Questions for the Record for Xavier Becerra

Committee on Energy and Commerce Hearing
"Fiscal Year 2025 Department of Health and Human Services Budget" April 17, 2024

The Honorable Michael Burgess, M.D.

Questions #1-3

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?

Response (1-3):
Patient cost sharing cannot be adjusted based on the IDR payment determinations. Plans are required to calculate the cost-sharing requirement as if the total amount that would have been charged for the services by such participating provider or participating emergency facility were equal to the recognized amount for such services, which (for disputes that are eligible for the IDR process) will be the lesser of the provider's billed amount or the QPA. By requiring plans and issuers to calculate the cost-sharing amount using the recognized amount, rather than the amount the plan or issuer ultimately pays the nonparticipating provider or nonparticipating emergency facility for the furnished items or services, the No Surprises Act and the interim final rules limit the effect of provider-payer disputes on participant, beneficiary, or enrollee cost sharing. Under the statute and the interim final rules, the provider or facility and plan or issuer separately determine the total payment amount for the furnished items or services, but that amount does not affect the cost-sharing amount the individual must pay. We have heard from stakeholders regarding this concern and are actively investigating the issue.

Question #4

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 consumers or 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.
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?

Response:
The statute and regulations are clear - the parties involved in a payment dispute are bound by the certified IDR entity's payment determination unless there is fraud or evidence of intentional misrepresentation of material facts given to the certified IDR entity by any party regarding the claim or any of the circumstances described in 9 U.S.C. § 10(a)(1)-(4) are present. Once a certified IDR entity makes a payment determination, the prevailing party must be paid within 30 calendar days after the determination.

With respect to your question regarding timely payment after a Federal IDR payment determination, the Departments and OPM have received a number of complaints regarding late payments after IDR payment determinations. We take the issue of late payments after IDR payment determinations very seriously. To ensure that we are aware of all issues related to timely payment, we strongly encourage parties who use the Federal IDR process to submit complaints related to timely payment to the NSHD so the Departments can follow up. After the NSHD receives a complaint, the complaint is reviewed in its entirety and is sent to the agency with the appropriate enforcement jurisdiction for further review. This could be CMS, the Department of Labor, the Department of the Treasury, or OPM, depending on the details of the complaint and which agency has jurisdiction over the plan or health insurance coverage. If the state has enforcement authority, the NSHD provides the appropriate contact information for that state so that the state may assist them with their specific situation.

CMS is actively investigating and addressing complaints under our jurisdiction. If a violation is found, CMS can take steps to encourage compliance with the requirement for payment and will ensure that future payments are made within the federally required time frame.

Questions #5 a-d

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:

a. 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?

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

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

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

Response:

CMS is committed to protecting and strengthening beneficiary access to high quality health care services, including by ensuring that people enrolled in Medicare Part D plans are able to access the medications they need. CMS continues to work closely with plan sponsors across the Medicare Advantage and Part D programs to ensure they are meeting all statutory and federal regulatory requirements.

CMS maintains, and will continue to maintain, a robust clinical formulary review process to ensure that all Medicare Part D plans meet applicable formulary requirements. Consistent with the requirements at 42 C.F.R. §§ 423.120(b)(2) and 423.272(b)(2)(i), CMS evaluates formularies based on the sufficiency of categories and classes, tier placement, and utilization management restrictions. This review process is consistent with section 1860D-11(e)(2)(D)(i) of the Social Security Act, which authorizes CMS to approve a prescription drug plan only if the Secretary "does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan." In addition, under § 423.272(b)(2)(i), "CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan." Furthermore, § 423.120(b)(2)(iii) requires each Part D plan formulary to "include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines." In addition, § 423.120(b)(1)(v) requires that in making decisions about formulary design, the entity designing the formulary must base "clinical decisions on the strength of scientific evidence and standards of practice."

§ 423.120(b)(2)(v) specifically requires that each Part D plan formulary include the categories and classes of clinical concern as specified in section 1860D-4(b)(3)(G)(iv) until such time as there are established—through notice and comment rulemaking—criteria to identify, as appropriate, categories and classes of clinical concern. As a result, under Medicare Part D, sponsor formularies currently must

include all or substantially all drugs in six categories or classes: 1) antidepressants; 2) antipsychotics; 3) anticonvulsants; 4) immunosuppressants for treatment of transplant rejection; 5) antiretrovirals; and 6) antineoplastics. "Substantially all" in this context means that all drugs and unique dosage forms in these categories are expected to be included in sponsor formularies, with certain limited exceptions. CMS instituted this "protected class" policy to mitigate the risks and complications associated with an interruption of therapy, and to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans.

For enrollees who are taking a drug in one of the protected classes at the time of enrollment, Part D sponsors may not implement prior authorization or step therapy requirements that are intended to steer beneficiaries to preferred alternatives. This prohibition applies to those beneficiaries already enrolled in the plan as well as new enrollees who were actively taking drugs in any of the six protected classes prior to enrollment into the plan. If a sponsor cannot determine at the point of sale whether an enrollee is currently taking a drug (e.g., new enrollee filling a prescription for the first time), the sponsor shall treat such enrollee as currently taking the drug.

Our current formulary review process includes evaluation of the placement of drugs in the Part D six protected classes, and CMS will continue to ensure that these drugs remain accessible to all enrollees who need them. We are aware that the changes in liability as a result of the redesigned Part D benefit may create incentives for plans to alter their formularies, and we will continue to monitor year-over-year formulary and utilization management changes to assess if these changes have the potential to reduce access to vital medications.

Questions #6

The Importance of Collaboration Between Civilian and Military Trauma Professionals:

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.

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

Response:
The President's Budget (PB) for FY 2025 proposes an elimination of the MISSION ZERO Program. As Congress is aware, the FY 2025 PB had to adhere to caps and limits in the overall top line request. MISSION ZERO is a complement to the National Disaster Medical System and overall partnership with the Department of Defense and integration of trauma care into the overall response to catastrophic incidents. HHS and ASPR will continue to support trauma care and commit to working with Congress on future efforts to enhance these capabilities.

Question #7
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?

Response:
MISSION ZERO is a complement to the National Disaster Medical System and overall partnership with the Department of Defense and integration of trauma care into the overall response to catastrophic incidents. HHS and ASPR will continue to support trauma care and commits to working with Congress on future efforts to enhance these capabilities.

Question #8
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.

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

Response:
Thank you for your support for boosting infectious disease (ID) workforce recruitment. The Department recognizes the importance of building the ID and bio-preparedness workforce to prepare our nation to respond to outbreaks, epidemics, and pandemics. As you know, Congress included this program in the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act), which was enacted at the end of 2022 as part of the Consolidated Appropriations Act, 2023. To date, the Bio-

Preparedness Workforce Pilot Program has not received appropriations.

The Honorable Robert Latta

Question #9

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?

Response:

As of April 2022, CMS has created 1 billable procedural code for "Prescription digital behavioral therapy, FDA-cleared, per course of treatment." CMS believes that establishing such a code may facilitate options for non-Medicare payers to provide access to this therapy in the home setting. CMS continues to be open to hearing from manufacturers and payers about their experience in implementing this code and is willing to work with Congress to increase access to care through an emerging field.

In the CY 2023 PFS final rule, CMS noted that we accepted the Relative Value Scale Update Committee's (RUC's) recommendation to contractor price CPT code 98978, a PE-only code that describes provision of a monitoring device for cognitive behavioral therapy (CBT) and that we would work with our Medicare Administrative Contractors (MACs) to better understand the kinds of devices and device costs they are encountering as they review claims for payment for the services described by this code. Additionally, in the CY 2024 Physician Fee Schedule final rule, we noted that the existing codes described by CPT codes 98978, 98980, and 98981 allow for the billing of remote therapeutic monitoring services, including monitoring patient adherence and therapy response for use with cognitive behavioral therapy. CMS continues to be interested in any feedback from interested parties on this topic, including feedback from interested parties about any potential codes that we would review under those processes and considerations we might need to take into account for future rulemaking to improve the accuracy of coding and payment under the Medicare PFS.

The Honorable Gus Bilirakis

Question #10

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?

Response:
CMS implements its programs consistent with the law, including requirements that federal funding be spent only on individuals who are lawfully present. Under federal law, people who are not lawfully present are not eligible for Medicaid or CHIP, except for emergency services in certain situations. To oversee how federal dollars are spent, CMS uses several tools to monitor states' efforts to accurately verify beneficiary eligibility, including audits of beneficiary eligibility determinations; Payment Error Rate Measurement (PERM) Corrective Action Plans; and the Medicaid Eligibility Quality Control Program.

Question #11
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?

Response:
HHS supports efforts to improve awareness of and access to voter resources for citizens when they engage with HHS and its agencies and divisions. In line with the Healthy People 2023 objective to increase the proportion of the voting-age citizens who vote, HHS's Office of Disease Prevention and Health Promotion has established voting as a public health priority, identifying it as a social determinant of health or a nonmedical factor that influences health and quality-of-life outcomes. Voting offers the chance for people to contribute to decisions that affect their communities and directly or indirectly impact their health and well-being.

Question #12
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?

Response:
On February 28, 2023, CMS issued an NPRM, *Medicare Disproportionate Share Hospital (DSH) Payments: Counting Certain Days Associated With Section 1115 Demonstrations in the Medicaid Fraction*, that proposed to explicitly exclude from the disproportionate patient percentage (DPP) Medicaid fraction numerator the days of patients with uncompensated care costs for which a hospital is paid from an uncompensated/undercompensated care funding pool authorized by a section 1115 demonstration project. In the fiscal year (FY) 2024 Inpatient Prospective Payment System (IPPS) final rule, CMS finalized these changes to the regulation governing the counting of days associated with individuals eligible for certain benefits provided by section 1115 demonstrations in the Medicaid fraction of a hospital's DPP (88 Fed. Reg. 58640).

CMS's overall policy for including section 1115 demonstration days in the DPP Medicaid fraction numerator rested on the presumption that the demonstration provided a package of health insurance benefits that were essentially the same as what a State provided to its Medicaid population. More recently, however, section 1115 demonstrations have been used to authorize funding a limited and narrowly circumscribed set of payments to hospitals. For example, some section 1115 demonstrations include funding for uncompensated/undercompensated care pools that help to offset hospitals' costs for treating uninsured and underinsured individuals. These pools do not extend health insurance to such individuals nor are they similar to the package of health insurance benefits provided to participants in a State's Medicaid program under the State plan. Rather, such funding pools "promote the objectives of Medicaid" as required under section 1115 of the Act, but they do so by providing funds directly to hospitals, rather than providing health insurance to patients. These pools help hospitals that treat the uninsured and underinsured stay financially viable so they can treat Medicaid patients.

By providing hospitals payment based on their uncompensated care costs, the pools directly benefit those providers, and, in turn, albeit less directly, the patients they serve. Unlike demonstrations that expand the group of people who receive health insurance beyond those groups eligible under the State plan and unlike Medicaid itself, however, uncompensated/undercompensated care pools do not provide inpatient health insurance to patients or, like insurance, make payments on behalf of specific, covered individuals. In these ways, payments from these pools serve essentially the same function as Medicaid DSH payments under sections 1902(a)(13)(A)(iv) and 1923 of the Act, which are also title XIX payments to hospitals meant to subsidize the cost of treating the uninsured, underinsured, and low-income patients and that promote the hospitals' financial viability and ability to continue treating Medicaid patients. Notably, as numerous Federal courts across the country have universally held, the patients whose care costs are indirectly offset by such *Medicaid DSH* payments are not "eligible for medical assistance" under the *Medicare DSH* statute and are not included in the DPP Medicaid fraction numerator.

We also note that demonstrations can simultaneously authorize different programs within a single demonstration, thereby creating a group of people the Secretary regards as Medicaid eligible because they receive health insurance through the demonstration, while also creating a separate category of payments that do not provide health insurance to individuals, such as uncompensated/undercompensated care pools for providers.

Nothing in the final policy diminishes or eliminates any benefit low-income patients receive from section 1115 demonstrations, including any "benefit" a patient might receive by having some part of their hospital bill paid for by an uncompensated care pool authorized by a demonstration or by receiving some portion of the cost of their premium paid for with premium assistance authorized by a demonstration; such patient will remain in the same position whether or not a hospital is permitted to include their patient day in the hospital's DPP Medicaid fraction numerator. The policies we finalized merely seek to clarify which days patients provided certain benefits under a Medicaid section 1115 demonstration may also be counted in calculating the Medicare DSH payment adjustment. And because the purpose of the DSH payment adjustment is not to provide as much money as possible to hospitals, but to reflect payment for a hospital's provision of a disproportionate share of care to low-income patients, we believe we have properly considered the effects of the proposal on such patients.

Question #13

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?

Response #12-13:
CMS strives to improve patient care and innovation while maintaining robust safeguards for the Medicare population. As part of our further efforts to streamline the national coverage process, on June 22, 2023, CMS announced a proposed procedural notice outlining a new Medicare coverage pathway, the Transitional Coverage for Emerging Technologies (TCET) pathway for Breakthrough Devices. This pathway is intended to offer more timely and predictable access to new medical technologies for people with Medicare (88 FR 41633).

As we noted in the proposed notice, we proposed limiting the TCET pathway to certain eligible FDA- designated Breakthrough Devices because we believe that this is the area with the most immediate need. (88 FR 41634). We also noted that the TCET process would build on Coverage with Evidence Development (CED) because CED has been used to support evidence development for certain innovative technologies that are likely to show benefit for the Medicare population when the available evidence is not sufficient to demonstrate that the technologies are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member under section 1862(a)(1)(A) of the Act. In instances where there is limited evidence, CED may be an option for Medicare beneficiaries seeking earlier access to promising technologies. (88 FR 41637). We note that the existing NCD pathway is also available for these devices; an NCD without coverage with evidence development is an option if there is sufficient evidence to support Medicare coverage under section 1862(a)(1)(A) of the Act.

While the TCET pathway would be limited to Breakthrough Devices, other potential expedited coverage mechanisms, such as Parallel Review, remain available. Eligibility for the Parallel Review program is broader than for the TCET pathway and could facilitate expedited CMS review of non-Breakthrough Devices. To achieve greater efficiency and to simplify the coverage process generally, CMS intends to work with FDA to consider updates to the Parallel Review program and other initiatives to align procedures, as appropriate.

Question #14a
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?

Response:

In recent years, the majority of the drugs in CDER's rare disease drug development programs are approved based on one adequate and well-controlled clinical investigation and confirmatory evidence.

FDA's medical product Centers collaborate through a variety of avenues to advance the development of rare disease therapies and disseminate our policy and experience with drug development through these avenues, including formal workgroups and training, guidance, policy document review, internal meetings, and informal communications. In addition, Center policy offices work to foster internal consistency in regulatory review by working closely with the review divisions to help ensure that laws, regulations, and policies are applied consistently, with due regard for the particular facts and circumstances underlying each decision.

FDA review staff have robust mechanisms available for policy, training, and consultation regarding guidance and flexibility for the development of rare disease therapies. In the rare disease space, for example, these approaches are the topic of our FDA Annual Reviewer Training Day and CDER Rare Disease Seminar Series and are a topic for discussion during Rare Disease Drug Development Council meetings. The Agency strives for alignment in the application of our regulations and policies across regulatory review programs, recognizing that differences in diseases, clinical endpoints, and the evidence submitted to support effectiveness may warrant an approach that is appropriately tailored to each application.

Question #14b
When does FDA intend to finalize this draft guidance?

Response:
FDA is reviewing comments submitted to the docket and is working on issuing the final guidance.

Question #15
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?

Response:
CDER's Accelerating Rare disease Cures (ARC) Program is a CDER-wide collaborative effort that brings together expertise from many CDER Offices and Programs. The Center's Rare Diseases Team works closely with FDA's rare disease stakeholders to fulfill its user fee commitments to facilitate, support, and accelerate the development of drug and biological products, in addition to leading the development of crosscutting rare disease guidance documents and ensuring that policies and practices are shared across the Center.

CDER's ARC Program has also launched the Learning and Education to Advance and Empower Rare Disease Drug Developers (LEADER 3D) project. The project aims to better understand the unique challenges in bringing rare disease products to market and produce educational materials on fundamental topics. To compliment the LEADER 3D effort, CDER's Patient-Focused Drug Development staff is working with the National Organization for Rare Disorders to develop an advanced drug development education series for patients and patient groups.

Another key development for CDER is setting up the Genetic Metabolic Diseases Advisory Committee (GeMDAC), which will allow the Office of New Drug's Division of Rare Diseases and Medical Genetics to seek expert advice from a committee of clinicians, industry experts, academics, patients, caregivers and other external stakeholders when evaluating the potential benefits and risks of a new therapy for genetic metabolic diseases.

Together, CBER and CDER established the Rare Disease Endpoint Advancement (RDEA) Pilot Program to support novel endpoint efficacy development for drugs that treat rare diseases. The RDEA Pilot Program is designed to:

- Advance rare disease drug development programs by providing a mechanism for sponsors to collaborate with FDA throughout the efficacy endpoint development process;
- Promote innovation and evolving science by sharing learnings on novel endpoint development through FDA presentations, guidance documents, public workshops, and a public-facing website; and
- Develop FDA staff capacity to enable and facilitate the development and use of novel endpoints to evaluate the efficacy of rare disease therapies.

In 2023 CBER and CDER announced the Support for clinical Trials Advancing Rare disease Therapeutics (START) Pilot Program, where participants will be able to obtain frequent advice and regular informal communication with FDA staff to address product-specific development issues, including, but not limited to, clinical study design, choice of control group and fine-tuning the choice of patient population. The program is open to sponsors of products currently in clinical trials under an active Investigational New Drug application (IND), regulated by CBER or CDER. CBER-regulated products must be a gene or cellular therapy intended to address an unmet medical need as a treatment for a rare disease or serious condition, which is likely to lead to significant disability or death within the first decade of life. CDER-regulated products must be intended to treat rare neurodegenerative conditions, including those of rare genetic metabolic type. The Agency will select pilot partners this summer. Once the pilot launches, we look forward to seeing whether this type of frequent and informal communication between sponsors and FDA staff can help to move development programs for rare diseases forward more efficiently.

Question #16

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?

Response:

FDA recognizes the challenges associated with rare disease drug development and applies regulatory flexibility to address particular challenges posed by each disease, while upholding our regulatory standards. Regulatory flexibilities include, for example, Accelerated Approval based on a surrogate endpoint that is reasonably likely to predict clinical benefit or intermediate clinical endpoint for serious conditions with an unmet medical need, reliance on one adequate and well-controlled trial, use of natural history study data as a source of external control data, novel trial designs, and novel statistical methodologies. FDA considers all relevant statutory authorities and any available flexibilities when making decisions appropriate to the particular rare disease and therapeutic product under consideration.

Further, FDA has developed several guidance documents that help inform both Agency staff and the public about the Agency's proposed or current thinking on medical product development in the rare disease space. For example, FDA's 2019 draft guidance, Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products, discusses CDER and CBER's longstanding flexibility when considering the types of data and evidence that can meet the substantial evidence of effectiveness standard in rare disease drug development and similar contexts. In 2023, FDA followed up with another draft guidance – Demonstrating Substantial Evidence of Effectiveness with One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence. This draft guidance specifically addresses meeting the substantial evidence standard with a single adequate and well-controlled clinical trial and confirmatory evidence. In addition, FDA's 2023 draft guidance, Considerations for Design and Conduct of Externally Controlled Trials for Drug and Biological Products, provides recommendations to sponsors and investigators considering the use of externally controlled clinical trials to provide evidence of the safety and effectiveness of a drug product. Finally, FDA's 2019 draft guidance, Rare Diseases: Natural History Studies for Drug Development, provides recommendations to help inform the design and implementation of natural history studies in planning controlled trials of investigational drugs to treat rare diseases.

Question #17

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?

Response:

FDA is committed to supporting innovation and continued progress in the development of therapies to treat rare ophthalmic diseases, including by issuing timely guidance and update to developers.[1] As noted above, CDER's Accelerating Rare disease Cures (ARC) Program is a CDER-wide collaborative effort that brings together expertise from many CDER Offices and Programs. The Center's Rare Diseases Team works closely with FDA's rare disease stakeholders to fulfill its user fee commitments to facilitate, support, and accelerate the development of drug and biological products, in addition to leading the development of crosscutting rare disease guidance documents and ensuring that policies and practices are shared across the Center.

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[1] https://www.fda.gov/media/172937/download

- Advance rare disease drug development programs by providing a mechanism for sponsors to collaborate with FDA throughout the efficacy endpoint development process;
- Promote innovation and evolving science by sharing learnings on novel endpoint development through FDA presentations, guidance documents, public workshops, and a public-facing website; and
- Develop FDA staff capacity to enable and facilitate the development and use of novel endpoints to evaluate the efficacy of rare disease therapies.

In 2023 CBER and CDER announced the Support for clinical Trials Advancing Rare disease Therapeutics (START) Pilot Program, where participants will be able to obtain frequent advice and regular informal communication with FDA staff to address product-specific development issues, including, but not limited to, clinical study design, choice of control group and fine-tuning the choice of patient population. The program is open to sponsors of products currently in clinical trials under an active Investigational New Drug application (IND), regulated by CBER or CDER. CBER regulated products must be a gene or cellular therapy intended to address an unmet medical need as a treatment for a rare disease or serious condition, which is likely to lead to significant disability or death within the first decade of life. CDER-regulated products must be intended to treat rare neurodegenerative conditions, including those of rare genetic metabolic type. The Agency will select pilot participants this summer. Once the pilot launches, we look forward to seeing whether this type of frequent and informal communication between sponsors and FDA staff can help to move development programs for rare diseases forward more efficiently.

Question #18

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?

Response:
On March 25, 2024, FDA proposed to ban electrical stimulation devices (ESDs) for self-injurious and aggressive behavior (SIB and AB), because these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated through new or updated device labeling. As you noted, this is the second time FDA has proposed to ban these devices for such uses. The ban would not affect ESDs intended for other uses, such as those used for smoking cessation.

The Agency only pursues such actions when a device, or a particular use of a device, presents substantial deception or an unreasonable and substantial risk of illness or injury. FDA has only banned four other devices since the authority was enacted in 1976.

To support the proposed ESD ban, FDA analyzed all available data and information relating to the risks and effects of ESDs for SIB and AB, including scientific and medical information that formed the basis of FDA's prior ban on ESDs for SIB or AB, as well as scientific information about ESDs for SIB or AB available since the prior 2020 ban. The scientific information that formed the basis of the 2020 ban included information presented to the Neurological Devices Panel of the Medical Devices Advisory Committee at a public meeting on April 24, 2014 (2014 Panel) (Docket Number FDA-2014-N-0238) regarding the risks and effects of the devices and state of

the art treatment for SIB and AB,[2] information considered for the 2020 ban (see "Proposal To Ban Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior" (April 25, 2016) at Section XI and "Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior" (April 6, 2020) at Section XI, Docket Number FDA-2016-N-1111), and other scientific information contained in comments thereto. While proponents have asserted the devices are safe and effective for the intended uses in question, FDA's review of the valid scientific evidence for the proposed rule indicates the devices present a substantial and unreasonable risk of illness or injury.

As stated in the preamble to the proposed rule, FDA determined that ESDs for self-injurious or aggressive behavior SIB or AB pose a number of risks based on scientific and medical literature, experts in the field of behavioral science, information from state agencies that regulate ESD use, and records from the only facility that has recently manufactured and is currently using ESDs for SIB or AB.

FDA found that the scientific and medical literature shows ESDs present a number of psychological harms including depression, PTSD, anxiety, fear, panic, substitution of other negative behaviors, worsening of underlying symptoms, and learned helplessness (becoming unable or unwilling to respond in any way to the ESD); and the devices present the physical risks of pain, skin burns, and tissue damage.

In addition to the scientific and medical literature, the other aforementioned sources further support the reports of risks in the literature and indicate that ESDs pose additional risks such as suicidality, chronic stress, acute stress disorder, neuropathy, withdrawal, nightmares, flashbacks of panic and rage, hypervigilance, insensitivity to fatigue or pain, changes in sleep patterns, loss of interest, difficulty concentrating, and injuries from falling.

The final rule is currently under consideration, and FDA is reviewing comments to the docket, including information submitted by proponents of ESDs for SIB or AB as proof of safety and effectiveness.

The proposed rule, if finalized, will ban the manufacture and distribution of ESDs intended for self-injurious or aggressive behavior, and the devices will no longer be considered legally marketed devices for such uses. We note that a device ban would not prevent study of the device under an investigational device exemption.

Question #19

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?

[2] see 2014 Panel meeting materials available at: *https://wayback.archive-it.org/7993/20170405192749/https:/www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/NeurologicalDevicesPanel/ucm394252.htm*

Response:
CMS is committed to strengthening and promoting access to high quality health care services for the people enrolled in our programs, within the confines of the law. We are happy to provide technical assistance on proposed legislation.

Medicare is a defined benefit program. For an item or service to be covered by the Medicare program, it must fall within one of the statutorily defined benefit categories outlined in the Social Security Act. The Medicare statute also includes specific statutory exclusions from coverage. Section 1862(a)(7) of the Social Security Act states that no payment may be made under part A or part B for any expenses incurred for items or services "where such expenses are for . . . hearing aids or examinations therefore. .."

Federal regulations define hearing aids as amplifying devices that compensate for impaired hearing. Hearing aids include air conduction devices that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound. They also include bone conduction devices that provide mechanical energy to the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.

Medicare policy covers certain devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.

Medicare Advantage plans may offer benefits that Original Medicare does not cover. These are known as supplemental benefits. Supplemental benefits may include hearing aids or other such items not covered by Original Medicare.

Question #20
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?

Response:
Thank you for recognizing the important work the Health Center Program plays in ensuring health care to the most vulnerable communities. In 2022, health centers served more than 30 million patients. The FY 2025 President's Budget requests $8.2 billion for the Health Center program, to include $6.3 billion in mandatory funding. The proposed mandatory investments continue progress on the President's plan to put the Health Center

Program on a pathway to doubling. Health centers provide cost-effective high-quality care. The health center model of care has been shown to reduce the use of costlier providers of care, such as emergency departments and hospitals. Investing in this program is essential to maintaining primary care services in underserved and rural communities.

Question #21a

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?

Response: HRSA-supported health centers are a key part of nation's health care system, serving 30.5 million patients in 2022 at nearly 15,000 service sites across the country. Health centers are a dependable source of high quality, affordable, and cost-effective primary care services in underserved communities. Ninety percent of Health Center patients in 2022 had incomes less than 200 percent of the federal poverty level and included 1 in 9 children and more than 9.6 million rural residents. Health centers patients have better outcomes at lower costs, and 97 percent of patients would recommend their health center to family or friends.

The Teaching Health Center Graduate Medical Education (THCGME) Program provides funding to support training residents in community-based settings to ultimately improve health outcomes and expand access to health care in underserved communities. It is one of the only federal programs to increase the number of physician trainees in the past 25 years. THCGME residents treated over 900,000 patients in those communities in Academic Year 2022-2023. That year, the THCGME Program provided funding for 969 resident full-time equivalent slots at 72 teaching health centers, which provided funding to support 1,096 individual full- and part-time medical and dental residents. Sixty percent of THCGME-supported residents worked in primary care settings after completing their residency, and 52 percent worked in medically underserved or rural communities.

Question #21b

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

Response:

The FY 2025 Budget Request for the Health Center Program is $8.2 billion, an increase of $2.4 billion above the FY 2023 Final level. The proposed mandatory investments continue progress on the President's plan to put the Health Center Program on a pathway to doubling. As a result of this expanded investment in FY 2025, approximately 3.9 million additional patients will be served by health centers, for a total of 37.4 million. Health centers will have resources to expand medical capacity at existing sites, including the expansion of behavioral health and oral health, as well as expanded maternal health services and enabling/patient support services such as transportation, translation,

outreach, and education to enable patients' initial and ongoing access to health center services, especially in rural areas.

The FY 2025 Budget Request for the THCGME Program is $320 million. Continued mandatory funding for the THCGME Program, as proposed in the FY 2025 Budget Request, will ensure that teaching health centers have the financial certainty required to plan for and recruit residents for upcoming academic years. It will also continue to advance the goal of improving health outcomes and expanding access to health care in underserved communities, including rural areas.

Question #22

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?

Response:

Health centers face challenges recruiting and retaining both clinical and non-clinical staff. Talented, high performing health center staff, dedicated to the organization, are often recruited to higher paying positions by providers with more resources. The President's FY 2025 Budget includes $100 million to support 500 health centers to recruit, retain, and "grow their own" workforce. This new program will create new career pathways and enable employees to advance their careers while continuing to support the health center in their existing roles. For example, administrative staff could be trained or supported in training to become medical assistants, medical assistants to become licensed practical nurses, and registered nurses to become advanced nurse practitioners.

The President's Budget further continues our investments in workforce pipeline programs that work directly with communities to provide training, financial assistance, and career opportunities for young people and mid-career individuals, including providers in primary care and allied health care fields. For example, the Health Careers Opportunity Program provides a pathway for students from disadvantaged backgrounds to enter health professions prepared to deliver high quality, culturally competent care to underserved communities. Grantees select rising high school juniors and seniors, adult non-traditional learners, allied health profession students, undergraduate students, and health professions students from disadvantaged backgrounds to participate in their training program. The program provides formal academic and research training; student enhancement and support services; scholarships and stipends; financial planning resources; and information on health careers and training throughout the academic year. Award recipients provide clinical and experiential training opportunities to health and allied health students through community-based training. The FY 2025 Budget Request proposes $16 million for this program, which is equal to the FY 2024 enacted level.

Additionally, the Area Health Education Centers Program develops and enhances education and training networks within communities, academic institutions, and community-based organizations to broaden the distribution of the health workforce and improve health care delivery to rural and underserved areas and populations. Among other activities, grantees support training activities for high school students (grades 9-12) to expose these young people

to various health careers. The FY 2025 Budget proposes $47 million for this program, which is equal to the FY 2024 enacted level.

Question #23

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?

Response:

HRSA's Health Center Program is a foundational element of the nation's health care safety net, providing primary care services regardless of patients' ability to pay. Through these investments, HRSA helps communities improve their health and well-being; prevent and manage chronic conditions like diabetes and hypertension; and care for families, children, and individuals with low incomes, experiencing homelessness, living with HIV, and who otherwise would not have access to a usual source of care. The President's Budget supports expanded service grants to all existing HRSA funded health centers, including $700 million to invest in all of the approximately 1,400 existing health centers across the country to expand access to comprehensive services.

Question #24

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?

Response:

Thank you for your support for boosting infectious disease (ID) workforce recruitment. The Department recognizes the importance of building the ID and bio-preparedness workforce to prepare our nation to respond to outbreaks, epidemics, and pandemics. As you know, Congress included this program in the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act), which was enacted at the end of 2022 as part of the Consolidated Appropriations Act, 2023. To date, the Bio-Preparedness Workforce Pilot Program has not received appropriations.

Question #25

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?

Response:

When verifying the medical necessity of home oxygen therapy, CMS requires medical record documentation from the ordering clinician as well as the supplier of the home oxygen. The authenticated order and the medical necessity documentation must come from the ordering clinician.

CMS previously had made available clinical templates and suggested clinical data elements for ordering home oxygen therapy that were designed to assist a clinician when completing an order for home oxygen therapy to meet requirements for Medicare coverage. However, in 2023, the National and Local Coverage Determinations for home oxygen therapy were modified. This required CMS to update the clinical template for home oxygen therapy.

As a result, CMS has been working with stakeholders to develop an electronic clinical template for home oxygen therapy to help ordering clinicians meet all the updated CMS coverage and payment requirements for home oxygen therapy when they are completing orders for home oxygen therapy. The home oxygen electronic clinical template would connect to the ordering clinician's electronic health record and allow CMS to authenticate the medical necessity documentation. The electronic clinical template being developed is based on the Fast Healthcare Interoperability Resources (FHIR) standard. As FHIR standards become more popular and their use expands, CMS is working on testing the home oxygen FHIR-based electronic clinical template with ordering clinicians. CMS is also considering making the electronic clinical template available for ordering clinicians to use in a paper format.

The Honorable Richard Hudson

Greensboro Influx Care Facility:

Question #26

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/

Response:
The Greensboro Children's Center (GCC) was operationalized on March 15, 2024. The facility is currently able to serve a bed capacity of 100 children and a maximum capacity of up to 800 beds, boys and girls ages 13–17. No children have been placed at the site. Since 2023, GCC has pursued operationalization efforts such as ensuring the site meets child safety standards, is properly staffed, that all staff are properly trained, and meets all ORR influx care facility (ICF) policies as outlined in Section 7 of the Unaccompanied Children (UC) Program Policy Guide. All staff have been trained accordingly. As required, ORR provided notification of at least 15 days to the House and Senate Committees on Appropriations, and to you as a courtesy, of the facility's operational status on March 1, 2024.

Question #27

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

Question #28

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?

Question #29

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

Question #30

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?

Response to Questions 27-30:

No children have been placed at GCC and current projections do not forecast an influx that would require imminent placements of children at that location. ORR will continue to comply with congressional notification requirements. ORR continuously monitors referral trends and capacity needs, and its contingency planning includes temporary capacity. In preparation for any potential influx, ORR seeks to maximize current efficiencies related to operations and bed capacity to ensure it is as well-positioned as possible to receive higher numbers of referrals. This includes the capacity to bring additional beds online as part of ORR's preparedness posture. While current projections do not forecast an increase in referrals of unaccompanied children to ORR, the savings from

demobilizing an ICF continue to be weighed against potential costs of not having influx capacity ready.

Question #31

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?

Response: ORR has three active contract agreements for direct care services, facility management, and armed guards, and one lease agreement with the American Hebrew Academy for GCC for which approximately $200 million had been obligated as of April 17, 2024. Additionally, in November 2023, ORR initiated a contract and obligated funds to provide armed guards around the facility.

Question #32

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?

Question #33

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

Response to Questions 32-33:

ORR is working with the Administration of Children and Families (ACF) Government Contracting Services to merge the Direct Care Services contract and the Facilities Management contract into one wraparound services contract. The award for this contract is currently projected for August 2024, which allows for a 90-day transition period. This is being competed with full and open competition.

Question #34

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?

Response:

ORR has a legal obligation, per congressional mandate under the Homeland Security Act of 2002 and the Trafficking Victims Protection Reauthorization Act of 2008, to care for all unaccompanied children referred to ORR by the U.S. Department of Homeland Security or other federal entities. While ORR's priority is to place children into standard care provider facilities, access to ICF capacity remains necessary to ensure that ORR can promptly accept referrals when standard network facilities reach capacity. Notably, ORR is not an immigration enforcement agency.

Question #35

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.

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

Response:
HHS was required to submit its FY 2025 budget request before congress finalized FY 2024 appropriations. The FY 2025 request was therefore set at the FY 2023 enacted level. As you may be aware, the recently released Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multiyear Budget for Fiscal Years 2023-2027 highlighted that the SNS does not receive adequate funding to purchase all the products necessary to fully prepare the country for whatever public health threat lies ahead. This report found that the SNS needs approximately $2.5 billion to fully fund its mission in FY 2025.

In addition, the threat-based review of the contents of the SNS, required by section 319F–2 of the Public Health Service Act (42 U.S.C. 247d-6b), determines product acquisition plans and stockpile targets. The threat-based review is an annual process that leverages PHEMCE expertise to prioritize MCM investment, development, procurement, and stockpiling efforts against a limited budget. The PHEMCE Multiyear Budget was provided to Congress in March 2024.

The threat-based review enables ASPR to identify gaps and prioritize MCMs for procurement or maintenance in upcoming budget cycles. Ultimately, the procurement and maintenance of the materiel in the SNS is dependent on congressional appropriations. An initial procurement begins the very expensive cycle of maintenance and sustainment. Products expire, degrade, require maintenance, and ultimately need to be repurchased. ASPR uses all methods available to us to extend the life of products, rotate products as part of vendor-managed inventory, and sell products to other parts of the U.S. government (USG) where opportunities exist. However, ensuring America's stockpile of critical CBRN vaccines, treatments, and personal protective equipment (PPE) are well-maintained is an expensive mission.

Question #36
What is HHS's strategy to replenish expiring doses of MCMs in the stockpile?

Response:
A key priority for ASPR is increasing the funding to the SNS. The recently released Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multiyear Budget for Fiscal Years 2023-2027 highlighted what we have known to be true for many years: the SNS does not receive adequate funding to purchase all of the products necessary to fully prepare the country for whatever public health threat lies ahead. This report found that the SNS needs approximately $2 billion to fully fund its mission in FY 2024.

Replenishment costs arise from products purchased previously by ASPR BARDA or SNS that expire and need to be restocked. A total of $5.3 billion is estimated to support the transition and replenishment of MCMs by ASPR SNS. The ASPR SNS does utilize, when and where possible, the Shelf-Life Extension program. The funding projection below takes such considerations, when available, into account. billion to fully fund its mission in FY 2025.

Additionally, Project Bio Shield (PBS) funding also is utilized to replenish expiring CBRN MCMs in the SNS. BARDA and SNS programs work closely to align available resources and adjust timelines for successful transitions of products to SNS sustainment.

Finally, to sustain good-dated product and avoid replenishment costs for as long as possible, ASPR, in collaboration with the FDA seeks to maximize the value of SNS funding through the Shelf-Life Extension Program (SLEP) and other methods. SLEP is a jointly managed program established in 1986 and operated by the Department of Defense and FDA to avoid the need to replace entire stockpiles of certain eligible pharmaceutical products every few years as they reach labeled expiration. While SLEP is the most well-known mechanism to extend the shelf-life of pharmaceuticals, there are other methods by which FDA can extend dating of products held by SNS and state, local, tribal, and territorial (SLTT) partners outside of SLEP. For instance, certain influenza antivirals held by SNS and SLTT jurisdictions have been extended by FDA outside of SLEP after FDA's review of scientific data made available by the manufacturer.

Question #37
Does the Administration intend to utilize both annual appropriations and existing unobligated supplemental funds to support the replenishment of expiring MCMs in the SNS?

Response:
Sustainment of stockpiled products remains the primary challenge to ensuring appropriate preparedness. Following the recission of supplemental balances under the Fiscal Responsibility Act of 2023 and the 2024 HHS appropriations language, ASPR is only able to allocate and use limited quantities of supplemental recoveries derived from closed or terminated contracts awarded in previous fiscal years. Current recoveries will support one additional purchase of influenza antivirals to diversify SNS holdings and increase pandemic preparedness. No additional purchases with supplemental funding are anticipated for SNS.

ASPR is committed to maintaining SNS's inventory of MCMs necessary to respond to chemical, biological, radiological, and nuclear (CBRN) threats. All funds provided to SNS as part of its FY 2024 annual appropriation will be used to support procurement of products for SNS's formulary as well as sustainment and operational costs necessary to support management, deployment, and utilization of such

products.

Question #38

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.

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?

Response:

The SNS currently holds two replicating smallpox vaccines – the ACAM2000 live virus vaccine for prevention of smallpox in most populations, and the WetVax vaccine; and one nonreplicating vaccine - JYNNEOS for prevention of smallpox and mpox in high-risk populations that cannot be vaccinated with ACAM2000. The SNS has supplies of the ACAM2000 vaccine for the general population, while the USG maintains a smaller amount of the JYNNEOS vaccine for use in populations with contraindications.

ASPR previously established an ordering system and shipped over 1 million vials of JYNNEOS to its federal and jurisdictional partners. ASPR also reallocated funding from other programs to support activities to procure additional doses of the JYNNEOS vaccine and accelerate the tech transfer of filling activities to ensure rapid access to additional filled doses during the response and beyond. The current USG owned supply of JYNNEOS is a mix between frozen bulk drug substance and filled vials, allowing for the flexibility to fill as a liquid or lyophilized (future) vaccine. The USG maintains over 5.5M filled vials of the JYNNEOS vaccine ready for deployment if needed during an emergency response. BARDA is also supporting the late-stage development of a lyophilized formulation of JYNNEOS that will offer longer shelf-life at lower temps. This formulation will be available over the next two years.

The near-term goals/focus of the ASPR program over the next few years includes:

- Procurement of JYNNEOS-using PBS funds to continue to grow the size of the available stockpile. Continue to store doses at ultra-cold temps to extend the shelf-life. Test product as it nears expiry.
- Support the licensure of the lyophilized formulation of JYNNEOS® and transition to that product once licensed using PBS funds. Late-stage manufacturing activities for the lyophilized formulation are ongoing and stability data to date indicates formulation will be stable at -20°C easing the burden/cost of -80°C storage.
- Maintain the ACAM2000 stockpile and continue stability monitoring and extension program to ensure adequate supply to address any smallpox emergency. This is expected to be part of

SNS funding.

Additionally, SNS continues to invest in procurement of ACAM2000 and testing costs to determine the potency of the WetVax vaccine for general population use that allow SNS to meet requirements to vaccinate the entire population of the US.

Question #39

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.

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

Response:

The vast majority of influenza antivirals in the SNS were procured with previous supplemental funding. While SNS has made small incremental procurements to diversify its holdings to include baloxavir using annual appropriations, the funding to replenish the entire stockpile of antivirals is not adequate. A key priority for ASPR is increasing the funding to the SNS. Released in March 2024, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multiyear Budget for Fiscal Years 2023-2027 highlighted what we have known to be true for many years: the SNS does not receive adequate funding to purchase all of the products necessary to fully prepare the country for whatever public health threat lies ahead. You should be aware that this report found that the SNS needs approximately $2.5 billion to fully fund its mission in FY 2025.

Question #40

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?

Response:

The SNS inventory includes both brand and generic flu antivirals.

Question #41

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

Response:

The SNS is currently executing a contract for Tamiflu replenishment.

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.

Question #42
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?

Question #43
If so, will you commit to working with us to establish a more stable environment for our laboratories?

Response #42-43:
The Department shares your desire to protect Medicare beneficiaries' access to laboratory testing services and provide stakeholders with transparency and predictability around payment for laboratory tests. Congress enacted PAMA with a phase-in for reductions such that for CY 2017 through CY 2019, the reduction cannot be more than 10 percent per year, and for CY 2020 through CY 2022, the reduction cannot be more than 15 percent per year. Congress subsequently modified PAMA in legislation. Most recently, the Further Continuing Appropriations and Other Extensions Act, 2024 (Public Law 118-22) maintained the payment amounts for clinical diagnostic laboratory tests for CY 2024 at the payment amount for CY 2020, limited reductions to 15 percent per year for CY 2025 through CY 2027, and amended the data reporting requirements to delay the next data reporting period for most clinical diagnostic laboratory tests by 1 year to January 1, 2025, through March 31, 2025.

The Honorable Earl "Buddy" Carter

Question #44a
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?

Response:

Section 1860D-11(i) of the Social Security Act generally prohibits CMS from interfering in negotiations between drug manufacturers, pharmacies, and prescription drug plan sponsors or from instituting a price structure for the reimbursement of covered Part D drugs. Consequently, CMS cannot prohibit PBMs from charging any retroactive DIR fees.

Nonetheless, we continue to encourage Part D plan sponsors to work with pharmacies to address cash flow concerns. On November 6, 2023, we published a memorandum to all Part D plan sponsors via CMS' Health Plan Management System (HPMS) titled "Application of Pharmacy Price Concessions to the Negotiated Price at the Point of Sale Beginning January 1, 2024," which reiterates and emphasizes several key points related to this issue that CMS also stated in the Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs final rule (87 FR 27704). Within this memo, we strongly encouraged Part D plan sponsors to consider options such as payment plans or alternate payment arrangements in advance of the January 1, 2024, effective date. CMS additionally emphasized that Part D plan sponsors must meet the prompt payment requirements at § 423.520 and pharmacy access standards at § 423.120.

More recently, we reiterated these points in our December 14, 2023, "CMS Letter to Plan Sponsors and Pharmacy Benefit Managers", which identified several concerns about practices by some plans and PBMs that threaten the sustainability of pharmacies and impede access to care. We encouraged plans and PBMs to work with pharmacies to alleviate these issues and safeguard access to care. To view this letter, please visit here: https://www.cms.gov/newsroom/fact-sheets/cms-letter-plans-and-pharmacy-benefit-managers.

CMS will use existing monitoring and enforcement operations to ensure that Part D plan sponsors comply with the pharmacy access requirements prescribed in § 423.120 and prompt payment requirements in § 423.520. CMS conducts quarterly analyses of all Part D plan sponsors' networks for the contract year to identify Part D plan sponsors that are not meeting the pharmacy access standards as required by § 423.120(a)(1). Part D plan sponsors that do not meet the standards will receive compliance actions, and the level of the compliance action escalates when there is repeated noncompliance in consecutive quarters. CMS monitors the status of Part D sponsors' complaints from beneficiaries and providers, such as pharmacies. Prompt payment or pharmacy access violations that come to CMS' attention can result in a compliance action.

We are committed to ensuring beneficiaries have access to necessary health services. We value the critical role pharmacies play in healthcare delivery and recognize that we must address the needs of

pharmacies to serve our beneficiaries effectively. We will continue to engage with stakeholders and consider policies for inclusion in future rule-making that would lower prescription drug costs for beneficiaries, address challenges that pharmacies face, and improve the quality of pharmacy care.

Question #44b

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?

Response:

BARDA appreciates congress' support of its role in the federal government's response to biological threats and antimicrobial resistant (AMR) pathogens that can complicate a public health emergency. Through its Antimicrobials Program and the Detection, Diagnostics, and Devices Infrastructure Division, BARDA has invested over $2.3 billion in public-private partnerships with industry since 2010, ranging from small biotechnology firms to global pharmaceutical companies. Through these partnerships, BARDA has supported over 160 AMR therapeutics, preventatives, and diagnostics. Within the Advanced Research and Development (ARD) portfolio, there are eight diagnostics and 13 therapeutics in development. In FY 2024 alone, BARDA has seen two drugs in its portfolio receive marketing authorization: Ceftobiprole and Aztreonam-Avibactam; this is in addition to the previous three drugs that were approved. These approvals bring new lifesaving drugs to physicians and patients in need. BARDA is also supporting the advanced clinical development and procurement of two antibiotics that address both AMR and biothreat infections. Under its FY 2025 budget proposal, BARDA will continue to support a pipeline of preclinical and early clinical stage antibacterial drugs, vaccines, and diagnostics through the CARB-X partnerships to ensure that the early-stage pipeline remains robust. Funding will also support the existing ~~A~~RD portfolio and seek to expand our development and procurement efforts under PBS. New funding awards in FY25 will target the addition of two new antimicrobials to the ARD portfolio and at least one new Project BioShield (PBS) award. All funded efforts are focused on the development of next generation therapeutic candidates that address the growing incidence of AMR, secondary infections, and the potential threat of a bioterrorism event.

Question #45

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?

Response:
HRSA anticipates approximately $3.8 million will be available to fund up to 8 new cooperative agreements in FY 2024 for the Technology-enabled Collaborative Learning Program. This program supports innovative technology-enabled collaborative learning and capacity building models (e.g., Project ECHO, tele-mentoring models, etc.) that connect health care professionals, particularly specialists, with other health care professionals to serve the target populations. The purpose of this program is to improve retention of health care providers and increase access to health care services, such as those to address chronic diseases and conditions—including Alzheimer's disease—and other specialty care in rural areas, frontier areas, health professional shortage areas, or medically underserved areas and for medically underserved populations or Native Americans.

Question #46
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?

Response:
Medicare covers certain diagnostic tests, provided by an audiologist, for non-acute hearing conditions and diagnostic services related to implanted auditory prosthetic device. Prior to the CY 2023 Physician Fee Schedule Final Rule, Medicare required audiologists to have an order from a physician or non-physician practitioner treating the patient. Under the new policy, audiologists are eligible for Medicare payments for these services, without requiring a prior order from a physician or non-physician practitioner.

CMS is committed to ensuring providers have the tools and resources they need to comply with Medicare billing requirements, such as fact sheets, webinars, and instructional videos. CMS has released guidance detailing the Medicare billing and coding requirements for audiologists to receive payment for providing certain diagnostic tests without a physician order. This guidance is available at https://www.cms.gov/files/document/mm13055-audiologists-may-provide-certain-diagnostic-tests-without-physician-order.pdf. For more detailed questions, we encourage providers to contact their Medicare Administrative Contractor (MAC), the entity that processes Medicare claims.

Question #47
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?

Question #48
How does HHS address regulation and oversight of Medicaid-funded youth residential treatment facilities to ensure federal dollars are being spent appropriately?

Response #47-48:
States also have the option to offer the Medicaid Psychiatric Services for Individuals Under Age 21 benefit. In addition to hospitals, these services can be rendered in psychiatric residential treatment facilities (PRTFs). PRTFs must meet certain Medicare Conditions of Participation, which include requirements on use of restraints and seclusion. In addition, PRTFs must be surveyed by a State Survey Agency or accredited by a national organization that has been approved by CMS with comparable standards that are recognized by the State. PRTFs are surveyed a minimum of every five years.

Children in foster care should receive the medical care that they need and to which they are entitled, without disruption, in a safe and nurturing setting that fosters their growth and development. CMS has worked within the confines of the law to provide states with flexibility to increase access to services for certain individuals residing in institutions for mental disease (IMDs), including foster youth in qualified residential treatment programs (QRTPs) that are IMDs. CMS has approved Medicaid section 1115 demonstrations that allow state Medicaid programs to pay for services provided to certain individuals in QRTPs that are IMDs. Similarly, managed care plans are permitted to pay for up to 15 days per month of treatment in QRTPs that are IMDs as an in-lieu of service—that is, a service that is not included under the state plan, but is a clinically appropriate, cost-effective substitution for a similar, covered service. States are expected to report data regarding any participating QRTPs as part of the monitoring and evaluation information states are expected to submit to CMS for these demonstrations.

Question #49a
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.

Response:
The President's Budget provides $75 million, with two-year availability, to expand and accelerate development and domestic production of medical countermeasures, including to onshore production of MCMs, essential medicines, and active pharmaceutical ingredients, consistent with Made in America and National Biodefense Strategy (NBS) goals. The Budget includes $20 million, also with two-year availability, to expand end-to-end visibility and management of the medical supply chains for priority drugs and devices. ASPR's targeted steps to enable commercialization of agile and distributed manufacturing technology and increasing domestic manufacturing infrastructure are important components of HHS' recent white paper that laid out proposals to address drug shortages.

Using COVID-19 supplemental appropriations, ASPR invested over $17 billion to expand the country's domestic manufacturing infrastructure, especially for PPE. Because of these investments, there is now domestic capacity to produce over 3.9 billion gloves, 690 million N95 respirators, and 531 million surgical masks per year. It took

decades for these industries to leave our shores, and it will take time and continued investment to bring them back. The United States relies on foreign sources of supply for much of the APIs and key starting materials (KSMs) needed to produce essential medicines. For example, 87% of generic API facilities are located overseas. The U.S. is also reliant on other key starting materials sourced from India and China. The U.S. also contributed only 4% of new API drug master files filed in 2021. Annual funding is required: (1) to preserve capacity investments made thus far by ensuring appropriate management and oversight of the existing contracts; (2) to evaluate and assess where the future investments should be made; (3) to make those future investments still needed to fill the gaps; and (4) to ensure the overall portfolio of investments is balanced, productive, and sustained. ASPR is appreciative of the $10 million included in the FY 2024 appropriations bill to continue this mission.

Question #49b
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.

Response:
Purchasing critical medical countermeasures and PPE from domestic sources reduces the risk of relying on international partners. Near-shoring could reduce risks from geographic concentration of manufacturing in a few foreign countries. However, ASPR has certain statutory requirements for domestic manufacturing, not near-shored domestic manufacturing.

Question #49c

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?

Response:
The Budget includes $20 million, also with two-year availability, to expand end-to-end visibility and management of the medical supply chains for priority drugs and devices.

Question #49d

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?

Response:
ASPR continues to engage with industry groups, trade associations, distributors, manufacturers, and academia to establish plans and policies that will continue growth of the domestic Public Health and Medical Industrial Base.

Question #49e

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.

Response:

Without the ability to monitor, measure, and analyze these trends, the USG cannot hope to develop an effective strategy to promote and build a resilient public health industrial base supply chain.

Visibility into upstream supply chain risks, such as geographic concentration of production, lack of redundancy, or lack of adequate inventory buffers, can help USG to target the most appropriate corrective actions to the most vulnerable products and areas of concern. With the appropriate visibility and management, the USG can assess and implement strategies to encourage market activity that will shorten supply chains, identify risks and vulnerabilities more quickly and communicate those risks, give manufacturers a greater degree of control, create new job opportunities, improve quality control, all while protecting manufacturer's trade secrets and intellectual property. This work will also enhance USG's ability to assess the risks of nearshoring/onshoring, such as increased costs in labor, raw materials, capital expenditures required to automate various production processes, and regulatory risks, to name just a few.

Question #49f
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?

Response:
ASPR has supported multiple efforts to define and prioritize essential and critical medicines with supply chain vulnerabilities, including assessments that have included vulnerability ratings, clinician input, market and trade analysis and interviews with companies that have a significant US market share for those drugs. Additionally, ASPR has invested in on-shoring production of drug substances and drug products, including an investment in domestic API production via a contract totaling $491M to date with PHLOW in Virginia. Originally awarded in 2021, PHLOW is on track to manufacture four of the top APIs identified on the FDA essential medicines list by September 2024. ASPR's FY25 budget request includes $95 million to expand and accelerate development and domestic production of medical countermeasures and improve visibility and management of medical supply chains to mitigate potential shortages of priority drugs and devices. In addition, ASPR has partnered with DARPA to award $50M for the commercialization of agile manufacturing solutions for drug substances and drug products. ASPR has also partnered with ONR to award $19M for cGMP sustainment of continuous manufacturing capacities for sterile injectables that went into shortage during the pandemic and $30M for distributed manufacturing of sterile saline on-demand. Furthermore, ASPR recently awarded $35M under the BioMaP Consortium for manufacturing of Key Starting Materials (KSMs) and active pharmaceutical ingredients (APIs) to support domestic production of sterile injectable medicines. More information is available via https://www.biomap-consortium.org/drug-substances-at-commercial-scale.

The Honorable Dan Crenshaw

Question #50
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?

Response:

Congress established the Provider Relief Fund (PRF) with an appropriation from the 2020 Coronavirus Aid, Relief, and Economic Security Act. This, along with subsequent acts of Congress through FY 2022, appropriated a total of $178 billion to the PRF. The authorizing statute for the PRF requires HRSA to submit to the Appropriations Committees a report of the dollars obligated through the PRF every 60 days. This report provides the total amount obligated through the PRF, including the PRF funds that were obligated to the COVID-19 Uninsured Program.

During the pandemic, Congress appropriated $2 billion of funding to support the Uninsured Program for COVID-19 testing claims reimbursement, through the Families First Coronavirus Response Act and Paycheck Protection Program and Health Care Enhancement Act. Due to the need for additional resources, beginning in 2020, HHS allocated resources from the Provider Relief Fund and the American Rescue Plan Act to the Uninsured Program for COVID-19 testing, treatment, and vaccine administration, these funds totaled $22.8 billion.

In early 2022, the cost of the Uninsured Program was unsustainable without additional funding. On March 15, 2022, the White House announced that the COVID-19 Uninsured Program would stop accepting claims for testing and treatment on March 22, 2022, and vaccine administration on April 5, 2022, due to lack of sufficient funding. HHS and HRSA followed up on this public announcement with additional notices to providers alerting them of the deadlines to submit claims.

All eligible claims that were submitted by the deadlines have been processed except those from providers flagged for program integrity reasons, including those related to law enforcement inquiries and in response to unusual billing activity. In total, the COVID-19 Uninsured Program reimbursed more than 276 million claims totaling $24.4 billion for COVID-19 testing, treatment, and vaccine administration.

In June 2023, the Fiscal Responsibility Act rescinded most of the remaining unobligated balances for the PRF. At this time, HRSA had obligated nearly $172 billion, therefore, $6 billion in program funds were rescinded. As a result, HRSA announced that no further payments would be made to providers under the PRF or the COVID-19 Uninsured Program. These recissions included $400 million in PRF funding that was allocated for the Uninsured Program.

Throughout the lifetime of the PRF and Uninsured Program, providers have returned money for various reasons. Initially, automatic PRF payments that providers did not wish to keep were returned and used by HHS to make additional payments. Later, as the PRF statutorily required reporting began, providers returned amounts that were not used in line with the program Terms and Conditions. HRSA developed a rigorous oversight and program integrity framework to safeguard taxpayer dollars. This framework consists of the statutorily required reporting in addition to internal and single/commercial audits, including after HRSA identified a provider as noncompliant and requested repayment.

In December 2022, HRSA began sending Final Repayment Notices to providers that failed to comply with the PRF Terms and Conditions. This notice offered providers a final opportunity to appeal HRSA's requested repayment. For those providers who remain out of compliance, HRSA works with the Department of Treasury on debt collection activities.

Question #51

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?

Response:
CMS has set a goal of having 100% of Traditional Medicare beneficiaries and the vast majority of Medicaid beneficiaries in accountable care relationships by 2030. A key way CMS supports the sustainability of value-based payment models is through multi-payer alignment, starting with Medicaid, and scaling successful models and features. The CMS Innovation Center's vision for broad health system transformation is ambitious and requires collaboration with, and actions by, a wide range of stakeholders. In particular, alignment with private payers, purchasers, and states is needed to increase the number of providers participating in value-based payment models and to make their participation sustainable across payers. The CMS Innovation Center continues to work towards multi-payer alignment on key dimensions of value-based payment by developing models that engage more than one payer, aligning quality metrics across CMS programs and payers, and supporting data exchange to improve care.

In addition, every CMS Innovation Center model test – including those that have not met the statutory criteria for expansion – have resulted in important learnings and investments in the health care system that have helped clinicians move towards value-based care. Care delivery trends and changes associated with the model tests extend beyond the CMS Innovation Center model tests themselves, with elements of model tests being incorporated into how clinicians furnish services even after the model test ends, because the clinicians have found the elements lead to improved quality and reduced costs. Several model tests have informed successor generations of model tests, which are designed to incorporate the lessons learned from initial model tests with the goal of producing further improvements in care delivery and reductions in spending. Participants in models that are concluding are often able to join another model, such as a successor model, to continue value-based care.

Question #52
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.

Response:
Information received in response to the Request For Information (RFI) was for HHS planning purposes only and not formal rulemaking. It is standard for the Department to not release comments from RFIs. The drafting of the Framework was led by the Office of the Assistant Secretary for Health (OASH) with valued

input from subject matter experts across HHS Operating Divisions, including but not limited to, FDA. FDA contributors and members of the Expert Advisory Group on Smoking Cessation included staff from the Center for Tobacco Products as well as members of the Commissioned Corps of the U.S. Public Health Service who, , as part of the Commissioned Corps duties were appointed by the Surgeon General to the Smoking and Tobacco Use Advisory Committee. All members were consulted or appointed to their roles due to their scientific or policy expertise and do not represent the FDA in this capacity.

Question #53

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?

Response:
CMS is committed to protecting consumers in the Marketplaces. CMS is taking swift actions to protect consumers from unauthorized activity by agents and brokers, and to root out non-compliant agents and brokers on the Marketplaces that use the HealthCare.gov platform who are violating CMS rules. CMS continues to improve its processes to resolve unauthorized plan switches and unauthorized enrollments performed by agents and brokers in the Marketplaces that use the HealthCare.gov platform.

First and foremost, CMS continues to ensure that affected consumers receive assistance to minimize the impact from these unauthorized activities. Unauthorized plan switch complaints are resolved through a combination of the following:

- CMS reviews the complaint to verify that the consumer's plan switch was unauthorized and identifies the plan that the consumer wants to be enrolled in.
- CMS instructs the issuer offering the plan the consumer wants to be enrolled in to reinstate the consumer's enrollment in that plan as if it had not been terminated. The issuer is instructed to cover all eligible claims incurred and accumulate all cost sharing toward applicable deductibles and annual limits on cost sharing.
- Consumers and the Internal Revenue Service (IRS) receive updated tax forms and information to prevent adverse tax implications as a result of the unauthorized plan switch activity.

CMS resolves unauthorized enrollment complaints by cancelling the unauthorized enrollment, ensuring any claims-related costs incurred because of the unauthorized enrollment are reimbursed, and sending the consumer and IRS updated tax forms and information to prevent adverse tax implications as a result of the unauthorized enrollment. CMS has accelerated review and resolution of all new complaints related to unauthorized plan switches and enrollments.

In addition to providing timely consumer assistance, CMS is focused on stopping non-compliant agents and brokers in the Marketplaces that use the HealthCare.gov platform. The agency is accelerating monitoring and oversight activities with respect to agents and brokers in the Marketplaces that use the HealthCare.gov platform and continues to work with our state and issuer partners. Specifically, CMS is ramping up its review where there is a reasonable suspicion of fraudulent or abusive conduct and issuing suspensions and terminations of these agents' and brokers' Marketplace agreements when appropriate, barring them from being able to enroll consumers in HealthCare.gov coverage and insurance affordability programs. CMS will also add new technological protections to prevent such unauthorized activities from occurring.

Question #54
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?

ii. 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?

Response:

Shortly after H5N1 was first detected in dairy cattle herds, the U.S. Department of Health and Human Services (HHS), U.S. Department of Agriculture (USDA), and the White House established the Unified Coordination Group (UCG) to align efforts across the USG with the Administration for Preparedness and Response (ASPR) leading the group. The interagency group has acted with urgency – working around the clock to stand up a response structure across HHS, the USDA, and the White House. The UCG facilitates the coordination, with ASPR in the lead on human health and USDA in the lead on animal health. The UCG is bringing together senior leaders from key agencies involved in monitoring this evolving situation, including HHS partners such as the CDC, FDA and OGA; and USDA officials, and partners from the National Security Council, to identify critical issues, work through next steps, and coordinate various elements of the response. Representatives use this forum to identify and subsequently recommend to the White House unified courses of action to strengthen the ongoing response.

ASPR has engaged the Department's Disaster Leadership Group (DLG) to provide HHS senior leaders with a forum to deliberate and make recommendations to the HHS secretary and address emergent health security policy issues, including domestic H5N1 influenza. The DLG provides an opportunity to foster continued monitoring and engagement and address policy issues that emerge in the response and recovery mission over time. ASPR, FDA, CDC, and the National Institutes of Health (NIH) each have important roles to play in the response, along with USDA. FDA and NIH are working together on the efficacy of pasteurization and milk safety studies. CDC is working on public health surveillance of H5N1 in humans and foodborne illnesses and has worked to expand those systems during this response, including wastewater surveillance.

Wastewater monitoring for influenza A virus (H5) and close coordination with local public health officials to better understand the likely sources of influenza A(H5) virus in wastewater can help refine methods for use in the upcoming influenza season. For example, detection of H5 in wastewater could trigger additional monitoring or testing of animals, milk, or humans. Wastewater monitoring is a relatively new public health tool that can complement our existing health-monitoring systems to help us better track infectious diseases and guide public health actions, such as alerting clinicians about viruses circulating in the community, positioning and increasing uptake of vaccines, and alerting the public of periods of increased risk and consideration for taking personal protective measures. It provides valuable data on virus levels at the community level, even when individuals may not have symptoms or seek clinical testing, and therefore is not limited to detecting the more severe cases that require medical attention. Though wastewater data is valuable for earlier detection, such data, however, cannot determine the source of avian influenza A(H5) viruses. Detections could come from a human or from an animal (like a bird) or an animal product (like

milk from an infected cow). Detections of avian influenza A(H5) virus in wastewater do not necessarily indicate human cases.

And ASPR, in addition to coordinating the Department's response, has provided PPE to impacted states, offered antivirals to states for treatment of symptomatic patients, and is working to ensure that well-matched vaccines are available if needed.

As the outbreak continues, this initial response structure has allowed ASPR to focus on coordinated communication and decision-making across the federal government. The focus throughout our response has been protecting the health of the American people and protecting the safety of our food supply.

i. What preparedness steps are they taking?

Additionally, HHS has two candidate vaccines that are well-matched to the circulating strain of H5N1 through ASPR's U.S. National Pre-Pandemic Influenza Vaccine Stockpile (NPIVS) program. Hundreds of thousands of vaccines doses could be deployed quickly, potentially in a matter of weeks if needed, subject to appropriate FDA review and action. Currently, ASPR/BARDA's NPIVS program would be best positioned to support a rapid response. The NPIVS was designed to support the development and manufacturing of vaccines for influenza virus strains as they evolve. NPIVS works closely with industry partners to make and test updated vaccines that match new strains of influenza viruses with pandemic potential as they emerge, while at the same time supporting manufacturing capacity to allow for large-scale vaccine production if needed. Vaccine candidates being developed and tested under this preparedness program, in close coordination with manufacturers, are expected to match the current strain.

As part of this program, BARDA has been forward leaning since 2022 following the human H5N1 case identified in Colorado. BARDA has supported vaccine seed lot production at each of the domestic manufacturers of licensed influenza vaccines, production of various bulk lots of material, and at this time, could support the filling/labeling/packing all available well-matched influenza vaccine antigen bulk/final container product in the event it is needed. Furthermore, BARDA initiated clinical trials, two of which are already in a safety follow-up phase and third scheduled to begin in Summer 2024, to ensure clinical safety and immunogenicity data exists for the well-matched vaccine for regulatory decision making if needed. Finally, mRNA platform technology could potentially further improve the Nation's pandemic influenza response capability. Currently, there is no licensed mRNA influenza vaccine for either seasonal or pandemic influenza. Since 2020, BARDA has funded development of several RNA-based influenza vaccine candidates, and in late 2023, BARDA released a solicitation "Accelerating Near-Term Availability of mRNA-based Pandemic Influenza Vaccine," which seeks to partner with companies to fill the mRNA vaccine gap for influenza virus.

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?

Response to 54 d and e:

If necessary, ASPR has several preparedness programs that HHS could leverage for H5N1. As always, states can

request personal protective equipment (PPE) from the Strategic National Stockpile (SNS) if needed, supplementing what is already commercially available or available in state-managed stockpiles. This PPE is available to protect farm workers and others who may come in contact with infected animals and includes face shields, N95 respirators, elastomeric half-mask respirators, goggles, and gowns.

In addition, ASPR has tens of millions of courses of antivirals in the SNS, many of which are also available on the consumer market. The antivirals are available to states who need to treat symptomatic patients. We are not seeing resistance to these antivirals in the current H5N1 strain.

Question #55

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?

Response:

HHS is dedicated to supporting the health and well-being of its employees and firmly believes that a strong, supported workforce is central to our public health mission.

To keep pace with the increasing complexity of rapidly evolving technology, and to help FDA staff conduct thorough reviews, FDA continues to advance new policies to strengthen the 510(k) Program to meet both patient needs and changes to the device marketplace. The 510(k) Third Party Review Program, for instance, provides medical device manufacturers with a voluntary alternative review process, in which accredited Third Party Review Organizations (3P510k Review Organizations) are allowed to review certain low-to-moderate risk medical devices. The program is intended to help yield more rapid 510(k) decisions and to allow FDA to focus its resources on higher risk devices, while still maintaining oversight of the review of lower risk devices eligible for third party review.

Under the Third Party Review Program, a 510(k) submission for an eligible device may first be submitted to an accredited 3P510k Review Organization rather than directly to FDA. Use of this program is voluntary. Approximately half of 510(k)s FDA receives are eligible for this program. The sole payment under the program is between the 510(k) submitter and the 3P510k Review Organization; there is no separate payment (i.e., user fee) to the FDA.

3P510k Review Organizations use the same criteria used by te FDA to review 510(k) submissions. A 3P510k Review Organization's review may include early interaction with FDA to ensure the 3P510k Review Organization is using up-to-date standards and guidance relevant to that type of device. It may also include requests for additional information from the 510(k) submitter. After the 3P510k Review Organization is satisfied with its review and has documented all the necessary information for the submission, it sends the submission to the FDA including the original 510(k) submission, the 3P510k Review Organization's review, and a recommendation of either substantially equivalent (SE) or not substantially equivalent (NSE).

FDA makes the final determination on the 510(k) submission based on the review and recommendation received from the 3P510k Review Organization. If the 3P510k Review Organization did not appropriately apply the 510(k) decision criteria or if there are substantive review quality issues with their documentation, the FDA may need to re-review all or part of the 510(k) submission. However, the FDA is updating this program to avoid the routine re-review of 510(k) submissions already reviewed by a 3P510k Review Organization.

On December 20, 2023, FDA issued the draft guidance *510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review*.[3] The draft guidance provides updates to the 510(k) Third Party Review program and includes how the FDA may use third parties to review EUA requests to enable the FDA to rapidly expand its resources during a future emergency.

The objectives of this guidance are:

- To describe and distinguish FDA's expectations for the 3P510k Review Program and for 142 3PEUA review;
- To describe the factors FDA will use in determining device type eligibility for review by 144 3P510k ROs;
- To outline FDA's process for the recognition, rerecognition, suspension, and withdrawal 146 of recognition for 3P510k ROs;
- To clarify FDA's expectations for review under both 3P510k review and 3PEUA review 148 for all stakeholders to ensure confidence and consistent quality of work by Third Party Review Organizations6 to eliminate the need for routine, substantive re-review by FDA;
- To outline FDA's expectations to prevent conflicts of interest between the Third Party Review Organization(s) and other entities; and
- To describe FDA's expectations regarding the compensation process between the Third Party Review Organization(s) and other entities.

The updated guidance further explains the early interaction process for the 510(k) Third Party Review Program and includes lessons learned from past emergencies to describe how the FDA may use third parties to review EUAs in future emergencies. When final, this guidance will replace the *510(k) Third Party Review Program* guidance.

Question #56

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.

Response:

The U.S. Department of Health and Human Services (HHS) is actively working to support laboratories seeking HHS certification for oral fluid drug testing.

Our commitment to uphold rigorous standards for test accuracy and reliability is underscored by a series of key initiatives led by the Center for Substance Abuse Prevention's Division of Workplace Programs (DWP) at the Substance Abuse and Mental Health Services Administration (SAMHSA). These initiatives include the creation and dissemination of essential resources, collaboration with oral fluid collection device and assay manufacturers, engagement with the U.S. Food and Drug Administration (FDA), and our collective approach to overcoming challenges faced by the laboratories which require HHS certification.

[3] 510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review | FDA

To assist laboratories and other interested parties, SAMHSA created and published the Oral Fluid Collection Handbook, the combined Urine and Oral Fluid Federal Custody and Control Form (https://www.reginfo.gov/public/do/DownloadDocument?objectID=130232301), and actively engages with oral fluid collection device manufacturers to identify their needs. Additionally, SAMHSA offers applicant laboratories, at no cost, initial inspections and proficiency testing and provides subject matter expert support to facilitate laboratory certification preparation.

At present, eleven laboratories have formally expressed their intent to seek HHS certification for the administration of oral fluid testing protocols. The certification process generally takes three to six months from the time of application. However, there are limitations in the availability of validated assays that align with the initial immunoassay testing criteria. These constraints are compounded by ongoing disruptions related to the COVID-19 pandemic. In response, SAMHSA is collaborating with the FDA, drugs of abuse test manufacturers, and the applicant laboratories to address these complexities.

Importantly, HHS cannot require private laboratories to submit certification applications, and each laboratory assumes responsibility for satisfying applicable certification requirements, including securing any required FDA-cleared collection devices and assays. In addition, each laboratory determines their own timeline for meeting certification requirements.

HHS understands the urgency to certify oral fluid testing laboratories and remains committed to expediting the certification process for the oral fluid testing laboratories. Since the DOT published its final rule on May 2, 2023, SAMHSA has made significant progress in assisting laboratories with navigating the application process. SAMHSA continues to work alongside our partners, including the FDA, to streamline and enhance the certification process. At this time, it is difficult to anticipate the exact timing for the certification of the first HHS certified oral fluid laboratories. SAMHSA remains resolute in our commitment to ensuring the highest standards of test accuracy within the regulated drug testing sectors and reliability for the benefit of all involved.

Question #57

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?

Response:

CMS's goals for Medicare Advantage (MA) and Part D mirror our vision for the agency's programs as a whole: to advance health equity; drive comprehensive, person-centered care; and promote affordability and the sustainability of the Medicare program. On April 1, 2024, CMS released the Announcement of Calendar Year (CY) 2025 MA Capitation Rates and Part C and Part D Payment Policies (the CY 2025 Rate Announcement). Under the policies finalized in the CY 2025 Rate Announcement, CMS anticipates adequate payment to MA and Part D plans to ensure stable premiums and benefits and plan options for individuals for CY 2025.

For CY 2024, following the updates finalized last year, the MA market for 2024 has remained strong. Beneficiaries continue to have access to affordable options. MA average premiums are stable for 2024 overall, with an increase of less than one dollar on average. Over 99 percent of people with Medicare have access to a $0 premium MA plan. Benefits for MA remained stable and plan choice and average supplemental benefit offerings (such as vision and dental) across plans increased. By continuing to

phase-in the routine updates finalized last year, CMS's work is ongoing to improve MA payment accuracy, with more money being paid to care for sicker and more costly Medicare enrollees, so that people in MA maintain access to the same care as people in Traditional Medicare. Paying MA plans more accurately for their costs of care will help ensure that people in MA will continue to access the care they need, including people with Medicare in rural areas and those who are dually-eligible for Medicare and Medicaid, all of whom particularly depend on MA for the care they need.

The Honorable John Joyce

Question #58

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?

Response:

The Medical Directors and clinical experts at the MAC review evidence (including published original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements and clinical guidelines), engage directly with experts and all interested parties, and consider all public comments to determine the LCD based on this information. The use of a Contractor Advisory Committee is optional in the LCD process that CMS has established, which is described in Chapter 13 of the Program Integrity Manual. However, the LCD process does require Open Meetings that must be convened for each LCD and provide an opportunity for all interested parties, including experts, stakeholders, and patient advocates to attend and participate in coverage policy development. This is in addition to the public comment period and the informal meetings that allow interested parties the opportunity to submit peer reviewed evidence and further participate in LCD development.

At this time, Novitas is reviewing comments that were received during the comment period and is also actively engaged in meeting with interested parties on this LCD. While MACs have the authority to develop LCDs, CMS has oversight responsibility to ensure that the MACs follow the LCD process that CMS has established, described in Chapter 13 of the Program Integrity Manual, which is intended to provide transparency, equal and fair access for the public, and public opportunity for engagement in the LCD process.

Question #59

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?

Response59 a:
ASPR's Center for Industrial Base Management and Supply Chain is focused on building a diverse, agile public health supply chain and sustainment of long-term U.S. manufacturing capabilities by investing in medical product Industrial Base Expansion (IBx) capacities that can enable ASPR to respond to future public health emergencies. IBMSC is expanding the industrial base through methods that can be sustained through the commercial marketplace after initial investment.

IBMSC coordinates strategic IBx efforts across ASPR, federal partners, academia, and the private sector to operationalize novel solutions and practices for response and recovery operations. IBMSC coordinates the activities related to medical product industrial base expansion and sustainment as described in the following objectives:

- Promote multi-functional capabilities, including advanced manufacturing and supply chain optimization, that ensure relevant stakeholders can access necessary raw materials and components needed for domestic manufacturing.
- Establish innovative domestic industrial base programs and enduring, sustainable partnerships across the medical countermeasure ecosystem including with biotech, pharma, distributors, healthcare, non-profit, and for-profit organizations; and
- Sustain critical medical countermeasures and public health supply advancement and capacity while prioritizing long-term, viable, adaptable domestic industrial base infrastructure to sustain commercial markets, partnerships, and life-cycle supply chain management.

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

Response 59 b:
The United States relies on foreign sources of supply for much of the APIs and key starting materials (KSMs) needed to produce essential medicines. For example, 87% of generic API facilities are located overseas. The U.S. also contributed only 4% of new API drug master files filed in 2021.

Annual funding is required: (1) to preserve capacity investments made thus far by ensuring appropriate management and oversight of the existing contracts; (2) to evaluate and assess where the future investments should be made; (3) to make those future investments still needed to fill the gaps; and (4) to ensure the overall portfolio of investments is balanced, productive, and sustained.

ASPR requested $95 million in the FY 2025 President's Budget to support sustained efforts in domestic manufacturing. This funding will support ongoing efforts to continue partnership with the private sector, as well as other U.S. government partners, to sustain and enhance domestic manufacturing. We cannot go back to pre-COVID times when we all experienced the failure of the domestic supply chain. We have learned too much and already made significant investment that needs to be sustained. Threats to our domestic medical and pharmaceutical industrial base supply chain still exist and must be addressed to ensure the nation is prepared to respond to the next public health emergency.

Growing and sustaining domestic manufacturing capacities for critical drug substances and drug products, PPE and diagnostics will be a priority for the utilization of these funds. Investments will be made to continue to commercialize agile and distributed manufacturing methods for drug substances and drug products, sustain and automate production for current and next-generation diagnostics and grow and maintain capacities for raw materials and finished PPE goods.

Question #60

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?

Response:

CMS has acted to make payments site neutral, where possible within its authority. HHS is happy to work with Congress and provide technical assistance on any legislation being considered.

Question #61

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?

Response:

As hospitals expand ownership of outpatient and physician office settings, consumers are seeing an uptick in fees for more than just the care provided to them. These "facility fees" are increasingly a driver of healthcare costs in America, and are leading to consumers being charged as though they received treatment in a hospital even if they never entered one. The President's FY 25 proposed budget includes a proposal that would prohibit hospitals from billing unwarranted facility fees for telehealth services and for certain other outpatient services.

Question #62

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?

Response:
Through the development and implementation of Merit-based Incentive Payment System (MIPS) Value Pathways (MVP), MIPS eligible clinicians can report on a subset of meaningful measures and activities relevant to a specialty or medical condition, which allows for an assessment of quality of care that is more connected to their specialty and allows CMS to offer the opportunity for enhanced performance feedback. In addition, implementing the MVP framework honors our commitment to continue to keep patients at the center of our work, and we anticipate that MVPs will result in more granular data being available to patients to help them make more informed healthcare decisions. CMS understands the importance of ensuring meaningful participation in MIPS through quality and cost measures that are aligned to a specific specialty, episode of care, or public health priority, and believes that MVPs reflect this goal. CMS is committed to continue working with physicians and provider organizations to develop and implement MVPs.

The Honorable Diana Harshbarger

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

Question #63

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?

Response:

The Final Rule has not been published yet. However, the Patient Protection and Affordable Care Act (ACA) itself makes clear that "[n]othing in this Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions[.]" 42 U.S.C. § 18023(c)(1). The ACA likewise includes a provision stating: "Nothing in this Act shall be construed to have any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion." *Id.* at 18023(c)(2)(A). In issuing and enforcing its Final Rule, HHS will comply with the ACA and all other applicable Federal law.

Question #64

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?

Question #65

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?

Response to #64 and #65

HHS is currently in the process of rulemaking, and the Final Rule has not yet been issued. HHS does not comment on the content of pending rules.

Drug Policy:

Question #66

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

Response:

In the last year, provisional data from CDC demonstrated that drug overdose deaths in the United States have declined by 3%, after remaining flat in 2022 compared to 2021 (CDC, 2024). These trends are even more encouraging given the historic increases seen in overdose deaths between 2019 and 2020 (approximate 30% increase) and 2020 and 2021 (approximate 15% increase). Specifically in Tennessee, drug overdose deaths are estimated to have decreased by 4.45% (CDC, 2024). However, there are a number of reasons why overdose deaths may increase in some communities. The primary driver of overdose deaths is an increasingly unpredictable and toxic illicit drug supply, fueled by the rapid increase and presence of fentanyl analogs and other synthetic drugs in the drug supply (NIDA, 2024). A newly published analysis conducted in Indiana observed that overdose deaths increased two-fold within 500 meters and less than one week after a law enforcement opioid related seizure (Ray, 2023), showing just how fast the number of overdose deaths can rise within a community in one week when

the illicit drug supply is unpredictable. While efforts to reduce the supply of illicit drugs are a necessary and critical component of responding to the overdose epidemic, rapid reduction in supply can cause individuals to experience withdrawal symptoms, resulting in an urgency to use a new and less familiar supply to find relief and may lead to a higher risk of overdose (Frank, 2023). In addition, we know that too few people receive life-saving medications for opioid use disorder as well as opioid overdose reversal medications, which can also drive up overdose deaths (Jones, 2024).

Harm reduction activities significantly contribute to the prevention of overdose deaths. Many studies show that community naloxone distribution programs demonstrate up to a 25% reduction in overdose deaths at the population level (Rao, 2021). Syringe service programs are one of the most ideal settings for naloxone distribution and do particularly well when adequately resourced to provide community support as this leads to increased naloxone saturation (Lambdin, 2023). There is longstanding evidence that harm reduction activities, such as syringe service programs, provide the majority of the naloxone responsible for community overdose reversals (CDC, 2015). In 2017, naloxone use and overdose death prevention rates were higher with community-based and pharmacy-initiated naloxone access points compared to provider-prescribed access (Townsend, 2020). In a 2020 cost-effectiveness analysis, the majority of health gains were realized when distributing naloxone to laypeople compared with other naloxone distribution interventions (Townsend, 2020). With $32 million in funding appropriated by Congress through the American Rescue Plan Act of 2021 (ARPA), SAMHSA funded 25 Harm Reduction Program (HRP) grant recipients in May 2022. Within the first two years of receiving the grant, HRP recipients have distributed 114,157 opioid overdose reversal medication kits and provided overdose prevention education to 50,061 people, reaching segments of the population most likely to witness and respond to an overdose.

Question #67

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

Response:

In general, federal HHS appropriated funds for harm reduction have traditionally excluded certain central aspects of syringe service programs (SSPs), specifically prohibiting the purchase of syringes and other safer drug use supplies. Despite evidence supporting the effectiveness of SSPs in reducing infectious diseases by up to 50% for HIV and HCV infections (CDC, 2024), increasing treatment admissions (SSP participants are five times more likely to enter substance use treatment, CDC, 2024) and decreasing substance use (SSP participants are three times more likely to stop using substances than those who do not utilize SSPs, CDC, 2024), these restrictions have persisted. SAMHSA's Harm Reduction Program (HRP) is funded by the American Rescue Plan Act, which does not have the same HHS appropriations prohibitions for syringes and needles. The HRP is the only federal program that allows for the purchase of sterile syringes, which are used to prevent the spread of infectious diseases such as HIV, hepatitis B, and hepatitis C, among people who inject drugs. Importantly, however, the HRP NOFO explicitly states: "Harm reduction programs that use federal funding must adhere to federal, state, and local laws, regulations, and other requirements related to such programs or services" (p. 8). In addition, no federal funding from the HRP is used directly or through subsequent reimbursement of grantees to purchase pipes in safer smoking kits.

In addition, all other SAMHSA substance use funding includes specific prohibitions consistent with federal laws and regulations. Specifically, no federal funding is used directly or through subsequent reimbursement of grantees to purchase pipes in safer smoking kits, and grants include explicit prohibitions on federal funds to be used to purchase drug paraphernalia.

Rural Health Care Talent:

Question #68

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

Response:

The FY 2025 Budget, consistent with the FY 2024 request, increases and extends mandatory funding of $790 million per year through FY 2026 to ensure primary care clinicians practice in high need underserved and rural areas in exchange for loan repayment and scholarships through the National Health Service Corps. Additionally, the FY 2025 Budget proposes, consistent with the FY 2024 President's Budget proposal, to increase and extend mandatory funding through FY 2026 for the Teaching Health Center Graduate Medical Education Program, to provide funding to support the training of more primary care physicians in community-based settings, such as community health centers, where most primary care is delivered. In FY 2025, the program will support over 1,800 resident fulltime equivalent slots.

In FY 2025, the Department plans to release a new competition for the Rural Residency Planning and Development Program, which expands the number of rural residency training programs, increases the number of physicians training in rural settings, and subsequently increases the number of physicians choosing to practice in rural areas. Recipients may use grant funds to cover planning and development costs incurred while achieving program accreditation through Accreditation Council for Graduate Medical Education. Eligible primary care and high need rural residency specialties include family medicine, family medicine with enhanced obstetrical training, internal medicine, preventive medicine, psychiatry, general surgery, and obstetrics and gynecology.

The FY 2025 President's Budget makes important investments in innovative new approaches to workforce development and training. The FY 2025 Budget invests in increasing the number of behavioral health professionals, peers, and other providers to expand access to mental health and substance use disorder services and provides targeted investments to support the next generation of nurses, including addressing the need to grow the nursing workforce that makes it possible to sustain labor and delivery services in underserved communities, including rural areas.

Question #69

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.

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?

Response:

On March 25, 2024, FDA proposed to ban electrical stimulation devices (ESDs) for self-injurious and aggressive behavior (SIB and AB), because these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated through new or updated device labeling. As you noted, this is the second time FDA has proposed to ban these devices for such uses. The ban would not affect ESDs intended for other uses, such as those used for smoking cessation.

FDA's first ban of these devices in 2020 was challenged in federal court and vacated based on the court's interpretation that FDA's authority to ban devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) did not permit FDA to ban a device for some (but not all) of its intended uses. Since that decision, in Section 3306 of the Food and Drug Omnibus Reform Act of 2022, Congress made clear that FDA has authority to ban devices for specific intended uses.

The Agency only pursues such actions when a device, or a particular use of a device, presents substantial deception or an unreasonable and substantial risk of illness or injury. FDA has only banned four other devices since the authority was enacted in 1976.

To support the proposed ESD ban, FDA analyzed all available data and information relating to the risks and effects of ESDs for SIB and AB. FDA found that the scientific and medical literature shows ESDs present a number of psychological harms including depression, PTSD, anxiety, fear, panic, substitution of other negative behaviors, worsening of underlying symptoms, and learned helplessness (becoming unable or unwilling to respond in any way to the ESD); and the devices present the physical risks of pain, skin burns, and tissue damage In addition to the scientific and medical literature, other sources including experts in the field of behavioral science, information from state agencies that regulate ESD use, and records from the only facility that has recently manufactured and is currently using ESDs for SIB or AB further support the reports of risks in the literature and indicate that ESDs pose additional risks such as suicidality, chronic stress, acute stress disorder, neuropathy, withdrawal, nightmares, flashbacks of panic and rage, hypervigilance, insensitivity to fatigue or pain, changes in sleep patterns, loss of interest, difficulty concentrating, and injuries from falling.

While proponents have asserted the devices are safe and effective for the intended uses in question, FDA's review of the valid scientific evidence for the proposed rule indicates the devices present a substantial and unreasonable risk of illness or injury. FDA found that studies supporting effectiveness suffer from significant limitations that limit confidence in the results, including weak design, small size, confounding factors, outdated standards for conduct, and study-specific methodological limitations.

The final rule is currently under consideration, and FDA is reviewing comments to the docket, including information submitted by proponents of ESDs for SIB or AB as proof of safety and effectiveness.

The proposed rule, if finalized, will ban the manufacture and distribution of ESDs intended for self-injurious or aggressive behavior, and the devices will no longer be considered legally marketed devices for such uses. We note that a device ban would not prevent study of the device under an investigational device exemption.

Question #70

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.

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?

Response:
The Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) have a long history of working across the Federal government to inform the Dietary Guidelines. Because of its expertise in this topic area, ICCPUD is an important Federal scientific committee for HHS and USDA to engage. In early 2022, the Substance Abuse and Mental Health Services Administration (SAMHSA), as the convener of the ICCPUD, initiated work on alcohol consumption and health as part of a broader scientific review and annual ICCPUD report. SAMHSA is responsible for providing administrative and operational support for ICCPUD under authority delegated by the HHS Secretary. Additionally, in the Consolidated Appropriations Act, 2023, after the ICCPUD work had begun, Congress mandated that USDA-enter into a contract with the National Academies of Sciences, Engineering, and Medicine (NASEM) to conduct a series of systematic reviews on alcoholic beverages and certain specific health outcomes.

The ICCPUD Alcohol Intake and Health (AIH) Study and the NASEM study are complementary, not duplicative. While both studies address the relationship between alcohol and health, there are key distinctions between the two, including the types of outcomes being examined and the methods being used to conduct the studies. Specifically, the NASEM study will use systematic reviews to examine evidence on the relationship between alcohol consumption and health outcomes, while the AIH Study will use modeling methods to estimate the effects of alcohol consumption (if any) on various health outcomes. Both projects will be complete by the end of December 2024. Each will result in a report with scientific findings, not recommendations, on alcohol consumption. These findings will subsequently be shared with HHS and USDA for consideration as the Departments develop the next edition of the Dietary Guidelines.

While both the NASEM and ICCPUD studies will address the relationship between alcoholic beverages and health, there are key distinctions between the two, including the types of outcomes being examined and the methods being used to conduct the studies. Specifically, the NASEM study will use systematic reviews to examine evidence on the relationship between alcohol consumption and health outcomes, while the ICCPUD study uses modeling to estimate risks (if any) between alcohol intake and a range of health outcomes. Thus, these two studies will provide complementary evidence to inform HHS and USDA as the Departments develop the next edition of the Dietary Guidelines.

Both projects will include opportunities for public input and external scientific peer review and will be complete by the end of December 2024.

Question #71
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.

> 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?

Response:
The ICCPUD Technical Review Subcommittee (Subcommittee) on Alcohol Intake and Health serves as an ongoing subcommittee of the ICCPUD to provide leadership, oversight, and consultation related to the review of current scientific evidence on the relationship between alcohol intake and related health outcomes.

The Subcommittee is composed of ICCPUD member agency representatives who are responsible for guiding and setting policies or have scientific expertise in alcohol intake and health research. The Subcommittee includes representatives from these agencies:

- U.S. Department of Agriculture
- Office of the Assistant Secretary for Health (at U.S. Department of Health and Human Services)
- Agency for Health Care Research and Quality
- Centers for Disease Control and Prevention
- Executive Office of the President, Office of National Drug Control Policy
- Indian Health Service
- National Institutes of Health, National Cancer Institute

- National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism
- Substance Abuse and Mental Health Services Administration

The individual members of the Subcommittee are career civil servants, who serve as a delegated representative of an Agency Principal.

The Scientific Review Panel is composed of the following experts:

- **Kevin Shield, Ph.D.** Independent Scientist, Institute for Mental Health Policy Research and Head of the World Health Organization (WHO)/Pan American Health Organization (PAHO) Collaborating Centre in Addiction and Mental Health; Centre for Addiction and Mental Health
- **Katherine M. Keyes, Ph.D., M.P.H.** Professor of Epidemiology, Columbia University, Mailman School of Public Health
- **Priscilla Martinez, Ph.D., M.Phil.** Scientist, Alcohol Research Group
- **Adam J. Milam, M.D., Ph.D.** Senior Associate Consultant, Department of Anesthesiology and Perioperative Medicine, Mayo Clinic
- **Timothy S. Naimi, M.D., M.P.H.** Director, Canadian Institute for Substance Use Research, University of Victoria
- **Jurgen Rehm, Ph.D.** Senior Scientist, Institute for Mental Health Policy Research and Campbell Family Mental Health Research Institute; Centre for Addiction and Mental Health

More information is available at: ICCPUD Study on Alcohol Intake and Health

Question #72

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

Response:

To ensure transparency and opportunity for public comment, ICCPUD is preparing two opportunities for public comment on the Alcohol Intake and Health Study, as well as a public meeting with interested stakeholders as part of the annual ICCPUD Stakeholders meeting. First, there will be an opportunity for public comment on the scientific methodology and study protocols of the Alcohol Intake and Health Study. This request for comment will be posted to the public docket OASH maintains on the Dietary Guidelines. Second, there will be an opportunity in late 2024/early 2025 for public comment on the draft study outcomes. In addition, on August 7, 2024, the ICCPUD will convene its annual stakeholders meeting which will be open to the public. During this meeting, ICCPUD members will provide updates on the Alcohol Intake and Health Study. It is also worth noting that we continue to update all of this information on the ICCPUD website to ensure transparency throughout the process.

Further, all Technical Review Subcommittee members and external subject matter experts involved in the Alcohol Intake and Health Study are required to declare sources of funding (direct or indirect) and any connection (direct or indirect) with the tobacco, alcohol, cannabis, or pharmaceutical industries, including any connection (direct or indirect) with any entity that is substantially funded by one of these organizations. This process is included in the 2023 ICCPUD Comprehensive Plan. Biographies and financial disclosures for the members of the Scientific Review Panel are available on ICCPUD's website.

Question #73

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.

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

Response:
Neither Dr. Koob nor the ICCPUD will be developing recommendations on adult alcohol consumption for the Dietary Guidelines as that is not the role of the ICCPUD. Rather, the ICCPUD Technical Review Subcommittee will review and assess the scientific evidence provided by the Scientific Review Panel (in conjunction with the NASEM study findings related to health effects of alcohol intake among adults) and provide a synthesis of the data, summarize the science, and provide their findings to the Secretaries of HHS and USDA for their consideration during the development of the 2025-2030 Dietary Guidelines. The findings of the Alcohol Intake and Health Study will also be summarized in the ICCPUD's 2025 Report to Congress.

Dr. Koob is one of 24 federal agency Principals who collaborates in the development and support of the federally coordinated approach to preventing and reducing underage drinking as part of 42 U.S.C. 290bb-25b - Programs to reduce underage drinking under the leadership of the Secretary of Health and Human Services and the ICCPUD designated Chair. Specifically, the act calls for the Secretary to conduct continued research and collect data on the short and long-range impact of alcohol use and abuse upon adolescent brain development and other organ systems, among other things.

The officials referred to in the act are the Secretary of Education, the Attorney General, the Secretary of Transportation, the Secretary of the Treasury, the Secretary of Defense, the Surgeon General, the Director of the Centers for Disease Control and Prevention, the Director of the National Institute on Alcohol Abuse and Alcoholism, the Assistant Secretary for Mental Health and Substance Use, the Director of the National Institute on Drug Abuse, the Assistant Secretary for Children and Families, the Director of the Office of National Drug Control Policy, the Administrator of the National Highway Traffic Safety Administration, the Administrator of the Office of Juvenile Justice and Delinquency Prevention, the Chairman of the Federal Trade Commission, and such other Federal officials as the Secretary of Health and Human Services determines to be appropriate.

Response:
NIAAA appreciates questions about Dr. Koob's role with the U.S. dietary guidelines. Last summer in a media engagement, Dr. Koob made comments based on the growing body of evidence demonstrating the adverse effects of alcohol at all levels. Although he mentioned Canada's recent guidance about alcohol consumption, the intent was not to suggest that the dietary guidelines in the U.S. would change. Development of the Dietary Guidelines for Americans is under the purview of the Department of Health and Human Services and the U.S. Department of Agriculture. Dr. Koob does not have a direct role in developing the guideline recommendations and does not decide what recommendations should be adopted in the U.S.
Dr. Koob does oversee NIAAA staff with scientific expertise in alcohol health research who are participating on the Technical Review Subcommittee on Alcohol Intake and Health along with scientists from eight other federal agencies. The Technical Review Subcommittee will synthesize findings from reports on alcohol and health

generated by a Scientific Review Panel comprised of external scientific experts and by a National Academies of Sciences, Engineering, and Medicine committee. This summary will be included in SAMHSA's annual Report to Congress and provided to HHS and USDA for consideration during their development of the 2025-2030 Dietary Guidelines for Americans. Decisions about guidance or advice in the Dietary Guidelines are the sole responsibility of HHS and USDA and will not be made by Dr. Koob or his staff.

Question #74
Is he a member of either of the ICCPUD subcommittees (technical or scientific review)?

Response:
No

Question #75
Is he overseeing the study and writing of recommendations?

Response:
No. The ICCPUD Technical Review Subcommittee will assess the available literature and the scientific evidence provided by the SRP in conjunction with the NASEM study findings related to health effects of alcohol intake among adults and provide a synthesis of the data and summarize the science for the 2025 Report to Congress. This information will also be provided to HHS and USDA for consideration during the development of the 2025-2030 Dietary Guidelines for Americans as they will be making all recommendations related to the Dietary Guidelines. Importantly, the ICCPUD will not be making recommendations on adult alcohol consumption for the 2025-2030 Dietary Guidelines for Americans.

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

Response:
Yes, Dr. Koob is one of 24 federal agency Principals and has attended the ICCPUD Principals Meetings as expected in order to review and approve the ICCPUD Comprehensive Plan and discuss priorities for programs to prevent and reduce underage drinking.

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.

Question #76
Why have you decided to redirect resources away from combating underage drinking to focus on adult legal consumption under the Dietary Guidelines?

Response:
The Alcohol Intake and Health study fits into the goals of the ICCPUD and is consistent with requirements of 42 U.S.C. 290bb-25b - Programs to reduce underage drinking, and the Sober Truth on Preventing Underage Drinking Act, which calls for, among other things, the following:

- The continued research and data collection on short and long-range impact of alcohol use and abuse upon adolescent brain development and other organ systems, and;
- The collection of surveillance data, including information on the onset and prevalence of underage drinking, consumption patterns and beverage preferences, trends related to drinking among different age groups, including between youth and adults.

The research is well documented and makes clear that key factors affecting youth drinking are adult drinking patterns and community norms related to alcohol use. Often, alcohol and substance use disorders have an onset during adolescence with continued impairment during adulthood.

The Alcohol Intake and Health Study is focused on assessing the best available science to estimate the effects of alcohol consumption (if any) on various health outcomes. Results of the study will be shared with HHS and USDA to inform their development of the Dietary Guidelines and may provide insights related to the short- and long-term impacts of alcohol use on youth to strengthen ICCPUD's efforts to advance strategies and approaches to reduce and prevent underage drinking. Importantly, no funds intended for STOP Act program grants to communities (i.e., funding to support current or former DFC program coalitions to implement strategies in communities to prevent underage drinking) are used to support ICCPUD's work on the Alcohol Intake and Health Study.

Question #77
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?

Response:
ICCPUD is comprised of federal officials defined in statute that is charged with guiding policy and program development across the Federal government with respect to underage drinking. ICCPUD contracted with a Scientific Review Panel (SRP), composed of nationally and internationally renowned subject matter experts. The SRP will conduct a series of studies to assess the available scientific research on alcohol intake and health and will provide the Subcommittee with an assessment of the best available science related to the risks of alcohol use on various health outcomes. Individuals of the SRP have expertise in the following areas:

- Public health strategies related to alcohol policies, programs, and practices.
- Health effects of alcohol
- Dietary guidance policy
- Cancer epidemiology
- Data quality and analysis
- Systematic reviews and meta-analyses
- Biostatistics
- Adverse pregnancy outcomes

Question #78

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?

Response:
In early 2022, the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD), asked the Substance Abuse and Mental Health Services Administration (SAMHSA), as the convener of the ICCPUD, to initiate work on alcohol consumption and health as part of a broader scientific review and annual ICCPUD report. SAMHSA is responsible for providing administrative and operational support for ICCPUD under authority delegated by HHS. Additionally, in the 2023 Consolidated Appropriations Act, after the ICCPUD work had begun, Congress mandated that USDA enter into a contract with NASEM to conduct a series of systematic reviews on alcoholic beverages and health. The studies are complementary with ICCPUD using modeling studies to estimate risks (if any) between alcohol intake and various health outcomes and NASEM conducting systematic review and/or evidence scans on alcohol intake and various health outcomes.

The Honorable Mariannette Miller-Meeks

Question #79
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?

Substance use disorders (SUD) impact the lives of millions of Americans, including individuals who are enrolled in the Medicare program. CMS is committed to ensuring that Medicare beneficiaries who have an opioid use disorder (OUD) have access to appropriate treatment, including medications for opioid use disorder (MOUD). Ensuring access to these benefits and addressing equity concerns is an important part of combatting the nation's opioid epidemic, and CMS has been actively engaged in the work necessary to meet these goals.

CMS is pleased to note that the OIG report entitled, "The Consistently Low Percentage of Medicare Enrollees Receiving Medication to Treat Their Opioid Use Disorder Remains a Concern, OEI-02-23-00250" found a 36 percent increase in the number of enrollees receiving naloxone through Medicare from 2021 to 2022 and found that indicators of misuse and diversion of prescription opioids in Part D continued to decline. However, CMS also recognizes there is more work to do in increasing access to SUD OUD treatment and addressing health equity.

Several recent changes have expanded Medicare beneficiaries' access to MOUD. First, on January 1, 2020, Medicare began paying Medicare-enrolled Opioid Treatment Programs (OTPs) with a bundled payment to deliver OUD treatment services to Medicare beneficiaries as required by the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act. Medicare Advantage plans must also include the Medicare OTP benefit and can contract with OTP providers in their service area, or agree to pay an OTP on a non-contract basis. To further promote continuity of care, in addition to on-site treatment, OTPs may also provide beneficiaries

with unsupervised take-home doses of medication in accordance with certain time in treatment standards.

Second, effective December 29, 2022, providers with a current Drug Enforcement Administration (DEA) registration no longer need the DATA-Waiver (X-Waiver) from the Substance Abuse and Mental Health Services Administration (SAMHSA) to prescribe buprenorphine, a type of MOUD, strengthening Medicare providers' ability to care for beneficiaries with OUDs.

Finally, in March 2023, the Food and Drug Administration (FDA) announced that Narcan, a brand-name formulation of the opioid overdose reversal drug naloxone, would be available without a prescription. While Medicare Part D generally does not cover over-the-counter medications, this change will remove barriers to access by allowing beneficiaries to purchase the medication without first meeting with a provider. Other options for Medicare-covered naloxone will remain available, such as other formulations or dosages of naloxone that remain prescription drugs, as well as other overdose reversal medications.

CMS will continue to monitor use of, and access to, these medications. CMS monitors prescription drug use in Part D (including over-utilization and/or under-utilization of opioids, buprenorphine, and MOUD) through prescription drug event (PDE) data to oversee sponsors' compliance with drug utilization review (DUR) requirements as described in 42 CFR § 423.153. CMS also monitors complaints in the Complaints Tracking Module (CTM) in the Health Plan Management System to identify potential access issues. CMS may follow up with Part D plan sponsors that are outliers, or share information with Departmental partners, as appropriate.

Combatting the opioid epidemic is a top priority for CMS, and CMS remains committed to ongoing examination of its payment and coverage policies to ensure healthcare providers are enabled to execute best practices with respect to pain management and treatment of OUDs. CMS continues to support opioid alternatives offered by Traditional Medicare, MA plans, and Part D plans, including the coverage of acupuncture to address lower back pain and educating providers on other non-opioid alternatives.

Question #80

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?

Question #81

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.

Response (80-81):

As detailed by the White House National Strategy of Hunger, Nutrition, and Health, the Administration set a goal of ending hunger and increasing healthy eating and physical activity by 2030 so fewer Americans experience diet-related diseases, while reducing related health disparities. Integrating nutrition and health can optimize Americans' well-being and reduce healthcare costs. Currently, only a limited number of Medicare beneficiaries are seeking nutrition and obesity counseling services.

Currently, Medicare covers an array of services that aim to address obesity. For example, obesity screenings, intensive behavioral therapy for obesity for the prevention or early detection of illness or disability, bariatric surgical procedures, and diabetes screenings and participation in a diabetes prevention program are covered under Medicare in certain cases.

Medicaid and the Children's Health Insurance Program (CHIP) can play a role in reducing the rate of obesity in the United States by improving access to health care services that support healthy weight. For eligible children enrolled in Medicaid, the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit covers medically necessary services described in section 1905(a) of the Social Security Act whether or not a state includes them in the state plan, including obesity-related services described in section 1905(a). For adults enrolled in Medicaid, the states have greater flexibility regarding which services to provide, with most states covering at least one obesity treatment.

Question #82

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?

Response:

CMS is continuing to work to improve Medicare Advantage (MA) and maintain high-quality health care coverage choices for all Medicare enrollees. MA organizations must provide enrollees with access to all

medically necessary Medicare Part A and Part B benefits available under Traditional Medicare (with some limited exceptions), in accordance with section 1852(a)(1) of the Social Security Act. Under section 1852 of the Social Security Act, MA plans are generally allowed to use utilization management tools, such as prior authorization.

On April 5, 2023, CMS finalized the CY 2024 MA and Part D final rule (88 FR 22120), which streamlined prior authorization requirements, including adding continuity of care requirements and reducing disruptions for beneficiaries. CMS' final rule required that coordinated care plan prior authorization policies may only be used to confirm the presence of diagnoses or other medical criteria and/or ensure that an item or service is medically necessary. Third, the final rule required coordinated care plans to provide a minimum 90-day transition period when an enrollee currently undergoing treatment switches to a new MA plan, during which the new MA plan may not require prior authorization for the active course of treatment. Additionally, to ensure prior authorization is being used appropriately, CMS required all MA plans that use utilization management policies and procedures to establish a Utilization Management Committee to review policies annually and ensure consistency with Traditional Medicare's national and local coverage decisions and guidelines. The final rule required that approval of a prior authorization request for a course of treatment must be valid for as long as medically necessary to avoid disruptions in care in accordance with applicable coverage criteria, the patient's medical history, and the treating provider's recommendation.

Finally, as part of the final rule, CMS clarified rules related to acceptable coverage criteria for basic benefits by requiring that MA plans must comply with national coverage determinations (NCDs), applicable local coverage determinations (LCDs), and general coverage and benefit conditions included in Traditional Medicare regulations. In situations where coverage criteria are not fully established, MA organizations may create internal coverage criteria based on current evidence in widely used treatment guidelines or clinical literature made publicly available to CMS, enrollees, and providers. In the final rule, CMS more clearly defined when applicable Medicare coverage criteria are not fully established by explicitly stating the circumstances under which MA plans may apply internal coverage criteria when making medical necessity decisions.

Medicare covers noninvasive ventilators, and other respiratory assistive devices, under the Medicare benefits for durable medical equipment (DME). Per NCD 280.1, ventilators are covered when reasonable and necessary for the diagnosis or treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. NCD 280.1 does not address every situation in which use of a noninvasive respirator is reasonable and necessary to treat a patient with one of these conditions. To address specific situations, Medicare Administrative Contractors (MACs) may issue LCDs that specify what items are reasonable and necessary and define what items or services are covered in their jurisdictions. If an MA enrollee's specific situation is addressed by an LCD that applies in the MA plan's service area, the MA plan must comply with the LCD. However, if there is not an applicable LCD to address when use of a noninvasive respirator is reasonable and necessary to treat a patient with neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease, the MA plan may develop its own internal coverage criteria to make consistent and appropriate medical necessity determinations for coverage of noninvasive ventilators. Such internal coverage criteria might potentially include use of another type of DME to determine whether other treatments are effective, provided this coverage policy meets the standards in 42 CFR § 422.101(b)(6).

Regarding enforcement and oversight of MA organizations, CMS has a well-established, robust, and successful process for ensuring organizations that offer MA plans are complying with our regulations, including those governing prior authorization. As a result of program audits and compliance activities, CMS may issue compliance and enforcement actions.

Question #83

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?

Response:

I recognize the devastating impact heart disease is having on the health outcomes of Americans broadly and, in particular, the disproportionate toll it has taken on communities of color. It is a priority of the Biden-Harris Administration to identify and address health inequities and improve patient outcomes across all of our programs.

In addition to services provided by a cardiologist, Medicare covers an array of services that aim to prevent and address heart disease. For example, cardiovascular disease screenings, cardiovascular behavioral therapy, and coordinated care services for beneficiaries with two or more serious health conditions (including heart disease), are covered under Medicare in certain cases. In addition, CMS, along with the CDC, co-lead the Million Hearts®, a national initiative to prevent 1 million heart attacks and strokes within 5 years (January 2022-December 2026).

In March 2024, CMS issued guidance to clarify that anti-obesity medications (AOMs) that receive FDA approval for a medically accepted indication other than weight management can be covered by Medicare Part D plans for that indication. For example, if an AOM receives FDA approval to treat diabetes or prevent cardiovascular disease, Part D plans may cover the medication for that specific use. If an AOM receives approval for an additional medically accepted indication during the contract year, Part D plans may add the drug to their current formulary for that specific use.
CMS will continue our work to improve the Medicare program and to ensure that all Medicare beneficiaries have access to the medications they need.

Question #84

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?

Response:

The KCC Model is designed to help improve the health and quality of care for patients with late-stage chronic kidney disease, end-stage renal disease and kidney transplant. Model participants in the Comprehensive Kidney Care Contracting (CKCC) Options of the KCC Model agree to take on financial risk, and expenditures for their beneficiaries are compared against an annual financial benchmark. These benchmarks are prospective and based on historical spending for their beneficiaries from 2017 through 2019 – that are then risk adjusted, trended forward to the current performance year, and then blended with regional rates to create performance targets for the year. CKCC participants can receive shared savings or owe shared losses based on their performance.

Benchmark trending is based on the growth in expenditures calculated by the independent CMS Office of the Actuary. The retrospective trend adjustment (RTA) is the mechanism CMS uses to ensure the benchmarks are accurate. As this trend is calculated before the start of the year, it may diverge from the actual observed expenditure trend for the performance year. Model participants agree (as part of their participation in the model) that if in a given performance year the observed expenditure trend differs from the prospective adjusted United States Per Capita Costs trend by more than one percent, CMS may apply an RTA to the preliminary benchmarks. This methodology helps to ensure that participants are measured against appropriate benchmarks and protects both the participants and the Medicare Trust Fund.

CMS applied the RTA to the KCC Model performance benchmark for both 2022 and 2023 based on updated figures from the Office of the Actuary. The Actuary's projected calculations tried to mitigate the COVID-19 effects, but still overstated the growth in projected expenditures during that period. The updated figures reflect the more accurate growth in expenditures that occurred.

Based on KCC Model participant feedback, however, going forward, CMS has updated the policy for the RTA. To increase predictability, starting in performance year 2024, CMS will establish three corridors for the RTA. Instead of participants being subject to 100% of the RTA without limitation, each corridor has a different level of risk, with lower levels of risk for higher RTAs. No participant will be at risk for an adjustment greater than 8%. All participants will be at full risk for adjustments 0% to 4% if the RTA is applied. This adjustment is symmetrical, which means participants are subject to the adjustment as described below, whether overstated or understated.

Percentage (+ or -)	**Level of Risk (starting in 2024)**
0-4%	100%
4-8%	50%
Greater than 8%	0%

Question #85

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?

Response:

CMS strives to improve patient care and innovation while maintaining robust safeguards for the Medicare population. As part of our further efforts to streamline the national coverage process, on June 22, 2023, CMS announced a proposed procedural notice outlining a new Medicare coverage pathway, the Transitional Coverage for Emerging Technologies (TCET) pathway for Breakthrough Devices. This pathway is intended to offer more timely and predictable access to new medical technologies for people with Medicare (88 FR 41633). In addition to the proposed TCET procedural notice, CMS issued an updated proposed Coverage with Evidence Development (CED) guidance document and a proposed Evidence Review guidance document. CMS also issued the first in a series of guidance documents that outline our current thinking on health outcomes within priority therapeutic areas. These documents offer insight into how CMS reviews clinical evidence and transparency regarding CED.

We sought comments from stakeholders on the proposed TCET procedural notice and the proposed guidance documents. We will respond to comments when we finalize the documents.

Question #86

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?

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?

Response:

In just over three years, the COVID-19 Uninsured Program processed more than 276 million claims. Eligible claims that were submitted to the Program by the March and April 2022 deadlines were adjudicated and paid in line with program requirements, with the limited exception of 0.3 percent of all providers whose claims activity was flagged for additional review. Claims were flagged and reviews were undertaken as part of standard program integrity review processes, law enforcement inquiries, and in response to unusual billing activity to safeguard taxpayer dollars against fraud or abuse. The Fiscal Responsibility Act of 2023 rescinded remaining funds for HRSA's provider relief programs, including those available for the Uninsured Program.

Question #87

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?

Response:
The No Surprises Act establishes a Federal Independent Dispute Resolution (IDR) process that providers, emergency facilities, and providers of air ambulance services and group health plans and health insurance issuers in the group and individual market, as well as Federal Employees Health (FEHB) Carriers, may use following the end of an unsuccessful open negotiation period to determine the out-of-network (OON) rate for certain covered services. The Federal IDR process does not apply to items and services payable by Medicare, Medicaid, the Children's Health Insurance Program, or TRICARE. The Federal IDR Process also does not apply in cases where a specified state law (SSL) or All-Payer Model Agreement (APMA) under Section 1115A of the Social Security Act provides a method for determining the total amount payable under a group health plan or group or individual health insurance coverage with respect to the OON items and services furnished by the provider or facility.

CMS has published a chart that provides a high-level summary to assist in determining whether the Federal IDR process or a state law or All-Payer Model Agreement applies for determining the out-of-network rate. This chart can be found at: https://www.cms.gov/files/document/caa-federal-idr-applicability-chart.pdf.

CMS is responsible for enforcement of provisions of the NSA and Transparency provisions applicable to providers, facilities, and providers of air ambulance services in a state, if CMS determines that the state is not substantially enforcing one or more of the applicable NSA requirements. To ensure compliance with the law, CMS conducts targeted market conduct examinations and other audit activities, as necessary, and responds to consumer inquiries and complaints. Through the CMS investigation process, CMS has directed plans, issuers, providers, health care facilities, or providers of air ambulance services to take remedial and corrective actions to address instances of non-compliance, which has resulted in approximately $3,036,421 in monetary relief paid to consumers or providers. More information can be found at the CMS Complaint Data and Enforcement Report which presents information on complaints and enforcement efforts related to the applicable provisions of title XXVII of the PHS Act with a focus on those over which CMS has jurisdiction. As of December 31, 2023, CMS has received over 12,291 of such complaints, most of which have been related to alleged violations of NSA requirements.[4]

The Honorable Anna Eshoo

Question #88
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:

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?

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

[4] February 2024 Complaint Data and Enforcement Report, available at: https://www.cms.gov/files/document/february-2024-complaint-data-and-enforcement-report.pdf

Response: When ORR receives a report of suspected labor exploitation or trafficking, ORR takes a range of actions, including:

- Immediately halting discharges to specific neighborhoods (utilizing street information) or individual sponsors until additional safety measures are put in place;
- Conducting welfare phone calls and/or in-person visits, and
- Flagging for the state's child welfare agency, local law enforcement, HHS's Office on Trafficking in Persons (OTIP), and other relevant entities for certain locations and a geographically appropriate radius around those locations.

While ORR's custodial responsibilities end when a child is discharged, ORR has policies in place to promote children's well-being as they transition into a new community, providing children with multiple ways to connect following their sponsor placement, such as through Safety and Well-being calls, post-release services, legal services, or the 24/7 ORR National Call Center (ORRNCC), which connects children and sponsors with community resources and is required to report all safety concerns to ORR and other federal, state, and/or local entities. Notably, ORR does not have the authority to remove a child from a home—that authority resides with law enforcement and state child welfare agencies. ORR recognizes the critical importance of its coordination and engagement with these agencies.

Per ORR's UC Program Policy Guide Section 2.8.4, care providers must conduct a Safety and Well-being follow up call with an unaccompanied child and their sponsor 30 days after the release date. The purpose of the follow up call is to determine whether the child is still residing with the sponsor, is enrolled in or attending school, is aware of upcoming court dates, and is safe. The care provider must document the outcome of the follow up call in the child's case file, including if the care provider is unable to contact the sponsor or child after reasonable efforts have been exhausted. If the follow up call indicates that the sponsor and/or child would benefit from additional support or services, the care provider must refer the sponsor or child to the ORRNCC and provide the sponsor or child the ORRNCC contact information. If the care provider believes that the child is unsafe, the care provider must comply with mandatory reporting laws, state licensing requirements, and federal laws and regulations for reporting to local child protective agencies and/or law enforcement. Additional information regarding required reporting of events related to an unaccompanied child's safety and well-being is available in UC Program Policy Guide Section 5.8.

Question #89a

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?

Response:

The Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA) provides ORR with authority to conduct follow-up services once ORR's custody ends. Congress's support has made the increased availability of follow-up services (referred to as post-release services, or PRS) to more unaccompanied children possible. In FY 2022, ORR more than doubled the rate of children provided PRS, serving more than 40 percent of children compared to just over 20 percent in FY 2021, and is currently on track—with the continued funding support from Congress—to achieve our goal of providing all children access to PRS by the end of FY 2024. The expanded post-release services will consist of three levels of services. "Level 1 Services" will consist of Safety and Well-Being calls, which will become in-person or virtual check-ins conducted at seven, 14, and 30 days following release from care. "Level 2 Services" will expand from 90 days to six months of supportive services including

ongoing assessments, safety plans, and referrals to community-based programs. Finally, "Level 3 Services," or "intensive PRS," will include ORR intervention with case managers conducting initial in-home assessments within seven days of referral followed by weekly in-person contact for the first 45 to 60 days—focused on family stabilization including crisis intervention as needed—to transition to monthly or continue as necessary depending on the needs of the child. HHS will continue to work with Congress to ensure ORR has the necessary funding to build on this expansion of post-release services.

Question #89b-c

a. To what extent have funding constraints limited ORR's ability to properly screen potential sponsors and monitor the treatment of discharged children?
b. In addition to increasing funding, how best can Congress support HHS in your efforts to protect children from exploitation?

Response:

Congress' support has made the increased availability of post-release services (PRS) to more unaccompanied children possible. ORR has expanded PRS to a historic level, from just over 20 percent of children offered access to PRS in FY 2021 to over 60 percent of children currently being referred for such services. Similarly, ORR has increased the number of unaccompanied children receiving direct legal representation. Expanded post-release services consist of three levels of services. "Level 1 Services" will consist of Safety and Well-being calls, which will become in-person or virtual check-ins conducted at 7, 14, and 30 days following release from care. "Level 2 Services" will expand from 90 days to six months of supportive services including ongoing assessments, safety plans, and referrals to community-based programs. Finally, "Level 3 Services," or "intensive PRS," will include ORR intervention with case managers conducting initial in-home assessments within seven days of referral followed by weekly in-person contact for the first 45 to 60 days—focused on family stabilization including crisis intervention as needed—to transition to monthly visits or continue as necessary depending on the needs of the child

Importantly, providing and expanding access to PRS and legal representation is only possible with continued congressional funding. It should be noted that on October 20, 2023, the Administration submitted a request to Congress which included $1.853 billion in emergency supplemental funding to provide assistance to ORR-eligible populations. Congress did not approve that request. The final FY 2024 appropriation includes $5.4 billion for UC, which is a $100 million cut from the base appropriation enacted in FY 2023 excluding contingency fund estimates. The Administration's 2025 Budget request restores the UC base funding to $5.5 billion and in addition proposes a contingency fund that modifies the one that has been enacted so that it is more responsive. These numbers will continue to affect ORR's ability to provide and expand PRS and legal representation.

c. 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?

Response 89d:

HHS policy does not tolerate any threats or retributory actions against whistleblowers. While ORR is not able to comment on individual personnel issues, HHS is committed to upholding all legal rights and protections for whistleblowers, including ensuring its policies abide by all applicable whistleblower

protection statutes and reporting directives in annual federal funding laws. Whistleblower protections are a key mechanism for ensuring the safety and well-being of all children in ORR care and the staff providing such care. ACF conducts whistleblower trainings for its staff, grant recipients, and contractors and regularly circulates resources and reminders about whistleblower rights and protections.

d. 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?

Response 89e: ORR has thorough sponsor screening and vetting processes in place for all sponsors. As part of these processes, ORR requires several safeguards to ensure children are placed in a safe and appropriate environment and conducts risk assessments in its release determinations. ORR's process for the safe and timely release of a child from federal custody includes several steps such as: separate interviews with the child and sponsor and speaking with the child's parents, if available; a sponsor application, address checks and supporting documentation; background checks and in some cases, FBI fingerprint checks; as well as home studies where applicable, including those required by the Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA), mandated by ORR policy, or required at the discretion of ORR staff reviewing the facts of the case. Additional details on this process are available in ORR's Unaccompanied Children (UC) Program Policy Guide Section 2: Safe and Timely Release from ORR Care.

ORR continuously reviews its vetting policies and procedures for ways to improve its processes to promote the safety and well-being of children and to be more efficient and effective. On February 13, 2024, ORR published policy and procedure revisions that enhance its sponsor vetting requirements. Among other enhancements, these revisions require parents and legal guardians (Category 1 sponsors) to provide proof of address documentation (already a requirement for all other sponsors) and also requires, at minimum, sex offender registry checks for all adult household members and adult caregivers, including in Category 1 cases. Further, the revisions require, at minimum, proof of identity and criminal history public records background checks for all adult household members and adult caregivers, with a narrow exception for certain Category 1 cases such as where there are no safety concerns. These recent revisions also strengthen and expand home study policies and guidance to include mandatory home studies for potential sponsors of more than two children, regardless of the potential sponsor's relationship to the children.

e. 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?

Response 89 f: Upon their release, ORR provides children with information on the ORR National Call Center (ORRNCC), a 24-hour, seven days a week, resource not only for released children, but their family members, sponsors, legal service providers, Child Advocates, and other members of the community who can request assistance or report concerns to the ORRNCC on a child's behalf.

Notably, the total number of calls made to the ORRNCC have steadily increased year over year, which reflects that ORR has successfully increased its efforts to educate and serve more released children, their family members, sponsors, legal service providers, Child Advocates, and other members of the community who can request

assistance or report concerns to the ORRNCC on a child's behalf. Improved outreach, training, and efforts to reduce stigma for victims of trafficking have resulted in an increase in individuals coming forward who have been trafficked previously and who are at risk of being trafficked, including unaccompanied children.

Question #90

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?

Response:

ORR already provides the majority of this data. Monthly data can be found here: Latest UC Data and composite Fiscal Year on the acf.hhs.gov Facts and Data Webpage. ORR takes seriously the obligation to publicize program data, along with its obligation to ensure the safety, security, and privacy of all children who come through ORR care, as detailed in Section 5.9 of the UC Program Policy Guide.

Question #91

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.

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?

Response:

Thank you for your support for boosting infectious disease (ID) workforce recruitment. The Department recognizes the importance of building the ID and bio-preparedness workforce to prepare our nation to respond to outbreaks, epidemics, and pandemics. As you know, Congress included this program in the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act), which was enacted at the end of 2022 as part of the Consolidated Appropriations Act, 2023. To date, the Bio-Preparedness Workforce Pilot Program has not received appropriations.

Question #92

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?

Response:

CMS is continuing to work to improve the Medicare Advantage and Part D prescription drug programs and maintain high-quality health care coverage choices for all Medicare enrollees.

CMS maintains, and will continue to maintain, a robust clinical formulary review process to ensure that all Medicare Part D plans meet applicable formulary requirements. Consistent with the requirements at §§423.120(b)(2) and 423.272(b)(2)(i), CMS evaluates formularies based on the sufficiency of categories and classes, tier placement, and utilization management restrictions. This review process is consistent with section 1860D-11(e)(2)(D)(i) of the Social Security Act, which authorizes CMS to approve a prescription drug plan only if the agency "does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan." In addition, under § 423.272(b)(2)(i), "CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan." Furthermore, § 423.120(b)(2)(iii) requires each Part D plan formulary to "include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines." In addition, § 423.120(b)(1)(v) requires that in making decisions about formulary design, the entity designing the formulary must base "clinical decisions on the strength of scientific evidence and standards of practice."

Additionally, CMS requires Part D sponsors to submit utilization management requirements applied at point of sale, such as prior authorization, step therapy, and quantity limits not based upon the FDA's maximum daily dose limits, as part of their Health Plan Management System formulary submission. Sponsors must perform adequate oversight of their PBMs and other delegated entities to verify that they are complying with all CMS requirements and not causing beneficiary harm due to impermissible delayed or denied access to Part D drugs.

We will continue to monitor formulary and utilization management changes to assess if changes from the redesigned Part D benefit have the potential to reduce access to vital medications.

The Honorable Raul Ruiz

Question #93
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?

Response:
Implementing policy, system, and environmental strategies that consider racial and ethnic disparities is critical to addressing the high burden of obesity and its negative consequences. Targeted approaches that address food insecurity, access to safe drinking water, and cultural nutrition and physical activity patterns, as well as broader environmental and policy contexts, are needed to address the risks that drive disparities. For individuals from the groups with the largest disparities, it is also important to focus attention on enhancing access to and reimbursement for quality health care services for growth assessment and obesity screening. For persons with obesity and diabetes risk, appropriate referral to evidence-based healthy weight or prediabetes management programs and other treatment modalities is also needed.

Actions that CDC is taking include:

- Studying what works in communities to make it easier for people to be more physically active and have a healthier diet.
- Monitoring trends in obesity and related risk factors.
- Developing and educating guidelines on dietary patterns and amounts of physical activity needed for good health.
- Funding programs and providing training and resources for initiatives that promote healthy eating, food and nutrition security, and physical activity.
- Working with state, tribal, local, and territory governments, academia, the private sector, and nonprofit and community groups to implement the White House National Strategy on Hunger, Nutrition, and Health—to end hunger and reduce diet-related diseases and disparities.

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.

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.

Question #94

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?

Response: While the Agency acknowledges that more work must be done to promote innovation in smoking cessation treatments, FDA's Center for Drug Evaluation and Research (CDER) has taken a number of steps to encourage development of additional effective smoking cessation products—pushing the envelope of traditional smoking cessation trials by encouraging novel pathways. In 2020, FDA finalized the guidance, *Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products*, which was the first time CDER provided recommendations for nonclinical testing of orally inhaled drug products of any sort.

This was followed in May of 2023 by a final clinical guidance, *Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy [NRT] Drug Products*,[5] which outlines recommendations for new potentially clinically relevant outcomes for NRT products. The NRT Guidance discusses innovations in NRT drug development and provides a clear roadmap to help firms that are considering entering or expanding in the NRT drug product space.

Many of the concepts that are outlined in this guidance are also relevant for development of non-nicotine smoking cessation products. Specifically, the guidance provides recommendations regarding potential opportunities for innovation including:

- For the first time, discussing "reduction in risk of relapse" as a potential indication to assist smokers in their continuation of quitting. Previously, the only indication for these products was cessation of cigarette smoking.
- Outlining new potential treatment regimens: 1) pretreatment before quit day, 2) reduce to quit, and 3) combination therapy.
- Clarifying recommendations for companies that seek approval for a product that alters the route of administration compared to approved NRT drug products, e.g., products with pulmonary route of administration rather than an oral route of administration.
- Explaining when simplified efficacy study requirements may be used (e.g., recommending a 4-week study as the minimum period of efficacy ascertainment for smoking cessation).
- For the first time, outlining considerations for pediatric populations and NRT products.
- Clearly outlining the abbreviated review pathways available for NRT products, including how to use FDA's previous findings of safety and how already approved NRT products and published literature can be leveraged. This includes reliance on the Agency's previous findings of systemic safety for a higher nicotine exposure drug product and Agency's previous finding of effectiveness for a lower

[5] https://www.regulations.gov/document/FDA-2019-D-0297-0015

nicotine exposure drug product.

- Encouraging sponsors to consider expedited development and review pathways and provides details on how to qualify.
- Describing how labeling for approved NRT products may include information about clinical benefits of smoking cessation such as lowering the risk of lung disease, heart disease and smoking-related cancers without generating additional data.

Question #95

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?

Response: See response to 96

Question #96

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?

Response 95-96:

In May of 2023, FDA finalized guidance titled, Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products[6], which replaces the draft guidance of the same name published in February 2019. FDA intends for this guidance to assist sponsors in the clinical development of nicotine replacement therapy (NRT) drug products intended to help cigarette smokers stop smoking.

This guidance provides recommendations regarding potential development program innovations for NRT drug products. For example, the guidance discusses "reduction in risk of relapse" as a potential indication to assist smokers in remaining smoke-free. The guidance provides development program recommendations for two new potential treatment regimens: 1) pretreatment before quit day, and 2) quitting by gradual reduction ("reduce to quit"). It also considers the combination and use of more than one NRT drug product. In addition, it discusses potential additional efficacy endpoints that may be used in NRT drug products that have already demonstrated effectiveness in smoking cessation or reduction of risk of relapse: reduction in urge to smoke, relief of cue-induced craving in former smokers, and relief of withdrawal symptoms not associated with a cessation attempt.

The guidance describes abbreviated pathways and drug development recommendations for NRT products, including a bracketing approach based on previous findings of safety and efficacy. Bracketing allows sponsors to rely in part on the agency's previous finding of safety for the higher nicotine exposure drug product and the agency's previous finding of effectiveness for the lower nicotine exposure drug product.

[6] https://www.fda.gov/drugs/drug-safety-and-availability/fda-issues-final-nicotine-replacement-therapy-drug-products-guidance

Further, the guidance states that NRT drug products that have demonstrated effectiveness for cessation or reduction in risk of relapse may include information in the labeling regarding how quitting smoking can lower a person's chances of having lung disease, heart disease, and the risk of getting certain types of cancer that are related to smoking, without providing additional data. The guidance outlines nonprescription drug development considerations specific to NRT drug products and makes recommendations for nonprescription label development, efficacy studies, and consumer behavior studies. It also discusses pediatric population study considerations and reinforces FDA's commitment to development of alternative products and treatment modalities for smoking cessation and vaping cessation in youth.

Question #97
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?

Response :
In May of 2023, FDA finalized guidance titled, Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products[7], which replaces the draft guidance of the same name published in February 2019. FDA intends for this guidance to assist sponsors in the clinical development of nicotine replacement therapy (NRT) drug products intended to help cigarette smokers stop smoking.

This guidance includes recommendations regarding potential development program innovations for NRT drug products. For example, the guidance discusses "reduction in risk of relapse" as a potential indication to assist smokers in remaining smoke-free. The guidance provides development program recommendations for two new potential treatment regimens: 1) pretreatment before quit day, and 2) quitting by gradual reduction ("reduce to quit"). It also considers the combination and use of more than one NRT drug product. In addition, it discusses additional efficacy endpoints that may be used in NRT drug products that have already demonstrated effectiveness in smoking cessation or reduction of risk of relapse: reduction in urge to smoke, relief of cue-induced craving in former smokers, and relief of withdrawal symptoms not associated with a cessation attempt.

The guidance describes abbreviated pathways and drug development recommendations for NRT products, including a bracketing approach based on previous findings of safety and efficacy. Bracketing allows sponsors to rely in part on the agency's previous finding of safety for a higher nicotine exposure drug product and the agency's previous finding of effectiveness for a lower nicotine exposure drug product.

Further, the guidance states that NRT drug products that have demonstrated effectiveness for cessation or reduction in risk of relapse may include information in the labeling regarding how quitting smoking can lower a person's chances of having lung disease, heart disease, and the risk of getting certain types of cancer that are related to smoking, without providing additional data. The guidance outlines nonprescription drug development considerations specific to NRT drug products and makes recommendations for nonprescription label development, efficacy studies, and consumer behavior studies. It also discusses pediatric population study considerations and reinforces FDA's commitment to development of alternative products and treatment modalities for smoking cessation and vaping cessation in youth.

[7] https://www.fda.gov/drugs/drug-safety-and-availability/fda-issues-final-nicotine-replacement-therapy-drug-products-guidance

Question #98

Diagnostic Innovation:

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.

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?

Response:

Under the OPPS, CMS packages several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. In particular, under § 419.2(b)(15), payment for drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure is packaged with the payment for the related procedure or service. Diagnostic radiopharmaceuticals, which include contrast agents, stress agents, and other products, are one specific type of product that is packaged under this policy.

In the Calendar Year 2024 OPPS/ASC proposed rule, CMS solicited comment on a number of potential new approaches to payment for diagnostic radiopharmaceuticals that might enhance beneficiary access, while also maintaining the principles of the outpatient prospective payment system. Overall, commenters described clinical scenarios in which they believed CMS' payment policies created the most significant access issues, and accordingly, commenters urged CMS to reform payment policy for diagnostic radiopharmaceuticals to address these concerns. However, there was not a general consensus among commenters as to the most effective way for CMS to reform its OPPS diagnostic radiopharmaceutical payment policy.

CMS agrees this is a complex and important issue and, given the wide array of information presented through the public comment process, we intend to further consider these points and take them into consideration for future notice and comment rulemaking. CMS welcomes ongoing dialogue and engagement from interested parties regarding suggestions for potential future payment changes.

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.

Question #99
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?

Response:
We concur with Congress on the critical importance of HHS in the public health response to sexual assault and other forms of violence. VAWA 2022 authorized several new programs to assess how medical forensic exams are conducted, improve clinician competencies, develop trauma-informed approaches, and implement pilot projects for continuing clinical education, including the Sexual Assault Nurse Examiners Program. I want to clarify that the VAWA authorities for rape kit backlog testing are assigned to the Department of Justice. HHS has not received any funding from Congress for the new VAWA forensic exam programs, but we have taken a series of actions to support survivors of sexual assault and intimate partner violence in accessing support and care. The Department has addressed sexual assault through interagency coordination and integration of sexual assault initiatives in training and technical assistance.

In September 2022, the HHS Office on Women's Health awarded funding to address the intersection of substance use disorder (SUD) and intimate partner violence (IPV) during the pregnancy and postpartum period, including integrating IPV and SUD protocols into medical practice. In November 2022, the position of HHS Director of Sexual and Gender-based Violence was established within the Office of the Assistant Secretary of Health (OASH) to coordinate implementation of the gender-based violence initiatives across the Department.

In March 2023, HHS established the Family Violence Prevention and Services Act Program as its own office, the Office of Family Violence Prevention and Services in the Administration of Children and Families (ACF), reflecting our commitment to 1) preventing and addressing intimate partner violence, domestic violence, dating violence, and sexual assault; 2) coordinating trauma-informed services across ACF, HHS, and the federal government; and 3) strengthening attention to policy and practice issues relating to addressing the needs of survivors. This office issued grant awards to Sexual Assault Capacity Building Centers to help provide specialized sexual assault intervention and prevention technical assistance for Family Violence Prevention and Services Act (FVPSA) grant recipients. ACF also provides funding through technical assistance providers to train health center staff to identify, treat, and refer patients experiencing or survivors of intimate partner violence or human trafficking. Training and technical assistance is provided for 1,400 health centers and over 15,000 service sites funded by HRSA's Bureau of Primary Health Care Health Center Program.

In May 2023, the Health Resources and Services Administration (HRSA) launched the *2023-2025 HRSA Strategy to Address Intimate Partner Violence*, outlining strategic objectives and activities for HRSA to undertake that will strengthen infrastructure and workforce capacity to address intimate partner violence, improve data collection about IPV-related measures, and deliver technical assistance and trainings for health care providers.

VAWA 2022 made critical improvements to the existing Rape Prevention and Education Program (RPE) which CDC has implemented. In February 2024, the Centers for Disease Control and Prevention announced two Notices of Funding Opportunity for the Rape Prevention and Education program to provide vital resources for coalitions to implement evidence-informed, community-level approaches to prevent sexual violence.

The Honorable Robin Kelly

Question #100
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?

Response: Thank you for your continued interest in protecting the public health from tobacco-related illnesses as a member of this committee and as the Chair of the Congressional Black Caucus Health Brain Trust. I underscore that this rule has garnered historic attention and the public comment period has yielded an immense amount of feedback, including from various elements of the civil rights and criminal justice movement. It is clear that there are still more conversations to have, and that will take significantly more time.

Question #101
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?

Response: The FY 2025 President's Budget dedicates $215 million across HRSA to improve maternal health outcomes. New investments include providing grants to community-based organizations (CBOs) to grow the doula workforce and grants aiming to improve access and continuity of maternal and obstetrics care in rural communities. These initiatives are aimed at targeting areas with disparities and high rates of adverse maternal health outcomes. In addition, the Budget continues to include $172 million for the Healthy Start program which supports grants to local entities in communities, including CBOs, to improve maternal health outcomes before, during, and after pregnancy and reduce racial and ethnic disparities in rates of infant death and other adverse perinatal outcomes.

HHS works to ensure our resources and awards are targeted to communities in need, including CBOs, through the SimplerGrants initiative which redesigns and simplifies the Notice of Funding Opportunity (NOFO). This initiative aims to lower barriers for potential applicants to finding and applying for grants and makes the grants application process less burdensome. In addition, HRSA Program and NOFO development are informed by research and engagement with stakeholders which includes listening sessions with key stakeholders. HRSA also leverages data to help ensure funding is going to areas/entities with the greatest need. In an effort to provide outreach and technical assistance to those communities with less resources including CBOs, HRSA is implementing activities such as providing a technical assistance webinar to share upcoming funding opportunities and tips for accessing and applying for NOFOs.

Additionally, this year, HRSA will support two new awards for the Rural Maternity and Obstetrics Management Strategies (Rural MOMS) grants to improve access and continuity of maternal and obstetrics care in rural communities. Rural MOMS improves maternal care in rural communities by collecting data on rural hospital obstetric services; building networks to coordinate continuum of care; leveraging telehealth and specialty care; and improving financial sustainability. Organizations that provide prenatal care, labor care, birthing, and postpartum care services in rural areas, frontier areas, or medically underserved areas, or to medically underserved populations or Indian Tribes or Tribal organizations are eligible.

The FY2025 President's Budget also includes $13,750,000 for the Office of Minority Health to fund continuation awards for its Healthy Families Community-Based Perinatal Health Initiative (COPHI). COPHI supports projects to develop innovative models for integrating community-based maternal support services (COMSS) into perinatal systems of care. Public or non-profit community-based organizations (CBOs), faith-based organizations and American Indian/Alaska Native/Native American organizations were included as eligible applicants for the funding opportunity. The Notice of Funding Opportunity also included an expectation for award recipients to establish collaborative partnerships with CBOs to support the development, implementation and evaluation of integrated COMMS models.

Question #102

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?

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

   a. Additionally, if there is a reason for the delay, will you commit to providing a transparent process for that reasoning? HHS has been working diligently internally to examine the issue of contraceptive deserts since receiving the reporting instructions. Our report to congress reflects the steps needed to thoroughly examine this issue and provide the requested information to Congress.

Response:

HHS expects to issue the report to Congress in June of 2024.

Question #103

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.

Response:
CMS is currently in the rulemaking process and cannot comment on or speculate about any potential changes to the proposed policies or when a final rule may be issued. As always, we are closely reviewing the comments received in response to the proposed rule. Input from stakeholders is an important contribution to CMS' policy-making process, and we are now considering the abundance of comments we received during the public comment period.

The Honorable Lisa Blunt Rochester

Question #104
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?

Response:
The Department, through the Health Resources and Services Administration (HRSA), supports a nursing workforce that meets the needs of the nation, especially its underserved and rural communities. This support includes financial assistance to individuals to help pay for nursing school or repay nursing student debt, and awarding grants to institutions that are training the next generation of nurses.

State-based nursing workforce centers could supply more precise and timely workforce projections for nurses, produce more accurate counts of the number of nurses currently employed, and more accurately identify the regions and demographics that require assistance. These resources could compare demographic and nurse count data with data on the local population to ensure the right distribution of nurses to serve local communities.

However, HRSA's existing statutory authority is limited to funding a nursing-focused research or technical assistance center related to our Public Health Service Act Title VII grant awards, which focus on various types of health professions education and training – not exclusively on nursing. Our existing authority does not support a broader nursing workforce center; instead, we would need a new authority to support expansive centers that focus on nurses or nurse education and training.

Question #105
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?

Response:
CDC recognizes the importance of preventing venous thromboembolisms (VTEs) or blood clots and of protecting Americans from the complications of blood clots when they do occur. From FY 2015 to FY 2020, CDC funded a national campaign to promote awareness of the signs, symptoms, and risk factors for VTE with special emphasis on high-risk conditions including pregnancy, surgery/hospitalizations, and cancer. The

campaign achieved over 800 million media impressions, an advertising value-added return on investment of up to 178 percent, and over 10,000 healthcare professionals registered for the accredited VTE e-learning course for providers. It remains a resource for families, caregivers, and healthcare professionals to obtain important information about blood clots and how to best act early to address them.

Through CDC's Chronic Disease Education and Awareness (CDEA) grant, CDC is funding the Board of Regent University of Oklahoma Health Science Center in FY 2023 and FY 2024 at $375,000/year to advance education, outreach, and public awareness of VTE and contribute to the knowledge base in VTE education, prevention, and management.

Question #106

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?

Response:

The Department of Health and Human Services, including NIH, is deeply committed to advancing research on menopause and using that knowledge to help improve the health and well-being of all women across the United States. Accordingly, menopause is a critical component of NIH's research portfolio. For example, NIH has been funding the long-running Study of Women's Health Across the Nation (SWAN), which has followed women from diverse backgrounds for nearly 30 years and played a key role in advancing our understanding of midlife women's health and menopause. NIH has also funded research on identifying and evaluating treatment and management options for menopause symptoms. In addition, researchers with SWAN and other NIH-funded programs have developed MyMenoplan, an online tool that helps people create a personalized plan for addressing their menopause symptoms.

NIH-funded researchers are building on these efforts to better understand the menopausal transition, underlying causes of symptoms, and opportunities for symptom management. NIH is also supporting research on how menopausal experiences influence health across women's middle and later life and how women from diverse racial and ethnic backgrounds can benefit from that scientific knowledge to live healthier lives — before, during, and after menopause.

In addition to ongoing NIH-funded research, more work is needed to help women and their health care providers navigate the menopausal transition and promote well-being through midlife and beyond. To help meet this need and as part of the White House Initiative on Women's Health Research, NIH is planning a Pathways to Prevention workshop in 2025 to identify research gaps in this important field.

Question #107

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?

Response:
We strongly support addressing workforce challenges throughout the health system, particularly those affecting underserved communities, which includes many people with HIV. The Department recognizes the importance of building the ID and bio-preparedness workforce to prepare our nation to respond to outbreaks, epidemics, and pandemics. As you know, Congress included this program in the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act), which was enacted at the end of 2022 as part of the Consolidated Appropriations Act, 2023. To date, the Bio-Preparedness Workforce Pilot Program has not received appropriations. Should Congress appropriate funds, this program would aid in ID workforce expansion, recruitment, and retention efforts and increase access to care.

Question #108
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?

Response:
HHS remains steadfast in its commitment to protecting access to reproductive health care, including contraception and family planning services. Under the Affordable Care Act, most group health plans and group and individual health insurance coverage are required to cover contraception without cost sharing. On June 27, 2022, HHS, the Department of Labor, and the Department of the Treasury (the Departments) sent a letter[8] to group health plan sponsors and issuers reminding them of their obligations under the ACA to provide coverage for contraceptive services at no cost. This letter was sent in response to complaints received regarding plans' failure to provide coverage of contraceptive services, without cost sharing, in a manner consistent with the standards set forth by the Departments.

In January of last year, the Biden-Harris Administration proposed a rule[9] to expand and strengthen access to this coverage so that all women who need or want birth control are able to obtain it. Additionally, in September 2023,

[8] https://www.cms.gov/files/document/letter-plans-and-issuers-access-contraceptive-coverage.pdf
[9] https://www.federalregister.gov/documents/2023/02/02/2023-01981/coverage-of-certain-preventive-services-under-the-affordable-care-act

the Administration issued a Request for Information to seek public input on how best to ensure coverage and access to over-the-counter preventive services, including the benefits of requiring most health insurance plans to cover these services at no cost and without a prescription by a health care provider. This includes access to over-the-counter contraceptive products, including the first daily oral contraceptive approved by the Food and Drug Administration in July 2023 for use in the United States without a prescription.

Additionally, the Center for Medicaid and CHIP Services (CMCS) has established the Maternal and Infant Health Initiative. Under this initiative, CMCS promotes the use of effective methods of contraception in order to improve health outcomes for both women and children. By ensuring individuals have access to the contraceptive method of their choice, and the support necessary to use their chosen method effectively, states can support not only the health of women and their children, but also reduce the number of unintended pregnancies.

Additionally, health centers play an important role in family planning, providing family planning services to patients, promoting access to affordable high-quality contraception, and supporting access to culturally and linguistically appropriate care, including by developing and disseminating materials on family planning services available. Investing in this program is essential to maintaining primary care services in underserved and rural communities.

Question #109

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?

Response:

As you may recall, the President's FY 2024 Budget request put forward a plan for a pathway to double the Health Center Program funding. The FY 2025 President's Budget builds on this request, including the second annual installment of funding, which targets expanding services across health centers, including high quality, patient-centered required primary and additional health services, patient support and enabling services like transportation and case managers, and supporting health centers in better serving people experiencing homelessness. It also invests in workforce training at health centers. The FY 2025 President's Budget requests $8.2 billion for the Health Center program, to include $6.3 billion in mandatory funding. In FY 2025, at the President's Budget Level, the Health Center Program plans to provide primary health care services to 37.4 million patients.

> The health center model of care has been shown to reduce the use of costlier providers of care, such as emergency departments and hospitals. Approximately 90% of health center patients are individuals or families living at or below 200% of the Federal Poverty Guidelines and approximately 63% of health center patients are racial/ethnic minorities. Health centers also serve over 1 million agricultural workers, about 1.3 million individuals experiencing homelessness, and approximately 5.7 million individuals living in or near public housing.

The Honorable Kim Schrier

Question #110

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?

Response:

CMS has set a goal of having 100% of Traditional Medicare beneficiaries and the vast majority of Medicaid beneficiaries in accountable care relationships by 2030. A key way CMS supports the sustainability of value-based payment models is through multi-payer alignment, starting with Medicaid, and scaling successful models and features. The CMS Innovation Center's vision for broad health system transformation is ambitious and requires collaboration with, and actions by, a wide range of stakeholders. In particular, alignment with private payers, purchasers, and states is needed to increase the number of providers participating in value-based payment models and to make their participation sustainable across payers. The CMS Innovation Center continues to work towards multi-payer alignment on key dimensions of value-based payment by developing models that engage more than one payer, aligning quality metrics across CMS programs and payers, and supporting data exchange to improve care.

In addition, every CMS Innovation Center model test – including those that have not met the statutory criteria for expansion – have resulted in important learnings and investments in the health care system that have helped clinicians move towards value-based care. Care delivery trends and changes associated with the model tests extend beyond the CMS Innovation Center model tests themselves, with elements of model tests being incorporated into how clinicians furnish services even after the model test ends, because the clinicians have found the elements lead to improved quality and reduced costs. Several model tests have informed successor generations of model tests, which are designed to incorporate the lessons learned from initial model tests with the goal of producing further improvements in care delivery and reductions in spending. Participants in models that are concluding are often able to join another model, such as a successor model, to continue value-based care.

Question #111

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?

Response:

Thank you for your support of the ACO REACH model. For 2024, the ACO REACH Model has 122 ACOs with 173,004 health care providers and organizations providing care to an estimated 2.6 million

people with Original Medicare. Beneficiaries whose doctor chooses to be a part of an ACO are notified by mail, electronically, or when the beneficiary checks in to see the doctor and a notification is posted in the doctor's office.

As an ACO is part of Original Medicare, not a separate plan, ACOs may not limit which doctor a beneficiary can see, require preapproval to see a doctor, or use other means of restricting care. Beneficiaries with Original Medicare retain all of their rights, coverage, and benefits, including the freedom to see any Medicare provider. ACOs are not permitted to undertake communication or marketing activities directed at influencing beneficiary insurance coverage choices. CMS reviews marketing materials and websites to ensure information on the ACO REACH model is accurate and beneficiaries understand their rights and freedom of choice.

CMS expects that beneficiaries whose primary care provider is part of a REACH ACO will see and feel improvements in the quality of health care they are getting because of the ACO REACH model. For example, beneficiaries may receive increased access to telehealth, home visits after leaving the hospital, cost sharing support to help with co-pays, or other enhanced services and incentives.

Question #112

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?

Response:

Since announcing the Pediatric Specialty (PS) Loan Repayment Program (LRP)'s first application cycle in June 2023, HRSA has engaged with various pediatric workforce stakeholder groups with expertise in pediatric specialty care, particularly as we analyze the PS LRP eligibility requirements and applicant criteria. HRSA also closely monitored the program's inaugural application and award cycle in Fiscal Year (FY) 2023, and we continually collect programmatic data and welcome a collaborative exchange of feedback with stakeholders to evaluate the efficacy of the PS LRP in meeting its established goals and purpose.

The FY 2025 Budget Request for the PS LRP of $10 million is equal to the FY 2024 Enacted Level. The request will support approximately 100 new awards to bolster the pediatric health care workforce by providing loan repayment to pediatric medical specialists, pediatric surgical specialists, and child and adolescent mental and behavioral health care providers. In FY 2025, the PS LRP will support an expanded eligible pool of pediatric subspecialties and broader list of eligible facilities to serve populations located in a Health Professional Shortage Area, a Medically Underserved Area, or to serve a Medically Underserved Population. HRSA will continue to adhere to the PS LRP's statutory authority to ensure that future cycles of the program support pediatric specialty providers, while prioritizing funding for these providers in financial need and considering factors including high amounts of provider educational debt.

The Honorable Lori Trahan

Question #113
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?

Response:
Section 1860D-2(b)(2)(E)(v)(I) of the Act requires CMS to provide educational materials to Part D enrollees on the option to participate in the Medicare Prescription Payment Plan. To support broad education of all Part D enrollees on the availability of the program, CMS will develop new Part D educational resources and will update existing Part D resources that provide individuals with information on Medicare Part D.

CMS plans to provide an educational product for Part D enrollees on the Medicare.gov website and through other communication channels. Additionally, Part D sponsors are encouraged to use this educational product to: provide additional information to pharmacies that pharmacists can furnish to Part D enrollees identified as likely to benefit at the POS alongside the "Medicare Prescription Payment Plan Likely to Benefit Notice"; communicate with contracted providers and other interested parties; and describe the Medicare Prescription Payment Plan in other Part D enrollee education, communications, and marketing materials.

CMS will also make appropriate modifications to CMS-provided Medicare Part D documents, web content, and tools to ensure that individuals have the resources needed to learn about the availability of the program before the plan year begins and understand how the program may benefit them based on their needs. Resources that CMS may modify include the Medicare & You Handbook, Medicare.gov, and the Medicare Plan Finder, among others.

CMS will work with interested parties to ensure that Part D sponsors, pharmacies, providers, and beneficiary advocates—including State Health Insurance Assistance Program (SHIP) counselors—have sufficient support and materials needed to effectively communicate the availability and nuances of this program to individuals.

Question #114
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?

Response:
CMS undertook substantial outreach with a variety of stakeholders and performed in-depth research to assess whether a real-time/point-of-sale (POS) election option would be feasible for 2025. CMS identified a number of policy and operational barriers that would bar real-time/POS election requirements for 2025 and determined that real-time/POS election would not be operationally or technologically feasible for 2025. The restricted lead-up time to the statutory implementation date of January 1, 2025, was a significant limiting factor for successful launch of a required real-time/POS election option. This was largely due to the need for several different parties, including the Part D sponsor, pharmacy benefit manager (PBM), pharmacy (including different pharmacy types, such as

specialty pharmacies, which have different processes in place), to each make operational adjustments and build up the necessary capabilities to be able to process real-time/POS elections.

While CMS will not require real-time/POS election in 2025, CMS does, however, encourage Part D sponsors to offer a real-time (or near-real-time) election mechanism to their Part D enrollees if they are able. We reiterate our commitment to exploring real-time/POS election mechanisms that can be implemented for future years.

Question #115

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.

Response:

As detailed by the White House National Strategy of Hunger, Nutrition, and Health, the Administration set a goal of ending hunger and increasing healthy eating and physical activity by 2030 so fewer Americans experience diet-related diseases, while reducing related health disparities. Integrating nutrition and health can optimize Americans' well-being and reduce healthcare costs. Currently, only a limited number of Medicare beneficiaries are seeking nutrition and obesity counseling services.

Currently, Medicare covers an array of services that aim to address obesity. For example, obesity screenings, intensive behavioral therapy for obesity for the prevention or early detection of illness or disability, bariatric surgical procedures, and diabetes screenings and participation in a diabetes prevention program are covered under Medicare in certain cases. The statutory definition of a covered Part D drug at section 1860D-2(e)(2) of the Social Security Act excludes certain drugs and medical uses—specifically, those that may be excluded by Medicaid under section 1927(d)(2) of the Act. This includes "agents when used for anorexia, weight loss, or weight gain." Since the beginning of the Part D program in 2006, all drugs when used for weight loss have been excluded from basic coverage. However, anti-obesity medications that receive FDA approval for an additional medically accepted indication, as defined by section 1927(k)(6) of the Act, can be considered a Part D drug for that specific use.

Medicaid and the Children's Health Insurance Program (CHIP) can play a role in reducing the rate of obesity in the United States by improving access to health care services that support healthy weight. For eligible children enrolled in Medicaid, the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit covers medically necessary services described in section 1905(a) of the Social Security Act whether or not a state plan includes them in the state plan, including obesity-related services described in section 1905(a). For adults enrolled in Medicaid, the states have greater flexibility regarding which services to provide, with most states covering at least one obesity treatment.

Question #116

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?

Response:

BARDA agrees that supporting the advanced development of these new technologies are pivotal to preparedness efforts and a rapid response to new outbreaks. BARDA has several lines of effort that support the advanced development of new medical countermeasures that incorporate these new technologies that span therapeutics, diagnostics, vaccines, and medical devices. BARDA launched a phase 2 platform clinical trial investigating treatments for acute respiratory distress syndrome (ARDS) regardless of etiology. The drugs being tested are host-directed, i.e., they mitigate the host response to infectious disease and other insults. If the drugs tested are proven efficacious, they may work against all causes of ARDS including ARDS caused by pandemic influenza, COVID-19, bacterial pneumonia, and even inhaled chemical threats. Other examples include the use of next generation sequencing-based diagnostics that, if successful, could potentially detect any pathogen from any sample type. In addition, BARDA is incorporating proven vaccine platforms into new development efforts to demonstrate the versatility of these platforms to rapidly respond to new outbreaks, as well as investing in new and adaptable therapeutics platforms through its Flexible and Strategic Therapeutics (FASTx) program, that can be utilized in a rapid response capability to enable more effective responses to viral outbreaks. The COVID supplemental funding provided to Efforts under Project NextGen have enabled several new starts in this area, to complement our ongoing work with Pandemic Influenza (PI) and Advanced Research and Development (ARD) annual appropriation funding. As supplemental funding runs out, progress will slow, but BARDA remains committed to working with our partners to continue to support these technologies.