Questions for the Record from Chairman Wyden

Finance Committee Hearing:

Andrea Palm, Nominee for HHS Deputy Secretary
Chiquita Brooks-LaSure, Nominee for CMS Administrator

April 15, 2021

Questions for Ms. Brooks-LaSure:

Nursing Home Quality

1. The crisis of COVID-19 in nursing homes has been a collision of mismanagement at every level of the industry from government regulators to individual facilities. More than 175,000 people living and working in the nation's long-term care facilities have died of COVID-19, including more than 130,000 in nursing homes participating in Medicare and Medicaid. The Senate Finance Committee heard from witnesses during a hearing on March 17, 2021 about ongoing issues in nursing homes that negatively affect patient care like understaffing, poor infection control and inadequate emergency preparedness. These issues have persisted for decades and left facilities particularly ill-prepared for a public health crisis like the COVID-19 pandemic. **If confirmed, what would you do to improve the care provided in our nation's nursing homes?**

***Answer*:** It has been heartbreaking to see how hard the COVID-19 pandemic has hit the nation's nursing homes, and as you noted, nursing home safety is not an issue newly created by the pandemic. Nursing homes' first obligation should be to their residents, and every nursing home that participates in Medicare and Medicaid must meet federal health and safety standards. If confirmed, it will be a top priority for me to hold nursing homes accountable for providing high quality care to their residents. Thank you for your leadership on this critical issue.

2. Thorough and publicly available information on the health and safety of nursing homes is essential. I've worked closely with Senator Casey over the last year to push and prod CMS to collect and make public information about COVID-19's impact on nursing homes that participate in Medicare and Medicaid. More recently, Senator Casey and I were joined by Ranking Member Crapo and Senator Scott (South Carolina) to request that CMS begin collecting and disseminating information regarding facility-level vaccination data. I was pleased to see CMS recently take some important steps toward improving transparency—such as requiring reporting of staff vaccination rates—but there is more work to do. For example, the Finance Committee has repeatedly received testimony about the shortcomings of the Five-Star System, which was created to provide

clear and meaningful information on the quality of nursing homes. Unfortunately, in many cases a "five-star" facility may not provide any better care or protection for residents than a one-star home. This system needs to be fundamentally rethought.

a. **Broadly speaking, if confirmed as CMS Administrator, 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?**

b. **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*:** If I am fortunate enough to be confirmed, it will be a top priority for CMS to work to address the disproportionate impact of the COVID-19 pandemic on nursing home residents, especially those of color. I will also work to improve transparency, evaluation and accountability, including increasing the available data regarding vaccinations in nursing homes.

3. For years, press reports and academic research have repeatedly shown the negative impact that private equity ownership of nursing homes takes on patient care—an issue that has long been of interest to the Finance Committee. Most recently, a study published by the National Bureau of Economic Research found that private equity ownership of nursing homes was associated with 10% higher short-term mortality of Medicare patients, was "accompanied by declines in other measures of patient well-being," and led to 11% higher taxpayer spending on a per-patient basis. Despite these issues, patients, families, and regulators are often hard-pressed to untangle when a nursing home is owned—or controlled through various subsidiaries—by a private equity firm. Section 6101 of the Affordable Care Act sought to address the black box of nursing home ownership by setting out statutory requirements to increase the amount of information made available to the public. CMS issued a proposed rule to implement the statute in 2011, but withdrew it in 2012 after receiving comments. At the time, the agency signaled its intention to reissue regulations that addressed the comments, but never did so.

   a. **Does private equity's growing role in the nursing home industry, and its impact on care quality, concern you?**

   b. **Do you plan to increase the transparency of nursing home ownership information, either through implementation of Section 6101, or other regulatory requirements and guidance?**

***Answer*:** Nursing homes' first obligation should be to their residents, no matter what kind of ownership arrangements they have, and nursing homes participating in Medicare and Medicaid programs must 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.

Senator Benjamin L. Cardin
Senate Finance Committee
Questions for the Record
Hearing to Consider the Anticipated Nomination of Andrea Palm and Chiquita Brooks-LaSure

DXA Reimbursements

1. Hip fracture is the most devastating fracture that someone with osteoporosis can experience. In Maryland, there has been an 18.5% decline in DXA testing of Medicare women since 2008, resulting in too many unnecessary and avoidable hip fracture related deaths each year.

Ms. Brooks-LaSure, will you commit to working with me and Senator Collins to improve access to Osteoporosis testing by restoring adequate reimbursement for screenings in the physician office?

Answer: Thank you for bringing this issue to my attention. If confirmed, I am happy to work with you and Senator Collins to explore options to encourage osteoporosis screenings.

Hospice Payments

2. Hospices in Montgomery County, Maryland are at a long-term competitive disadvantage due to a Medicare hospice federal payment inequity imposed in 2006 by CMS involving the use of core-based statistical areas (CBSAs) when Metropolitan Divisions are present. Since CMS began using CBSAs to determine payment, hospices in Montgomery County have received lower payments than hospices in adjacent counties, or even those in more rural, low cost parts of the tri-state area.

Using CBSAs in this manner is flawed for the following reasons. Montgomery County has a similar cost of living compared to Washington, DC and shares the same labor market when competing for labor. As a result, hospices in Montgomery County are having difficulty providing the same level of services as hospices in D.C., the three nearby Maryland counties, and the neighboring counties of Northern Virginia, all of which are paid a higher reimbursement.

I sought an administration solution to this issue in two delegation letters to CMS in 2017 and 2018 and hospices in Montgomery County have commented on this problem to CMS annually since 2005.

Ms. Brooks-LaSure, in your role as CMS Administrator, will you commit to work to resolve this problem?

***Answer*:** Thank you for raising this concern. I know you have been a leader in making sure Montgomery County, Maryland, is treated fairly. I, too, want to make sure the Medicare program operates in an equitable and transparent way. If confirmed, I would be happy to work with you

and others in the Maryland delegation on this issue to make sure your constituents have access to high quality hospice services.

Questions for the Record

"Hearing to Consider the Nominations of Andrea Palm, of Wisconsin, to be Deputy Secretary of Health and Human Services, and Chiquita Brooks-LaSure, of Virginia, to be Administrator of the Centers for Medicare and Medicaid Services"

Witnesses: Andrea Joan Palm, to be Deputy Secretary of Health and Human Services & Chiquita Brooks-LaSure, of Virginia, to be Administrator of the Centers for Medicare and Medicaid Services

Finance Committee Hearing Date: April 8, 2021 at 9:30am
Questions Submitted: April 16, 2021

Questions for Ms. Brooks-LaSure [From Senator Brown]

Mental Health Services in Child Welfare

One of the ongoing challenges in child welfare is the greater need for mental health services including a greater supply of health professionals with knowledge and experience in child psychology. This is true in the need for post-adoption services as well as families we are trying to keep together.

If confirmed, will you commit to working with states to improve coordination between state child welfare agencies and state Medicaid departments to streamline services and supports for children and young people? How would you work to increase the supply of health professionals to better meet children and young people's mental health needs?

Answer: I share your commitment to making quality mental health services available to children and families involved in the child welfare system, including families who adopt children from the child welfare system. If confirmed, I will make it a priority for CMS to encourage better coordination between state Medicaid and child welfare agencies. The pandemic has created challenges for Americans' mental health, especially for children, and increasing the number of providers is an important step to address these challenges. If I have the privilege of being confirmed, I also want to focus on improved coordination with other Agencies in HHS, including SAMHSA, to make sure we are better integrating mental and behavioral health into the health care system.

HCBS Workforce

In order to strengthen Medicaid's home and community-based services (HCBS), it is essential that we prioritize policies to develop, support, and build our nation's long-term care/HCBS workforce. We need to find ways to ensure higher wages for our home care workers and direct support professionals, and support their professional development.

If confirmed, will you work with me and other members of Congress, the labor community, and other stakeholders on ways to provide more support for this essential workforce?

Answer: I appreciate your leadership in this area, and I understand we still have a ways to go to make HCBS a reality for seniors and individuals with disabilities in need of long-term care. Developing, supporting and building the workforce is key to ensuring access to these important services. If confirmed, I look forward to working with you and our state partners to champion further progress to rebalance Medicaid's long-term care services and supports, including looking at what we can do together to help bolster the workforce.

Continuous Eligibility

Each year, millions of Medicaid and CHIP beneficiaries who enroll in coverage are at risk of losing that coverage as a result of taking on an extra shift or working overtime, simply because their income fluctuates slightly. As a result, these short-term changes set in motion bureaucratic snafus that cause taxpayers to be disenrolled from their insurance. This breakdown in coverage often disrupts treatment plans and undermines the progress of their care, but can also cause significant administrative challenges that result in higher costs for states, providers, and health plans. This can be particularly disruptive for Medicaid beneficiaries using care coordination and care management services, which are interrupted every time a beneficiary is disenrolled.

The Stabilize Medicaid and CHIP Coverage Act – legislation I've introduced with two other members of this Committee, Senators Whitehouse and Warren – would ease the burden caused by churn by ensuring beneficiaries can depend on their coverage for a continuous 12-month period regardless of their age.

Do you agree that we should work to minimize churn in health insurance coverage and eliminate disruptions in care that result when a beneficiary churns in and out of coverage?

If confirmed, will you work with me and my colleagues to strengthen the Medicaid and CHIP programs to minimize churn and ensure continued access to care for beneficiaries?

Answer: I agree that reducing churn in health care coverage is critical to ensuring continuity of care and positive health outcomes. I look forward to working with you on solutions to ensure that beneficiaries have continued access to health care coverage they can rely on.

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?

CMS has the legal authority to implement some of the provisions included in the *Improving Seniors' Timely Access to Care Act.* As Administrator, will you consider regulatory action to move forward with the provisions of this legislation that are within your current authority to implement?

Answer: I believe that ensuring Americans have timely access to health care is critical, and I agree with you that both providers and beneficiaries 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.

Nursing Schools

42 U.S.C. 1395ww(l) provides an important source of support for hospital-based nursing schools across the country. Unfortunately, nearly a decade ago mistakes in the implementation of 42 U.S.C. 1395ww(l) resulted in several hundred million dollars of CMS overpayments. After becoming aware of these prior overpayments, CMS issued Transmittal 10315, requiring the recoupment of funds from hospitals to correct for past program overpayments.

Unfortunately, this has resulted in a situation where hospital- based nursing schools in Ohio and across the country, due to no fault of their own, are required to pay back millions in funds that CMS mistakenly sent out in past years. While this claw back of funding would be hard for hospital-based nursing schools to endure during normal times, this recoupment effort during the middle of a global pandemic that has decimated hospital revenues and highlighted the importance of our nursing workforce is both impossible and ironic.

I have shared draft legislation with CMS that could help provide relief to these hospital-based nursing schools for the Agency's technical assistance. **If confirmed, will you help expedite the process for agency feedback on this proposed fix and work with me and my colleagues on a solution that will support our hospital-based nursing schools and their students?**

Answer: I am committed to supporting hospital-based nursing schools training the nation's next generation of practitioners. If I am fortunate enough to be confirmed, I will look into this important issue and look forward to working with you.

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: Small and rural pharmacies are critical to our nation's health care system and have been especially important during the pandemic. It can be hard for these pharmacies to predict retroactive DIR fees. 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 and to lower drug prices for patients and families.

Social Determinants of Health

As was discussed during Thursday's hearing, entities across the health care and political spectrum are increasingly focused on ways to address the social determinants of health. The Centers for Medicare and Medicaid Services (CMS) – 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.

Reimbursements for New Technologies

In January 2021, HHS released its Artificial Intelligence (AI) strategy, which reads, in part: *together with its partners in academia, industry, and government, HHS will leverage AI to solve previously unsolvable problems by continuing to lead advances in the health and wellbeing of the American people, responding to the use of AI across the health and human services ecosystem, and scaling trustworthy AI adoption across the Department.*

While the growth of technology in health care has the potential to facilitate access to care and improve quality for beneficiaries, it is critical that any strategy to incorporate AI in HHS policy center consumers. As the Department works to leverage AI and incorporate AI applications and other advanced technologies across health care, HHS should use all existing tools, including payment systems, to support the adoption of technology that increases access to and quality of care.

CMS payment policy has lagged behind when it comes to coverage of newer technologies that offer more personalized approaches to diagnosis and treatment, including those that utilize a form of AI. If confirmed, will you commit to reviewing CMS payment policies for disparities in coverage of AI and other new technologies and acting to update payment systems, where appropriate, to ensure access to those technologies that improve access to and quality of care?

Answer: Thank you for raising this important issue. It is incredible what scientific progress has been made with innovative drugs and treatments, and we need to continue to modernize the Medicare and Medicaid programs to make sure beneficiaries have access to proven new treatments. I understand that in 2019, CMS launched the AI Health Outcomes Challenge, to engage with innovators with harness AI solutions to predict health outcomes for potential use in CMS Innovation Center innovative payment and service delivery models. If confirmed, I commit to continuing to review how CMS can harness new technologies that utilize AI to improve health outcomes for beneficiaries.

Senator Casey - Question for the Record

Finance Committee Hearing

Hearing to Consider the Nominations of Andrea Joan Palm to be Deputy Secretary of Health and Human Services and Chiquita Brooks-LaSure to be Administrator of the Centers for Medicare and Medicaid Services

4/15/2021

Question for Chiquita Brooks-LaSure, Nominee, CMS Administrator

The COVID-19 pandemic has underscored the urgent need to enhance quality in our Nation's nursing homes. The profound loss of life we have experienced over the last year is a tragedy within the broader tragedy of this pandemic. More than 182,000 residents and workers have died of COVID-19 in nursing homes and other long-term care facilities. Well before the pandemic, I worked alongside Senator Toomey to shed light on cases of abuse and neglect in underperforming nursing homes. These nursing homes are part of what's known as the Special Focus Facility program.

My 2019 investigation with Senator Toomey found that this subset of nursing homes consistently fails to provide quality care, and yet not every nursing home that needs it is receiving intervention. We have an obligation to use every tool available to ensure that the residents who live in these homes receive the highest standard of care.

That is why, last month, Senator Toomey and I reintroduced our bill, the *Nursing Home Reform Modernization Act* (S.782). Together, we have laid out a bipartisan path forward to strengthen, target and expand oversight and give help and assistance to nursing homes that need it.

Ms. Brooks-LaSure, can I count on you to prioritize making improvements to nursing home quality and to work with me and Senator Toomey to identify how to enhance oversight for the poorest performing facilities?

Answer: It has been heartbreaking to see how hard the COVID-19 pandemic has hit the nation's nursing homes, and this is not an issue newly created by the pandemic, as you noted. I agree that nursing homes must provide high quality care to their residents. Nursing homes' first obligation should be to their residents, and every nursing home that participates in Medicare and Medicaid must meet federal health and safety standards. If confirmed, it will be a top priority for me to hold nursing homes accountable for providing high quality of care to their residents.

Thank you for your leadership on this critical issue. I know this has been a priority of yours, and I would be happy to work with you and Senator Toomey on this issue if I am fortunate enough to be confirmed.

Senator Mark R. Warner Questions for the Record for Palm/Brooks-LaSure Hearing

Question on PACE Program to Nominee Brooks-LaSure

The PACE (Program of All-Inclusive Care for the Elderly) was established by federal statute to provide the full range of Medicare and Medicaid benefits to seniors who want to remain safely in their homes, rather than enter a nursing home setting. The COVID-19 pandemic bolstered the attractiveness of the PACE program as these programs were able to pivot from providing services in PACE centers toward doing more telehealth and in-home visits, showing that PACE can help maintain seniors' wellbeing when it is dangerous for them to be in group settings.

We have a number of large and successful PACE programs across Virginia. I have always been a fan of PACE, and Virginia is one of the more active and supportive states for PACE. PACE does have a big runway for growth, considering that more than two million people in the United States qualify for PACE, but only about 55,000 individuals are currently enrolled.

- **How do you feel about PACE? Do you have a plan for promoting more PACE centers in the states?**

Answer: PACE is an important option that helps individuals in need of nursing home-level care to get health care at home or in community-based settings. PACE provides Medicare and Medicaid services under a model of care that includes comprehensive care management. More can be done to encourage the kind of care coordination and alternative to institutional care seen in PACE. If I am fortunate enough to be confirmed, I will look forward to working with you on this important issue.

Question on Labor Negotiations to Nominee Brooks-LaSure

The American Federation of Government Employees (AFGE) Local 1923, the union that represents employees at Centers for Medicare & Medicaid Services (CMS), has expressed concerns to my office about unfair labor practices enacted by the previous Administration. Specifically, these dedicated public servants have expressed concern they were forced to accept an unfair collective bargaining agreement (CBA) due to the Trump Administration's Executive Orders (EOs) of 2018 and the Federal Services Impasses Panel (FSIP).

- **If confirmed, will you commit to reexamining this collective bargaining agreement (CBA) to ensure it is fair to the dedicated public servants you will oversee?**
- **Will you also ensure that CMS engages in good faith negotiations with AFGE and that the agency and its managers appropriately implement EO 14003?**

Answer: Thank you for raising this important issue. Our workforce is critical to the continued success of CMS's programs. If I am so fortunate to be confirmed, I would like to learn more about the issues that have been raised to your office, and I will look into this issue to make sure CMS employees have the protections they deserve.

Questions for the Record of Sen. Sheldon Whitehouse
Nomination of Chiquita Brooks-LaSure and Andrea Palm
Senate Committee on Finance
April 15, 2021

Questions for Chiquita Brooks-LaSure

Eleanor Slater Hospital

The Rhode Island Department of Behavioral Health, Developmental Disabilities and Hospitals stopped billing CMS for Medicaid claims in 2019 following a state audit that flagged the need for some technical fixes to the Rhode Island Medicaid State Plan. CMS recently approved an amendment to the State Plan, but the suspension of billing may amount to approximately $60 million of lost Medicaid dollars for my state. I have contacted CMS with number of questions regarding the suspension and the possibility of the state recouping some of the $60 million. Will you commit to providing me with detailed information regarding the billing suspension at Eleanor Slater Memorial Hospital and to working with me to recoup some of the funding that was lost?

Answer: If confirmed, I would be happy to work with you on this issue. Responsiveness and communication with Congress will be a key priority for me, as I understand your important role in helping your constituents.

Imputed Rural Floor Implementation

As part of the American Rescue Plan, I championed a legislative fix to restore the imputed rural floor for Medicare hospital reimbursement rates. CMS is responsible for implementing the legislative fix and should include the imputed rural floor in the FY22 Inpatient Prospective Payment System rule. Do you commit to restoring the imputed rural floor in the forthcoming IPPS rule?

Answer: Thank you for your leadership on this issue. I want to make sure we operate the Medicare program in an equitable and transparent way. I know you worked very hard to make sure this was addressed in the American Rescue Plan Act, and I have every reason to anticipate that CMS is working hard to ensure that the provision will be implemented as quickly as possible. I would be very happy to stay in touch with you, if confirmed, on CMS's implementation of this provision.

Medicaid

Rhode Island's Medicaid 1115 waiver will expire on December 31, 2023. The current 1115 waiver focuses on social determinants of health, long term services and support rebalancing and alternative payment methodologies. How will CMS work with the state when it is time to renew the 1115 waiver?

Answer: Medicaid is an important lifeline for many American families. Section 1115 demonstration projects, or waivers, are one available tool to states to help test new and innovative policies in Medicaid. I have worked closely with states throughout my career, so I know they face different challenges and need consistency and predictability. If confirmed, I will keep in mind what I have learned working on behalf of states to make sure waiver requests are appropriately evaluated while giving them consistent guidance. I will support state innovation and the ability of states to test out different models that meet the objectives of the Medicaid program. I look forward to seeing the ideas states bring to the table and will consider each one on its merits.

Rhode Island is committed to alternative payment methodologies, including Medicaid accountable care organizations but the federal funding for this program is time-limited. What additional funding, policy support or technical assistance will CMS provide to advance alternative payment methodologies?

Answer: Alternative payment methodologies and delivery reform, generally, are so important to moving our health care system towards one that rewards value over volume. States, like Rhode Island, are often the leading innovators in this effort, and we should be learning from their successes. More integrated and coordinated care can help to improve care and lower costs. If confirmed, I want to work with you to make sure we are pursuing demonstration projects that achieve these goals, and I would be happy to work with you to support states' efforts to innovate in their Medicaid programs.

Health IT

CMS played a leading role in supporting significant HIT infrastructure under the HITECH Act. What resources does CMS need in order to fund new investments in HIT infrastructure that are compliant with interoperability standards?

Answer: Interoperability of patient records is so critical to ensure appropriate coordination of care. We need to improve health information technology across our health care system, particularly for behavioral health providers – an important issue I know you have worked to address. I look forward to working with you on this issue, including determining what additional resources might be needed, if confirmed.

Affordable Care Act

How will CMS work with states like Rhode Island that fully embraced the ACA to reduce the remaining barriers to universal coverage?

Answer: If I am fortunate enough to be confirmed, it will be a priority of mine to build on the successes of the Affordable Care Act (ACA). The ACA has extended coverage for millions of

American families. It is so important that American patients and families be able to afford health insurance, and I appreciate Congress's leadership in taking action through the American Rescue Plan Act to bring down premiums during the pandemic. We need to continue to work on this issue to make health care more affordable. This includes working with states, like Rhode Island, that have been leaders in ACA implementation to learn from their successes and continue to move the ball forward.

QUESTIONS FOR THE RECORD
Senator Cortez Masto

Hearing to Consider the Nominations of Andrea Joan Palm to be Deputy Secretary of Health and Human Services and Chiquita Brooks-LaSure to be Administrator of the Centers for Medicare and Medicaid Services

April 9, 2019

Senate Finance Committee

Question to Ms. Brooks-LaSure: A noteworthy pattern over the course of the pandemic has been the high utilization of telehealth services via telephone, without any video. This flexibility has allowed physicians to keep their doors open and continue treating patients, and vulnerable individuals who don't have access to a smart phone or might struggle with technology are able to seek services.

In your view, is it important that we maintain access to these services for both Medicare and Medicaid beneficiaries who are still unable to utilize in-person care?

***Answer*:** Telehealth has been invaluable during this pandemic to keep patients, their providers and their families safe. My brother is a psychologist, and telehealth has really helped his patients get the care they need. If I am fortunate enough to be confirmed, I will be taking a careful look at the telehealth flexibilities under Medicaid and Medicare before the Public Health Emergency ends. During that review, I will pay special attention to the issues of equity and access. I will look at what we can and should extend administratively and where we will need Congress's help to ensure that we bring the lessons learned about telehealth during the pandemic forward to modernize our health care system.

Question to Ms. Brooks-LaSure: Medicare Advantage plans serve more than 26 million vulnerable beneficiaries that have similarly benefited from this expansion in telehealth services. I'm concerned that current CMS risk adjustment policies that exclude audio-only diagnoses could hamper MA's ability to serve beneficiaries during this crucial period and negatively impact the program, its provider partners, and MA enrollees in the future.

Will you further commit to reviewing this policy promptly to ensure that the policy does not negatively impact premiums, benefits, out-of-pocket costs, or the availability of plans in 2022?

Answer: Medicare Advantage serves millions of Americans and is an important option for Medicare beneficiaries. During the pandemic, we have been able to see the value telehealth brings for patients, including those enrolled in Medicare Advantage. If confirmed, I look forward to working with you to ensure that beneficiaries enrolled in Medicare Advantage plans can continue to benefit from these services.

Questions for the Record from Senator Elizabeth Warren
U.S. Senate Committee on Finance
Full Committee Hearing: Hearing to Consider the Nominations of Andrea Joan Palm to be Deputy Secretary of Health and Human Services and Chiquita Brooks-LaSure to be Administrator of the Centers for Medicare and Medicaid Services

Ms. Chiquita Brooks-LaSure

Unique Device Identifiers
Although medical device failures are rare, when they do occur, they can create serious health problems and significant financial costs. A 2017 investigation by the Office of Inspector General at the Department of Health and Human Services found that recalls or premature failures of just seven faulty cardiac devices resulted in $1.5 billion in Medicare payments and $140 million in out-of-pocket costs to beneficiaries. Furthermore, the Inspector General was not able to examine the total cost of all device failures because of the lack of information about specific devices in claims data. Instead, OIG examiners were forced to engage in a "complex and labor-intensive audit" to assess the impact of the seven faulty devices. As a result, the OIG recommended that CMS add unique device identifiers (UDIs) to Medicare claims. Including device identifiers on claims transactions would greatly improve the health system's ability to identify risks and reach patients who may be affected by device failures.

The process of adding UDIs to Medicare claims is a complex one, but ultimately will require CMS to agree to act on the recommendations of X12, an entity that establishes accredited standards for claims transactions. X12 recently recommended that the device identifier portion of a medical device's UDI be included on the electronic claims transaction. **As the Administrator of CMS, will you commit to implementing X12's recommendation and adding UDIs to Medicare claims?**

***Answer*:** Thank you for your bipartisan leadership on this issue. I understand that a revised claims form that includes the device identifier has made it through the first step in the consensus-based process and that the next step is for the National Committee on Vital and Health Statistics to make recommendations. If I am fortunate enough to be confirmed, I would be happy to look into this issue further and to stay in touch about it with you.

Electronic Visit Verification
The 21st Century Cures Act of 2016 included a requirement that states implement electronic visit verification (EVV) systems for certain Medicaid services. EVV systems are designed to certify that personal care services and home health services in Medicaid are actually provided. They must verify the type of service provided, the date of service, the location of the service, the time the service begins and ends, and the identities of the patient and provider. States that fail to implement EVV programs are subject to a 1%, incremental FMAP reduction unless they can demonstrate that a "good faith effort" has been made to comply. States were required to begin implementing EVV for personal care services in January 2020, and they must begin doing so for home health services in January 2023.

Since the 21st Century Cures Act was passed, advocates for workers, people with disabilities, older adults, and Medicaid patients have expressed concern about the lack of worker and patient privacy protections in EVV programs. Meanwhile, they have expressed concern about the possibility of states losing Medicaid funding in the midst of the COVID-19 pandemic. **As the Administrator of CMS, will you commit to reviewing existing federal EVV guidance to determine (1) whether worker and service recipient civil rights are adequately protected, particularly with regard to the use of biometric and GPS data and (2) whether existing EVV guidance contributes to workforce shortages, and what improvements could made to the guidance to mitigate those shortages? Will you commit to ensuring that states do not lose funding for critical services via an FMAP decrease during the COVID-19 pandemic? Will you commit to improving existing federal EVV guidance and considering the possibility of using the rulemaking process to ensure that worker and service recipient privacy and other rights are protected in EVV programs?**

***Answer**:* Protecting the privacy of patients and our health care workforce is critically important. If confirmed, I will fully examine these issues to determine the administrative or legislative actions that would be needed to make sure that these requirements are protecting privacy and not placing an undue burden on states and health care workers.

Hearing on CMS Administrator Nominee Chiquita Brooks-LaSure
April 15, 2021
Questions for the Record

Questions Submitted by Ranking Member Crapo

Medicare / Medicare Advantage

Question. During the COVID-19 pandemic, CMS provided Medicare Advantage (MA) plans with additional flexibilities, such as expanding telehealth services, providing beneficiaries with devices to use telehealth and remote patient monitoring, and reducing cost sharing and premiums. How would you work with stakeholders and Congress to continue certain enhanced benefits and flexibilities, which could continue to further the MA program?

Answer: Medicare Advantage serves millions of Americans and its enhanced benefits and plan flexibilities provide important options for beneficiaries who choose to enroll in it. I believe we have to take every approach we can in order to get people the health care they need at an affordable price, including through the appropriate use of telehealth services. Telehealth has been invaluable during this pandemic in helping to keep patients, their providers and their families safe. I want to be sure we take in the lessons from this pandemic, including the value of telehealth, and look at what flexibilities we can and should extend administratively, and where we may need to work with Congress. If confirmed as CMS Administrator, I look forward to working with you to achieve this important goal.

Medicare Solvency

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 health care providers, taxpayers, and beneficiaries. Given the looming fiscal crisis, how soon can we expect a comprehensive legislative proposal from HHS that extends the life of the HI trust fund?

Answer: Medicare solvency is an incredibly important, longstanding issue. I look forward to working with Congress on a bipartisan basis to address this. We will need both short-term and long-term strategies to make sure Medicare remains a bedrock of our health care system. It is essential that we protect this program for Americans who have spent their lives paying into it.

Drug Prices

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: We all agree that too many Americans cannot afford their prescription drugs. Lowering prescription drug costs for American patients and families is a priority on both sides of the aisle, as is ensuring that the United States continues to allow for innovation in drug development. I want to work with you and other members of Congress to find ways to ensure patients have access to innovative drugs and bring down prescription drug prices.

CMMI

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: The Innovation Center has been an important tool to test new models to move our system from one that rewards volume to one that rewards value. It will continue to be important, as we move forward, to test models that improve patient care, advance health equity, and lower patient costs. We have now had 10 years of experience to learn from at the Innovation Center. We need to look at what has worked and what hasn't, and I look forward to hearing from you about what you think is working well and what experiences you've seen in Idaho.

Payments

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 is it important for Medicare beneficiaries, particularly patients with complex medical conditions such as ESRD, to have access to medically necessary treatments such as calcimimetics. If confirmed, I will work to preserve access to critical treatments and improve patient outcomes.

Question. In the "Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems" proposed rule for 2021, CMS solicited comments on the use of its "equitable adjustment" authority for pass-through products adversely impacted by the reduction in surgical procedures during the COVID-19 pandemic. Will CMS use this authority to ensure that products impacted by the pandemic receive pass-through payments for a length of time that enables adequate cost data collection that ensures reasonable payment once these products are bundled into an ambulatory payment classification (APC) group?

Answer: The COVID pandemic is taking a toll on Americans in so many ways, including reducing and delaying surgeries. If confirmed, I will work with you and other members of Congress as we look for ways to help providers, suppliers, and other stakeholders recover from the financial impacts of the pandemic and maintain access for beneficiaries.

<u>New Treatments</u>

Question. The 21st Century Cures Act that was enacted in 2016 created a home infusion therapy benefit to provide for the nursing services necessary to support drug administration in the home setting when patients are unable to self-administer. To date, no new drugs requiring healthcare professional administration have been able to get covered for home infusion. CMS issued a "Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)" proposed rule in 2020 that would create a pathway for drugs requiring healthcare professional administration to be covered for home infusion. This rule has not yet been finalized, even though many seniors would continue to benefit from being able to receive treatment at home during the COVID-19 pandemic. Will CMS prioritize the finalization of this DMEPOS proposed rule to expand seniors' access to the home infusion benefits?

Answer: Thank you for raising this important issue. We share the goal of making sure people can receive care in their homes, when appropriate, especially during the pandemic. If confirmed, I am happy to make the review of this proposed rule a priority.

Question. Cell and gene therapies present a paradigm shift in the treatment of disease: no longer just treating symptoms, but using cutting-edge technology to address the root-cause of the disease itself. The FDA has previously predicted that it will be approving 10 to 20 cell and gene therapies a year by 2025. Many of the initial diseases that these groundbreaking therapies aim to treat are disproportionately insured by Medicare and Medicaid. The cost of these potentially life-saving therapies has led to a national conversation on the use of value-based arrangements to ensure broader access for beneficiaries, especially for rare disease and cancer patients where the population that is eligible for the therapy could be in the hundreds or thousands.

- Would you agree that CMS should do all they can to ensure access to FDA-approved cell and gene therapies when a doctor and a patient agree it is the best treatment option?
- As Administrator, would you commit to utilizing existing program flexibility and considering innovative demonstration programs to enable Medicare and Medicaid beneficiaries' timely access to innovative cell and gene therapies? Will you commit to working with Congress on a statutory solution that maximizes access without threatening future development of these innovative products?

Answer: Thank you for raising this important issue. It is incredible what scientific progress has been made with innovative drugs and treatments, and we need to continue to modernize the Medicare and Medicaid programs to make sure beneficiaries have access to proven new treatments. I would be happy to work with you and other members of Congress on ways to spur innovation and facilitate beneficiary access to proven new advances in medicine.

Senator Chuck Grassley's (IA) Questions for-the-Record

for Centers for Medicare & Medicaid Services Administrator-Nominee
Chiquita Brooks-LaSure
Submitted April 16, 2021

Questions for Brooks-LaSure

1. American taxpayers expect us to be good stewards of federal money. Under section 1903(u) of the Social Security Act, the federal government is required to recoup any improper Medicaid eligibility-related payments in excess of three percent made by states. The Centers for Medicare & Medicaid Services (CMS) has made little improvement since 1992 to recover any of these payments. In 2019, Congress passed the Payment Integrity Information Act requiring CMS to periodically review programs it administers, identify programs that may be susceptible to significant improper payments, estimate the amount of improper payments, and report on the improper payment estimates. The most recent annual reported improper payments figure across all Medicare and Medicaid/CHIP programs was $134.21 billion (2020 CMS estimated data) and $106 billion (2019 CMS data). The Medicaid improper payment rate for 2020 was 21.36% (or $84.49 billion) and the Medicare fee-for-service improper payment rate for 2020 was 6.27% (or $25.74). This has been ongoing for decades. If confirmed, how will you as CMS administrator address the improper payment rate and the waste of taxpayer dollars?

***Answer*:** Medicaid is a critical lifeline for beneficiaries across the country and typically the largest expenditure for states. Reducing Medicaid improper payments is a priority because it helps ensure the fiscal health of the program. If confirmed, I will work with states and leaders in Congress to be responsible stewards of taxpayer dollars across both Medicaid and Medicare.

2. Ensuring access and protections for individuals with serious disabilities who rely on complex rehabilitative manual wheelchairs is important. In 2019, Congress provided 18-month relief for complex rehab technology (CRT) by including protections for complex rehab manual wheelchairs. On June 30, 2021, a temporary policy allowing users of complex rehabilitative manual wheelchairs the same benefits as complex rehabilitative power wheelchair users will expire. This policy has given equal access for the people with disabilities who depend on this new technology. If confirmed, would you support a permanent policy maintaining the equal access between manual and power wheelchairs?

***Answer*:** I agree that is important to make sure Medicare beneficiaries have access to the durable medical equipment they need. If confirmed, I will work with you on this issue.

3. 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. In December 2019, 56 other state and territory attorneys general asked 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. While CMS does not have a role in the scheduling process, I understand that HHS plays a key role that effort.

4. 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 was happy to see that Congress included incentives for states to expand Medicaid postpartum coverage in the American Rescue Plan and that CMS has approved section 1115 demonstration projects to this effect. I look forward to working with members of this Committee and Congress to expand access to affordable, quality care, including through the Medicaid program.

5. 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*:* If confirmed, I will provide responses to requests from any members of this Committee.

6. In 2019, Congress passed bipartisan the Advancing Care for Exceptional (ACE) Kids Act to improve health outcomes and care coordination for children with complex medical conditions in Medicaid. In 2020, I introduced the bipartisan Accelerating Kids' Access to Care Act to further help families gain access to life-saving care for children with complex

medical conditions. The legislation aims to facilitate access to care while retaining program safeguards and reducing regulatory burdens on providers. If confirmed, what steps would you take to improve the system of care for children with complex medical conditions?

***Answer*:** Thank you for your leadership on the ACE Kids Act and your focus on access to care for children with complex medical needs. I agree that we should do all we can to remove barriers to care for these children. If I am fortunate enough to be confirmed, I will look forward to working with you on solutions to ensure children with complex medical needs get the best care possible.

7. In Iowa, transitional health plans (including grandmothered 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 grandmothered health plans. To put this in context, about 60,000 Iowans signed up for the federal health insurance exchange in 2021. Iowans have chosen these grandmothered health plans that meet their individual needs. Currently, grandmothered 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?

***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, and I look forward to learning more from you about what is working in Iowa.

8. Since this COVID-19 pandemic began, the Department of Health and Human Services (HHS) including within the Centers for Medicare & Medicaid Services (CMS) has provided health care providers and patients many flexibilities under the public health emergency authority including over 80 services now furnished through telehealth for Medicare patients. 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 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 those telehealth barriers for certain providers?

***Answer*:** Telehealth has been invaluable during this pandemic to keep patients, their providers and their families safe. My brother is a psychologist, and telehealth has really helped his patients get the care they need. If I am fortunate enough to be confirmed, I will take a careful look at the telehealth flexibilities under Medicaid and Medicare before the Public Health Emergency ends. During that review, I will pay special attention to the issues of equity and access. I will look at what we can and should extend administratively and where we will need Congress's help to ensure that we bring the lessons learned about telehealth during the pandemic forward to modernize our health care system.

9. 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, will you work to maintain, 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.

10. 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 work to maintain, modify, or rescind current regulations enabling employers and employees access to Association Health Plans?

***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 all rules and policies to ensure all Americans can access the care that they need.

11. 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.

12. If confirmed, will you take actions that stifles innovation and competition in health care?

***Answer*:** I believe it is important to foster innovation and competition in our health care system. CMS has a critical role in promoting these goals and ensuring access to care. Americans should have access to health care services and products at an affordable price.

13. In 2019, the Trump administration issued two rules requiring price transparency for hospitals and health plans. 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. Consumers should have the ability to compare health care prices online so they can make an informed choice about what's best for them and their families. If confirmed will you modify, rescind, or maintain the Trump administration's health care price transparency regulations?

***Answer*:** I agree that the variation in pricing across hospitals is not always justified and ultimately can be bad for consumers. For transparency measures to work properly, patients and their families must be able to understand them in a meaningful way. If I am fortunate enough to be confirmed, I look forward to continuing to work on this issue.

14. Some states have lacked transparency in reporting their nursing home COVID-19 deaths data. For example, the state of New York undercounted nursing home deaths by as much as 50% and state officials intentionally withheld data for months. The New York Attorney

General Letitia James released a report in January 2021 suggesting that many nursing home residents died from COVID-19 in hospitals after being transferred from their nursing homes. These figures were not reflected in the New York Department of Health's nursing home death figures for many months suggesting the state was undercounting by as much as 50%. There are also reports finding New York state officials including members of New York Governor Andrew Cuomo's staff intentionally withheld data on COVID-19-related deaths in the state's nursing homes. Following the release of the New York Attorney General report, the New York Department of Health reported 12,743 nursing home residents occurred. This included an additional 3,829 confirmed COVID-19 fatalities of those residents who had been transported to hospitals. I have warned President Biden that an across-the-board termination of 56 U.S. attorneys could imperil ongoing sensitive investigations. This concern has been expressed by Senate Democrats. Currently, Toni Bacon is serving as the U.S. attorney for the Northern District of New York. Ms. Bacon previously served as Justice Department's national elder justice coordinator and who currently has jurisdiction over federal public corruption crimes in the state. Bacon is the obvious choice to continue a fair and unbiased investigation into possible violations of civil liberties of the elderly and the public corruption. Do you believe Department of Justice must have a fair, unbiased, and experienced U.S. Attorney in the Northern District of New York, such as Ms. Bacon?

***Answer*:** I defer to the Department of Justice on the selection of U.S. Attorneys.

15. I led an effort in the Senate making additional resources available to support elder justice initiatives that assist older Americans especially throughout the COVID-19 pandemic. During the 116th Congress as Senate Finance Committee chairman I convened two hearings on elder justice initiatives and gaps in nursing home oversight. In December 2020, I urged Senate leadership to make resources available for regional or statewide strike teams to support nursing homes in crisis during this pandemic. Through this work, the end-of-year COVID-19 relief package included $100 million to support elder justice initiatives, including $50 million for state adult protective service agencies as they cope with unique challenges of serving vulnerable populations during the pandemic. This work includes nursing home strike teams who have provided needed support when an outbreak occurs at a nursing home or when additional resources are needed to meet the infection control or diagnostic testing requirements. Have state or federal nursing home strike teams been effective at controlling outbreaks and protecting vulnerable Americans? If so, can you describe how their work slowed-the-spread and protected lives?

***Answer*:** It has been heartbreaking to see how hard the COVID-19 pandemic has hit the nation's nursing homes. Nursing homes and long term care facilities are the homes for some of our most vulnerable, and we must do everything we can to work to protect them. If confirmed, I look forward to reviewing the work of the federal nursing home strike teams.

16. The global pandemic has exposed grave concerns our society must confront to protect the nation's most vulnerable citizens. Approximately 1.4 million Americans live in about 15,000 nursing homes across the country. Many Iowans have a loved one who lives in a long-term care facility. In 2019, as Chairman of the Senate Finance Committee, I conducted a series of hearings to examine gaps in enforcement of nursing home abuse. A Government Accountability Office (GAO) investigation found a 103% increase in abuse deficiencies between 2013 and 2017. The GAO noted abuse in nursing homes is often underreported. The report documented physical, mental, verbal and sexual abuse perpetrated against residents. The number of nursing home deaths attributed to COVID-19 delivers a wake-up call we can't afford to ignore. The federal government needs to do a better job enforcing compliance with standards of care. When a loved one requires a long-term care facility to deliver around-the-clock services, every family deserves peace of mind that every nursing home resident will receive high-quality, compassionate care and be treated with dignity and respect. If confirmed, how will you as administrator ensure nursing homes uphold the standard or care that is necessary while not placing onerous requirements and excessive administrative burdens on nursing home staff?

***Answer*:** Thank you for your longstanding leadership on this important issue of preventing elder abuse. This will be a focus of mine if confirmed. Nursing homes and long term care facilities are the homes for some of our most vulnerable, and we must do everything we can to work to protect them.

Senator John Cornyn
Senate Finance Committee
Questions for the Record
Nomination Hearing of Andrea Palm and Chiquita Brooks-LaSure

Brooks-LaSure Questions

End Stage Renal Disease

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 spur innovation in medical technology that improves health outcomes, particularly for patients with complex illnesses such as ESRD. I will always look for ways to improve access to innovative and effective treatments for ESRD patients, and I believe there is plenty of room for bipartisan work in this area. If confirmed, I will work with you and other members of Congress on ways to improve access to these innovative treatments.

Medicare Program Integrity

I'm very concerned about the billions 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: 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 in addition to a host of other tools it uses to detect waste, fraud and abuse. If confirmed, I will work with you to make sure that we are good stewards of the Medicare program and taxpayer dollars.

Bundled Payments

CMMI has recently expressed their commitment to value-based payment programs but is no longer allowing new participants in the BPCI model and last week announced they won't take new applicants to the new direct contracting model. This is creating uncertainty about the agency's commitment. My constituents have made substantial investments in participating and/or preparing for these programs and strongly believe in their importance in driving value for Medicare beneficiaries and the trust fund.

- Can you assure me as CMS Administrator that you are indeed committed to these innovative models and that you will be open to stakeholder input to improve upon CMMI models before canceling them?"

Answer**:** The Innovation Center has been an important tool to test new models to move our system from one that rewards volume to one that rewards value. It will continue to be important, as we move forward, to test models that improve patient care, advance health equity, and lower patient costs. We have now had 10 years of experience to learn from at the Innovation Center. We need to look at what has worked and what hasn't and chart a path forward from there. This absolutely includes getting stakeholder and Congressional input. If confirmed, I will work with you to make sure we are pursuing models that recognize the strides providers have already made and improve our health care system.

Laboratory Date of Service Policy

In 2017, CMS established regulations at 42 CFR §414.510(b)(5) to revise its date of service policy for clinical laboratory tests to allow a laboratory to bill Medicare directly for molecular pathology tests and certain Advanced Diagnostic Laboratory Tests (ADLTs) (as defined under Section 1834A(d)(5)(A) of the Social Security Act) performed on specimens collected from hospital outpatients. These regulations eliminated access delays for Medicare beneficiaries that

resulted from the previous requirement that the hospital at which the specimen was collected bill Medicare for these relatively uncommon tests. Under the current policy, hospitals and SNFs are similarly incentivized to delay submitting samples which can have an impact on patient care and time to treatment.

- Ms. Brooks-LaSure, can you commit to working in future rulemaking to address this payment policy for skilled nursing facilities and inpatient hospitals as the agency has already done in the outpatient setting?

Answer: I share your desire to protect Medicare beneficiaries' access to laboratory testing services. My understanding is that payment to a hospital or skilled nursing facility for laboratory tests furnished to an inpatient whose stay is covered under Part A is generally included in the prospective payment system rate for the facility. If I am fortunate enough to be confirmed, I would be happy to hear more from you on this important issue and work with you to improve beneficiary access to laboratory testing.

Surprise Billing

Ms. Brooks-LaSure, complex molecular diagnostic tests for advanced cancer have tremendous benefit for patients and oncologists hoping to identify the best treatments. Many of these tests are viewed as out-of-network and have limited comparable tests for setting benchmarks.

- Can you commit to working with my office to make sure that access to these important tests is not delayed due to surprise billing regulations promulgated under the No Surprises Act?

***Answer*:** Making sure that all Americans have access to quality, affordable health care is one of the Biden Administration's top priorities. I know that there will be a lot of work to do to implement the No Surprises Act. If confirmed, I look forward to working with you and other members of Congress to make sure that consumers are protected from surprise bills while ensuring they have access to the care that they need.

Disproportionate Share Hospitals Payments

Disproportionate Share Hospitals (DSH) are owed more than $10 billion in reimbursements going back to 2005. CMS has challenged these payments based on a formula that defied congressional intent. The court have consistently ruled that CMS's interpretation is wrong and therefore its rule making is invalid. The agency continues to fight and is planning to issue yet one more rule despite a loss on this issue at the Supreme Court.

- Will you commit to working to ensure DSH hospitals receive the DSH payments they are owed.

***Answer*:** Disproportionate Share Hospitals are critical to our nation's health care system, providing care to low-income patients and the uninsured, and I know that this pandemic has placed significant pressure on these health care providers. If confirmed, I look forward to working with you and other members of Congress to ensure CMS is using taxpayer dollars appropriately while supporting these providers and the work they do on behalf of their patients. I will also ensure that states and providers have the guidance they need to administer and participate in the Medicaid program.

Dialysis-Related Amyloidosis

We have watched for years as the Medicare program has delayed coverage for important medical breakthroughs offered by both prescription drugs and medical devices. Although we are aware of certain improvements over the past two years in the coding process for new drugs and devices, the coverage process lags far behind. The result is that patients are not receiving the care they need.

One recent example involves Dialysis-Related Amyloidosis (DRA), a disease that affects an estimated 3,000-5,000 patients who have been receiving dialysis treatment for 5 or more years. DRA results from the failure of the kidneys to filter and remove a protein called "beta-2 microglobulin," cause cysts across the body, from joints to internal organs. These cysts can be extremely painful, and sometimes fatal, for those with DRA. Although for years there was no treatment available in the United States, a treatment was approved in 2015. Unfortunately, the Medicare program does not cover the treatment, which is of great concern to me and my constituents.

In March of 2015 the FDA approved a new treatment for DRA using a special apheresis "column" in which blood is taken from the patient, processed to remove an accumulation of the bad protein (beta-2 microglobulin) and returned to the patient. Because the patient population is so small and the treatment was sufficiently safe, the FDA approved the treatment as a Humanitarian Use Device. Yet, despite being approved six years ago, I am told the Medicare program is still evaluating the appropriate coverage pathway for the treatment. Until Medicare reaches a decision, Medicare beneficiaries continue to be denied access to the only FDA approved treatment for DRA.

- Can you commit to work expeditiously to apply an appropriate Medicare benefit category and finally decide coverage for this DRA treatment, and any other Humanitarian Use Devices approved by FDA but not yet covered by the Medicare program?

***Answer*:** I agree that is it important for Medicare beneficiaries, particularly patients with complex medical conditions such as ESRD, to have access to medically necessary treatments. If confirmed, I am happy to look into this further and work with you on this issue.

Hospice

Ms. Brooks-LaSure: The COVID-19 pandemic has brought telehealth to the forefront of care, dramatically increasing accessibility and making strides toward health equity. The hospice community has rapidly expanded its telehealth services for the entire Interdisciplinary Team, from nursing to chaplains. However, CMS does not appropriately capture telehealth claims and therefore lacks visibility into a critical aspect of hospice care delivery. The 2021 shift by CMS to only claims based hospice quality measurement, exacerbates this gap in essential care delivered. Creating telehealth codes for the entire hospice Interdisciplinary Team including the required chaplains' visits, would give CMS proper visibility into the hospice landscape.

- Will CMS commit to implementing appropriate codes for hospice's telehealth services for every IDT discipline, including chaplain visits?

Answer: Improving the safety and quality of end-of-life care is important and telehealth has been and continues to be an important tool during the pandemic. While often at end-of-life, hands-on care is needed to manage symptoms, sometimes telehealth may be an appropriate and safe way to receive hospice care. If I am fortunate enough to be confirmed, I look forward to learning more from you about this issue and working to ensure that hospice patients have access to the highest quality care.

MA Plan Treatment of New Technology in ESRD

Ms. Brooks-LaSure: As you know, Medicare Advantage plans are required to ensure coverage equal to that offered under fee-for-service. However, patient groups and other stakeholders have noted that Medicare Advantage plans may not have, or may not plan to, appropriately reimburse for End Stage Renal Disease (ESRD) drugs that are under the transitional drug add-on payment adjustment (TDAPA) through their negotiated monthly rates. Under certain circumstances this may just be a failing of timing, but what happens when new technologies appear after plans have already negotiated their rates? Failing to appropriately account for TDAPA payments puts a strain on dialysis organizations and hurts patient access to top of the line therapies. Additionally, many stakeholders continue to be concerned about the TDAPA "cliff." After two years of additional payment for these innovative therapies, drugs which fall into minimally funded categories represent undue financial pressure for providers when the transitional payment goes away. This cliff can result in providers having to make difficult choices about how to continue to provide innovative products to their patients.

- While CMS does not interfere in direct negotiations between Medicare Advantage plans and their contracted providers, it does bear responsibility for upholding parity of coverage. How will CMS rectify this patient access issue?

- Can you commit to patients that this and other over-arching issues with TDAPA will be something that you have CMS look at so that we can feel comfortable knowing that the sickest patients will have access to all of these innovative therapies in the pipeline?

***Answer*:** It is important for Medicare beneficiaries with ESRD to have access to the ESRD therapies they need. Given that people with ESRD had the new option to enroll in Medicare Advantage plans for coverage beginning this year, Medicare Advantage now has a crucial role in providing access to ESRD therapies for Medicare beneficiaries. If confirmed, I will work to ensure that beneficiaries have access to ESRD therapies under Medicare Advantage plans. I will also work to ensure that Medicare beneficiaries continue to have access to innovative therapies and to improve patient outcomes.

Global and Professional Direct Contracting Model

Recently CMS announced that it would not be allowing a second round of applications for the Global and Professional Direct Contracting Model. However based on multiple polls, letters to the Agency, and media reports, there is a significant coalition of providers, including Baylor Scott and White in Texas, that were interested in participating in the second application cohort. Many providers apparently delayed participating in the program because of the pandemic.

- What will you be doing to ensure that those providers are given an opportunity participate if they want to take on risk in the Global and Professional Direct Contracting Model and what are the Administration's plans for this model and other models like it?

***Answer*:** The Innovation Center has been an important tool to test new models to move our system from one that rewards volume to one that rewards value. It will continue to be important, as we move forward, to test models that improve patient care, advance health equity, and lower patient costs. We have now had 10 years of experience to learn from at the Innovation Center. We need to look at what has worked and what hasn't and chart a path forward from there. This absolutely includes getting stakeholder and Congressional input. If confirmed, I will work with you to make sure we are pursuing models that recognize the strides providers have already made and improve our health care system.

Allina Ruling

As CMS Administrator, would you respect the ruling of the Supreme Court in the Allina Case with regard to calculating DSH payments by including Medicare Advantage enrollees inpatient days who are also eligible for Medicaid?

***Answer*:** If confirmed, I will absolutely respect the Supreme Court rulings and follow the law.

Questions for Both

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 from Ms. Brooks-LaSure*:** Programs such as Medicaid and the Children's Health Insurance Program (CHIP) are critical programs that help ensure that children have adequate access to quality health care. If confirmed, I would work to ensure children are receiving necessary health care through both programs. I would also look to better ensure access to oral health and vision care for children, as both are necessary for children to thrive in school. And we cannot 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 CMS and working collaboratively with colleagues across HHS. I look forward to working with Congress, and with state and local partners to make sure that we are doing all we can to improve child health in this country.

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 from Ms. Brooks-LaSure*:** If confirmed, I would work to support and strengthen 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. If confirmed, I look forward to working with you to make sure our children have access to quality care.

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 from Ms. Brooks-LaSure*:** I am deeply concerned about the impact of the COVID-19 pandemic on the mental, emotional, and other behavioral health outcomes of our children, 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 Medicaid and CHIP to connect children to the behavioral health care they need to navigate this unprecedented time, and to work toward better integration of physical and behavioral health care. If confirmed, I would seek to collaborate with other HHS agencies, including SAMHSA, to do a better job of tackling this important issue.

- The pediatric health care safety net has been affected by the pandemic in different ways then 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 from Ms. Brooks-LaSure*:** 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 work within CMS and with my HHS partners and state Medicaid agencies, 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 from Ms. Brooks-LaSure*:** If confirmed, I will work with the resources within CMS and partner with state Medicaid agencies to support the health care workforce, including those who work with pediatric populations. I would look forward to working with HHS partners as well, including HRSA, on ensuring access to needed health care for our nation's children.

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 from Ms. Brooks-LaSure*:** 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. Under current law, states have a great deal of flexibility with respect to delivering Medicaid services via telehealth. 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 under Medicaid and determine how we can build on this work to improve health equity and improve access to health care for children.

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 ACE Kids Act passed in 2019 and is 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 from Ms. Brooks-LaSure*:** Medicaid and CHIP are crucial to ensuring children have adequate access to quality health care, especially those with complex needs. If confirmed, I will work to ensure children are receiving necessary health care under both Medicaid and CHIP. I look forward to working across the Administration and with Congress to make informed decisions that address the specific needs of children with complex medical conditions.

Oftentimes, changes in the larger health care landscape take place, for example in the Medicare program, without a full examination of how these changes could potentially impact children, even inadvertently. At times, Medicare policies designed with the elderly population in mind have been applied to Medicaid or adopted by state Medicaid programs and private payers.

- As you look at health care changes at the national level as HHS Secretary, how will you ensure that children's unique health care needs are taken into account?

***Answer from Ms. Brooks-LaSure*:** If confirmed, I will work with Congress and states 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.

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 from Ms. Brooks-LaSure*:** If confirmed, I will work with Congress and states 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.

Senator Richard Burr, Questions for the Record

Ms. Chiquita Brooks-LaSure, Nominee for Administrator of the Centers for Medicare and Medicaid Services (CMS)

CMS-FDA Coordination

1. I often hear from constituents about the reluctance of the Medicare program to cover new and innovative therapies. Even as the commercial market recognizes the benefits of breakthrough technologies and medicines, the Medicare program lags behind in covering novel products that can save and improve lives.

A recent CBO report on pharmaceutical R&D provided a stark reminder of just how difficult it is to develop these new medicines. The costs of bringing a new drug to market have been estimated to top $2 billion.[1] Given this immense cost, the federal government should ensure a clear pathway to coverage for companies that work to meet the FDA's gold standard of safety and efficacy and bring new treatments to patients.

If confirmed, you will lead the agency at a time when innovative therapies and technologies are changing the way care is delivered. To meet this moment, Medicare must also adapt. I have long been a proponent of increasing the coordination between CMS and FDA to ensure that our federal health programs – and the Americans that rely on them – are prepared for the upcoming pipeline of novel technologies.

a. Will you commit to working with my office to further the goal of enhanced coordination between CMS and FDA to bring innovative medical products to Americans in as timely a manner as possible?

b. If so, what are some of the ways in which CMS could work with FDA in order to reduce the time patients wait for new treatments and therapies?

c. Currently, there is a therapy under review at FDA that, if approved, would be indicated for the treatment of Alzheimer's disease – a uniquely devastating illness in terms of its breadth and lethality. The action date for this therapy under the Prescription Drug User Fee Act is June 7, 2021. To date, FDA has only approved one method of diagnosis for Alzheimer's disease – a PET scan. CMS has denied Medicare coverage of PET scans for Alzheimer's pathologies, however. If this therapy is approved, Medicare's decision to forego coverage of this diagnostic could present a barrier to access for patients with no other effective therapeutic options. This specific situation is just one that demonstrates the broader need for FDA and CMS coordination. Will you commit to working with me on ensuring appropriate Medicare coverage of PET scans and other diagnostics that may benefit patients with Alzheimer's disease?

Answer: Thank you for your leadership on the issue of expanding access to the benefits of innovative medical technologies to American patients and families. It is incredible what science

has been able to do with innovative drugs and treatments in recent years. We need to make sure we're looking at modernizing the Medicare program to make sure beneficiaries have access to proven new treatments. I also think it is important for CMS to be collaborating with other agencies, including the FDA, to make sure we work better together. If I have the honor of being confirmed, I would be happy to work with you on this important issue.

2. In 2019, now-Acting FDA Commissioner Janet Woodcock testified before the House Energy and Commerce Committee that advanced manufacturing technologies could enable domestic drug producers to compete with China's lower labor, supply, and operating costs.[2]

a. How can the programs administered by CMS play a role in strengthening the security of supply chains, both broadly and for specific fields, like synthetic biology?
b. Do you agree that if CMS is to play a role in addressing supply chain issues that it needs to coordinate with FDA to better understand the nuance and complexities of global supply chains?

Answer: America continues to be a leader in medical innovation. This has been crucial during the pandemic. I agree that the nation's supply chain must be secure. If confirmed, I will make sure CMS is a helpful partner to FDA in this effort.

HI Trust Fund:

3. Medicare Part A has a longstanding insolvency problem. The Hospital Insurance (HI) Trust Fund that finances Part A is funded by payroll taxes and as program spending has outpaced payroll tax revenues, the balance of the trust fund has steadily declined. In February, the Congressional Budget Office (CBO) projected that the HI Trust Fund will run out of money by 2026. CBO also estimates that expenditures will continue to outpace payroll tax revenue after the trust fund has been depleted.

Addressing Medicare's finances sooner rather than later would allow for subtle, gradual changes that protect seniors' access to high-quality care while ensuring sustainability for future generations. The alternative would threaten sudden and steep benefit cuts for tens of millions of senior citizens.

As Administrator of CMS, if confirmed, you will be looked to by the President and Congress for leadership and assistance on reform proposals small and large. What specific experience do you have in crafting or evaluating proposals to reform the Medicare program?

Answer: Medicare solvency is an incredibly important, longstanding issue. We will need both short-term and long-term strategies to make sure Medicare remains a bedrock of our health care system, and I look forward to working with Congress on a bipartisan basis to address this. I look forward to working with you on ways to improve the solvency of the Medicare program.

Price Transparency:

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

Answer: I agree that empowering consumers with health care price information is important. For transparency measures to work properly, patients and their families must be able to understand them in a meaningful way. If I am fortunate enough to be confirmed, I look forward to continuing to work on this issue.

Foster Care

5. 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 if I am confirmed as CMS Administrator. I share your conviction that children in foster care should receive necessary medical care without disruption. If I am fortunate enough to be confirmed, I will be happy to work with you on this critical issue.

MACPAC Proposal

6. As you know, the statutory Medicaid Drug Rebate Program (MDRP) requires drug manufacturers to provide rebates on drugs to state Medicaid programs rebates to ensure Medicaid receives the lowest price relative to private payers. There is an additional mandatory rebate on drugs calculated according to increases in price that exceed inflation. Earlier this month, the Congressional Budget Office cited research showing that the MDRP contributes to higher prices paid by private payers, as offering additional discounts in the private markets would result in lower Medicaid revenues.[3]

The Medicaid and Chip Payment and Access Commission (MACPAC) recently voted on recommendations to increase the amount of rebates manufacturers must pay for drugs brought to market under the accelerated approval pathway at FDA.

a. Do you think this recommendation is appropriate?
b. If so, what are your reasons for supporting this unprecedented approach to tying rebates to FDA approval pathways?
c. MACPAC has acknowledged that this policy could create access issues for the Medicaid population. How would you ensure equitable access to these treatments and therapies if this policy were to be adopted?

Answer: We can all agree that prescription drug costs are too high for American patients and families. From my many meetings with Senators in the last few weeks, I have seen that addressing this is a priority on both sides of the aisle. I think there is an opportunity for real impact here to lower costs for American patients and families, while making sure to continue to support innovation.

Prescription drug costs, including in the Medicaid program, are very complex. Ultimately, we need solutions that produce real results to bring down overall costs for American patients and families while avoiding barriers to access. I would be happy to examine this particular MACPAC proposal in more detail. If confirmed, I look forward to working with you and your colleagues to find solutions to the high cost of prescription drugs without reducing access to necessary treatments.

Clinical Trials

7. Late last year, the Clinical Treatment Act, was signed into law. Senator Cardin and I crafted this legislation to ensure Medicaid beneficiaries have access to clinical trials by requiring state Medicaid programs to provide coverage of routine medical care associated with the trial – a benefit already provided by Medicare. This law will improve access to potentially life-saving therapies for sick Americans as well as broaden the base of clinical trial participants, which will improve the ability of manufacturers to conduct these trials.

How will you ensure that this important benefit is available to Medicaid beneficiaries as expeditiously as possible?

Answer: If I am fortunate enough to be confirmed, I will work with the National Institutes of Health and with trusted partners in the community to help to encourage participation in clinical trials, which – as you noted – can offer potentially life-saving treatment opportunities to patients. One barrier to participation in these trials can be payment for routine medical care associated with the trial, so I think it is so important that Medicaid will pay for covered items and services provided as part of qualifying clinical trials starting January 1, 2022. If confirmed, I would look

forward to working with you, Senator Cardin and other Members of Congress on this issue as we work to implement this important benefit in a timely manner.

CMMI

8. The Patient Protection and Affordable Care Act (PPACA) created the Centers for Medicare and Medicaid Innovation (CMMI) and afforded it broad authority to test new payment models. The law requires the termination or modification of any model that does not improve quality of care without increasing spending; reduce spending without reducing quality of care; or improve quality of care while also reducing spending. Shockingly, the PPACA also included a clause attempting to block any administrative or judicial review of CMMI demonstration models, leaving the Administrator as a key, potentially unaccountable, arbiter of whether or not the law's requirements are being followed.

How specifically will you ensure that statutory requirements for CMMI models are stringently adhered to? Will you commit to working with members of this Committee to establishing a permanent mechanism for Congressional input and oversight?

Answer: The Innovation Center has been an important tool to test new models to move our health care system from one that rewards volume to one that rewards value. It will continue to be important, as we move forward, to test models that improve patient care, advance health equity, and lower patient costs. We have now had 10 years of experience to learn from at the Innovation Center. We need to look at what has worked and what hasn't and chart a path forward from there. If I am fortunate enough to be confirmed, I want to have open lines of communication with Congress, and I look forward to hearing from you about CMMI models.

Clinical Laboratory Fee Schedule

9. The Medicare Clinical Lab Fee Schedule (CLFS) payment rates for antigen testing that use visual interpretation for results have traditionally been the same as the tests that utilize instruments to interpret results. However, CMS has recently changed this practice for COVID-19 testing, bifurcating the rates for these types of tests. This bifurcation occurred in June 2020.
    a. Why does CMS believe that a bifurcation in reimbursement rates was warranted in the case of SARS-CoV-2 antigen testing?
    b. Under your leadership, how would CMS incentivize the development of digital health technologies that make diagnostic test results accurate and reliable?

Answer: Access to safe and reliable testing is key to combating the COVID-19 pandemic. If I am fortunate enough to be confirmed, I look forward to hearing from you about Medicare's clinical laboratory fee schedule rates and protecting beneficiary access to laboratory testing services, including digital technologies where appropriate.

[1] https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf
[2] https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019
[3] https://www.cbo.gov/system/files/2021-04/57020-Public-Option.pdf

Senator Toomey

Question for the record for Chiquita Brooks-LaSure

Hearing to Consider the Nominations of Andrea Joan Palm, of Wisconsin, to be Deputy of Health and Human Services, vice Eric D. Hargan, and Chiquita Brooks-LaSure, of Virginia, to be Administrator of the Centers for Medicare and Medicaid Services, vice Seema Verma

Question #1

As part of the American Rescue Plan Act (ARPA; P.L. 117-2), approximately $35 billion is estimated to be spent to temporarily expand Obamacare subsidies to current marketplace enrollees and individuals making over 400 percent of the federal poverty level, including high-income earners or those making over six figure salaries. The majority of these subsidies will go to individuals who already have health insurance. Furthermore, taxpayers are expected to spend an additional $6 billion to temporarily pause premium tax credit reconciliation for plan year 2020 – meaning individuals who received more than they should *will not* be asked by the federal government to repay taxpayers for those improper subsidies. In the past, multiple government watchdogs have concluded that these taxpayer subsidies are susceptible to significant improper payments. As the federal deficit hits records highs, more must be done to ensure our taxpayer dollars are spent wisely.

Ms. Brooks-LaSure, you have extensive programmatic experience with the federal marketplace and Virginia's state marketplace. If confirmed, how will you work with the Internal Revenue Service to reduce the advance premium tax credit program's susceptibility to improper payments? Please be specific.

***Answer*:** Advance payments of premium tax credits have helped make health insurance more affordable for millions of Americans and improved their access to care. This has been especially important during the pandemic when access to affordable health care has been more critical than ever. If confirmed, I will take seriously these responsibilities, including working with the Internal Revenue Service to make sure that we are good stewards of federal dollars.

Question #2

Over the years, the Medicare improper payment rate has dropped well below 10 percent. In fact, the improper payment rate for FY2020 dropped to 6.27 percent from 7.25 percent in FY2019 – its lowest rate in more than a decade. Further, over the past decade, the Medicare Advantage and Part D improper payment rates at their highest reached 11 percent and 3.7 percent respectively. In FY2020, the Medicare Advantage and Part D improper payment rates dropped to 6.78 percent and 1.15 percent respectively. Unlike the Medicare program, however, the Medicaid improper payment rate has ballooned. Most recently, the national improper payment rate in Medicaid was 21.36 percent, or $86.49 billion. Not only has the Medicaid improper payment rate doubled since 2010, but it is now more than triple the improper payment rate of the Medicare program.

Ms. Brooks-LaSure, if confirmed, what actions will you take to bring the improper payment rate in the Medicaid program under 10 percent? Please be specific.

***Answer*:** Medicaid is a critical lifeline for beneficiaries across the country. Reducing Medicaid improper payments is a priority because it helps ensure the fiscal health of the program. If confirmed, I will work with states and leaders in Congress to be responsible stewards of taxpayer dollars.

Question #3

Last fall, Senator Stabenow and I sent the Department of Health and Human Services a detailed letter recommending specific regulatory actions to improve our federal health care programs for beneficiaries with Alzheimer's disease. These recommendations were formed with input from more than 30 organizations that responded to a request for information as well as hearings and briefings led by Senator Stabenow and myself. Recently, the Biden administration took action on one of our recommendations and finalized a centralized website for patients and their caregivers to access information regarding their care options and clinical trial enrollment. However, other recommendations remain unimplemented.

Ms. Brooks-LaSure, if confirmed, how will you help increase access to innovative diagnostic tools and/or make improvements to existing methods of assessing cognitive impairment, such as direct observation, in the Medicare program to improve early detection of Alzheimer's disease? Additionally, with the potential for the first disease modifying drug to be approved by the U.S. Food and Drug Administration, existing tools like the amyloid PET scan are the only option for confirmatory diagnosis until a noninvasive, affordable and rapid diagnostic tool, such as a blood test, is made available to the public. Coverage determinations play a large role in diagnosing, treating, connecting to wrap-around services, and clinical trial enrollment. If confirmed, will you examine existing CMS coverage policies to ensure the Medicare program provides seamless access to the best diagnostic tool(s) available to this patient population and other similarly situated disease groups?

How can the Medicare Advantage program play a role in strengthening care coordination among this population?

What other policies will you prioritize to improve the lives of Medicare and Medicaid beneficiaries living with Alzheimer's disease?

***Answer*:** Alzheimer's disease is a devastating condition for patients and families. Early detection is critical to improve care, and I agree that CMS should work to improve coverage of proven diagnostics. I also agree that better coordinating health care benefits patients, and we should strive to improve care coordination across programs. Medicaid and Medicare, including Medicare Advantage, have an important role to play in providing this type of quality care, including to those living with complex conditions like Alzheimer's disease. I would be happy to work with you on this important issue should I be confirmed.

Question #4

Through Section 1115 waiver authority, state Medicaid programs can waive certain programmatic requirements to implement greater flexibilities with their eligibility, benefit, and delivery systems. CMS plays an instrumental role in the implementation of Section 1115 waivers through the negotiation process and oversight of their financial performance.

Ms. Brooks-LaSure, if confirmed, how would you work to uphold and enforce the longstanding policy of budget-neutrality for Section 1115 waivers and ensure the integrity of their financial performance?

***Answer*:** Each state is unique, and innovation is critical to improving the health care system. Section 1115 demonstration projects, or waivers, are one available tool to states to help test new and innovative policies in Medicaid. I agree that it is important that we are good stewards of taxpayer dollars while pursuing innovation. If confirmed, I will support state innovation and the ability of states to test out different models that meet the objectives of the Medicaid program.

Sen. Tim Scott's Questions for the Record, 4/15/21 Finance Committee Hearing

For Ms. Brooks-LaSure:

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

On Enhancing Telehealth Access:

Earlier this Congress, 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. Ms. Brooks-LaSure, if confirmed, can you commit to making the expansion of telehealth access, particularly for seniors and vulnerable populations, a priority for the Centers for Medicare & Medicaid Services (CMS)?
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 subsides. 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 access supporters to ensure that the tens of millions of Medicare beneficiaries enrolled in FFS do not face a 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 CMS Administrator, 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 has been invaluable during this pandemic to keep patients, their providers, and their families safe. My brother is a psychologist, and telehealth has helped his patients get the care they need. Additionally, I agree that telehealth services have improved health equity as beneficiaries have used telehealth to access care during the COVID-19 pandemic. Broadband access is a challenge for many patients, however, and I agree that digital infrastructure is an important issue to consider in the context of addressing health disparities. If confirmed, I want to be sure we learn lessons from this pandemic on telehealth about what we can and should extend administratively and what will need Congressional action.

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. 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, suggesting that the inclusion of virtual suppliers in MDPP, among other actions to strengthen the program, could help to address disparities, reduce costs, and improve outcomes for older Americans across the board.

1. Ms. Brooks-LaSure, if confirmed, can you commit to working, in consultation with my office, Sen. Warner's office, and other policymakers, 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, how do you envision CMMI's role 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: The Medicare Diabetes Prevention Program is an important model, and I appreciate your leadership in supporting patients with diabetes. I absolutely want to look at all options to help prevent diabetes, and I look forward to hearing more from you, Senator Warner, and other Members of Congress on ways we can improve the program for Medicare beneficiaries.

The Innovation Center has been an important tool to test new models to move our system from one that rewards volume to one that rewards value. It will continue to be important, as we move forward, to test models that improve patient care, advance health equity, and lower patient costs. We have now had 10 years of experience to learn from at the Innovation Center. We need to look at what has worked and chart a path forward from there. I look forward to hearing more of your thoughts on the direction of CMMI.

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.

I appreciate the emphasis that you placed, in your testimony, on advancing innovation.

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 CMS commit to implementing the VBP components of this rule and ensuring that patients have timely access to lifesaving cell and gene therapies?

4. If and when CMS 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 working 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?
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?
6. Generally speaking, what changes do you envision to CMS's policies that would promote the development of curative medicines to ensure that they are available to Americans as soon as possible?
7. With respect to sickle cell disease (SCD) in particular, can you commit to making efforts to combat SCD, both through novel gene therapies and through other innovative treatments and care models, a priority for CMS?
8. While surveillance data on the SCD patient population remains limited in many ways, research suggests that the majority of individuals affected by SCD may receive health care coverage through Medicaid, giving CMS an especially significant role in ensuring access to care for these Americans. Would you be willing to consider pilot programs, demonstration projects, or other innovative models to drive care improvement for those affected by SCD?

Answer: It is incredible what scientific progress has been made with innovative drugs and treatments in recent years. We need to make sure we are looking at modernizing the Medicare and Medicaid programs to foster innovation and to make sure beneficiaries have access to proven new treatments. Thank you for your leadership on Sickle Cell Disease.

If confirmed, I look forward to working with you and other members to find solutions to improve treatments, care models, and access to new therapies, including for Sickle Cell Disease.

FDA has testified "that advanced manufacturing technologies could enable U.S.-based pharmaceutical manufacturing to regain its competitiveness with China"

1. How can CMS leverage and advance the U.S. advantage in synthetic biology to solidify our domestic drug supply chain security?

Answer: America continues to be a leader in medical innovation. This has been crucial during the pandemic. I agree that the nation's supply chain must be secure. If confirmed, I will make sure CMS is a helpful partner to the FDA in this effort.

On Coverage and Payment for Products Approved via Accelerated Approval:

As described by FDA, the Accelerated Approval Program "allow[s] for earlier approval of drugs that treat serious conditions, and that fill an unmet medical need based on a surrogate endpoint," meaning "a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit." Furthermore, as explained by the agency, "[t]he FDA bases its decision on whether to accept the proposed surrogate or intermediate clinical endpoint on the *scientific support* for that endpoint" (*emphasis* mine).

In explaining the rationale for the creation of Accelerated Approval, FDA has noted that the use of intermediate or surrogate endpoints "can save valuable time in the drug approval process." In the example of cancer survival, for instance, the agency points out that measuring the extension of survival for cancer patients could take many years, whereas trials can assess tumor shrinkage, which is reasonably likely to predict the desired endpoint, much more efficiently. In this broad example, the use of accelerated approval could result in patient access to a life-saving product literally years earlier than might have been possible otherwise. For countless Americans, from children suffering from debilitating cancers to adults afflicted by rare blood disorders, access to drugs and biologics cleared through the Accelerated Approval pathway have been the difference between life and death.

As we look towards the months and years ahead, scores of patients can look to Accelerated Approval and other innovative, evidence-based pathways as a source of hope, recognizing that a new generation of game-changing therapeutics could feasibly cure conditions like sickle cell disease.

1. In 2018, CMS wrote to states affirming that drugs approved via the Accelerated Approval pathway "must be covered by state Medicaid programs, if the drug meets the definition of "covered outpatient drug," noting that said products "must meet the same statutory evidentiary standards for safety and effectiveness as those granted traditional approvals." Can you commit to ensuring, if confirmed, that every state Medicaid program covers all covered outpatient drugs approved via the Accelerated Approval Program, with no difference in treatment between these products and products approved via the traditional approval pathway?
2. Despite substantial pushback from patient advocates and policymakers, the Medicaid and CHIP Payment and Access Commission (MACPAC) has moved to advance a proposal that would create a differential rebate structure for products approved via the Accelerated Approval Program, essentially penalizing drugs and biologics for moving to market and serving patients more quickly. In addition to disincentivizing the use of the Accelerated Approval pathway and thus denying scores of Americans, including many childhood

cancer patients, with timely access to potentially lifesaving medications, this policy risks deterring, chilling, or otherwise redirecting investment in products that do not lend themselves to efficient trials with easily and expeditiously measured primary endpoints. Moreover, the framing of the proposal itself suggests a misunderstanding of the scientific integrity and underlying purpose of the Accelerated Approval Program. Before advocating for or otherwise seeking to advance any policy proposals that might weaken, penalize, or otherwise chill the use of the Accelerated Approval Program, can you commit to engaging with FDA officials and experts, patient advocates, manufacturers, policymakers on the Hill, and other relevant stakeholders to assess the potential consequences of such policies?

3. Regardless of the Administration in question, critics have often argued that FDA and CMS could and should work more collaboratively to ensure that safe and effective products can come to market as efficiently as possible. Can you commit to working with your counterparts at FDA to bolster collaboration and communication between the two agencies?

Answer: Thank you for your leadership on the issue of expanding access to the benefits of innovative medical technologies to American patients and families. It is incredible what scientific progress has been made with innovative drugs and treatments in recent years. We need to make sure we're looking at modernizing the Medicare and Medicaid programs to make sure beneficiaries have access to proven new treatments. I also think it is important for CMS to be collaborating with other agencies, including the FDA, to make sure we are working together to serve patients. I would be happy to examine this particular MACPAC proposal in more detail. If confirmed, I look forward to working with you and your colleagues to find solutions to the high cost of prescription drugs without reducing access to necessary treatments.

On Payment for FFR/iFR Technologies:

CMS has recently committed to reexamining the Medicare payment policy for specific procedures performed in an Ambulatory Surgical Center (ASC) to ensure that physicians can "exercise their clinical judgement in making site-of service determinations." One such policy that warrants reexamination is the ASC payment for fractional flow reserve and instantaneous wave-free ratio (FFR/iFR), technologies that accurately measure blood pressure and flow through a specific part of the coronary artery which can be critical for physicians in making treatment decisions for their patients.

Many doctors rely on these technologies to assess whether to perform percutaneous coronary intervention (PCI), driving improvements in quality of care and cost savings. However, the current Medicare ASC payment policy to package payment for FFR/iFR results in a payment rate that is three times lower than the outpatient hospital setting, where a complexity adjustment accounts for the cost of this important technology. The current ASC payment policy for FFR/iFR has made these procedures out-of-reach for physicians and Medicare beneficiaries in an ASC. Many stakeholders, including the Society for Cardiovascular Angiography and Interventions (SCAI) and the American College of Cardiology (ACC), have expressed concerns

over this policy and have called for a change, whether by separately paying for FFR/iFR or providing a payment adjustment similar to the adjustment provided under the outpatient setting.

1. If confirmed as Administrator, will you commit to reexamining this ASC policy in the upcoming rulemaking cycle and considering changes to the policy to make FFR/iFR a viable option for providers and patients in an ASC?

Answer: As more and more services can be provided on an outpatient basis in various settings, we need to be thoughtful about the incentives Medicare payment policies have on utilization in these sites of care. If confirmed, I will make sure that CMS continues to examine how payment policies that vary by site of care impact quality of care and cost savings, especially for technologies that are critical for making treatment decisions.

<u>On Vaccines:</u>

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*:** Making sure that all Americans have access to quality, affordable health care is one of the Biden Administration's top priorities. I look forward to working with Congress to find ways to ensure preventive care, including recommended vaccinations, is accessible for all populations served by CMS programs. If confirmed, I will work with stakeholders and trusted partners to educate providers, beneficiaries, and families, and encourage individuals to seek preventive care.

On Medicare Advantage:

A growing share of Medicare beneficiaries, rising from just one-quarter in 2010 to 39% in 2020, have chosen to enroll in Medicare Advantage (MA) plan, which enjoy 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. Ms. Brooks-LaSure, 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 an important option for all beneficiaries, including older Americans and people with disabilities. I believe that we have to take every approach we can to provide people access to quality health care. If confirmed as CMS Administrator, I look forward to working with Congress on this important issue.

On Integrating Certain Diagnoses Obtained via Audio-Only Telehealth Visits for Risk Adjustment Purposes:

South Carolina has seen substantial growth in MA market penetration in recent years. As a share of all Medicare beneficiaries across the state, MA enrollment has nearly doubled in the past decade, from 16% of total Medicare enrollment in 2010 to 31% in 2020. We have also seen increased interest in Programs of All-Inclusive Care for the Elderly (PACE), another innovative model intended to drive value-based care, particularly for those dually eligible for Medicare and Medicaid. While PACE has a much smaller population of participants, more than 400 reside in SC, receiving care across three different programs, which enjoy a high satisfaction rate.

Last Spring, I was pleased to see the Centers for Medicare & Medicaid Services (CMS) relax previous telehealth restrictions in Medicare to allow high-risk individuals more options for care, including allowing diagnoses obtained via telehealth to be used for risk adjustment in MA and PACE. However, CMS's guidance requires a video component to validate any diagnosis for risk adjustment purposes, even though many beneficiaries and participants have received care via audio-only visits during the pandemic, due in part to broadband and technological access gaps. According to some surveys, the majority of seniors who have access to a cell phone lack smartphone capabilities, and for many older Americans living in rural areas, including more than 27% of South Carolinians, broadband hurdles persist, making audio-visual visits challenging for many beneficiaries.

I have heard from plans, providers, and researchers from across South Carolina that audio-only services have accounted for a substantial portion of telehealth services during the pandemic emergency, and lower-income patients disproportionately utilize audio-only telehealth over both in-person and video telehealth services. According to CMS's data, only 65% of beneficiaries making less than $25,000 have access to any internet service in their homes.

Disqualifying diagnoses obtained via audio-only telehealth services, especially for chronic conditions that have been previously documented, will result in inaccurate and incomplete documentation for MA and PACE risk adjustment purposes, arbitrarily reducing risk scores. This could lead to unequal access, fewer choices, higher premiums, or reduced benefits for seniors and individuals with disabilities.

Notably, CMS has taken the opposite approach for insurers participating in the Department of Health and Human Services (HHS)-operated risk adjustment program in the commercial market. On April 27 and August 3, 2020, the Center for Consumer Information and Insurance Oversight (CCIIO) published sets of frequently asked questions (FAQs) clarifying that HHS will allow diagnosis codes from audio-only telehealth services for risk adjustment purposes in 2020. On March 24, 2021, CCIIO issued updated FAQs stating that the policy would continue for 2021. The same logic underlying the exchange policy should justify the application of these flexibilities to MA and PACE risk adjustment as well.

1. Ms. Brooks-LaSure, if confirmed, can you commit to thoroughly reviewing this policy within the agency to ensure consistency, parity, and alignment between departments and programs regarding audio-only telehealth and risk adjustment in the future?
10. The deadline for plan bid submission for 2022 is less than two months away. Will you commit to working with my office and other interested offices on this issue to prevent adverse impacts for MA beneficiaries and PACE participants through reduced benefits, higher costs, or fewer choices next year?
11. I understand and share potential concerns about beneficiary, participant, and taxpayer protections around fraud, waste, and abuse. For that reason, I have partnered with Sen. Cortez-Masto to introduce bipartisan legislation including numerous guardrails to prevent potential misuse. Will you commit to working with us on *The Ensuring Parity in Medicare Advantage for Audio-Only Telehealth Act of 2021* by providing technical assistance for congressional action or looking to it as a potential guide for implementing policy changes within the agency?

***Answer*:** Medicare Advantage serves millions of Americans and is an important option for Medicare beneficiaries. During the pandemic, we have been able to see the value telehealth brings for patients, including those enrolled in Medicare Advantage. If confirmed, I look forward to working with you to ensure that beneficiaries enrolled in Medicare Advantage plans can continue to benefit from these services.

On Pending DME Rule:

Last year, CMS issued a Durable Medical Equipment (DME) proposed rule that would make the 50/50 blended rate for rural areas permanent. Rural access to services and care has been a longtime priority for me, given that more than one-fourth of South Carolinians live in rural areas. The proposed rule would also create a pathway for drugs requiring health care professional administration to be covered for home infusion, helping to address an urgent challenge that the pandemic has exacerbated.

I appreciate all of the work that CMS has undertaken thus far regarding the Medicare Durable Medical Equipment benefit, and we appreciate the agency's engagement with stakeholders regarding refinements to this and other rules.

1. Can you commit, if confirmed, to working to finalize the DME rule as efficiently as practicable?

***Answer*:** I recognize that rural areas have unique needs and challenges, including access to durable medical equipment. If I am fortunate enough to be confirmed, I am happy to look into the status of this regulation and work with you and your office on this important issue.

On Medicaid Work Requirements:

A report on health equity that you co-authored last year criticized work requirements and the Trump Administration's public charge rule, writing that both policies "disproportionately impact people of color" and "perpetuate historic structural inequities and widen the health equity gap." The report described both as "discriminatory policies."

1. Ms. Brooks-LaSure, in 1996, bipartisan majorities in both chambers of Congress voted to pass the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA), which President Clinton signed into law, authorizing work requirements for a number of safety-net programs. As Democrats and Republicans who supported the legislation at the time explained, these requirements aimed to encourage self-sufficiency and promote opportunity. What did you mean, last year, when you described work requirements as "discriminatory," and do you stand by that assessment?
2. Do you believe in the core principle of welfare-to-work—namely, that workforce entry or reentry provides the ideal avenue out of poverty and dependency?

***Answer*:** Medicaid is an important lifeline for many American families. Section 1115 demonstration projects, or waivers, are one available tool to states to help test new and innovative policies in Medicaid. I have worked closely with states throughout my career, so I know they face different challenges and need consistency and predictability. If confirmed, I will keep in mind what I have learned working on behalf of states to make sure waiver requests are appropriately evaluated while giving them consistent guidance. I will support state innovation

and the ability of states to test out different models that meet the objectives of the Medicaid program. I look forward to seeing the ideas states bring to the table and will consider each one on its merits.

For Both Ms. Brooks-LaSure and Ms. Palm:

<u>On Support for Nursing Home I-SNPs:</u>

As you know, Institutional Special Needs Plans (I-SNPs) are a type of Medicare Advantage plan where the only beneficiaries enrolled are seniors living in nursing homes. When nursing homes offer these plans, they are 100% at risk for all the care their residents need, either at their facilities or elsewhere. In the push towards value-based care, nursing homes taking on risk via I-SNPs are doing exactly what we want to see, but in 2020, being 100% at risk for a population exclusively made up of the individuals most vulnerable to COVID-19, and most likely to need high-cost hospitalization, created serious financial challenges for nursing homes with I-SNPs, including numerous communities in South Carolina. While nursing homes in general have received funds from the Provider Relief Fund (PRF), neither HHS nor CMS has provided relief to address the specific challenges nursing home I-SNPs have faced in order to ensure this model's continued viability.

1. Will you commit to using administrative authority to support I-SNPs and to recognize the significant increased and unexpected costs that these plans have faced during the COVID-19 emergency?

Answer from Ms. Brooks-LaSure: It has been heartbreaking to see how hard the COVID-19 pandemic has affected the nation's nursing home residents. Nursing home care will absolutely be a focus of mine if confirmed. Medicare Advantage serves millions of Americans, and Institutional Special Needs Plans provide important options for people in need of the level of care provided in nursing homes and long-term care facilities. This pandemic has given us the opportunity to take in lessons across a variety of issues. Moving forward, it is critical we examine every approach we can to improve affordability, quality, and access in long-term care. If confirmed as CMS Administrator, I look forward to working with you and other members of Congress to find ways to achieve this important goal.

Senator James Lankford
Questions for the Record
Senate Finance Committee Hearing
Nominations of Chiquita Brooks-LaSure and Andrea Palm
April 15, 2021

Chiquita Brooks-LaSure:

Biosimilar medicines are projected to save more than $100 billion in the next four years and increase patient access to lifesaving medicines. Recent analysis found roughly 40% of first generics are not covered under Part D three years after launch. Over the last ten years, generic medicines have been increasingly placed on higher cost-sharing tiers in Medicare Part D. I have been an advocate for the creation of a specialty tier to provide lower cost-sharing for biosimilars and specialty generics.

1. **What steps could CMS take to encourage the use of lower- cost biosimilars and generics?**
2. **Will you work with Congress to ensure generics are covered soon after launch and seniors are provided rapid access to these lower-cost medicines?**
3. **Will you work to reverse the trends of generics being placed on the inappropriate Part D tier in order to ensure patient access to low-cost generics with low cost-sharing?**

***Answer*:** Prescription drug costs are too high for American patients and families. From the meetings I have had with Senators in recent weeks, I have seen that lowering drug prices is a priority on both sides of the aisle. I agree that patient access to lower-cost generics and biosimilars is important. Competition in the market has helped control the growth in spending on prescription drugs, and generics biosimilars certainly have a role to play in creating competition for reference products. If I am fortunate enough to be confirmed, I look forward to working with you and other Members of Congress to lower the cost of prescription drugs.

I recently sent a letter to GAO alongside many of my colleagues asking for an investigation into some recent reports on fraud in the Medicaid program.

1. **What holes in the system did you see when you worked as a program analyst for Medicaid, and what possible solutions do you look toward to help solve the problem?**

***Answer*:** Fighting fraud and abuse is so important for maintaining a strong Medicaid program. Medicaid is a critical lifeline for beneficiaries across the country. If I am fortunate enough to be confirmed, I will be prepared to work with you, other Members of Congress, and states to make sure that payments are made properly and we are good stewards of the Medicaid program and taxpayer dollars.

The pandemic has underscored the importance of managing and preventing chronic disease and removing health disparities. We also recognize that higher out of pocket costs correlate with less prescription drug access. To this end, we need to be proactive and address system challenges that inadvertently drive out of pocket costs up for seniors. For example, certain system fees, called DIR fees, lead to increased costs for seniors at the pharmacy counter, while also threatening the viability of pharmacies across the nation, leading to gaps in care. As you are aware, 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.

1. **To reduce out of pocket costs for seniors and safeguard access to care provided at local pharmacies, how will you commit to DIR fee clawback reform and the establishment of standardized performance measures for pharmacies in Part D to help drive quality for seniors and control rising costs?**

***Answer*:** Small and rural pharmacies are critical to our nation's health care system and have been especially important during the pandemic. It can be hard for these pharmacies to predict retroactive DIR fees. 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 pharmacies have predictability.

As you know, the Medicare Advantage institutional special needs program is an important source of personalized support for long-term care residents. It has proven to deliver quality care with supplemental benefits at a lower cost. As a result, Congress has seen the value and made the I-SNP program permanent. Since I-SNPs only serve long-term care populations, they cannot shift the risks they may assume. One of these plans is currently servicing several of the long-term care facilities in Oklahoma and, unsurprisingly, the COVID pandemic has had a particularly devastating effect on them, as nursing home residents continue to be on the front lines of those most negatively impacted. Special needs plans have fallen through the cracks of COVID support and have been subject to unintended consequences, leading to enrollment disincentives and further increasing the pressure on I-SNPs.

1. **Do you acknowledge that the I-SNPs are facing a significant problem?**
2. **If so, will you commit to working with the struggling plans to address the disparities they currently face, ensuring there are equitable private options available for nursing home residents, and finding a solution?**
3. **If not, please explain why.**

***Answer*:** It has been heartbreaking to see how hard the COVID-19 pandemic has affected the nation's nursing home residents. Nursing home care will absolutely be a focus of mine if confirmed. Medicare Advantage serves millions of Americans, and Institutional Special Needs Plans provide important options for people in need of the level of care provided in nursing homes and long-term care facilities. I agree that it is critical we examine every approach we can to improve affordability, quality, and access in long-term care. If confirmed as CMS Administrator,

I look forward to working with you and other members of Congress to find ways to achieve this important goal.

Your career has focused on expanding health coverage for Americans.

1. **If confirmed, do you plan to increase the role of the federal government in healthcare by promoting a public option? Please detail your plans for expanded health coverage.**

***Answer*:** President Biden has been 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. Ensuring that all Americans have access to affordable, quality health care will be a priority of mine. I want to work with states to expand coverage through Medicaid and the Marketplaces. I look forward to working with you to expand access to affordable, quality health care.

Questions for the Record from Senator Daines

Finance Committee Hearing for Andrea Palm, Nominee for Deputy Secretary of HHS, and Chiquita Brooks-LaSure, Nominee for CMS Administrator

April 15, 2021

Questions for Ms. Chiquita Brooks-LaSure:

1. One of the silver linings of this pandemic has been the wide-spread adoption of technology to bring people together, whether it be families scattered across the nation or patients and their providers. Telehealth has truly taken root and we have seen exponential growth in telehealth adoption across Americans of all ages, locations and conditions. Much of the growth in usage among Medicare beneficiaries has been made possible by temporary flexibilities in place for the duration of the public health emergency. These include allowing Medicare beneficiaries to have telehealth visits from their home, regardless of where they live across the country. This has also allowed new types of providers, such as physical therapists and speech pathologists to practice via telehealth.
    - Do you agree that the expanded access to telehealth services has been an important component in protecting patients and providers during the nation's response to COVID-19?
    - As Congress considers permanent telehealth reform, I hope you will be willing to work with us to ensure that telehealth is available to all of those that wish to use it. Do you believe that there are some telehealth regulatory restrictions that Congress and CMS can work together to address in the near term?

***Answer*:** Telehealth has been invaluable during this pandemic to keep patients, their providers and their families safe. My brother is a psychologist, and telehealth has really helped his patients get the care they need. If I am fortunate enough to be confirmed, I will be taking a careful look at the telehealth flexibilities under Medicaid and Medicare before the Public Health Emergency ends.

I want to look at what we can and should extend administratively and what will need Congressional action to ensure that we bring the lessons learned about telehealth during the pandemic into our health care system going forward. I look forward to hearing more from you about what existing flexibilities you view as especially important.

2. Emerging science indicates that addressing risk factors – including cardiovascular disease, diabetes, obesity, and hypertension – can delay the onset of dementia and Alzheimer's. However, we continue to see our health care system, particularly Medicare, fail to pursue low-cost, effective policies to reduce the risk for chronic conditions, including Alzheimer's. Instead, our system waits until people are sick and treatment costs are significantly higher.
    - If confirmed, how will CMS pursue wellness and early intervention policies that reduce the risk of chronic diseases like Alzheimer's?

***Answer*:** Alzheimer's disease is a devastating condition for patients and families. It is only going to be a growing challenge for the Medicare program and our aging population in coming years. Preventive care is crucial to improving health outcomes, and it is so important to catch the signs of cognitive impairment early. I'd be happy to work with you on this should I be confirmed.

3. Late last year, CMS issued a Durable Medical Equipment proposed rule, which would make the 50/50 blended rate for rural areas permanent. This rule has not been made final as of yet. I appreciate all the work HHS and CMS have done regarding the Medicare Durable Medical Equipment benefit.
    - When will HHS and CMS issue the final DME rule?

***Answer*:** I recognize that rural areas have unique needs and challenges, including access to durable medical equipment. If I am fortunate enough to be confirmed, I am happy to look into the status of this regulation and work with you and your office on this important issue.

4. The coronavirus pandemic has underscored the value of vaccines for infectious diseases, including those that originate abroad. We all recognize that COVID-19 will not be the last time we have to respond to an outbreak for which vaccinations are necessary in order to stem an emerging public health threat.

Public policy should make vaccines as accessible as possible for our citizens. That is why current law requires that insurers provide coverage without cost sharing for all recommended vaccines, without limitation.

Yet, inexplicably, current HHS regulations implementing the law limit mandatory coverage to so-called "routine" vaccines on the Immunization Schedules. As a result, many vaccines for infectious diseases are not covered without cost-sharing, including those for current vaccines such as rabies, anthrax, Japanese Encephalitis, yellow fever and cholera, and those vaccines in the pipeline for malaria, chikungunya, dengue, and Zika.

Last year, my colleagues and I worked on bipartisan legislation included in the CARES Act that ensures immediate coverage of COVID-19 vaccines with no cost-sharing. As I said then, Montanans and Americans across the country need access to vaccines, and financial barriers should not stand in the way during a national emergency or otherwise.

Congress should not have had to be reactive. A forward-looking, uniform approach is needed to ensure that we are prepared to move quickly on vaccinations when the next pandemic occurs.

- If confirmed, will you commit to quickly bringing agency regulations in line with the statute requiring no cost-sharing for all CDC recommended vaccines to maximize access to the best preventative measures against infectious diseases?

***Answer*:** I agree that the COVID-19 pandemic has underscored the importance of vaccines to preventing the spread of disease, and I agree that we should remove barriers for patients to get proven vaccines. We need to be prepared for any potential future outbreak, and I agree we cannot afford to be reactive on such an important issue. I am happy to work with you to ensure we are ready for the next public health emergency.

Hearing to Consider the Nominations of Andrea Joan Palm to be Deputy Secretary of Health and Human Services and Chiquita Brooks-LaSure to be Administrator of the Centers for Medicare and Medicaid Services

Questions for the Record

Senator Todd Young

Questions for Ms. Brooks-LaSure:

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 (CHIP).

As we discussed during our meeting, I feel there is absolute value in innovating with healthcare payment and service delivery systems. We won't know if we're truly making a difference unless we test and evaluate – it's how we find out what works and what's most effective for patients and doctors alike.

However, the actual experience of CMMI can too often be marked by a lack of transparency and little stakeholder engagement in the development and implementation of models.

At times, models also seem to initiate wholesale policy changes rather than serve as true tests, circumventing Congress' role in establishing Medicare policy. I also want to ensure that proposed models sufficiently take into consideration the potential health care access disparities for vulnerable populations.

- Will you work with the members of this Committee on establishing protections to guarantee better transparency, stakeholder input, data sharing, and equity in the development of proposed models by CMMI?
- Will you commit to come back to this Committee to share updates and release progress reports on CMMI actions and models?

***Answer*:** The Innovation Center has been an important tool to test new models to move our health care system from one that rewards volume to one that rewards value. It will continue to be important, as we move forward, to test models that improve patient care, advance health equity, and lower patient costs. We have now had 10 years of experience to learn from at the Innovation Center. We need to look at what has worked and what hasn't and chart a path forward from there. This includes getting stakeholder input, and if I am fortunate enough to be confirmed, it will be a priority for me to have open lines of communication with Congress. I look forward to hearing from you about CMMI models.

Telehealth
Even prior to the pandemic, I heard from my constituents in Indiana—particularly those in rural areas—about the ways in which telehealth can both increase access to underserved Americans and reduce health care costs. Since the start of the public health emergency, telehealth flexibilities provided by Congress and HHS have been a lifeline for vulnerable seniors and others accessing care from the safety of their own homes.

Currently, authorizations included in the CARES Act to create additional flexibility for patients and providers using telehealth only extend through the pandemic.

- We don't want to take a step back on telehealth. The Medicare Payment Advisory Commission (MedPAC) has recommended that we should "temporarily continue some of the telehealth expansions for a limited duration of time (e.g., one or two years after the public health emergency) to gather more evidence about the impact of telehealth on beneficiary access to care, quality of care, and program spending to inform any permanent changes". What data or evidence is CMS collecting now to determine what waivers should be made permanent?
- How should telehealth be used moving forward to expand access to mental and behavior health services for Medicare beneficiaries?

***Answer*:** Telehealth has been invaluable during this pandemic to keep patients, their providers and their families safe. My brother is a psychologist, and telehealth has really helped his patients get the care they need. If I am fortunate enough to be confirmed, I will be taking a careful look at the telehealth flexibilities under Medicaid and Medicare before the Public Health Emergency ends to determine what we can extend administratively and what we will need Congress's help on to ensure that we use the lessons learned about telehealth during the pandemic to modernize our health care system.

Organ Procurement
Thirty-three Americans die every day waiting for a lifesaving organ transplant, and Medicare spends roughly $36 billion annually on care for dialysis patients because there are not enough kidney transplants available to meet the need. The problem is a network of unaccountable government monopoly contractors that run the organ donation system, called organ procurement organizations (OPOs), with a history of severe performance failure.

Recently, CMS finalized a rule started in the previous Administration that would allow HHS to replace failing OPOs with high performers, and is projected to save more than 7,000 additional lives every year, as well as over $1 billion annually to Medicare.

- This rule has broad bipartisan support, and is even more important since COVID-19 damages organs. As CMS Administrator, will you commit to its swift implementation?

Answer: Thank you for bringing up this important issue. Federal law tasks CMS with conducting surveys of OPOs and recertifying them. As you noted, the rule replacing current OPO measures

with new transparent, reliable, and objective outcome measures is now effective. My understanding is that the new outcome measures will be implemented on August 1, 2022, the start of the next recertification cycle. If confirmed, I will work to implement this rule in a timely way and ensure that all parts of the organ transplant system are as effective and efficient as possible in order to save as many lives as possible.

Medicare Advantage

We have seen a growth in the private/public partnership program in Medicare Advantage (MA). Over 40% of Medicare beneficiaries are choosing Medicare Advantage and they report high satisfaction with the provider networks, cost savings and coordinated care.

- What role do you see Medicare Advantage having in the future of Medicare as we work towards modernizing the program?

Medicare Advantage is showing that it can provide lower consumer costs, offer additional benefits, and achieve better outcomes, like fewer avoidable hospitalizations including for high need, high risk patients for the same or lower cost as FFS Medicare.

Research from UnitedHealth Group shows that Hoosiers enrolled in a Medicare Advantage plan spend nearly $1,800 less on premiums and out-of-pocket costs than a Hoosier enrolled in traditional Medicare and a prescription drug plan; and, in addition to the dental, vision, and hearing benefits typically offered, the average MA beneficiary in Indiana receives $170 annually in additional benefits such as care coordination, meals, and non-emergency transportation not offered by traditional Medicare.

- Do you see Medicare Advantage as an important part of modernizing Medicare while getting better results for our taxpayer dollars?
- What will you do to protect this public/private partnership and keep the program strong?

***Answer*:** Medicare Advantage serves millions of Americans and is an important option for Medicare beneficiaries. I believe that we have to take every approach we can to provide people access to quality health care. If confirmed as CMS Administrator, I look forward to working with Congress on this important issue.

Sepsis Testing Standard of Care

More than 20 million Americans present with symptoms of sepsis in acute care hospitals annually, and are treated under a "sepsis protocol" where blood culture tests are urgently drawn to diagnose bloodstream infections. However, approximately 40 percent of these blood culture tests are false positives. This results in patients being subjected to extended hospital stays and the unnecessary use of potent antibiotics, which have been proven to contribute to the spread of antibiotic resistance.

- What is CMS doing to ensure that hospitals across the country are working to reduce their false positive sepsis test rates to ensure patient safety?

***Answer*:** Thank you for raising this important issue. Timely diagnosis and treatment of sepsis is a critical issue as are actions that will enhance antibiotic stewardship. If confirmed, I look forward to working with you to continuously improve the quality of care that hospitals are providing to patients, including with respect to accurately diagnosing sepsis while avoiding unnecessary use of antibiotics.

End Stage Renal Disease (ESRD)

Last November, my staff shared some concerns we heard from representatives of the kidney care community about the proposed methodology to incorporate certain drugs into the ESRD bundle. There have been reports of dialysis patients on these therapies being forced off treatments that are working for them onto therapies that have not worked for the patient in the past.

- As CMS Administrator, how you will ensure patient quality of care is not being impacted- specifically for communities of color who are disproportionately impacted by kidney disease- so that patients can continue to access these medicines best suited for their treatment?

***Answer*:** I agree that is it important for Medicare beneficiaries, particularly patients with complex conditions such as ESRD, to have access to medically necessary treatments. Promoting health equity – particularly for communities of color and rural areas – needs to be at the forefront of CMS decision making. If confirmed, I will work to preserve access to these treatments in Medicare and improve patient outcomes.

Senator Sasse Questions for the Record

Questions for both nominees:

Telehealth

While my colleagues have pointed out many of the ways COVID-19 has challenged our health care system and exposed existing inequities, one bright spot in the pandemic has been increased access to telehealth services as a way for patients to maintain their health from the safety of their homes. This has been particularly important for states like Nebraska with large areas of rural population.

1. We know that CMS has allowed expanded use of audio-only services during the pandemic, but how is CMS working to ensure that those without broadband access can utilize appropriate telehealth services in a post-pandemic world?
2. Where do you stand on audio-only telehealth coverage? What about on payment parity between in-person and virtual services?
3. How will you approach geographic restrictions, both in patient location and provider licensure?
4. If confirmed, how do you plan to evaluate the use of telehealth over the last year and the places where it should—and potentially should not—be expanded beyond the end of the national emergency period?

Answer from Ms. Brooks-LaSure: Telehealth has been invaluable during this pandemic to keep patients, their providers and their families safe. My brother is a psychologist, and telehealth has really helped his patients get the care they need. If I am fortunate enough to be confirmed, I will take a careful look at the telehealth flexibilities under Medicaid and Medicare before the Public Health Emergency ends. During that review, I will pay special attention to the issues of equity and access. I will look at what we can and should extend administratively and where we will need Congress's help to ensure that we bring the lessons learned about telehealth during the pandemic forward to modernize our health care system.

Individuals with chronic disease place an immense strain on our health care system and account for a huge percentage of the overall costs to taxpayers. I think you would agree that early identification and treatment is crucial not only among those with chronic diseases but in our health systems in general. Remote patient monitoring (RPM) can be beneficial in managing both acute and chronic conditions and identifying deteriorations in health as early as possible to allow for the best level of care. Issues with reimbursement continue to constrain Medicare recipients' access to this level of monitoring.

5. Do you see value in increased access to remote patient monitoring and what are your views on the co-pay requirement for these services?

***Answer from Ms. Brooks-LaSure*:** Individuals with chronic disease benefit from access to comprehensive and coordinated care to manage and treat their chronic conditions and prevent the

need for more costly care. Ensuring access to remote patient monitoring services, including through evaluating the adequacy of payments, will be important to beneficiaries who may benefit from these and other virtual services that allow their physicians to help manage and treat their health conditions outside of regular office visits.

Most Favored Nation Model

I have concerns with the Most Favored Nation Model rulemaking, both with the policy of tying Medicare reimbursements to the prices foreign countries pay and with the creation of the expansive rule through the Center for Medicare & Medicaid Innovation (CMMI) under the guise of being a pilot program.

1. If confirmed, how will you approach this policy? Do you support tying the prices of American drugs to foreign prices?
2. Will you commit to ensuring that CMMI is used as intended rather than as a congressional workaround?

Answer from Ms. Brooks-LaSure: Prescription drug costs are too high for American patients and families. From the meetings I have had with Senators in recent weeks, I have seen that this is a priority on both sides of the aisle. I think there is an opportunity for real impact here to lower prescription drug costs, and – if I am fortunate enough to be confirmed – I look forward to working with you and other Members of Congress to achieve that goal.

Regarding the Center for Medicare and Medicaid Innovation, the Innovation Center has been an important tool to test new models to move our system from one that rewards volume to one that rewards value. It will continue to be important, as we move forward, to test models that improve patient care, advance health equity, and lower patient costs. With 10 years of experience to learn from at the Innovation Center, we need to look at what has worked and what hasn't, and I look forward to hearing from you about what you think is working well and what experiences you've seen on the ground in Nebraska.

<u>Questions for Chiquita Brooks-LaSure:</u>

Medicaid

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. The Families First Coronavirus Response Act (FFCRA) offered states an increased Federal Medical Assistance Percentage (FMAP) for their traditional Medicaid populations and in turn restricted them from maintaining control over their Medicaid programs via maintenance-of-effort requirements. Across the country there are millions of Medicaid enrollees whose redetermination has been delayed, and in just seven states where we have data we know that roughly half a million enrollees are receiving benefits who are ineligible for the program.

1. Do you commit to working with states and Congress to actually identify which enrollees are eligible and which are not?
2. Do you commit to making sure that the Medicaid program is able to serve those individuals who are truly in need?
3. Do you believe states should have the right to remove ineligible enrollees, which is currently restricted by FFCRA?

Answer: Medicaid is a critical lifeline for beneficiaries across the country. If I am fortunate enough to be confirmed, I will also be prepared to work with you, other Members of Congress, and states to make sure that payments are made properly and we are good stewards of the Medicaid program and taxpayer dollars. The requirement related to enrollment at section 6008(b)(3) of the Families First Coronavirus Response Act for states receiving the Medicaid FMAP increase will be in effect until the end of the month in which the COVID-19 public health emergency ends. As that time grows nearer, it will be important for CMS to work closely with states to plan for the transition.

Durable Medical Equipment

HHS and CMS have done a lot of work on the Medicare Durable Medical Equipment benefit, including issuing a proposed rule late last year that would have made the 50/50 blended rate for rural areas permanent.

1. When does CMS plan to issue the final DME rule given the change of administrations?

Answer: I recognize that rural areas have unique needs and challenges, including access to durable medical equipment. If I am fortunate enough to be confirmed, I am happy to look into the status of this regulation and work with you and your office on this important issue.

We know that some of our most vulnerable in society rely on ventilators for their care, yet access to new-generation, multi-function ventilators can often be restricted by complicated payment policies that have not adapted for new technologies. This is particularly important in light of the pandemic, when ventilation in home care settings allows for more hospital space.

2. If confirmed, will you work to update CMS payment regulations to account for advancements in ventilator technology, including adjusting irregularities in payment that impede patient access?

Answer: We know that some of our most vulnerable patients rely on ventilators for their care, yet access to new-generation, multi-function ventilators can often be impeded by statutory payment policies related to paying for equipment on a cap rental basis and the reasonable useful lifetime of the equipment. To help ensure access to ventilators in light of the COVID-19 public health emergency, I understand that CMS is allowing payment for multi-function ventilators even if separate devices have not met their reasonable useful lifetime.

I agree that it is incredible what science has been able to do in recent years with innovative new drugs, treatments and devices. If I am fortunate enough to be confirmed, I will make sure we are looking at modernizing the Medicare program to make sure beneficiaries have access to proven new technology, and I would be happy to work with you on that.

Senator Barrasso Questions for the Record
Chiquita Brooks-LaSure
Nomination Hearing
Thursday, April 15, 2021
10:00 a.m.

Question 1: At the end of 2020, Congress provided relief from reductions in reimbursement to certain physicians which was included in last year's physician fee schedule final rule. This was the result of budget neutrality requirements within the fee schedule. With many physician practices experiencing substantial challenges as a result of the COVID-19 pandemic, it is important to ensure providers are able to continue caring for patients.

- Can you please discuss your approach regarding future changes to the physician fee schedule? In particular your feelings on reducing reimbursements to providers during the pandemic.

***Answer*:** I believe that ensuring adequate payments for primary care and specialty physicians is essential to maintain beneficiary access to high-quality and affordable health care. If confirmed, I will work to ensure that payments under the Medicare physician fee schedule are implemented in accordance with the law while preserving beneficiary access.

Question 2: Current law requires zero cost sharing for COVID therapeutics. However, when the Public Health Emergency (PHE) is lifted many of these policies linked to the PHE declaration will no longer be in effect under the law and will potentially be subject to CMS' discretion.

- Please discuss your approach to reimbursement for COVID therapeutics. In particular your feelings on how this issue should be approach once the PHE is lifted.

***Answer*:** I appreciate Congress's leadership in making sure that patients suffering from COVID-19 have been able to get the care they need during the public health emergency. I think we need to look at the policies in place during the pandemic and determine what we should do after the pandemic is over, either administratively or with legislation from Congress. If confirmed, I will be happy to work with you and other members of Congress as we look beyond the pandemic.

Question 3: Drugs approved via accelerated approval at the Food and Drug Administration (FDA) are novel treatments that address urgent and unmet medical needs involving serious and life-threatening diseases.

As a doctor, I am particularly passionate about the new treatments approved through this pipeline to treat Duchenne Muscular Dystrophy. As you know, this is a deadly disease, which until very recently had no approved treatments. Today we have five treatments approved through this

pathway with many more in development. While certainly not a cure, these therapies are an important step forward.

Recently, the Medicaid Payment Advisory Commission (MacPAC) issued recommendations to increase the required Medicaid rebates for drugs specifically approved through the accelerated pathway.

While I appreciate that MacPAC is a Congressional advisory body, I believe their recommendation to single out these therapies is troubling. In particular, when you consider medications approved in this manner treat some of our most vulnerable patients and make up a very small percentage of total Medicaid spending.

- Can you discuss your views on federal reimbursement policies on the development of new therapies for people with rare diseases?

***Answer*:** Thank you for raising this important issue. It is incredible what scientific progress has been made with innovative drugs and treatments, and we need to continue to modernize the Medicare and Medicaid programs to make sure beneficiaries, including those with rare diseases, have access to proven new treatments. If confirmed, I would be happy to examine this particular MACPAC proposal in more detail, and to work with you and other members of Congress on ways to spur innovation and facilitate beneficiary access to new advances in medicine.

Question 4: Last year I led a bipartisan letter with Senate and House colleague to CMS expressing concerns about cuts to hip and knee replacement in the Calendar Year 2021 (CY21) Physician Fee Schedule and the implications for value based care.

Specifically, the letter urged CMS to recognize the patient preoptimization work physicians are doing in alternative payment models. The CY'21 rule substantially cut lower joint arthroplasty even though physicians performing those procedure are doing more work and saving the Medicare Trust Funds money through their record-high participation in alternative payment models (APMs).

These cuts are concerning. This appears to be a disconnect between the legacy fee-for-service evaluation of procedures, and innovative care we are encouraging in APMs. However, the Final Rule indicated CMS's interest in capturing this patient preoptimization work.

- Would you please work with the stakeholders and I on the preoptimization issue?
- More broadly, can you discuss your feeling on alternative payment models and if there are specific areas where you wish to focus?

***Answer*:** I agree that we should continue efforts to further move our health care system towards one that rewards value over volume. Delivery system reform efforts, including alternative payment models, can improve quality of care while reducing health care costs. The Innovation

Center has been an important tool to test new models to move our system from one that rewards volume to one that rewards value. It will continue to be important, as we move forward, to test models that improve patient care, advance health equity, and lower patient costs. We have now had 10 years of experience to learn from at the Innovation Center. We need to look at what has worked and what hasn't, and if confirmed, I will work with you to make sure we recognizing the good work providers are doing to move our system in the right direction, improve care, and lower Medicare spending.

Question 5: I support price transparency in the health care system. The Trump Administration made good progress on this problem with their hospital price transparency rule, which went into effect on January 1, 2021.

- It appears from media reports that many hospitals are not following the rule. If confirmed, how will you address price transparency in health care, especially in terms of enforcement of the price transparency rule?

***Answer*:** I agree that the variation in pricing across hospitals is not always justified and ultimately can be bad for consumers. For transparency measures to work properly, patients and their families must be able to understand them in a meaningful way. If I am fortunate enough to be confirmed, I look forward to continuing to work on this issue.