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RANKING MEMBER

ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-3641
Minority (202) 225-2927

June 6, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Becerra:

Thank you for appearing before the Subcommittee on Health on Wednesday, April 17, 2024, to testify at the hearing entitled "Fiscal Year 2025 Department of Health and Human Services Budget."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Wednesday, July 31, 2024. Your responses should be mailed to Emma Schultheis, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Emma.Schultheis@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Brett Guthrie
Chair
Subcommittee on Health

cc: Anna Eshoo, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Michael Burgess, M.D.

No Surprises Act (NSA):

One of the main drivers behind enactment of the No Surprises Act was to give patients certainty on what they owe for out-of-network services. To that end, the NSA established a method for calculating patient cost-sharing for out-of-network services that is based on the "recognized amount," which is distinct from the "out-of-network rate." If the "out-of-network" rate later turns out to be higher than the "recognized amount" on which cost-sharing was initially based, the patient is not later affected. Instead, according to the NSA, the plan has to make up the difference to the provider. The very first NSA interim final rule expressly confirmed this basic structure. This is one of the most basic concepts in the NSA, which, together with banning balance billing, keeps patients out of the "middle" of payment issues. Unfortunately, it's been brought to my attention that health plans are changing the patient cost-sharing amounts extremely late in the process and calculating patient cost-sharing amounts based on the ultimate outcome of the independent dispute resolution process. That is in direct violation of the statute and implementing regulations.

1. Has the Department received reports of these kinds of cost-sharing adjustments by plans?

2. What is the Department doing to ensure that health plans are held responsible if patients receive erroneous bills based on health plans incorrectly calculating patient cost-sharing?

3. Will you commit to using all available enforcement discretion against plans that are engaging in this behavior?

Nonpayment By Plans:

The No Surprises Act established an independent dispute resolution (IDR) process to resolve disputed payment amounts between insurance companies and providers. Providers have repeatedly informed Congress that, even after the provider prevails in the IDR, health plans fail to actually pay the amounts owed in the timeframes specified in law and regulation. In some instances, the insurers pay incorrect amounts; in others, they fail to pay at all. Although the agency has an online portal for complaints about these issues, providers consistently report never receiving response or follow-up communication from the agency. This behavior by the plans poses a significant issue for cash flow for providers and eviscerates one of the most fundamental provisions in the law Congress passed. As long as the Department fails to meaningfully enforce the thirty-day payment deadline, it will continue.

1. What concrete enforcement plan does the Department have to support the integrity of the IDR process for providers with regard to nonpayment by health plans?

Medicare Six Protected Class:

Last fall, nearly 20 patient advocacy groups representing vulnerable Americans throughout the country sent the Centers for Medicare and Medicaid Services (CMS) a letter regarding the security of Medicare's Six Protected Class (6PC) policy – a longstanding and critical safeguard that ensures access to medication for some of Medicare's most at-risk patients. I share their concerns. Even though CMS regularly conducts formulary reviews and other oversight activities, lawmakers have little insight into the steps your agencies take to ensure compliance with this important policy. Transparent access to this type of data will help Congress evaluate the effectiveness of HHS policy over time and ensure that health plans are not inappropriately limiting access to 6PC medicines.

To better understand CMS's process, and provide lawmakers with a clear baseline of current plan compliance against which to assess future compliance, I request you provide the following information:

1. What steps are you taking to proactively ensure that patients have access to drugs in the 6PC considering significant forthcoming changes to Part D plan benefit design?

2. Do you have the internal data and analysis systems to accurately evaluate access before and after implementation?

3. Please provide a list of all initiatives and the major actions taken or planned for each, including any improvements to data collection.

4. If you are not taking steps to ensure patients have access to 6PC drugs in the future, please explain why.

<u>The Importance of Collaboration Between Civilian and Military Trauma Professionals</u>:

In 2016, the National Academies of Science, Engineering, and Medicine (NASEM) released a report entitled, A National Trauma System: Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths After Injury. In the report, NASEM recommended that the United States adopt an overall aim for trauma care of "zero preventable deaths after injury," and sets forth elements of system redesign that would provide military personnel with real-world training and experience at civilian trauma centers. Out of this recommendation came the 2019 passage of the Military Injury Surgical Systems Integrated Operationally Nationwide to Achieve ZERO Preventable Deaths Act or the MISSION ZERO Act as part of the Pandemic and All Hazards Preparedness and Advancing Innovation Act.

The MISSION ZERO grant programs have allowed trauma centers to learn from military best practices, provide essential clinical training for our military health care personnel, and help trauma centers manage and recover from workforce shortages that have plagued the industry. Additionally, MISSION ZERO allows military trauma providers to maintain their clinical skills while they are not deployed, ensuring that our nation's Armed Forces benefit from high quality and state of the art trauma care while on the battlefield.

Despite the demonstrated value of this program, in its fiscal year (FY) 2025 budget proposal, the Department of Health and Human Services proposed to end funding for MISSION ZERO,

and other strategic readiness programs, such as the Pediatric Disaster Care program. These programs seek to ensure individuals receive high quality and ready access to medical care both at home and on the battlefield.

1. What factors or justifications led to the Department of Health and Human Services' (HHS) recommendation to eliminate funding for the MISSION ZERO program?

2. Further, what actions will HHS take, in the event of Congress defunding the program, to ensure continued synergies between civilian and military trauma care providers?

Public Health Workforce:

As a physician, I have seen firsthand how infections can negatively impact many aspects of medical care, including infections related to childbirth. Sepsis — the body's overwhelming response to infection — is the second leading cause of maternal mortality in the US. Infectious diseases (ID) physicians are critical to prevent, diagnose and treat serious infections, but we have a serious shortage. Nearly 80 percent of US counties lack even a single ID physician, and only half of ID physician training programs in the US filled last year. The Bio-Preparedness Workforce Pilot Program would incentivize health professionals to pursue careers in ID by offering student loan repayment in exchange for service in an area with a health professional shortage. This is important, since high student debt has been cited by medical students and residents as a key reason they don't enter ID — one of the lowest paying specialties.

1. Do you agree that we need to boost ID recruitment, such as through the Bio-Preparedness Workforce Pilot Program?

The Honorable Robert Latta

1. According to a 2022 Kaiser Family Foundation analysis of National Survey on Drug Use and Health (NSDUH), an estimated 29 percent of Medicaid enrollees have a mental illness, relative to 21 percent of privately insured and 20 percent of uninsured people, and about one in five (21 percent) Medicaid beneficiaries have a substance use disorder. Further, nearly 40 percent of the nonelderly adult Medicaid population had a mental health or substance use disorder. For many of these patients living with chronic and complex mental health conditions, a new class of treatments prescription digital therapeutics (PDTs) may offer an innovative solution and treatment. However, PDTs do not currently fit into one of the statutorily defined coverage categories for the Medicare or Medicaid programs. As a result of these categories, the patients most in need of these novel treatments are facing access barriers. How is HHS ensuring that beneficiaries of those programs are not left without access to these treatments?

The Honorable Gus Bilirakis

1. We have significant health challenges in this country: The skyrocketing costs of hospital bills, the scourge of fentanyl poisoning, and even you have called the maternal mortality

situation in this country a crisis. Despite these priorities Americans are struggling with on a daily basis, you have approved 1332 waivers in two states that would allow taxpayer resources to be diverted to the coverage of illegal immigrants. On top of that, HHS has spent time and resources turning the healthcare.gov website into a voter registration drive. Why does HHS think it is more valuable to use taxpayer dollars to subsidize coverage for illegal immigrants instead of using that money to improve maternal care and help taxpaying Americans?

2. How much time and money did your department spend on voter registration that could have been spent implementing bipartisan priorities to lower the actual cost of health care, like by implementing and enforcing bipartisan price transparency policies for patients?

3. Last year, CMS departed from longstanding interpretation of the law spanning multiple Administrations when it changed Disproportionate Share Hospital (DSH) Payments by counting certain days associated with Section 1115 demonstrations in the Medicaid Fraction Rule when it no longer counted uncompensated care pools, such as Florida's Low Income Pool, in the DSH adjustment. As you know, this greatly affects the 340B Drug Pricing Program eligibility, meaning hospitals that provide this care to those who are often the greatest in need of services, the uninsured and underinsured populations in particular, are disproportionately affected. I am concerned that this is a tactic by the Agency to target states that rely on 1115 Waivers, such as Florida and Texas. Can you please justify your reasoning behind this change in precedent and explain how the change in calculation is affecting low-income patients?

4. I want to reiterate my strong desire to work with the Administration and this Committee in a bipartisan manner to ensure that the finalized TCET policy provides a robust and meaningful separate expedited pathway for transitional coverage of innovative FDA-approved devices. I am concerned that the TCET procedural notice as proposed seems to move in the wrong direction toward just expanding or refining the Coverage with Evidence Development (CED) process for just a few devices and technologies with evidence viewed as inadequate by CMS. This would be a significant departure from creating a separate pathway for transitional coverage for those many truly innovative products that may not need to develop additional data for coverage due to existing sound clinical data, and for whom existing protracted National Coverage Determination (NCD) and Local Coverage Determination (LCD) coverage processes have led to significant delays in patient access to treatment. From my standpoint, one of the most important purposes of the TCET pathway is to facilitate patient access to new and innovative technologies that can improve their overall health and extend their lives. Lack of an option for TCET coverage without additional data collection in certain cases just impedes patient access to care and stifles innovation in the medical device field where I understand a significant amount of promising early R&D is occurring today. Are you committed to ensuring that there is a separate meaningful pathway for expedited Medicare coverage of new devices with existing sound data that does not require additional evidence generation, that Congress, patients, and those developing innovative technology have urged the Administration to pursue?

5. In September 2023, the Food and Drug Administration issued a draft guidance for industry entitled "Demonstrating Substantial Evidence of Effectiveness Based on One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence." How is the FDA ensuring that the current and best thinking on this topic is being applied consistently across the agency in its regulatory decision-making, including in the review of products intended to treat children and rare diseases?

    a. When does FDA intend to finalize this draft guidance?

6. What actions are HHS and FDA taking to prioritize the development of rare disease therapies, given that 95 percent of rare diseases lack an approved treatment?

7. Traditional clinical trial design may pose challenges for the study of rare diseases as patient pools are small and often geographically dispersed. Clinical trial challenges are further compounded in pediatric populations where participation may be especially burdensome for these populations. How can regulatory flexibility support adaptive and single-study trials that accelerate the development of rare disease therapies and help patients access safe and effective therapies in as timely a manner as possible?

8. Many rare eye diseases are progressive and may lead to vision loss and blindness, including in children and young adults. What additional actions, if any, is FDA taking to accelerate the development of therapies for rare ophthalmic diseases and ensuring regulatory certainty in this therapeutic area for patients so they can benefit from innovative new therapies in as timely a manner as possible?

9. I understand that FDA recently proposed for a second time to ban a medical device for certain uses, specifically for those who engage in life-threatening self-abusive and aggressive behaviors. Why has HHS consistently directed FDA to issue this ban, despite FDA's repeated assertions to HHS that it lacks the evidence to support this regulatory action?

10. I am deeply interested in issues related to hearing health. People with hearing loss, especially those in our Medicare population, deserve to have access to breakthrough and innovative hearing technologies that could allow them to live healthier and better lives. You may not be aware, but there are innovative implanted hearing devices that can improve the hearing of an individual with significant, disabling hearing loss in situations where hearing aids are no longer enough for one reason or another. Some of these devices, such as fully implanted active middle ear implants, have been improperly classified as hearing aids and therefore excluded from Medicare. I recently cosponsored legislation that directs CMS to clarify that fully implanted active middle ear hearing devices are prosthetics and not subject to the hearing aid coverage exclusion under the Medicare program. How will you work to address this matter so that Medicare beneficiaries with profound hearing loss will have access to these types of devices?

11. As a champion for Community Health Centers, I know it's one of the best investments we can make, with recent research showing health centers have an almost a 5-to-1 return on investment, saving billions by averting unnecessary Medicare and Medicaid spending.

Recently, the Congressional Budget Office recognized these significant savings for the first time in their accounting of a health center funding bill. Yet your testimony spent a significant amount of time on expanding Medicaid subsidies instead – wouldn't you agree that your priority should instead focus on expanding on Community Health Centers so they can continue their lifesaving work in underserved communities?

12. Last year this Subcommittee advanced the PATIENT Act, which later became the Lower Costs, More Transparency Act. That bill contained unprecedented increases and extensions in funding for Community Health Centers and Teaching Health Centers. It passed the House floor by a big bipartisan vote. While we could not get a final agreement on extending their funding beyond December, what have these two programs accomplished thus far?

    a. What can they do for access to primary care in rural communities if fully funded this year?

13. Community Health Centers in my district and others across the country are investing in allied health workforce development programs in partnership with their local high school or community college. These programs give young people apprenticeship opportunities and mid-career folks access to career laddering. They can create and retain good-paying jobs in our districts and enrich the economy while expanding access to cost-saving primary and preventive care. How can HHS and Congress better support these community-driven workforce programs?

14. The recently enacted Consolidated Appropriations Act, 2024 package contained an increase in mandatory funds to Health Resources and Services Administration (HRSA) for Community Health Centers (42 U.S.C. 254b–2(b)(1)(F)), the first substantive increase in years. However, recently HRSA decided rather than using this increase for the base grant funding for existing Community Health Centers, it would instead prioritize new access points for expansions and behavioral health centers, a small portion of the provider population. While it's a worthy goal, I'm concerned that existing health centers, many of whom are already stretched thin, are going to be forced to close their doors without a base grant adjustment. Will you commit to providing a base grant adjustment for the Health Center program, and can you explain what HRSA is doing to ensure that these existing Health Centers are maintained for underserved communities?

15. The infectious diseases (ID) workforce shortage in my state and nationwide is cause for great concern, as infections cause serious complications for hip and knee replacements and other surgeries as well as cancer care, and ID health professionals are needed to prevent and manage these complications. Hospitals that serve my constituents have not filled their training spot for new ID physicians, making clear that we need to do more to boost recruitment. Patients with serious infections do better and have lower health care costs when they are seen by an ID physician, but many patients lack access, as nearly 80 percent of counties in the nation do not have a single ID physician. Launching the Bio-Preparedness Workforce Pilot Program would greatly facilitate efforts to attract and retain ID professionals at health care delivery sites in Florida including 700 Federally Qualified Health Center (FQHC) delivery sites, 84 Veterans Health Administration, and

270 Ryan White sites. Do you agree that we must boost the ID workforce and increase access to ID care, including by implementing the Bio-Preparedness Workforce Pilot Program to incentivize health professionals to pursue ID careers and work in underserved areas?

16. One of the areas where improper Medicare payments have remained consistently above 60 percent during the last decade has been for supplemental oxygen. The CERT contractor annual reports indicate that the problem is with the underlying physician medical notes and not the documentation submitted by suppliers. Yet, CMS has done little to address the problem. We understand that the agency developed a clinical data element template a few years ago that the Medicare contractors could use to ensure that physicians prescribing supplemental oxygen know what information is needed to support their prescription as medically necessary. I understand more than 14 organizations – including patient advocates, physicians, respiratory therapists, suppliers, and manufacturers – have been asking CMS for the last few years to require the contractors to use these templates. Despite these pleas, CMS has refused to require the contractors to do so and the contractors have refused to adopt them without such direction from CMS. Patients are unfortunately caught in the middle. Can you describe how CMS will address this problem immediately, ideally by exercising its oversight authority over the contractors and require the contractors to adopt these clinical data element templates to once and for all address this staggering improper payment rate?

The Honorable Richard Hudson

Greensboro Influx Care Facility:

1. According to a Carolina Journal Article published on April 12, 2024, residents in the Greensboro area reported "flurries" of activity at the facility that took place in 2023, including multiple charter buses coming and going from the Greensboro Facility. What was this activity and why it was not reported to Congress?

    - Link: https://nsjonline.com/article/2024/04/despite-biden-admin-claims-greensboro-migrant-facility-saw-activity-in-2023/

2. Why did the Department of Health and Human Services (HHS) choose to operationalize the Greensboro facility at this time?

3. When Congress was alerted about the Greensboro facility moving into operational status, we were also told that unaccompanied minors would not be housed there at this time. Is it still the case that unaccompanied minors will not be housed at the Greensboro facility at this time?

4. Can you confirm there is no plan to house minors at the Greensboro facility in the near term?

5. If this circumstance changes, can you confirm your department will notify Congress of this change immediately, as well as provide all necessary details about this change as soon as possible?

6. How much money has been obligated for vendors at the facility?

    a. I understand over $220 million has been obligated by HHS for vendors – can you confirm this is accurate?

    b. What has this sum of $220 million been used for?

7. I'm aware your office issued a draft Request for Proposal (RFP) on March 7, 2024, for the primary services contract for the Greensboro ICF, with a final RFP expected sometime this month. I also know 39 possible vendors visited the site on March 28, 2024, as part of the selection process. Can you provide me with an exact date of when a final RFP will be issued for the joint contract?

8. Can you give an exact, or as close to exact as possible, date a vendor will be selected for the facility?

9. Do you believe the fact that HHS operationalized Greensboro despite there being so much uncertainty surrounding its ability to adequately care for unaccompanied minors reflects the fact that the Biden administration's immigration policies have led to a crisis at our southern border?

Strategic National Stockpile (SNS) replenishment:

HHS's most recent Medical Countermeasures Preparedness Review found the SNS often relies on decades-old products to fulfill stockpiling requirements. The review also found the SNS doesn't maintain nearly enough countermeasures for some of the most serious threats we face. This failure raises critical questions about the long-term strength of the stockpile, and HHS's ability to replenish MCMs against numerous threats in a timely fashion. To make matters worse, there is a $1.3 billion gap between your FY25 SNS budget request and HHS' stated needs for the stockpile this year alone.

1. Why did you lower the SNS budget request and what are you doing to address this growing gap in funding needs?

2. What is HHS's strategy to replenish expiring doses of MCMs in the stockpile?

3. Does the Administration intend to utilize both annual appropriations and existing unobligated supplemental funds to support the replenishment of expiring MCMs in the SNS?

Smallpox Countermeasures:

For FY25 you requested $820 million for the Project BioShield program, which is less than the final FY24 funding level. This successful program is having its 20-year anniversary this year, after being established in 2004 to better prepare the country for chemical, biological, radiological, and nuclear threats identified by the Department of Homeland Security. One of the major successes coming from this program was the long-term public private partnerships that led to the development and stockpiling of medical countermeasures for smallpox, which were able to be used to respond to the recent mpox outbreak.

1. Given the ongoing threats of smallpox and mpox, what are your plans for maintaining and improving our country's preparedness for poxviruses through Project BioShield over the next few years?

Influenza antivirals

Right now, there is a concerning outbreak of avian influenza circulating in American livestock. This outbreak has already spread to seven states. While currently contained to cattle, if this particular virus jumped to humans, it could be a catastrophic pandemic. Avian influenza has shown a mortality rate over 50 percent in humans.

Yet despite the urgency of this outbreak, and lessons learned from COVID, the SNS still hasn't replenished its stockpile of decades-old influenza antivirals. Earlier this year, SNS cancelled a procurement after protests by generic Tamiflu manufacturers who pointed out HHS was proposing to pay four times more to stockpile brand-name Tamiflu.

1. Given the threat posed by pandemic influenza, why has HHS failed to replenish the stockpile with antivirals?

2. There are numerous low-cost generic Tamiflu options available today. Do you think it's a wise use of taxpayer dollars to supply the SNS with only brand-name Tamiflu?

3. Can you give the Committee an estimate when the SNS will be resupplied with Tamiflu, including estimated costs and amounts?

Saving Access to Laboratory Savings:

During COVID, we saw how critical access to diagnostic tests were and how quickly our laboratories stepped up to the plate for public health. But it's not just COVID when testing is needed, tests are critical to early diagnosis of cancer, patients finding the right treatment for their disease, and couples trying to start a family who need to know their genetics. Unfortunately, because of the flawed implementation of the Protecting Access to Medicare Act (PAMA) and specifically, the data collection process used to set clinical laboratory fee schedule rates, reimbursements to laboratories have not changed since 2016, in eight years and clinical laboratories sustained three straight years of 10 percent cuts. Congress has stepped in to prevent continued damaging cuts to labs annually, but we need a long-term solution to ensure continued access to laboratory services for Americans, especially those living in rural and underserved communities.

1. Do you agree that we need PAMA reform and to ensure long-term stable payments for labs is critical to maintain access to laboratory services, especially in rural and underserved communities across this country?

2. If so, will you commit to working with us to establish a more stable environment for our laboratories?

The Honorable Earl "Buddy" Carter

1. A common theme in the PBM listening session at the White House is that the big-three PBMs are bad partners. Commissioner Khan stated that the PBMs FTC is investigating are not fully complying with FTC's mandatory requests for data; governor Bashear talked about his experience investigating PBMs overcharging Medicaid during his time as Kentucky AG; the community pharmacists at the session highlighted the unfair fees that PBMs force local pharmacies to pay and the radically low reimbursements that PBMs pay to them in turn; Mark Cuban explained how the big-three PBMs try to block his company from implementing innovative models to lower patient costs with PBM's business partners by scaring them out of it. The list goes on. It seems to me that middlemen, who say that they are here to lower costs and create efficiencies, instead are enriching themselves and cry foul whenever anybody takes the time to see if the claims they make about their business practices are true or not. Our health care system needs more transparency, and we need to curtail PBM business practices that enrich them at the expense of patients. Can you explain to me any problems that HHS has learned about PBM business practices and how PBM reform could empower HHS and others to help patients afford their medicines?

2. I appreciate that the FY25 budget proposal encourages the development of innovative, urgently needed new antimicrobial drugs to combat antimicrobial resistance. As cosponsor of the PASTEUR Act, I am encouraged to see this language, especially as we sponsors are working to enact the PASTEUR Act so it can be launched and funded. Can you share the Administration's next steps on this promising proposal reinvigorate the antimicrobial R&D pipeline?

3. I've recently introduced along with my colleague Nanette Barragán of California, H.R. 7688, the Accelerating Access to Dementia and Alzheimer's Provider Training (AADAPT) Act, which will empower primary care providers to better diagnose Alzheimer's and other dementia and deliver high-quality, person-centered care in community-based settings. My bill provides grants to organizations to set up dementia-specific Project ECHO programs to educate and support primary care providers in detecting, diagnosing, treating, and caring for Alzheimer's and other related dementia. This bill would expand access for people in rural, frontier, and medically underserved areas to receive the diagnosis, care, and support they need from providers that participate in the Alzheimer's and Dementia Care ECHO Program. What is HHS undertaking to ensure access to specialized dementia care training in rural areas, considering the unique challenges and needs of this population, and what role has Project ECHO played in these initiatives?

4. In the CY 2023 Physician Fee Schedule Final Rule, CMS finalized a policy to allow direct access to an audiologist for beneficiaries with non-acute hearing conditions. The finalized policy will allow beneficiaries, once every 12 months, direct access to an audiologist to receive care for non-acute hearing assessments that are unrelated to disequilibrium, hearing aids, or examinations for the purpose of prescribing, fitting, or changing hearing aids. Over-the-counter (OTC) hearing aids are often recommended for adults with non-acute, mild-to-moderate hearing loss. Will you commit to working with me to ensure that CMS issues a communication to audiologists to provide information on the availability and effectiveness of OTC hearing aids for non-acute mild-to-moderate hearing loss conditions?

5. How much in federal funds does HHS spend annually on Medicaid, specifically for youth residential treatment programs, and what is the current system for tracking this data?

6. How does HHS address regulation and oversight of Medicaid-funded youth residential treatment facilities to ensure federal dollars are being spent appropriately?

7. The President's Budget Request includes a notable increase of $95 million for the Biodefense Production of Medical Countermeasures and Essential Medicines, including $75 million to onshore production of medical countermeasures (MCMs) and active pharmaceutical ingredients (APIs), and $20 million to expand end-to-end visibility and management of the medical and public health supply chain for priority drugs and devices.

    a. How does the Department plan to utilize the proposed $75 million allocated for the on-shoring of medical countermeasures and APIs to enhance our national security and health preparedness? Please provide a detailed spend plan.

    b. Has the Department considered near-shoring to North America as a way to supplement domestic MCM and health preparedness efforts? If so, please detail your efforts.

    c. What specific outcomes does the Department anticipate from the additional $20 million proposed for enhancing the visibility and management of our medical and public health supply chains?

    d. What plans, if any, does the Department have to engage with non-profits, academic institutions, or private companies, or other federal agencies to identify and coordinate ongoing work in this space?

    e. Please explain the importance of enhancing the visibility and management of our medical and public health supply chains in the context of on-shoring or near-shoring in order to mitigate potential shortages of priority drugs and devices.

    f. How is the Department prioritizing essential and critical medicines that may have an API supply chain vulnerability and should be prioritized for nearshoring to protect against shortages and supply chain disruptions?

The Honorable Dan Crenshaw

1. What are the flows of money into and out of the Provider Relief Fund, in general, and the Uninsured Program account, specifically, between March 1, 2020 and April 17, 2024?

2. As you know, many providers have invested in participating in CMS Innovation Center models, including two-sided risk ACOs, kidney models, and others. How are you and the agency working to ensure that there is a continuity plan for these providers – so that these models don't abruptly end?

3. HHS recently released an updated Framework to Support and Accelerate Smoking Cessation (the Framework).

    a. On June 30, 2023, HHS issued a notice in the Federal Register detailing the request for information related to the Draft Framework and directed comments to be submitted to an HHS email address. Yet, to date, none of the comments submitted have been made public. Will the Department make publicly available all of the comments received on the draft Framework and the meetings held with stakeholders?

    b. The Framework lists an "HHS Smoking Cessation Initiative, Expert Advisory Group" and "Additional Contributors to the HHS Smoking Cessation Initiative" in Appendix A of the Framework. For each FDA participant listed in this appendix, please specify on which FDA Center such participant was representing in their contributions to the Framework, including denoting whether the participant was on detail to an op or staff division outside of FDA during their work on the Framework.

4. Who at HHS or CMS is responsible for overseeing beneficiary enrollment in Affordable Care Act programs?

    a. What mechanisms exist to hold bad actors accountable for these unauthorized enrollments?

    b. What changes will be implemented to ensure that unauthorized enrollments are not possible in the future?

    c. How quickly can HHS and CMS work to nullify unauthorized enrollments?

    d. How will cost sharing and deductibles be computed once people are restored to their original plans so that individuals do not lose credit for out-of-pocket payments already made?

    e. How will HHS and CMS coordinate with the private sector and the Labor and Treasury Departments to ensure beneficiaries who suffered unauthorized

enrollment are not unfairly penalized with respect to advance premium tax credits and out of pocket obligations?

5. The United States has now detected highly pathogenic avian influenza A(H5N1) virus in domestic cattle — the first time this subtype of influenza has ever been detected in this species. These detections have occurred in sick animals in at least 21 multiple states, including my home state of Texas.

    a. Early Detection and Warning Systems: Are any efforts ongoing to determine whether the virus may already be circulating in people or animals asymptomatically or undiagnosed?

        i. How is HHS coordinating its multiple sequencing programs with USDA to ensure a common operating picture of the threat environment?

    b. Public Health Communication: What would have to happen to trigger the CDC to raise the level of its risk assessment?

        i. If the CDC does change its assessment, how will it communicate this to the general public?

    c. Coordination: What are CDC and ASPR doing right now to get out ahead of such a declaration?

        i. What preparedness steps are they taking?

    d. The HHS Pandemic Influenza Plan was last updated in 2017. Based on the many challenges of the national COVID-19 response, is HHS confident that executing against this plan will be effective?

    e. Flu Countermeasures: Do we expect the pandemic influenza medical countermeasures we have available in the U.S. work against this strain of influenza?

6. Two FDA reviewers committed suicide during the pandemic due to overwork and isolation. What is the FDA doing to improve and expand upon the 510k third party review program?

7. In May 2023, the U.S. Department of Transportation (DOT) issued a final rule to add oral fluid drug testing for safety-sensitive transportation employees to its Transportation Workplace Drug and Alcohol Testing program.

    a. Please describe the current status of HHS's efforts, what hurdles HHS is facing in completing the process, and any remaining steps to approve a collection device and certify two laboratories to conduct the drug testing.

8. What factors contributed to changes in premiums and benefit offerings in Medicare Advantage plans for CY2024?

    a. What do you anticipate the CY2025 rate notice impact to be on beneficiaries?

The Honorable John Joyce

1. In July 2023, one of CMS's Medicare Administrative Contractors (MAC), Novitas, issued a proposed Local Coverage Determination (LCD) concerning Genetic Testing for Oncology. This LCD, if finalized, would discontinue coverage for a number of gene expression tests currently used by clinicians and beneficiaries to guide treatment decisions for various cancers. According to stakeholders, who have sent comments to Novitas and letters to CMS raising concerns about this LCD, Novitas would rely on third-party compendia to make coverage determinations, and in reviewing individual tests Novitas may not have reviewed all available clinical studies.

    a. Please tell us the current status of this LCD and CMS's expected timing for finalizing the LCD.

    b. What would be the implications for beneficiaries if Novitas finalizes this LCD?

    c. Is there precedent for a MAC to defer to compendia to make coverage determinations?

    d. Why did Novitas not convene a Contractor Advisory Committee in this instance?

2. In your FY 2025 Budget, you requested $95 million at ASPR for "Biodefense Production of Medical Countermeasures and Essential Medicines", which would be managed by IBMSC. Why do you think it is important that the U.S. establishes long-term domestic manufacturing capabilities of critical medical countermeasures and essential medicines in the United States?

    a. How is the new Office of Industrial Base Management and Supply Chain within ASPR working to ensure these supplies are manufactured here?

    b. Why is dedicated annual funding needed to achieve this objective?

3. MedPAC's June 2022 report supports expansion of site neutral payment policies, noting that payment differences across settings encourage hospitals to acquire physician practices and result in care being billed at the highest rates. Adopting site neutral payment policies in Medicare for services that are commonly delivered outside the hospital and eliminating the grandfathering provision of the site neutral payment reforms in the Balanced Budget Act of 2015 would reduce taxpayer spending and beneficiary costs without a meaningful change in patient care. Given a recent Avalere study that reports that in 2022, only 2.3 percent of hospital outpatient department Medicare billings were site-neutral, and removing the grandfathering provision would have increased this

by an additional 10.3 percent, would you support these policies to drive affordability in health care?

4. The budget proposal prohibits hospitals from billing unwarranted facility fees for telehealth services and for certain other outpatient services, citing a net savings of $2.3 billion over 10 years. Could you elaborate on what "other outpatient services" the budget is referring to?

5. As the Secretary is aware, in 2021, CMS created a new participation pathway under the Quality Payment Program called MIPS Value Pathway (MVP). In mid-December 2023, CMS unveiled six candidate MVPs, including an MVP for Dermatological Care. However, there are significant concerns with the Agency's approach to constructing MVPs, as it is using excessively broad measure sets that lack alignment and provide no added benefit in terms of enhancing patient care or helping patients determine the value of the clinician managing their care. CMS's approach fails to account for the realities of clinical practice and adds yet another layer of complexity to an already confusing program.

   Each subspecialty within dermatology provides unique services to distinct patient populations with varying practice patterns. This diversity in the practice of dermatology makes a one-size-fits-all model ineffective for comparing the cost and quality of care. For example, dermatologists who treat psoriasis, which is currently considered in the candidate MVP's quality measures may not treat melanoma, which is currently the only measure related to cost available in the candidate MVP. Regardless of how CMS ultimately scores MVP participants, if CMS finalizes an MVP that includes a cost measure for a cancer-related disease and quality measures for an inflammatory skin disease, patients and clinicians will question its purpose and the extent to which it fails to drive value-based care.

   Despite nearly two years of discussions and meetings between CMS and dermatology stakeholders, CMS continues to express interest in the use of a single MVP for dermatology. This decision ignores the critical problem of the one-size-fits-all approach, which falls short in effectively comparing costs and quality of care.

   a. Because of the apparent flaws in the candidate MVP for Dermatological Care, will CMS commit to working with dermatology stakeholders, such as the American Academy of Dermatology Association, to develop meaningful MVPs around episodes of care and ensure the MVP framework, in general, reflects clinical practice and fosters patient-centered value-based care?

The Honorable Diana Harshbarger

Non-Discrimination in Health Care; Sec. 1557 of the Affordable Care Act:

1. Under HHS's nondiscrimination final rule interpreting Section 1557 of the Affordable Care Act, does HHS contend that the statute requires physicians to provide elective abortions even when doing so would violate state law?

2. Does HHS contend that the statute requires physicians to provide sex-reassignment surgeries and hormone therapy treatment to minors even when doing so would violate state law?

3. And is it HHS's position that Section 1557 of the Affordable Care Act requires state Medicaid programs to pay for sex-reassignment surgeries for persons with gender dysphoria?

Drug Policy:

1. Why are overdose deaths increasing under the Biden administration's supposed "harm reduction" strategy?

2. Additionally, could you clarify what limits are set on how federal funds can be used to promote harm reduction?

Rural Health Care Talent:

1. What is the Department's strategy for ensuring sufficient medical talent is available to serve rural areas in the coming decade?

FDA's Proposed Ban of Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior (89 Fed. Reg. 20882):

Since 2010, the U.S. Food and Drug Administration (FDA) has been publicly attempting to ban the use of a harmless skin shock device (the GED) that is court-approved on an individual basis, and only used at one program in the Nation (the Judge Rotenberg Center) for 54 patients from across the country who suffer from the worst cases of severe self-mutilation and violent aggression. The GED has safely and effectively treated the most difficult and dangerous behavior disorders in the Nation since the early 1990's when the FDA cleared the first GED for this use.

Nonetheless, in response to pressure by the Department of Health and Human Services (HHS), and with HHS's assistance, FDA banned electrical stimulation devices (ESDs) for self-injury and aggression, including the GED, falsely claiming that the device was not effective and causing harm. On July 6, 2021, the Federal Court of Appeals for the D.C. Circuit vacated FDA's ban as not compliant with the law.

The FDA is now proposing again to ban ESDs to treat severe self-mutilation and aggression (89 Fed. Reg. 20882). Despite this second ban attempt, it is my understanding that FDA admits that the patients' disorders could be fatal, and that there is no other effective treatment capable of stopping their life-threatening self-abuse and aggression.

1. Why has HHS consistently directed FDA to issue this ban, despite FDA's repeated assertions to HHS that it lacks the evidence to support this regulatory action?

Dietary Guidelines and Adult Alcohol Consumption:

Mr. Secretary, on the topic of the Dietary Guidelines and alcohol, a decision was made to break with a 40-year precedent and replace it with a new process. Your department directed the Interagency Coordinating Committee to Prevent Underage Drinking (ICCPUD) at the Substance Abuse Mental Health Service Administration (SAMHSA) to write recommendations on adult alcohol consumption.

Dietary guidance is beyond the scope of SAMHSA, whose mission is to "promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery." And guidance on moderate alcohol consumption for legal drinking age adults is entirely outside the mandate of ICCPUD, whose mission is to "provide resources and information on underage drinking prevention, intervention, treatment, enforcement, and research." ICCPUD membership also does not include USDA, one of the two agencies who statutorily have the purview to develop such guidance.

This, in contrast to the Congressionally mandated and appropriated ($1.3million) NASEM study, which is being conducted by experts who have been publicly vetted; has a scope of research defined by law and reflective of the topics and methodologies used to develop previous editions of the Dietary Guidelines; and offers ongoing opportunities for public comment and stakeholder participation in meetings.

1. Why is the Congressionally mandated NASEM panel that addresses alcohol impact on 8 specific health issues (including but not exclusive to: cancer, cardiovascular, neurocognitive and all-cause mortality) not sufficient to inform the recommendations on Dietary Guidelines?

Dietary Guidelines, ICCPUD Transparency:

Compounding the problem, SAMHSA recently revealed that, in addition to a "technical subcommittee" under ICCPUD that has been tasked with making the recommendations on adult alcohol consumption, there is a "scientific review panel" of non-federal contractors who will be conducting the actual evidence review and developing the conclusions that will inform these recommendations.

It was also revealed that these groups began meeting a year ago, despite public statements that indicated the work had not yet begun. To date, neither the ICCPUD subcommittee, nor the scientific review panel have met publicly, revealed their membership, or allowed for public comment on their efforts. Most recently, it was revealed that SAMHSA plans to implement research protocols not previously used to develop alcohol recommendations in the Dietary Guidelines.

1. Will you commit to providing the names and biographies of the members on the ICCPUD technical subcommittee and scientific review panel, who are tasked with writing recommendations — including a list of those who met last spring and summer?

2. If not, why are you not holding SAMHSA and ICCPUD to the same standard of transparency that governs the NASEM and the DGAC process?

Dietary Guidelines: Dr. George Koob's Timely and Controversial Comments — Summer 2023

As you may know, last summer, Dr. George Koob, Ph.D. — Director of the National Institute on Alcohol Abuse and Alcoholism — commented that the U.S. was going to adopt recommendations proposed by a Canadian activist NGO, to limit alcohol to two drinks per week. Dr. Koob said this recommendation had been adopted by the Canadian government when in fact the Canadian government has declined to adopt the recommendation.

1. As member of ICCPUD, what is Dr. Koob's role in developing the DGA recommendations on alcohol?

2. Is he a member of either of the ICCPUD subcommittees (technical or scientific review)?

3. Is he overseeing the study and writing of recommendations?

    a. Did he attend or participate in any of the ICCPUD meetings on alcohol last summer?

Dietary Guidelines, ICCPUD Expanding Jurisdiction:

The Interagency Coordinating Committee for the Prevention of Underage Drinking (ICCPUD) was formally established by the Sober Truth on Preventing Underage Drinking Act (STOP Act) of 2006, which was reauthorized in 2022 as part of Consolidated Appropriations Act, 2023 (Public Law No. 117-328).

ICCPUD's foundational mission is to: (1) address norms regarding alcohol use by youth, (2) reduce opportunities for underage drinking, (3) create changes in underage drinking enforcement efforts, (4) address penalties for underage use, and/or (5) reduce negative consequences associated with underage drinking.

1. Why have you decided to redirect resources away from combating underage drinking to focus on adult legal consumption under the Dietary Guidelines?

2. What expertise does ICCPUD have on nutrition, healthy dietary patterns or moderate alcohol consumption by adults who choose to consume alcohol?

    a. What specific expertise does ICCPUD have that the NASEM panelists do not already have?

3. Congress appropriated $1.3 million for NASEM to study 8 questions that HHS and USDA have identified as the key questions that must be answered to inform the Dietary Guidelines on alcohol. How are ICCPUD efforts not subverting the explicit direction and appropriation Congress has provided to address the alcohol recommendations in the Dietary Guidelines?

The Honorable Mariannette Miller-Meeks

1. Has HHS analyzed factors that might steer patients towards lower-risk acute pain management options, such as novel nonopioid alternatives, once approved, and the potential effects of successful steering along these lines?

    a. Do you believe that cost sharing requirements could be a disincentive and even a burden for patients?

2. Secretary Becerra, according to a July 2023 Joint Economic Committee Report, "Obesity is one of the largest contributors to Medicare and Medicaid spending." Further, the report suggests that in light of such spending, identifying diseases [in Medicare and Medicaid] "…that impose the largest financial burden, or which offer the most practical means of cost reduction…" should be addressed. Obesity and obesity-related diseases fit both categories. The JEC economists project that the combined Medicare and Medicaid spending on obesity and obesity-related diseases will total $4.1 trillion. In your opinion, what needs to be done to modernize comprehensive obesity care in Medicare and Medicaid?

3. Secretary Becerra, I understand that the total estimated cost of diabetes care and impact on productivity in the U.S. is at least $327 billion per year. When we consider all forms of diabetes, such as those who are undiagnosed, that number is over $400 billion per year. I also understand many people who have diabetes have obesity – their obesity played a part in developing diabetes. According to the CDC – nearly 100 million Americans have pre-diabetes and most of them have obesity or overweight.

    a. What can we do to better treat people with pre-diabetes, better manage their obesity, and reduce the number who develop diabetes? I am interested in your thoughts for Medicare and Medicaid.

4. Mr. Secretary, Medicare Advantage is growing in popularity in part because it offers patients greater benefits with lower out-of-pocket costs, including plans that even give back Medicare patients portions of their premiums they paid. Some of the benefits not offered in Medicare fee-for-service include limits on annual out-of-pocket costs, reduced cost-sharing, and supplemental benefits such as dental, vision, hearing, prescription drugs, transportation and more. However, one of the tradeoffs involved is that MA plans may use tools such as prior authorization to limit or delay access to health care services, including items such as Non-Invasive Ventilator (NIV) devices which are critical for patients with both acute and chronic respiratory failure. I've received reports that suppliers of NIV products are being denied authorization for patients that previously had

NIV products in traditional Medicare, even with supporting clinical evidence that NIV therapy is the most clinically appropriate therapy for the patient. Considering Medicare Advantage's appealing features and superior structure to traditional Medicare, it is imperative that patients still receive timely access to medical products that are appropriate for their individual needs when entering Medicare Advantage.

a. What kind of oversight are HHS and CMS conducting as it relates to access to these products in both traditional Medicare and Medicare Advantage, including for patients who switch over to the more popular Medicare Advantage program from Medicare fee-for-service?

b. What does your Department plan to do to ensure MA plans provide timely access to such products as clinically appropriate?

5. Mr. Secretary, heart disease has been the leading cause of death for seniors for the past several decades. Forty-two percent of Medicare beneficiaries aged 65 years and over have at least one heart condition. By 2035, nearly half of the U.S. population will have some form of cardiovascular disease. The direct medical costs associated with heart disease are projected to skyrocket to more than $1 trillion by 2035 with the majority being spent on seniors aged 65 and over. Such costs as you know include money spent on medical services via a physician, hospital, or health care system, and corresponding or follow-up costs, such as prescription drugs, home health or nursing home care.

a. With a GLP1 now being approved to treat cardiovascular disease, do you believe there will be savings in Medicare in the form of lower direct medical costs associated with heart diseases as more patients take a GLP1 medication?

b. Do you believe direct medical costs will also go down in Medicare because of Medicare patients taking a GLP1 to treat a heart disease condition?

c. Can the department provide estimates on the potential number of lives that could be saved annually among Medicare beneficiaries if AOMs were covered by Medicare, specifically focusing on reducing cardiovascular disease mortality?

d. Are there existing studies or models that project the impact of increased AOM access on cardiovascular disease death rates in the Medicare population?

e. Alongside the potential lives saved, could the department share any analyses on the cost-effectiveness of covering AOMs in Medicare, considering the potential reduction in future healthcare costs associated with treating cardiovascular disease?

6. Mr. Secretary – One of the focuses of your tenure as Secretary has been to help reduce inequities for disadvantaged populations, particularly minority and underserved populations. One of the diseases which disproportionately hits these populations is kidney disease. The Centers for Medicare & Medicaid Services (CMS) has attempted to address some of these disparity issues through a number of actions such as the Comprehensive

Kidney Care Choices (CKCC) model which received bipartisan congressional support and has seen significant uptake. However, recent decisions made by CMS to retroactively adjust the benchmark for calendar years 2022 and 2023 have now put this successful model at risk as financially providers will not be able to sustain the level of risk they are being asked to burden despite being able to successfully manage care and lower spending for these vulnerable patients. Despite being asked to re-evaluate their stance, or put in place risk corridors, CMS and CMMI has thus far neglected to take action and as a result providers are already beginning leave the demonstration thus impacting this underserved population.

   a. Will you commit to engaging with CMS and determining what is going on with respect to the financial incentives in the CKCC model and whether adjustments can be made for 2022 and 2023?

7. I am very committed to ensuring that patients have access to life-saving treatments that make their lives longer and healthier. That is why I am concerned that, as proposed, CMS has limited TCET coverage to up to only 5 devices annually that have a "breakthrough" designation from FDA. This very limited approach may expand patient access to only a small number of new and innovative life-saving technologies – even though there are so many in clinical development right now from which patients ultimately could benefit if they had access to them. Again, I am very concerned that CMS has proposed to limit TCET only to up to 5 devices with FDA "breakthrough" designation each year. This approach is simply inadequate for expanding patient access to innovative treatments, which the Administration committed to when it first began discussing TCET. Can you assure me that the Administration is committed to establishing a separate pathway for Medicare coverage that does not restrict eligibility to just a few devices with "breakthrough" designation, but rather expands access to the many innovative and life-saving treatments that are under clinical development today?

   a. What administrative actions will the Administration take to ensure that Medicare beneficiaries can access the life-saving treatments they need?

8. Secretary Becerra, as you're undoubtedly aware the Health Resources and Services Administration (HRSA) COVID-19 Uninsured Program provided billions of dollars for the provision of testing, treatment, and vaccines to uninsured patients nationwide through funding included in the FFCRA, the PPPHCA, and the CARES Act, among others. Because of the unique needs of this population, the program represented a critical and successful public-private partnership that allowed external stakeholders to establish creative programs for treatment, testing, and vaccination, such as mobile medical facilities and testing labs, while also decompressing more traditional healthcare sites that were hard hit by COVID. However, as you know the Uninsured Program halted acceptance of new claims for testing, treatment, and vaccinations in March 2022. Despite the fact that the Provider Relief Fund still had billions of dollars left in its account to issue payments for legitimate COVID-related care at the time the program stopped accepting claims, I understand that there are still tens of millions of dollars' worth of legitimate claims submitted to the program for payment that have still not been paid. This situation provides a significant financial hardship for external stakeholders who engaged

in this work during a critical time in the nation's COVID response and runs counter to federal requirements for prompt payment of contractors for agency-sanctioned work. Secretary Becerra, can you commit to assembling an accounting of the total number of claims submitted to the HRSA COVID-19 Uninsured Program account that were submitted prior to the closure of the program and adjudicated for payment but remain unpaid or partially paid, including applicable amounts owed stratified by Zip Code and State?

   a. Can you commit to working with Congress and your colleagues in the Administration to create a mechanism for repayment of legitimate claims in this program to make providers whole using funds returned to relevant accounts?

9. Secretary Becerra, please describe the measures taken by your Department to ensure that health plans inform clinicians and hospitals fully and appropriately whether claims submitted to the IDR process under the No Surprises Act are subject to state (if there is a state specified law) or federal law?

   a. Additionally, please describe the enforcement actions taken if any against the health plans for failing to pay IDR determinations made against the plan and any civil monetary penalties assess against the plans for non-compliance as permitted under the law?

The Honorable Anna Eshoo

1. Following your testimony before the House Energy and Commerce Committee in July 2023, I submitted 12 questions for the record (QFRs) about the Office of Refugee Resettlement's (ORR) Unaccompanied Children program. However, the response I received from HHS on March 13th either ignored or only partially answered most of my questions. I therefore respectfully request that you answer the following seven questions that were included in my previous QFRs but not fully addressed:

   a. The *New York Times* reportedly spoke with "more than 100 migrant child workers in 20 states" to inform their article titled, "Along and Exploited, Migrant Children Work Brutal Jobs Across the U.S. (2/23/23)." Are you aware of whether these specific children are still being subjected to illegal labor exploitation?

      i. Have the specific children mentioned in the article received follow-up phone calls and post-release services furnished by ORR?

   b. ORR currently lacks the legal authority to reclaim custody of children once they have been released to sponsors. Would granting this authority to ORR strengthen the agency's ability to protect children from abuse?

   c. To what extent have funding constraints limited ORR's ability to properly screen potential sponsors and monitor the treatment of discharged children?

d. In addition to increasing funding, how best can Congress support HHS in your efforts to protect children from exploitation?

e. Over the past two years, how many ORR employees have been fired or quit after having made a complaint to a superior, either formally or informally, about the treatment of children?

f. What steps have you taken to change the culture of ORR to ensure that the agency prioritizes the safety and well-being of children over the speed of their release from custody?

g. According to the New York Times, monthly calls to HHS reporting trafficking, neglect, and abuse of children increased fivefold from less than 50 calls in January 2021 to nearly 250 calls in December 2022. How many calls reporting trafficking, neglect, and abuse of children has the ORR National Call Center (ORRNCC) received each month since December 2022?

2. On April 16th I introduced the *Transparency for Unaccompanied Children Act* which requires HHS to issue publicly accessible reports each month about ORR's Unaccompanied Children Program. Is HHS willing to voluntarily issue monthly reports containing the data fields listed in the bill?

3. Last year, only half of infectious diseases (ID) physician training programs in the U.S. were filled, including leading institutions like Stanford. When I chaired the Health Subcommittee in 2022, Congress enacted the Bio-Preparedness Workforce Pilot Program to incentivize health professionals to pursue ID careers and work in underserved communities by offering student loan repayment in exchange for service.

    a. Do you agree that we need to reduce the financial barriers preventing health professionals from pursuing ID, such as through the Bio-Preparedness Workforce Pilot Program?

4. The Inflation Reduction Act (IRA) made changes to Medicare Part D that will increase plan sponsors' liability for costs in the catastrophic phase beginning in 2025. As a result, plans have additional incentive to apply utilization management, including step therapy, in order to limit their expenditures and such actions could adversely impact patients access to timely and appropriate care. It's essential to protect beneficiaries, including providing clear direction to health plans and pharmacy benefit managers, to ensure timely patient access to therapy.

    a. How is CMS monitoring changes in formulary design to ensure that beneficiaries maintain timely access to appropriate therapies? Please provide specific examples.

    b. What actions are CMS taking to prevent the inappropriate use of step therapy and other utilization management techniques? Please provide specific details, including the corresponding timeline for implementing such actions.

c. Will HHS commit to ensuring enrollees have greater visibility into Part D plans' use of utilization management policies so they can make as informed a decision as possible when comparing plan options?

d. What steps is CMS taking to protect against changes to access or formulary design that are not based on clinical best practice and ensure a "patient first" approach?

e. Will you commit to ensuring beneficiaries have the same level of access to therapeutics and care as they did before the Part D redesign?

The Honorable Raul Ruiz

1. Studies show communities of color suffer the greatest burden of obesity and its associated comorbidities. Black Americans and African Americans are 1.3 times more likely to be obese than non-Hispanic whites and about 4 out of 5 African American women are overweight or obese. Hispanic Americans were 1.2 times more likely to be obese than non-Hispanic whites and about 4 out of 5 Hispanic women are overweight or obese. As we look for ways to provide more equitable care, because it is the smart thing to do from an economic perspective and the right thing to do from an ethical perspective, how can we address these health disparities in the prevention and treatment of obesity?

The Honorable Ann Kuster

Smoking Cessation:

The Department of Health and Human Services (HHS) recently released an updated Framework to Support and Accelerate Smoking Cessation (the Framework). The Framework acknowledges that despite the progress made in the last 60 years to reduce the rates of cigarette smoking among U.S. adults, cessation efforts have stalled: cigarette smoking and secondhand smoke exposure still claim nearly half a million lives in the United States each year. Cigarette smoking remains the leading cause of preventable disease, disability, and premature death in the United States, including about 25 percent of all cardiovascular disease deaths and 30 percent of all cancer deaths.

- Link: https://www.hhs.gov/sites/default/files/hhs-framework-support-accelerate-smoking-cessation-2024.pdf

For Americans trying to quit smoking, smoking cessation therapies can be life changing. It is critical that we help all Americans who want to quit smoking be more successful in their quit attempts, and new, safe and effective pharmacotherapies can play an important role in helping more people successfully stop smoking. Yet, despite the overwhelming need for new, more effective pharmacotherapies for cessation, the Framework fails to acknowledge FDA's critical role and simply called for more NIH-funded research.

1. As acknowledged by the Framework, while most adults who smoke want to quit, and more than half try to quit each year, few successfully quit each year. Multiple comments were submitted on this key point in response to the draft framework issued last year. Why did HHS choose not to incorporate any discussion of the need for innovation in smoking cessation treatments?

2. HHS states that the Framework is intended to "enhance collaboration and coordination to drive further progress in increasing smoking cessation." What steps is HHS taking to hold the Food and Drug Administration (FDA) accountable to being more proactive and modern in their regulatory approach to smoking cessation products?

3. Last year, on June 1, 2023, at a Cancer Moonshot event at The White House, Commissioner Califf acknowledged some of the challenges those seeking to bring forward new cessation products may encounter and said that there are things that FDA is trying to do to reduce the "friction" related to bringing forward medical products in this space. What actions has FDA taken to address the "friction" at FDA that he referenced?

    - Link: https://www.youtube.com/watch?v=v283m-0Mpmw (1:09:14-1:11:00)

4. What actions will FDA take to expand and improve treatment options for smokers trying to quit today and, in the future, including for new-found interest in quitting by smokers?

<u>Diagnostic Innovation:</u>

Ensuring that Medicare beneficiaries can obtain accurate and timely diagnoses is critical to improved outcomes and quality of life for seniors. From a Medicare spending perspective, accurate and timely diagnoses are also essential to avoiding more expensive courses of treatment that result from delayed diagnoses and repeat scans.

To that end, I believe the Department of Health and Human Services (HHS) should ensure that Medicare's payment system for hospital outpatient services does not create disincentives for hospitals to use cutting-edge diagnostic radiopharmaceuticals, such as those used in PET scans, to detect diseases in early stages, including in particular prostate cancers and other cancers that have a disproportionate impact on people of color.

Last year, the Centers for Medicare and Medicaid Services (CMS) sought information from stakeholders on Medicare payment approaches that could avoid payment disincentives for these innovative diagnostic radiopharmaceuticals. One such approach, as envisioned in H.R. 1199, the Facilitating Innovative Nuclear Diagnostics (FIND) Act is to provide separate payment for innovative diagnostic radiopharmaceuticals rather than packaging the payment into the payment for the imaging scan.

- Link: https://www.congress.gov/bill/118th-congress/house-bill/1199/text

1. Secretary Becerra, will you commit to working with me and my office to help ensure that Medicare payments provide the appropriate incentive for hospitals to utilize innovative diagnostic radiopharmaceuticals for imaging scans?

Implementation of VAWA:

In 2022, Congress reauthorized the bipartisan *Violence Against Women Act* (VAWA) and assigned several new authorities to the Department of Health and Human Services, such as programs to address the availability of Sexual Assault Forensic Exams and the backlog of untested sexual assault kits. However, these new VAWA programs at HHS have yet to be implemented.

1. What steps have you taken to operationalize these new programs so that victims of sexual assault and other forms of violence may access the healthcare they need?

    - Link: https://www.congress.gov/117/plaws/publ103/PLAW-117publ103.pdf

The Honorable Robin Kelly

Thank you for taking the time to testify at the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health entitled, "Fiscal Year 2025 Department of Health and Human Services Budget". Please accept these questions for the record.

1. I appreciate the leadership of HHS and FDA in sending the menthol rule to the White House for final review in October, which I have been an advent supporter of. This rule is critical to addressing health equity and achieving the President's cancer moonshot objectives. Secretary Becerra, will you commit to continuing to push the White House to finalize this rule?

2. Furthermore, I hear from so many providers and groups, especially those providing services to these minoritized populations or those in rural areas, that they are unable to access the funding streams from the Administration, particularly in the maternal health space. How will the Administration work to ensure that funding for these endeavors reach not only those communities serving individuals most in need, but also community-based organizations who lack the resources held by larger, more established institutions to complete for grants?

3. Roughly 19 million women in the United States live in contraceptive deserts, or places where options for contraceptives don't exist. In FY23, Congress passed report language directing the Administration to conduct a nation-wide study on contraceptive deserts accompanied by policy recommendations to address the situation. It's my understanding that since the passage of the funding bills in FY23, that study has been stuck and, as a result, we still don't have that data. Secretary Becerra, will you commit to following up with this committee to finalize and release that study in the next few months?

    a. If so, can you give me a deadline in which you expect it will be released?

    b. Additionally, if there is a reason for the delay, will you commit to providing a transparent process for that reasoning?

4. Finally, CMS has proposed a rule that would make sweeping changes to how Medicaid drug rebates would be calculated. Several providers and patient groups have reached out expressing concern regarding the potential unintended consequences this rule could have on patient care and access. Given that this proposed rule is still under consideration by the Administration, would your office be willing to follow up with me to discuss these concerns? Thank you for taking the time to address these important questions.

The Honorable Lisa Blunt Rochester

1. We are in the midst of a nursing workforce crisis. According to a research project from the National Council of State Boards of Nursing, about 100,000 registered nurses left the workforce in 2021 and 2022 due to stress, burnout, and retirement. Do you agree that providing grants to state-based nursing workforce centers to develop programs to recruit and retain nurses, collect localized and granular workforce research data, support programs to decrease workplace violence against nurses, and conduct strategic nursing workforce planning and program development will help address shortages?

2. The severe health complications associated with blood clots and fatal pulmonary embolisms (PE) are among the most significant threats to public health in America. One American dies of a blood clot every six minutes and one in four pulmonary embolism (PE) victims die suddenly and without warning. How important is it to invest in increasing public awareness of blood clot signs and symptoms, and educate health care providers and hospitals on the signs, symptoms, and treatments of blood clots?

3. Menopause is a naturally occurring phase of life that all women will experience if they live long enough. In the United States alone, approximately 1.3 million women enter menopause every year, but many with little or no guidance. Symptoms such as hot flashes, brain fog, urinary problems, and depression can severely affect daily activities and work performance. How understudied is menopause, a condition that directly impacts over half of our population if they live long enough?

    a. How important is it to increase research funding for menopause?

4. I am very concerned by the impact of HIV workforce shortages on HIV-related health disparities – particularly in the Southern U.S. and in rural areas. Growing the HIV workforce and ensuring that everyone who needs it has access to expert HIV care allows individuals with HIV to live long and healthy lives and is necessary for us to end HIV as an epidemic in our country. Once funded, the Bio-Preparedness Workforce Pilot Program can help build the HIV and ID workforce by incentivizing healthcare professionals to go into the field and work in underserved and workforce areas, including at Ryan White Program-funded clinics. Do you agree that we must strengthen the HIV workforce to expand access to HIV care, such as through the Bio-Preparedness Workforce Pilot Program?

5. Secretary Becerra, with so many women in this country facing barriers to contraception, I wanted to get your feedback on improving access to contraception care in the health centers that millions depend on.

    a. What can HRSA do to support the capacity of the contraceptive workforce to maximize patient access to care?

    b. How can HHS and HRSA expand provider training and stocking options for the full range of contraceptive care, including longer-acting forms?

    c. How can HHS support evolving care delivery systems, like telehealth and OTC access, to expand patient access to contraception?

    d. Are there specific policy barriers that HHS has identified to improving contraceptive care or coverage that Congress can help support?

    e. What is HHS doing to ensure people have insurance coverage for all contraceptive methods, including OTC methods without requiring a prescription?

6. Community Health Centers are an essential part of the healthcare safety net in Delaware. Health centers care for 7 percent of Delawareans on Medicaid but only account for 0.6 percent of Delaware's Medicaid spending. With additional funding, health centers could reach more patients and provide more comprehensive services, including mental and behavioral health care, while reducing healthcare costs. Can you explain what the President's plan to double federal funding for health centers would mean for the patients and communities they serve?

The Honorable Kim Schrier

1. **Value based care models and continuity**: As you know, many providers have invested in participating in CMS Innovation Center models, including two-sided risk ACOs, kidney models, and others. These capitated models show the most promise for delivering cost savings to the trust fund and better outcomes for patients. These models require investment from providers, including hiring staff, putting in place robust IT systems, and building care management infrastructure. How are you and the agency working to ensure that there is a continuity plan for these providers – that these models don't abruptly end and that we continue to see benefits to patients and the trust fund?

2. **ACO beneficiary information**: The ACO Reach model run by CMS Center for Innovation is doing a great job improving care for beneficiaries in my state — and many others — by allowing physician practices willing to take full risk for the total cost of care to add innovative programs to improve and coordinate care, like behavior health programs, getting rides to appointments and even proving meals for seniors in need. But ACO participants in the program say that CMMI has marketing restrictions which severely limit the ACOs' ability to reach out to patients to let them know that they are part of the program and eligible for these great extra benefits that can keep them

healthy. Medicare Advantage can also do some of these activities in a more limited fashion — but they don't have the same marketing restrictions placed on them that the ACO Reach programs do. What is CMS doing to improve information sharing with patients to properly inform beneficiaries about the benefits of the ACO Reach program that they are enrolled in?

3. **Physician loan repayment**: As a pediatrician, I was pleased to see that HRSA awarded the first ever loan repayment awards for pediatric subspecialists through the Pediatric Specialty Loan Repayment Program this past fall. However, only 34 of the 122 awards offered went to physicians, which is just 4.1 percent of the 836 physicians who applied and were deemed eligible, and I am concerned that HRSA's criteria for selecting applicants does not account for the high debt burden pediatric subspecialists bear. High medical education debt is a key driver of the major shortages of pediatric medical subspecialists, pediatric surgical specialists, and child and adolescent psychiatrists we are seeing. Pediatric subspecialists undergo between 5 and 7 years of training after medical school before they begin their careers and are able to pay off their debt. Could you please share how HRSA will address this in future PSLRP funding cycles to ensure that high debt providers can benefit equally from this important program so that kids are able to get the care they need?

The Honorable Lori Trahan

1. Starting in October 2024, patients will need to enroll through their plans to smooth their drug costs. Your guidance to date lays out what plans need to do for education, but has lacked details thus far on CMS's role in the education effort. To ensure strong participation, how are you prioritizing patient education by CMS of the Medicare Prescription Payment Program, which requires patients to opt-in to smooth their drug costs in monthly installments over the plan year?

2. In your first guidance, you noted that you're looking at point-of-sale enrollment for 2026. What is the status of your evaluation, considering that point-of sale enrollment would play a significant role in ensuring that patients have immediate opportunities to smooth their costs over the plan year, and the law requires plans and pharmacies to notify beneficiaries at the point of sale if they are likely to benefit from the Medicare Prescription Payment Program?

3. Secretary Becerra, I understand that the total estimated cost of diabetes care and impact on productivity in the U.S. is at least $327 billion per year. When we consider all forms of diabetes, such as those who are undiagnosed, that number is over $400 billion per year. I also understand many people who have diabetes have obesity – their obesity played a part in developing diabetes. According to the CDC – nearly 100 million Americans have pre-diabetes and most of them have obesity or are overweight. What can we do to better treat people with pre-diabetes, better manage their obesity, and reduce the number who develop diabetes? I am interested in your thoughts for Medicaid, Medicare, and the private sector.

4. Researching and developing medical countermeasures that are pathogen agnostic or are versatile by providing protection from entire viral families will best help protect the American people from the next emerging pandemic threat. These innovative technologies need support from BARDA in coordination with NIH and FDA to ensure that they are supported from early stage through licensure. How are you working to bolster BARDA's ability to invest in and develop viral family type medical countermeasures?