth continues to enable access to care for people of all ages?**

Answer: Telehealth is an important tool to improve health equity and improve access to health care. Health care should be accessible, no matter where you live. If confirmed, I will look at the telehealth flexibilities developed for the current public health emergency and determine how we can build on this work to improve health equity and improve access to health care.

10. Diabetes is the seventh leading cause of death in America. More than 34.2 million Americans, equivalent to 10.5% of the population, have diabetes. Minorities are up to three times more likely to be diagnosed with the disease. About 1.25 million Americans suffer from Type 1 Diabetes alone. Insulin is the most common treatment option for those with Type 1 diabetes. Over the past ten years, the price of insulin has nearly quadrupled, even though the product has been on the market for almost 100 years, with no significant changes to warrant such a dramatic price increase. The skyrocketing price of insulin has put the lives and livelihoods of millions of Americans at risk due to many families having to make the tough choice of affording life-sparing medication or other necessities such as food or rent.

Though insulin has largely remained the same, innovation in America is at work to create insulin products through many different means – hoping to bring more competition to the insulin market, thus driving down prices.

As of March 23, 2020, insulin is now considered a biologic product and is regulated under the Public Health Services Act. The Biologics Price Competition and Innovation Act (BPCIA) passed as part of the ACA, created an abbreviated Biologic License Application process for biosimilars. The biosimilar definition to receive access to this abbreviated pathway requires a product to 1) be highly similar, and 2) have no chemically important differences to the originator product. In the months and years to come, many are hopeful to see this transition bring about more treatment options for Diabetes patients.

In the fiscal year 2021 appropriations bill, my office worked for report language that would require the FDA to prioritize the approval of biosimilar insulin applications, including chemically synthesized insulins, should such a product request approval and provide examples of

how FDA has given express attention to biosimilar insulin applications and FDA's plans in place to ease the application process for such products.

- a. **Will you ensure that all new insulin products have the ability to approach the FDA for an approval application in order to ensure robust competition for insulin products so the millions of Americans living with diabetes may have access to new and affordable insulin?**

Answer: As you note, millions of Americans are impacted by diabetes. If confirmed, I look forward to working with you and other Congressional leaders to expanding access to and lowering the costs of insulin.

11. **Given the severe dependence on foreign active pharmaceutical ingredients (API) production, what do you believe the federal government's role should be to support domestic API manufacturing and related pharmaceutical supply chains?**

Answer: The global pandemic has highlighted the vulnerabilities of the global supply chain for many products. In order to continue responding to the COVID-19 pandemic and better preparing the federal government to respond to any future public health emergencies, it is critical that HHS work to improve and expand domestic supply chain capabilities. If confirmed, I'm committed to working on this urgent matter.

Questions for the Record

Nomination of Xavier Becerra, of California, to be Secretary of Health and Human Services

Senator Todd Young

February 26, 2021

1. United Network for Organ Sharing

I have been championing oversight and reform of Organ Procurement Organizations (OPOs) for a few years now, including via an active, bipartisan investigation in this committee into OPOs and their oversight body, the United Network for Organ Sharing (UNOS), led by Chairman Wyden and former Chairman Grassley. Because UNOS has not been compliant with the investigation, however, the Senate Finance Committee was forced to issue UNOS a subpoena for the documents necessary for Congress to assess important issues related to system failures, patient safety lapses, and potential Medicare fraud. By virtue of the OPTN Final Rule, however, the HHS Secretary has broad authority to request any documents he or she deems necessary from OPOs or UNOS.

- As HHS Secretary, will you commit to using this authority in all ways appropriate to support the ongoing bipartisan Senate Finance Committee investigation?

Answer: I am committed to making sure that patients who need organs receive the help they need with organ transplantation. To that end, we will work with the Committee to support their oversight efforts related to organ procurement, where appropriate.

2. Office of Organ Policy

On January 15, 2021, HHS notified Congress that the Division of Transplantation was moving from HRSA to the Office of the Assistant Secretary for Health, in line with calls from patient advocates to create a dedicated Office of Organ Policy.

- Can you commit to ensuring that oversight will be a key function of that new office?
- Would you be willing to work with us on oversight of OPOs and UNOS so we can hold these organizations accountable?

Answer: I am committed to making sure that patients who need organs receive the help they need with organ transplantation. To that end, I will look into all options that move us closer to this goal.

3. Center for Medicare & Medicaid Innovation (CMMI)

The Center for Medicare and Medicaid Innovation (CMMI) is charged with testing and evaluating voluntary healthcare payment and service delivery models with the intent of increasing quality and efficiency while reducing program expenditures under Medicare, Medicaid, and the Children's Health Insurance Program. There is absolute value in innovating and experimenting with healthcare payment and service delivery systems. We won't know if we're truly making a difference unless we experiment and evaluate.

- What are your plans for CMMI?
- What issues and models do you hope to test in the innovation center?
- Do you plan on cancelling any existing or announced models?

Answer: Innovation is critically important to advancing the Administration’s goals in health care. The CMS Innovation Center is integral to the Administration’s efforts to accelerate the move from a health care system that pays for volume to one that pays for value and encourages health care provider innovation.

4. **Drug Pricing**

President Biden’s healthcare plan he campaigned on highlighted several policies to address drug pricing including allowing Medicare to negotiate drug prices, limiting launch prices for drugs, and limiting drug price increases beyond inflation.

- Which Biden policy for controlling drug pricing will be the top priority for implementing quickly if you become HHS Secretary?
- Do you plan on implementing all of these policies? When?
- We’ve heard a lot about the Most Favored Nation model– do you plan on going forward with this model? Or do you plan on rescinding it?
- We’ve also heard a lot about the Rebate Rule which has recently been delayed for a year – do you plan on going forward with this model? Or do you plan on rescinding it?

Answer: Like President Biden, I believe we must do all we can to lower the costs of prescription drugs and make them more accessible for Americans. If confirmed, I look forward to working with Congress to build upon the good work you did in the Finance Committee on this important issue.

There have been proposals in Congress to repeal or significantly modify the Average Manufacturer Price (AMP) cap in the Medicaid Program, including a provision in the House Democrats’ COVID relief package to repeal the AMP cap.

- What do you think the impact will be on the commercial market and patients if the cap is removed?

Answer: I believe that people should have timely access to prescription drugs, biologics, devices, and other medical products. If confirmed, I look forward to working with you and other Members in a bipartisan fashion.

5. **Social Determinants of Health**

Social determinants of health (SDOH) are the economic and social conditions that affect an individual’s health and well-being, such as access to reliable transportation and stable housing. Addressing these factors can have a meaningful impact on the prevention and management of chronic diseases in our communities.

- Do you have plans to address social determinants of health?
- Are you considering establishing some sort of commission or interagency council to address potential SDOH barriers?

Answer: The COVID-19 pandemic has laid bare inequities within our society and how social and economic conditions impact an individual’s health and well-being. If confirmed, I intend to take a department-wide approach to the advancement of equity, consistent with President Biden’s

charge to federal departments and agencies, and this would include examination of ways to address the social determinants of health.

6. **Future of Telehealth**

According to the Centers for Medicare and Medicaid, weekly telehealth visits increased from 12,000 a week before the coronavirus spread in March to more than one million a week across the country. Currently, authorizations included in the CARES Act create additional flexibilities which allow the use of telehealth services, including remote patient monitoring (RPM) technologies; however, these flexibilities are only extended until the end of the public health emergency.

- Does this administration have any plans to advance policies specifically related to the permanency of telehealth waivers that were implemented during the pandemic?
- Will HHS continue to support telehealth applications like RPM beyond the public health emergency?

Answer: Telehealth is an important tool to improve health equity and improve access to health care. Health care should be accessible, no matter where you live. If confirmed, I will look at the telehealth flexibilities developed for the current public health emergency and determine how we can build on this work to improve health equity and improve access to health care.

7. **Medicaid Integrity**

Medicaid is a very significant portion of the portfolio at HHS as more than 77 million people are currently enrolled in Medicaid and CHIP. In December 2018, the Office of Inspector General released a report showing that California "made Medicaid payments of \$959.3 million on behalf of 802,742 ineligible beneficiaries and \$4.5 billion on behalf of 3.1 million potentially ineligible beneficiaries."

- As Attorney General of California at the time, were you aware of these major program integrity issues?
- Did your office take action to recoup any of these funds for taxpayers?
- How would you fix this systemic issue as head of HHS?

Answer: The Medicaid program is a lifeline for American families all around the country. With this in mind, it is vitally important that the Department works together with states to protect the integrity of the Medicaid program. If confirmed, I look forward to working within the Department and with Congress and states to make sure we are doing all we can to protect the Medicaid program and the millions of people it serves.

8. **Welfare Reform**

A half-century ago, President John Kennedy memorably declared, "A rising tide lifts all boats." Generations of public leaders have since invoked Kennedy's metaphor as shorthand for the notion that if enough economic growth can be achieved, every American will benefit. Even in the best of times, not all boats are rising - because some boats inevitably need holes patched. Our system only works when everyone is able to seize the economic opportunities that are available. However, our complex and uncoordinated federal welfare system, with its various benefit cliffs and phase-outs, discourage millions of low-income adults from seizing those economic opportunities to

work and provide for their families. For some, our safety net has effectively become a poverty trap, keeping low-income individuals and families stuck in poverty for generations instead of acting as a springboard to prosperity.

- With so many of our health and human services programs housed at HHS, what are some ideas you have for welfare reform?
- Are you planning on making this issue a priority?

Answer: HHS' Administration for Children and Families (ACF) administers the Temporary Assistance for Needy Families (TANF) block grant which, through states, provides cash assistance to low-income families as well as other services and supports. I welcome the opportunity to work with Congress to address improvements in the TANF program and the federal welfare system.

9. **Mental Health**

Our nation is facing an unprecedented mental health challenge in response to the coronavirus outbreak. For many people who live with mental illness and substance use disorders, the fear of the virus and increased economic hardship, have created new mental health and addiction challenges for people across the country. A Kaiser Family Foundation poll found that 45 percent of adults say the outbreak has affected their mental health, while a separate study estimated that the pandemic could cause as many as 150,000 additional "deaths of despair" from suicide and overdose.

- If confirmed, how would you try to address this growing crisis?

Answer: Unfortunately, the COVID-19 pandemic has dramatically impacted mental health and wellbeing for too many Americans. If confirmed, I am committed to working on this issue, including supporting programs and initiatives across the continuum of prevention, intervention, treatment, and recovery support services as well as strengthening enforcement of this country's mental health parity laws.

- What kinds of resources and flexibilities would you consider providing to states in order to address this issue head on?

Answer: The COVID-19 pandemic has brought with it additional resources and flexibilities for telehealth services. Telehealth services are a key piece of the puzzle for increasing access to behavioral health services. If confirmed, I look forward to working to build on the lessons learned during the COVID-19 pandemic to support health care access for more Americans.

- What additional tools might you need from Congress in order to accomplish these goals?

Answer: HHS has many tools to expand access to health care services. If confirmed, I commit to thinking critically about this issue and supporting robust investments that will sustain and expand access to behavioral health services.

10. **Abortion/Conscience Protections**

As a member of Congress, you voted against a ban on partial-birth abortions; penalties for sex-selective abortions; protecting minors from being driven across state lines to procure an abortion without parental consent; and making it a federal offense of harming or killing a child in utero during a violent crime.

- Can you explain why you voted these ways?
- Will you use HHS's trillion-dollar budget to advocate for policies that promote abortion and attack conscience protections for health workers?

Answer: Throughout my career, I have always sought to protect and expand men and women's access to health care. I believe in making sure that women have access to the health care they need under the law. If I am confirmed as HHS Secretary, I will follow the law.

11. **Coverage of Innovative Technologies**

The COVID-19 pandemic has furthered the necessity for access to medical technology including medical devices and diagnostic testing. CMS recently has made great strides to ensure coverage and improved payment for new and innovative technologies, including "breakthrough" technologies, which will help to make it easier for clinicians and patients to access life-saving or life-altering devices and diagnostic tests.

- How will you work to continue these efforts as HHS Secretary?

Answer: I agree that it is important to foster innovation in medical technology that improves health care outcomes. If confirmed, I look forward to working with you to increase Americans' access to lifesaving technologies.

12. **Private Practice**

Prior to the pandemic, we saw private practices start to disappear because of hospital mergers and acquisitions, bankruptcies, or physician retirements. I am concerned this trend will only continue.

- If confirmed, what steps would you take to address this issue?

Answer: As Attorney General, I took on hospital consolidation that raised prices on patients and created noncompetitive markets that left consumers with little choice. This has been a major focus of mine on the health care front, and if confirmed as HHS Secretary, I will continue to examine ways that we, at the federal level, can confront this issue, and I hope to work with you on this front, Senator.

13. **Supply Chains**

- Given the number of supply chains critical to the US economy, what level of insight do you have into their vulnerabilities?
- Do we have the necessary levels of insight into medical supply chains, including pharmaceuticals and PPE, to securely source these critical supplies?
- What industrial supply chains were prepared or unprepared to handle the stresses caused by the pandemic?

Answer: The COVID-19 pandemic has highlighted the vulnerabilities of the global supply chain for many products. I am aware that HHS's Biomedical Advanced Research and Development

Authority (BARDA) has invested in and is working to expand pharmaceutical manufacturing in the United States for use in producing medicines needed during the COVID-19 response and future public health emergencies. This work will expand domestic manufacturing of raw materials and active pharmaceutical ingredients for drugs. If confirmed, I will continue to support ongoing efforts in this area, as well as support the work HHS is doing with the FDA and DOD to expand domestic capacity for supplies needed in the ongoing COVID-19 response.

14. Biden's Health Care Promises

Last year, then-candidate Biden proposed increasing federal healthcare spending by more than \$2 trillion – and proposed to offset some of that cost with direct and indirect offsets, and cost reductions.

- What are those offsets and cost reductions?

Answer: President Biden has an ambitious plan to get the COVID-19 pandemic under control, improve access to affordable quality health care for American families. If confirmed, I look forward to working with Congress to further those efforts.

15. State Licensure/Geographic Restrictions

State licensing barriers and geographical restrictions have made access to care difficult for some patients, especially those in rural and/or underserved areas.

- Do you have plans to address these barriers to access?

Answer: As you know, provider licensing is generally under the purview of state governments. To date, HHS has taken steps under Public Readiness and Emergency Preparedness (PREP) Act authorities to expand the vaccination workforce and enable states to utilize qualified health care professionals (e.g., pharmacists) to respond to the pandemic. If confirmed, I look forward to working with you to explore other avenues to expand access to health care, especially for those in rural and other underserved areas.

Senator Sasse Questions for the Record for Xavier Becerra

1. The previous administration was criticized frequently for denying science in their handling of the pandemic, and yet this administration has done the same with regards to school re-opening. Study after study has shown that schools can reopen safely and that transmission in schools is dramatically lower than community transmission. We also know that there is a huge public health risk to keeping schools closed, with low-income children, minority children, and children with disabilities suffering the most. You spoke in your committee questionnaire about launching a Disability Rights Unit to “ensure that students with disabilities have received their legally entitled quality education,” so I would hope that you share these views.

a. Do you agree that schools remaining closed creates its own public health risk that disproportionately impacts these high-need groups?

Answer: Schools play a critical role in promoting equity in education and health for groups disproportionately affected by COVID-19. If confirmed, I commit to working with the CDC and state and local leaders to ensure everyone has the resources and support necessary to ensure children nationwide are able to attend school safely.

b. Do you agree with the view that access to vaccinations for teachers should not be a prerequisite for reopening?

Answer: The CDC’s school reopening guidance noted that vaccinations were a key tool for reopening, and I agree with President Biden who has said teachers should be a priority in any vaccination effort. At HHS, we will follow the science and commit to helping states and localities have the information they need to reopen schools safely, if they choose to reopen.

2. Setting back school reopenings even further, the CDC guidance released earlier this month recommends virtual-only learning in middle and high school and hybrid learning in elementary school for schools in “red zones,” and then defines red zones in such a way that it’s estimated that 76% of students would fall into a school in a so-called “red zone.” The administration also claimed its goal was for most students to have the option of in-person instruction one day a week, even though roughly two-thirds of students already have the option of in-person learning.

a. If confirmed, will you work with the Centers for Disease Control to make sure that their guidance does not directly contradict the stated goal of increasing in-person learning?

Answer: I understand the importance of providing robust resources and support to schools in order for them to open as safely and as soon as possible. If confirmed, I look forward to working with the experts at CDC on the issue of safely reopening schools nationwide.

b. Will you consider encouraging the CDC to amend or rescind their guidance?

Answer: I understand the importance of providing robust resources and support to schools in order for them to open as safely and as soon as possible. If confirmed, I look forward to working with the experts at CDC on the issue of safely reopening schools nationwide.

- c. Can you explain how billions of dollars provided to schools years from now (as seen in the American Rescue Plan Act) could possibly aid in a quick reopening for kids that are suffering now, many of whom have been out of school for nearly a year?

Answer: I understand the importance of providing robust resources and support to schools in order for them to open as safely and as soon as possible. If confirmed, I look forward to working with the experts at CDC on the issue of safely reopening schools nationwide.

3. As California Attorney General you sued the federal government to ensure that California could force churches to pay for abortions in their health care plans and sued the federal government to ensure that the Little Sisters of the Poor would not be provided an exemption from paying for contraception. In *NIFLA v. Becerra* you argued, incorrectly according to the justices of the Supreme Court, that pro-life pregnancy centers should be forced to tell women how to obtain state-funded abortions.

- a. Given your track record, how can we trust you to successfully run the Department of Health and Human Services and carry out the law?
- b. Will you commit to protecting the Hyde amendment, and if not, what is your justification for failing to protect the amendment, which has been the law of the land since 1976 and is supported by a majority of Americans who do not believe that taxpayer dollars should fund abortions?
- c. As a Member of Congress, you also voted against the Born-Alive Abortion Survivors Protection Act, a bill that I first introduced in 2015. Can you explain your opposition to babies being provided medical care in the rare cases where they survive abortion attempts?
- d. Will you commit to not re-impose the contraception mandate on religious ministries like Little Sisters of the Poor?
- e. Will you commit to ensuring that medical professionals are not forced to perform procedures, like abortion, that go against their religious convictions?

Answer: If I am fortunate enough to be confirmed as HHS Secretary, I will follow the law.

4. Medicaid Improper Payments rates have hit an all-time high, and during your time as Attorney General of California we saw California pay out an estimated \$30 billion in fraudulent unemployment claims.

- a. Can Americans feel safe putting over a trillion dollars in the taxpayer-funded Medicare and Medicaid programs in your hands given the mismanagement of your state?
- b. If confirmed, what are your plans to fix improper payment rates across all HHS programs and ensure that dollars are going to those individuals who need them most?

Answer: Fighting fraud and abuse, while ensuring payments are made properly, are important for maintaining the strength of HHS's programs, including the Medicare and Medicaid programs. As California Attorney General, I made it a priority to crack down on health care fraud. If confirmed, I will work with you to strengthen HHS programs and make sure resources are spent wisely and effectively.

5. Enrollment in the Medicaid program has exploded during the pandemic, partially due to problematic language in last year's relief bills where states have no choice but to provide services even to people who are not actually eligible for the program.
 - a. Do you commit to working with states and Congress to actually identify which enrollees are eligible and which are not?
 - b. Do you commit to making sure that the Medicaid program is able to serve those individuals who are truly in need?
 - c. Do you believe states should have the right to remove ineligible enrollees, which is currently restricted by FFCRA?
 - d. Wouldn't Medicare-for-All threaten not only the care for the people in the Medicare program but also those on Medicaid given the already weak financial status of the trust fund, which is currently projected to run out of funds in 2026?

Answer: Medicaid is a lifeline for millions of Americans around the country. As California Attorney General, I made it a priority to crack down on health care fraud, waste, and abuse. If confirmed, I will work with you and your colleagues to strengthen Medicaid and ensure resources are spent wisely and effectively.

6. We have too often ignored the fact that states like Nebraska actually lost health care options as a result of the ACA. My state benefited tremendously from Trump administration rules expanding Associations Health Plans and Short-Term Limited Duration Plans, and I'm concerned about the rules establishing these plans potentially being rescinded due to politics rather than actual data. These plans are very popular in my state and often cost half as much as ACA plans while providing more personalized coverage.
 - a. Can you point to any actual evidence that these plans destabilized the market, as you warned they would in a 2018 letter to CMS?
 - b. Will you commit to working with Congress and other agencies to preserve these plan options for the millions of Americans who have enrolled?

Answer: Making sure that all Americans have access to quality, affordable health care is one of the Biden Administration's top priorities. If confirmed, I will examine rules and other policies to ensure all Americans can access the care that they need.

7. In Congress you voted against allowing Americans to save more of their money tax-free in Health Savings Accounts. Can you explain your opposition?

Answer: Making sure that all Americans have access to quality, affordable health care is one of the Biden Administration's top priorities. As health care costs have continued to rise, more burden has been shifted to consumers in the form greater cost-sharing. We must work to reduce barriers to access, including excessive cost-sharing.

Senator Barrasso Questions for the Record
Xavier Becerra
Nomination Hearing
Wednesday, February 24, 2021
2:00 p.m.

Question 1: As a doctor, I have grave concerns about the impact a one size fits all system would have on access to care, especially in rural communities.

Previously, Obamacare took a step in this direction with the Independent Payment Advisory Board (IPAB).

This 15 person unaccountable board was supposed to make decisions regarding Medicare reimbursements.

I was disturbed about giving so much power over Medicare to an unelected and unaccountable group of bureaucrats.

Congress thankfully repealed the IPAB after you left Congress in 2018.

- **Do you support the recreation of the IPAB or any new government board that has the power to reduce access to care for patients?**

Answer: Ensuring that Americans have access to high quality health care, including in rural areas, is a priority of mine. I believe that beneficiaries should come first, and if I am confirmed, I will work you and other members on solutions to reduce the cost of care and lengthen the trust fund's solvency.

Question 2: Currently, illegal immigrants are not allowed to receive most federal health care benefits.

In particular, they are not eligible to receive insurance through the ACA exchange.

- **Do you support maintaining the ban on illegal immigrants receiving health insurance through the exchange?**

Answer: If I am confirmed as HHS Secretary, I will follow the law.

- **Do you support expanding Medicaid to require the use of federal taxpayer dollars to pay for illegal immigrants to receive full Medicaid benefits?**

Answer: If I am confirmed as HHS Secretary, I will follow the law.

Question 3: As a doctor, I want to ensure the United States continues to lead the world in medical and scientific innovation.

This has never been more important than during the COVID-19 pandemic.

We have seen firsthand the importance of generating new vaccines and therapeutics to combat COVID-19.

Looking forward, we must do more to address drug pricing. We must do it of course without harming innovation.

The White House Counsel of Economic Advisers found H.R. 3, the House Democrats drug pricing proposal, would reduce the number of new drugs by up to 100 over a decade.

- **Are you concerned about legislative proposals that will decrease the number of new and innovative treatments for American patients?**

Answer: The United States is a leader in medical and scientific innovation. The COVID-19 vaccines were developed faster than any vaccine in history. Innovation can only help patients if it's affordable. That's why I, like President Biden, believe we must do all we can to lower the costs of prescription drugs. If confirmed as Secretary of HHS, I look forward to working with you to find ways to reduce drug prices and ensure Medicare beneficiaries have access to the drugs that they need.

Question 4: It is vital for the United States to learn from the COVID-19 pandemic and ensure we are better prepared for future public health emergencies. In particular, I am interested in addressing the supply chain for personal protective equipment (PPE).

- **How do you anticipate partnering with the private sector supply chain to ensure that the country is ready for the next public health emergency?**
- **Do you believe HHS has a role in creating greater supply chain resiliency, in particular ensuring more PPE is made in the United States?**

Answer: The global pandemic has highlighted the vulnerabilities of the global supply chain for many products. In order to continue responding to the COVID-19 pandemic and better preparing the federal government to respond to any future public health emergencies, it is critical that HHS work to improve and expand domestic supply chain capabilities. If confirmed, I'm committed to working on this urgent matter.

Question 5: Telehealth utilization has increased significantly as a result of the COVID-19 pandemic.

- **What steps or policies is the administration considering to ensure the American health care system continues to move forward with more telehealth innovation?**

Answer: Telehealth is an important tool to improve health equity and improve access to health care. Health care should be accessible, no matter where you live. If confirmed, I will look at the telehealth flexibilities developed for the current public health emergency and determine how we can build on this work to improve health equity and improve access to health care.