Questions for the Record for
XAVIER BECERRA

Committee on Ways and Means Hearing:
"Hearing with Health and Human Services Secretary Becerra"
Wednesday, March 20, 2024
2:00 PM

Rep. Jodey Arrington (R-TX)

Question #1

The fiscal year 2025 President's Budget proposes new statutory authority to collect more comprehensive data on TANF and maintenance-of-effort expenditures to improve monitoring of TANF's non-assistance expenditures and activities, including developing an improper payment rate for TANF. Just a few weeks ago I introduced the Eliminate Fraud and Improper Payments in TANF Act (H.R. 7431), which would require HHS to collect and report on improper payments. Do you believe this is a necessary reform to protect TANF dollars against waste fraud and abuse? Are you committed to working with Congress to pass this legislation?

Response:
HHS is not commenting on specific proposed legislation at this time. We note that the FY 2025 President's Budget proposes the authority to collect additional data in TANF in order to improve monitoring on TANF expenditures and activities, including to develop an improper payment rate for TANF.

Rep. Earl Blumenauer (D-OR)

Question #2

On March 9, 2024, the Wall Street Journal reported that HHS officials have in recent weeks "asked the Justice Department's Office of Legal Counsel to weigh in on legal issues related to moving [marijuana] to a less-restrictive status." Regarding this question to the Office of Legal Counsel:

- How does this outreach conform or differ from standard practice in scheduling reviews under the Controlled Substances Act?
- What concerns prompted HHS' communication with the Office of Legal Counsel regarding the scheduling of marijuana?
- What legal authority can HHS leverage to uphold its recommendation to reschedule marijuana to Schedule III in the event that DEA proposes scheduling marijuana higher than Schedule III?

Response:
The Department of Health and Human Services did not request that the Office of Legal Counsel conduct an analysis of legal issues related to rescheduling marijuana. As HHS has stated before, the Department concluded its independent review, guided by the evidence. The scheduling review documents reflect HHS' evaluation of the scientific and medical evidence and its scheduling recommendation to DOJ.

Rep. Vern Buchanan (R-FL)

Question #3

Mr. Secretary: I introduced the *Permanent Telehealth from Home Act* which would eliminate the originating site and geographic limitations for using telehealth. This will help patients continue to be able to receive care through telehealth regardless of their location.
Will you commit to working with me to ensure seniors can access providers via telehealth services regardless of their location?

Response:
HHS and CMS continually consider how to best ensure access to medically necessary items and services and make changes where appropriate and permissible under our statutory authority. We recognize the vital role that telehealth can play in the delivery of care, particularly among populations that are underserved. We implemented Section 4113 of the Consolidated Appropriations Act, 2023, which extended many telehealth flexibilities adopted during the public health emergency for COVID-19 through December 31, 2024. Additionally, through notice-and-comment rulemaking, CMS solicited public comment and implemented regulatory changes that have permanently expanded certain telehealth policies that are within the agency's authority to modify. Some changes to Medicare telehealth policy would require legislative action to amend the statute, and we look forward to our continued work with Congress on this crucial issue.

Question #4

Mr. Secretary*:* I'm concerned that we allocate less than 3% of health care spending toward prevention. What can we do in a bipartisan way to ensure prevention is at the top of your docket at HHS?

Response:
HHS is investing in communities to prevent the devastating effects of substance use, chronic health conditions, and injuries before they start. Access to primary care and behavioral health services improves long-term health outcomes by promoting prevention and early detection of potentially serious conditions. Even small out-of-pocket costs may deter consumers from seeking medical care, including behavioral health services. About half of U.S. adults say they or a family member delay care because of the cost. Additionally, CMS continues to promote the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) mandate for eligible youth Medicaid beneficiaries by issuing guidance to state Medicaid Directors to encourage maximum use of this benefit to support the screening, prevention, and management of substance use, mental illness, and chronic health conditions that often begin during childhood and adolescence.

The President's Fiscal Year 2025 Budget invests in prevention through several critical ways:

> The budget makes the Medicare Diabetes Prevention Program Benefit permanent, which includes under Medicare Part B an evidence-based set of services aimed to help prevent the onset of type 2 diabetes among Medicare beneficiaries with an indication of prediabetes.
>
> The budget also invests in prevention and early detection of behavioral health conditions through a

proposal to require Medicare to cover three behavioral health visits without cost-sharing, and a proposal which requires all private plans and issuers to cover three behavioral health visits and three primary care visits each year without charging a copayment, coinsurance, or deductible-related fee.

Investments in the Centers for Disease Control and Prevention, including investments in prevention-focused research, continue to build a sustainable and resilient public health system.

The budget proposes a new mandatory Pre-Exposure Prophylaxis (PrEP) Delivery Program to End the HIV Epidemic in the United States to provide PrEP and associated services at no cost to uninsured and underinsured individuals and expand the number of providers serving underserved communities. The budget also proposes to remove barriers to accessing PrEP under Medicaid.

The budget proposes a national Hepatitis C Elimination Program to prevent further spread of hepatitis C by significantly expanding screening, testing, treatment, prevention, and monitoring of hepatitis C infections, with a specific focus on populations with high infection levels.

The budget proposes to expand the Vaccines for Children (VFC) program to include all children under age 19 enrolled in CHIP and covers the vaccine administration fee for all VFC-eligible uninsured children.

Question #5

Mr. Secretary: In December, NIST issued a draft framework to provide guidance to federal agencies on what to assess when considering whether to exercise march-in authority in the Bayh-Dole Act.

Former Director of the NIH Harold Varmus concluded that the pricing clause, which this administration now references, drove industry away from beneficial scientific collaborations with government scientists without providing any benefit to the public.

Aren't you concerned that this new unworkable approach to an already incredibly successful law will send us back to a less efficient time in public-private partnerships?

Are you not concerned the administration's recent draft framework will discourage public sector collaboration with our nation's universities?

Response:

The Bayh-Dole Act was designed to promote the commercialization of research results, maximize the potential for federally funded technologies to become products, and serve the broader interest of the American public.

HHS is fully committed to implementing the law to uphold these aims and support the innovation needed to deliver new safe and effective drugs to patients. To that end, HHS has continued to engage with the Department of Commerce through an interagency working group on non-binding guidance for agencies considering the use of march-in rights.

Question #6

Mr. Secretary: U.S. companies are not competing with Chinese companies; they are competing with the Chinese Government. Overall factors such as predatory economics, lower labor costs, state sponsored capitalization and subsidies, lack of automation, and a completely different state of play for foreign inspections versus domestic inspections have allowed China to dominate and domestic manufacturing to suffer as a result.

What can the U.S., and specifically HHS, do to create a competitive marketplace to reshore essential pharmaceutical manufacturing and incentivize new production domestically?

Response: During the initial response to the COVID-19 pandemic in 2020, the U.S. medical supply chain struggled due to reliance on foreign manufacturing and production of supplies and products. Using COVID-19 supplemental appropriations, ASPR invested over $17 billion to expand the country's domestic manufacturing infrastructure, especially for personal protective equipment (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. Annual funding is required to: (1) 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 investments; and (4) to ensure the overall portfolio of investments is balanced, productive, and sustained. ASPR is appreciative of the $10 million included in the FY24 appropriation bill to continue this mission.

ASPR has made a number of awards to on-shore pharmaceutical manufacturing. ASPR, through DoD, has awarded $45M to On-Demand Pharmaceuticals for continuous and distributed drug production of cisatracurium, midazolam, dexmedetomidine and propofol. ASPR, through DoD, has also awarded $30M to DEKA Research and Development Corporation for the distributed production of 0.9N saline and other supportive care fluids. ASPR has also awarded a contract to Phlow for $491.9M in 2020 to support domestic manufacturing of active pharmaceutical ingredients (API). This work will require continued support from Congress.

Question #7

Mr. Secretary: The Alzheimer's community has heard anecdotally that many infusion centers haven't begun to offer Leqembi because there is ongoing confusion around reimbursement.

What has CMS done or do they plan to do around education for infusion centers around administering Leqembi? What would that look like?

Response:
HHS shares the goal of developing effective treatments and cures for Alzheimer's disease and ensuring access to innovative life-saving therapies. When the FDA converted accelerated approval of lecanemab to traditional approval, broader Medicare coverage was available the same day. CMS understands the importance of ensuring providers have the tools and resources they need to accurately submit claims to Medicare, particularly when payment or billing policies are updated. That's why the CMS website offers a variety of educational materials on billing, coding, and payment policies, including a provider fact sheet.[1] Providers can also directly contact

[1] Available at: https://qualitynet.cms.gov/files/64a7151bd15911001c695b32?filename=Provider%20Factsheet%20Alzheimers%20Treatment.pdf

their Medicare Administrative Contractor (MAC) that processes Medicare claims.

Question #8

Mr. Secretary: BRG estimates that the Advance Notice would reduce MA payments by 1% and that plans would need to cut benefits by approximately $33 per member per month in order to offset the lower payments and the increased utilization and costs that plans are experiencing.

Do you have any comments on the BRG analysis?

Response:
CMS's release of the Calendar Year (CY) 2025 Advance Notice continues to build on our actions to keep the MA program strong while improving MA payment accuracy. Medicare Advantage payments from the government to MA plans are expected to increase by 3.7 percent on average from 2024 to 2025, as proposed. This is over a $16 billion increase in expected MA payments for the next year.[2] This expected increase includes consideration of various elements that impact MA payment, such as growth rates of underlying costs, 2024 Star Ratings for 2025 quality bonus payments, continued phase-in of risk adjustment model updates that were implemented in CY 2024, and increases to risk scores because of MA risk score trend, which can be driven by a number of factors including MA demographics and coding patterns. This increase represents the average expected payment update across plans, and thus, there will be variation among plans in terms of their plan-specific payment impacts, including plans that would see a larger or smaller impact year over year. As in past years, the projected change in payment can change between the Advance Notice and Rate Announcement, which is statutorily required to be published no later than April 1, 2024.

Question #9

Mr. Secretary: I wanted to gauge your thoughts on a promising and innovative program being run out of CMS, the acute Hospital-at-Home waiver. This program has great outcomes for patients, reduced readmissions, and better care coordination, but it is also shown to reduce labor costs and keep hospital beds available for the sickest patients that need them the most.

Do you see this waiver as an opportunity to generate savings for Medicare and beneficiaries?

Do you have thoughts on extending the program as it's temporary and potentially expanding it to more patients?

Response:
The Acute Hospital Care at Home (AHCAH) Initiative began in November 2020 as a way to provide certain services in a patient's home that would otherwise be provided to them as a hospital inpatient. This was one of the actions taken by CMS to treat individuals safely during the COVID-19 public health emergency. Under the initiative, the Secretary grants certain waivers and flexibilities to hospitals that submit an application and meet specified criteria. They also must agree to submit required data, which CMS is releasing publicly at https://www2.ccwdata.org/web/guest/data-dictionaries.

Section 4140 of the Consolidated Appropriations Act, 2023, extended this initiative through the end of 2024.

[2] Calendar Year (CY) 2025 Advance Notice Fact Sheet: https://www.cms.gov/newsroom/fact-sheets/2025-medicare-advantage-and-part-d-advance-notice-fact-sheet

This law also requires that additional data be collected, and that a study be done to analyze certain factors, including: (1) the criteria used by hospitals to determine which individuals may be furnished services at home; (2) quality of care furnished to individuals with similar conditions and characteristics in the inpatient setting and through the Acute Hospital Care at Home initiative, including health outcomes and patient experience of care; (3) costs of care; (4) quantity, mix and intensity of services; and (5) socioeconomic information on beneficiaries treated. The study is required to be completed by September 30, 2024, and will provide additional information about services furnished, best practices, and outcomes. Continuation of the AHCAH initiative beyond December 31, 2024, is contingent on further Congressional action.

Rep. Mike Carey (R-OH)

Question #10 a and b

Last November, the Work and Welfare Subcommittee and Oversight Subcommittee held a joint hearing on Strengthening the Child Support Enforcement Program for States and Tribes. At this hearing we investigated the need for Congress to pass legislation to allow states and tribes continued flexibility in administering the child support program due to a recent and sudden policy change by the Internal Revenue Service (IRS).

As you know, each state's Child Support Enforcement (CSE) program receives Federal Tax Information (FTI) for the purposes of collecting child support from non-custodial parents through the Federal Tax Refund Offset Program. This is a vital source of income for millions of families and children, and I know this firsthand as I was one of those children that received child support growing up. To service these families participating in the Federal Tax Refund Offset Program, many states rely on sharing FTI with third-party contractors.

In February, the IRS reversed course on a policy in place since at least 2004 that would result in strict limitations on states' ability to continue to use contractors to manage their CSE programs.

Question #10a

Specifically, the IRS provided a deadline of October 1, 2024, for states to cease using contractors to obtain child support collections obtained through the Federal Tax Refund Offset Program. Last month my colleague, Rep. LaHood asked Commissioner Werfel if this deadline has been pushed back and he was unable to provide an answer. Are you in agreement with the IRS that October is a reasonable deadline for states to implement new systems and hire hundreds of new employees?

Response:

Neither HHS nor IRS believe that October 2024 is a reasonable deadline for states to implement new systems and hire hundreds of new employees, nor are states required to do so.

The IRS's Superseding Security and Privacy Alert issued on June 9, 2023, instructed child support services agencies to develop plans for mitigating contractor access to federal tax information beyond the limits of section 6103 of the Internal Revenue Code. The Superseding Alert directs that the agencies submit their mitigation

plans to the IRS by October 1, 2024. The Superseding Alert envisions that the IRS will collaborate with the agencies to assist them in developing their plans. Importantly, the Superseding Alert does not mention any consequences for failing to submit a mitigation plan and neither requires states to cease using contractors nor sets forth any deadline for doing so. In sum, all that the Superseding Alert (the IRS) requires is the creation and submission of a mitigation plan on or before October 1, 2024. Beginning on that date, the Superseding Alert promises that the IRS will review the submitted mitigation plans, consider each plan's compliance with section 6103 of the Internal Revenue Code, and work in partnership with child support services agencies on the next steps and implementation of the plans.

Question #10b

According to your budget, the Administration's proposal to implement a statutory solution to the above problem would save $1.2 billion over 10 years. How was that estimate generated and do you have the information you need from states to understand cost implications?

Response:
To comply with the requirements regarding contractor access to Federal Tax Information (FTI) set forth in the Internal Revenue Code, many child support agencies will be forced to replace their contractors who have access to FTI with state or local employees. This will require a massive overhaul of program operations and systems over a significant period with a tremendous impact on collections and the cost effectiveness of the agencies' programs. ACF estimates child support funding to states will increase starting in FY 2025 as states make changes to operations and systems. These cost increases are included in the Child Support baseline.
The legislative update in the child support proposal will allow contractor and tribal access to FTI and will result in savings as child support agencies will not have to make changes to operations and systems.

Savings as a result of the legislative update are estimated to be $1.2 billion over ten years:

- Savings in funding provided to state child support agencies due to not having to overhaul program operations and systems to meet FTI requirements in the Internal Revenue Code are estimated to be $1.181 billion over ten years.
- Savings from not replacing contract staff assigned to state disbursement units with state staff and other systems changes to restrict FTI access are estimated to be $436 million over ten years.
- Savings from not hiring and training new state staff are estimated to be $744 million over ten years.
- Additionally, ACF estimates increased collections from tribal cases due to access to FTI will result in TANF and SSI costs avoided to the government of approximately $2.5 million over ten years.

At a high level, ACF has preliminary information from states. However, only a handful provided a thorough cost analysis, so these estimates could vary when states finalize their transition plans.

Question #11

Last year when you came before the committee, I mentioned my concerns about Medicare not reimbursing Emergency Medical Services (EMS) providers adequately for the care they provide when they don't need to transport a Medicare beneficiary to the hospital. I recently released draft legislation to require the Center for Medicare and Medicaid Innovation to launch a model to reimburse EMS providers for treatment in place. Are you willing to commit to working with me and my staff on this legislation to work towards policy that

reimburses our first responders and emergency medical personnel properly for the care they provide, and provide technical assistance for my legislation?

Response:
Currently, Medicare primarily pays for unscheduled, emergency ground ambulance services when beneficiaries are transported to a hospital emergency department (ED), creating an incentive to transport all beneficiaries to the hospital even when an alternative treatment option may be more appropriate. The CMS Innovation Center's Emergency Triage, Treat, and Transport (ET3) was a voluntary payment model that tested two new ambulance payments, while continuing to pay for emergency transport for a Medicare beneficiary to a hospital ED or other destination covered under current regulations:

- payment for treatment in place with a qualified health care practitioner, either on-the-scene or connected using telehealth; and
- payment for unscheduled, emergency transport of Medicare beneficiaries to alternative destinations (such as 24-hour care clinics) other than destinations covered under current regulations (such as hospital EDs).

In 2023, after careful review, CMS made the decision to end the ET3 Model ahead of schedule. The lower-than-expected model participation levels contributed to a low number of interventions and, as a result, CMS was not able to adequately evaluate the model. In addition, administrative costs associated with maintaining the model exceed any potential cost savings. All Innovation Center models, including the ET3 Model, provide valuable impacts and lessons learned and contribute meaningfully toward health system transformation. The CMS Innovation Center continues to explore potential opportunities to support the emergency medical services community.

CMS appreciates the importance of this issue and would be happy to provide technical assistance on any draft legislation.

Question #12
In October, my office requested technical assistance for legislation I introduced with Representative Chu, the Connecting Caregivers to Medicare Act. This legislation aims to improve coordination between caregivers and Medicare beneficiaries and make it easier for caregivers to access pertinent health information. Can you commit to working with Representative Chu and I on this important bipartisan legislation and provide my staff with the proper technical assistance?

Response:
Caregivers can have an important role in care coordination for Medicare beneficiaries. CMS works to build bridges with caregiver organizations, both federal and non-federal, to better serve Americans in need with national and local resources to assist in their caregiving efforts. CMS has many requests for technical assistance on draft legislation and is working to review the legislation as soon as it can.

Question #13
Lastly, in your budgeting process I'm sure you're aware that States have been stockpiling Temporary Assistance for Needy Families (TANF) program dollars instead of getting these dollars into the hands of the families who need them most. In the most recent report, States with the largest buildup of TANF funds in 2021 were New York ($1.2 billion), Tennessee

($798 million), Pennsylvania ($669 million), Hawaii ($378 million), Texas ($363 million), and Oklahoma ($333 million).

To address this issue, last month I introduced the Improve Transparency and Stability for Families and Children Act to expedite the disbursement of payments to families in need through TANF. This legislation requires states to obligate and distribute the federal funding they receive for TANF within three years.

Do you support reforming TANF in this way to ensure these valuable dollars get into the hands of the families who need them most in a timely manner? Are you willing to work with me to reform TANF and put these necessary financial guardrails in place?

Response:
The Department supports and provides technical assistance to Congress and has encouraged TANF agencies to spend down their unobligated balances to support vital benefits and services for families experiencing economic hardships. For example, see this Dear Colleague Letter from the ACF Acting Assistant Secretary encouraging states, territories, and tribes, especially those with unobligated balances, to use federal TANF funds strategically to reduce family poverty, alleviate economic crises, and respond to emergency needs in communities across the nation.

Rep. Danny Davis (D-IL)

Question #14
I thank you and your agency for its leadership in implementing the Family First Prevention Services law according to Congressional intent. Successful implementation will be key to keeping children safe by strengthening families and reducing the number of children entering foster care. Although most eligible states, territories, and tribes have submitted prevention plans for implementation, some still have not.

Can you please share what steps HHS is taking to engage with all jurisdictions and to support those states, territories, and tribes who have yet to submit prevention plans so they can implement a Title IV-E Prevention plan and access these funds so more families can access prevention services and avoid unnecessary placement in foster care?

Response:
Although it is an optional program, 47 jurisdictions (42 states, the District of Columbia and four Tribes) have been approved to operate the Title IV-E Prevention Program. Five additional jurisdictions have submitted plans to operate the program and are working toward approval. The Administration for Children and Families' Children's Bureau (CB) is working closely with those jurisdictions to modify the plans as necessary to comply with the statutory requirements for operation of the program.
Twelve jurisdictions (four States, the United States Virgin Islands, and seven Tribes) have not yet submitted plans for operation of the program. The CB has been in close contact with these jurisdictions to offer support in developing and submitting plans for program operations.

Jurisdictions' rationales for not submitting plans vary. A couple jurisdictions have determined the program is not a good fit and have no intention of submitting. Others are taking a deliberate approach to analyzing and

evaluating their capacity to operate the program to determine if it is a good fit. In general, the Tribes have pointed to resource constraints as a barrier to taking up this option.

The President's FY 2025 budget includes several proposals to increase resources for Tribes to help facilitate their access to the Title IV-E Prevention Program and other programs that can fund prevention services. To increase resources for Tribes, the budget proposes to consolidate tribal mandatory and discretionary Title IV-B Child Welfare Services and Promoting Safe and Stable Families funding and tribal mandatory and discretionary John H. Chafee Program for Successful Transition to Adulthood and the Education and Training Voucher funding into a new single uncapped mandatory grant, while maintaining the existing option for Tribes to directly operate a Title IV-E program. A streamlined application process would be accessible to all Tribes with no minimum qualification amount. Participating Tribes would realize a significant increase in funding over current allotments.

To facilitate access to the Title IV-E Prevention Program, the budget proposes to:

- allow for increased tribal and cultural adaptations of approved prevention services programs; and
- allows Tribes that participate in the Title IV-B, subpart 1 Child Welfare Services program, but do not currently participate in the Title IV-E foster care and adoption assistance programs, to submit a plan to directly operate the Title IV-E Prevention Services program.

Rep. Randy Feenstra (R-IA)

Question #15

Does HHS know the number of unaccompanied children that come into the long-term care of the state when a sponsor family is not able to be located and what those long-term placements require of state child welfare agencies?

Response:

The Office of the Refugee Resettlement's (ORR) Unaccompanied Children (UC) Bureau operates separately from the domestic foster care system administered by state child welfare systems and is not funded at the state level. While ORR requires appropriate state licensure of long-term home care facilities, ORR "foster" placements are not the same as state foster care placements. Children in long term home care facilities remain in ORR care and custody and are not served by the state's foster care system but by ORR grantees. On March 20, 2024, there were 57 long-term home care (LTHC) providers in the ORR network and 449 unaccompanied children placed in ORR's LTHC.

Under the Homeland Security Act of 2002 (6 U.S.C. 279) and the Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA) (8 U.S.C. 1232), ORR is responsible for the care and custody of unaccompanied children in federal custody by reason of their immigration status. Any federal department or agency that has custody of an unaccompanied child is required to transfer custody of such child to HHS within 72 hours absent exceptional circumstances. Typically, ORR receives referrals of unaccompanied children from the Department of Homeland Security (DHS) or another federal entity. ORR has legal custody of such children until they are discharged, typically as a release to a vetted sponsor. Further, ORR's recently published UC Program Foundational Rule establishes minimum standards for specific services for unaccompanied children under ORR-funded programs.

ORR-funded UC Bureau care providers facilitate licensure of the individual foster homes, as well as their own agency. The UC Bureau care provider is also responsible for recruiting, assessing, selecting, training, monitoring, and retaining foster parents and foster care sites.

UC Bureau foster parents are licensed by the state as applicable and, as such, adhere to standards of care as outlined by the state-licensed child placement agency, state licensing regulations, and any ORR UC Bureau policies related to foster care. UC Bureau foster care providers must comply with all applicable state child welfare laws and regulations and all state and local building, fire, health, and safety codes. State licensing agencies that allow for ORR care providers to receive licenses conduct regular monitoring and are responsible for citing, suspending, or delicensing foster homes. These States establish their own licensing requirements and monitoring activities, including the frequency of monitoring. The UC Bureau also monitors all ORR care providers, including ORR foster care providers, through routine and monitoring site visits and desk monitoring. Please see section 410.1303 of title 45, Code of Federal Regulations, and UC Bureau Policy Guide Section 5.5 for more information on ORR monitoring and compliance.

Question #16

Has there been any recent updates to the 2018 report from HHS as to the connection between fentanyl overdoses and foster care entry rates?

Response:

In 2018 the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) published a study on "Substance Use, the Opioid Epidemic and the Child Welfare System," which documented how the opioid crisis at the time was contributing to increases in child welfare and foster care caseloads, along with other ways the crisis was affecting child welfare systems. This specific ASPE study has not been updated. However, the role of the substance use crisis – particularly fentanyl and other opioids – on child welfare has been a substantial concern for HHS. The Department recognizes the detrimental effect that opioids have on families and the healthy development of children and continues to leverage existing programs as well as conducting research to assess the effectiveness of interventions. Example programs include:

- SAMHSA's State Pilot Program for Treatment for Pregnant and Postpartum Women, complements existing residential pregnant/postpartum women's treatment program by developing a continuum of family-centered care services in an outpatient setting.
- ACF's Regional Partnership Grant Program supports interagency collaborations and integration of programs, services, and activities designed to increase the well-being, improve the permanency, and enhance the safety of children who are in, or at risk of, out-of-home placements as the result of a parent or caregiver's substance use disorder.
- SAMHSA continues to fund the National Center on Substance Abuse and Child Welfare (NCSACW) as a national resource center providing information, expert consultation, and training and technical assistance to child welfare, dependency court and substance use disorder treatment professionals to improve the safety, permanency, well-being and recovery outcomes for children, parents and families.

HHS has conducted other studies on related topics since 2018. For example, ASPE studies include:

- Challenges in Providing Substance Use Disorder Treatment to Child Welfare Clients in Rural Communities. This study summarizes the challenges involved in serving rural child welfare-involved families with substance use issues.

- Treatment for Opioid Use Disorder May Reduce Substantiated Cases of Child Abuse and Neglect. This study finds that increased availability of buprenorphine treatment predicts reductions in certain types of child maltreatment caseloads in 25 states.
- Identifying and Supporting Human Services Participants with Substance Use Disorder. This project identified promising strategies to identify substance use disorder among human services participants and refer them to treatment and recovery supports, with a focus on child welfare services among other programs.

An example of ongoing research includes NIH's HEALthy Brain and Child Development Study, which is studying the long term effects of exposure to substances and other environmental, social and biological factors during pregnancy and beyond.

Question #17a

Can you explain the process the Office of Refugee Resettlement (ORR) uses to find placements and shelter for unaccompanied migrant children as it relates to the availability of state licensed homes and placements for children in foster care?

Response:

Under the Homeland Security Act of 2002 (6 U.S.C. 279) and the Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA) (8 U.S.C. 1232), ORR is responsible for the care and custody of unaccompanied children in federal custody by reason of their immigration status, from the time they are transferred to ORR from the Department of Homeland Security (DHS) or another federal entity until they are discharged from federal custody, typically as a release to a vetted sponsor.

While ORR works to identify and vet sponsors for unaccompanied children in its custody, ORR places these children into ORR-funded care provider facilities based on child welfare best practices to provide a safe environment in the least restrictive setting appropriate for the child's needs. The goal for ORR placements is to be short-term, and to release the unaccompanied child to their vetted sponsor without undue delay. ORR care providers consider multiple factors when making a placement determination, as described in section 410.1100 and the sections that follow of title 45, Code of Federal Regulations and the UC Bureau Policy Guide Section 1.2.1. While ORR requires appropriate state licensure of long-term home care facilities, ORR "foster" placements are not the same as state foster care placements. Children in long-term home care facilities remain in ORR care and custody, and are served not by the state's foster care system but by ORR grantees.

Consistent with child welfare best practices, ORR concurs with experts that the best place for a child is with a family in a community. Unaccompanied children who are initially assessed to not have a viable sponsor should be placed in ORR's grant-funded, community-based care programs, including foster care, to ensure they do not indeterminately remain in congregate care.

ORR's UC Bureau places unaccompanied children in long-term home care ("LTHC" also called "Long Term Foster Care") programs, as well as transitional home care ("THC" also called "Transitional Foster Care"). ORR's long-term home care serves unaccompanied children who have been in ORR custody for an extended period, which is typically four months or more, due to not having potential sponsorship options. According to UC Bureau Policy Guide Section 1.2.6, children are eligible for LTHC if they are expected to have a protracted stay of four months or more in ORR custody because they do not have a viable sponsor and are under the age of

17 and 6 months at the time of placement, unless waived by staff. Unaccompanied children in an ORR LTHC program reside in licensed foster or group homes, attend public school, and receive community-based services. Unaccompanied children in a LTHC program are eligible to remain in care until they age out at 18 or, if they meet the eligibility requirements as codified at 45 C.F.R. § 410.1208 for discharge into the Unaccompanied Refugee Minors (URM) Program. *See also* UC Bureau Policy Guide Section 1.4.3.,

ORR's transitional home care is a short-term foster care placement for unaccompanied children. This is an initial placement option for unaccompanied children who are under 13 years of age, sibling groups with at least one sibling under 13 years of age, pregnant/parenting teens, or unaccompanied children with other specific individualized needs so that children falling into these categories do not have to be placed in a congregate care setting. Unaccompanied children are placed with ORR-funded TFC group homes or families in the ORR network of care and attend school and receive most service components at the care provider site. Unaccompanied children in TFC often stay in ORR care for a brief length of time until they are released to a sponsor.

Question #17b

Does HHS report on the number of state-licensed foster care parents or congregate care providers who are caring for unaccompanied children? If not, can you commit to working with the Committee to provide that information?

Response:

As of March 20, 2024, there were 57 ORR LTHC providers and 80 ORR THC providers, and 154 congregate care providers within the ORR network. Children in LTHC and THC facilities are still in ORR custody, not state child welfare systems, and these foster care providers and state-licensed foster families are fully funded through ORR grants. ORR UC Bureau congregate provider facilities, providing 24/7 supervision of children, include shelter care, heightened supervision facilities, residential treatment centers, and therapeutic group homes.

Question #18a-c

Some news reports have found that HHS is looking for placements for migrant children by recruiting from limited foster homes available to provide care to the nearly 400,000 children and youth already in America's child welfare system. For example, Governor Pete Ricketts (R-NE), Governor Kristi Noem (R-SD), Governor Kim Reynolds (R-IA), and Governor Henry McMaster (R-SC) have all publicly declined the Administration's requests due to existing pressures on the foster care system.

a) To what extent is HHS relying on state child welfare agencies to find placements to accommodate migrant children?

b) Can you explain how the rates provided through ORR contracts for providers handling unaccompanied migrant children compare to state payment practices and foster care maintenance payments? Does ORR pay more for placement of migrant children?

c) Has HHS assessed the burden placed on state child welfare agencies in placing foster children due to ORR contracting practices, particularly in states with high numbers of migrant children?

Response (18a-c):
As previously noted, ORR programs operate separately from domestic foster care systems administered by state child welfare agencies. ORR does not rely on state child welfare agencies to find placements for unaccompanied children. While unaccompanied children may be placed at an ORR foster care program run by an ORR care provider that also operates a domestic foster care program, the state child welfare agency is not involved with facilitating the placement of unaccompanied children in an ORR-funded foster care program, nor is this arrangement paid for by the state.
The ORR UC Bureau care provider pays foster parents stipends based on their state licensing foster care rates. Each state's foster care rate is structured differently, and rates vary greatly from state to state. Some rates are determined by the age of the child, while other states separate the rate by level of the child's need (i.e., standard or therapeutic). ORR typically allows a foster care rate that aligns with the state's standard level; however, it may meet but not exceed the rate for the highest level of care in their state. Notably, the state child welfare agency pays domestic foster parents directly, while the UC Bureau provides funds to foster care provider organizations, which in turn provide payments to UC Bureau foster parents.

Rep. Brian Fitzpatrick (PA-R)

Question #19
Can you provide an update on HHS' development of best practices for medical providers as it relates to brain aneurysms? Have you begun work to develop such best practices? Can you please provide a timeline of related efforts, including when you expect these best practices to be final.

Response:
CDC is not developing, nor has it been asked to develop, best practices for medical providers on brain aneurysms.

Question #20
Moving to a different topic of concern, last year, I joined colleagues across committees to raise questions and concerns about CMS' recent effort to consider Medicare payment changes for skin substitute technologies used to treat complex wounds for people with diabetes and leg ulcers. Concerns were raised about how the proposed changes would diminish the technologies' value, would limit patient access to the technologies, and would inhibit continued manufacturer innovation of these products. The OIG provided recent recommendations to CMS to support fair payment for these technologies through the enforcement of ASP reporting, as required under current law.[1] What actions is CMS taking to require and enforce ASP reporting by all manufacturers of skin substitute technologies?

Response:
CMS recognizes there are numerous factors to consider when establishing a consistent payment approach for all skin substitute products. In the Calendar Year 2023 Physician Fee Schedule (PFS) proposed rule, CMS outlined several objectives related to refining skin substitute policies under Medicare. When considering potential changes to policies involving skin substitutes, we noted that we believe it would be appropriate to take a phased approach over multiple rulemaking cycles to examine how we could appropriately incorporate skin substitutes as supplies under the PFS ratesetting methodology with opportunities for stakeholder feedback .CMS solicited and received comments in

the CY 2023 PFS proposed rule from interested parties to help us consider an approach to pricing these products as supplies, and we summarized and responded to these comments in the CY 2023 PFS final rule. Additionally, on January 18, 2023, CMS held the virtual Skin Substitutes Town Hall. During the Town Hall, CMS requested feedback from the public on specific questions related to changes in payment and terminology of skin substitute products under the PFS.
The Consolidated Appropriations Act, 2021 required manufacturers to report ASP information for items, services, supplies and products payable under the Medicare Part B Program to CMS regardless of whether they have a Medicaid drug rebate agreement. All manufacturers were required to report first quarter 2022 ASP data to CMS no later than April 30, 2022. In November 2022, CMS sent drug manufacturers and repackagers guidance reminding them of their obligations to report ASP data to CMS. This includes reviewing to ensure that all products are properly reported. The notice also outlined enforcement mechanisms available to CMS. In January 2024, CMS published a fact sheet on the requirement that manufacturers submit ASP data for skin substitutes. The fact sheet discusses a few nuances to submitting quarterly skin substitute information, including using an Alternate ID and submitting verifiable product data.

Question #21

The third area of interest relates to nonopioid alternatives. According to the Department of Health and Human Services Office of the Inspector General, 50,400 Medicare Part D beneficiaries experienced an opioid overdose in 2021.[2] When it comes to treating acute pain with nonopioid alternatives, what direction are you giving as Secretary to HHS agencies to ensure that patients will have access and incentives to move to alternative nonopioid medicines once approved by the FDA?

Has HHS analyzed factors that might steer patients towards lower-risk acute pain management options, such as nonopioid alternatives, and the potential effects of successful steering along these lines? Do you believe that cost sharing requirements could be a disincentive and even a burden for patients who may benefit from nonopioid alternatives?

Response:

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, an opioid antagonist that rapidly reverses an opioid overdose, through Medicare from 2021 to 2022 and found that indicators of misuse and diversion of prescription opioids in Part D continued to decline. CMS also recognizes there is more work to do in increasing access to 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 for an episode of care 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 cover 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 section 423.153 of title 42, Code of Federal Regulations. 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 #22

Finally, the last topic of concern I have is related to foreign research organizations. Currently, foreign research organizations that receive annual funding totaling less than $750,000 are exempt from NIH audits of their records for that year.[3] Ninety percent of overseas grants awarded in the last five fiscal years fall within this category. Although NIH could request that these awardees make their grant-related records available for review or audit, it's unclear whether or how often it does so. Given that foreign funded animal laboratories don't have to prove they abide by the basic requirements of U.S. laboratories, and there have been a number of paper retractions for fraudulent data from animal experiments, how does HHS work with NIH to ensure that animals aren't neglected or abused? Is there a way to verify the information submitted by foreign organizations that apply for grants before the disbursement of funds? How do you verify that grantees' progress reports submitted by foreign organizations are true and accurate?

Response:
Before an award is made, NIH rigorously and thoroughly reviews and verifies the information NIH applicants provide. In general, applications for research grant support from foreign organizations are treated as if they were applications from domestic organizations.

The peer review of applications from foreign institutions is the same as that for applications from U.S. institutions. Applications submitted to NIH are evaluated for scientific and technical merit through the NIH peer review system. Applications from foreign applicants are also assessed to determine whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources.

NIH may ask the applicant to submit additional information to ensure NIH can fully assess any scientific, budgetary, or commitment overlap before making a funding decision. As required, NIH uses the Foreign Award and Component Tracking System (FACTS) to process requests for foreign collaborations State Department clearance. State Department reviews for potential foreign policy implications and to flag potential issues with sub-award recipients and/or concerns that may affect the ability of the proposed study to be completed.

When recipients draw down grant funds from the HHS Payment Management System, they accept the terms and conditions of the award. Recipients report on their progress and compliance with all terms when submitting the annual Research Performance Progress Report (RPPR). They also verify the accuracy and validity of all administrative, fiscal, and scientific information in the progress report. NIH program and grants management staff carefully and thoroughly review progress reports as part of their standard grant oversight procedures. If challenges within the project are identified, NIH staff work closely with the recipient institution to identify and implement appropriate remedies.

Oversight of Animal Welfare

NIH takes very seriously the humane care and use of laboratory animals used in NIH-funded research. All animals used in NIH-funded research are protected by laws, regulations, and policies to ensure the smallest possible number of subjects and the greatest commitment to their welfare.

Institutions receiving funds from the Public Health Service (PHS) must conduct research involving live vertebrate animals in accordance with the PHS Policy on the Humane Care and Use of Laboratory Animals (PHS Policy). Institutions in foreign countries must comply with the PHS Policy or provide evidence to the PHS that acceptable standards for the humane care and use of the animals in PHS-conducted or supported activities will be met. The PHS Policy requires all institutions to comply, as applicable, with the Animal Welfare Act and other Federal statutes and regulations relating to animals. Compliance with this Policy is a collaborative effort between NIH, HHS and other federal agencies, scientific investigators, and research institutions.

The NIH Office of Laboratory Animal Welfare (OLAW) provides oversight of compliance with the PHS Policy for NIH supported research involving live, vertebrate animals. The Policy requires that institutions in foreign countries that conduct animal activities onsite have an approved foreign animal welfare assurance on file with OLAW in order to receive PHS support for activities involving animals. The Foreign Assurance documents that

the foreign institution agrees to follow the International Guiding Principles for Biomedical Research Involving Animals and comply with all laws, regulations, and policies listed in the Assurance regarding the humane care and use of laboratory animals in the country of origin.

All applicant organizations must submit a Vertebrate Animals Section (VAS) in grant applications. This section:

- Describes all proposed animal procedures;
- Justifies that the species are appropriate;
- Explains why the research goals cannot be accomplished using an alternative model;
- Describes minimization of discomfort, distress, pain, and injury; and
- Addresses euthanasia.

OLAW reviews the VAS to ensure that all required information is present and to assess that the proposed animal activities have been planned with appropriate considerations for humane animal care and use. OLAW conducts VAS reviews for all new assurances. Since the end of 2021, OLAW also performs VAS review as part of the Foreign Assurance renewal process.

OLAW investigates allegations concerning animal welfare and appropriate animal care in NIH-funded studies. NIH-funded institutions must report promptly to OLAW any violation of the PHS Policy. OLAW considers these reports and requires the institution to make appropriate corrections and to prevent further violations.

When the recipient is a domestic institution and performance sites are foreign (i.e., domestic grant with a foreign component), the Institutional Animal Care and Use Committee (IACUC) approval is required. Accordingly, the recipient remains responsible for animal activities conducted at the foreign site and must provide verification of IACUC approval. When the award recipient is a foreign institution with animal work being conducted in their animal facility or at another foreign institution, the institution(s) are subject to foreign oversight requirements, which have been strengthened for greater oversight as discussed below.

NIH is taking several steps in response to a 2023 GAO report on NIH oversight of research with animals it funds in foreign facilities. Starting in the spring of 2024, OLAW expects to:

- Initiate virtual site visits for a subset of foreign facilities performing NIH-funded animal research.
- Confirm assessment and other related documentation from appropriate independent oversight entities (e.g., AAALAC International accreditation and the Canadian Council on Animal Care certification), as available.
- Include a new section in the foreign animal welfare assurance for institutions to describe the animal research oversight process and provide an overview of the Animal Welfare Committee or Oversight Body responsibilities.
- Require foreign recipients to submit an annual report affirming either that there was no reportable noncompliance with animal care and use standards during the year or that it notified NIH OLAW of any such noncompliance.

Rep. Jimmy Gomez (CA-D)

Question #23A

Why is it so critical that we address this child care affordability crisis for American families?

Response: The Biden-Harris Administration continues to call on Congress to make the significant long-term investments needed to lower family costs for child care because working families across income levels currently struggle to find and pay for high-quality child care, and child care costs are a significant and destabilizing financial strain on low- and middle-income families. Yet the child care workforce is deeply underpaid for the essential work they do, and child care providers struggle to fully staff their programs because of challenges recruiting and retaining staff. Difficulty in finding high-quality, affordable early care and education leads some parents to drop out of the labor force entirely, reduce their work hours, or turn down promotion opportunities. Subsidizing child care costs for low- and middle-income families will facilitate a stronger U.S. economy, strengthen family economic stability and security, support businesses and communities while allowing parents the freedom to select high-quality child care for their children that meets their families' needs. The President's Council of Economic Advisers found that recent federal investments in child care increased labor force participation among mothers of young children by roughly three percentage points, equivalent to over 300,000 more women in the labor force.

Question #23B

Earlier this month members of the Dads Caucus and the Black Maternal Health Caucus sent you a letter asking you to support a pilot program for collecting public health data from fathers. As you know, CDC's Pregnancy Risk Assessment Monitoring System (PRAMS) has been the gold standard for data on maternal health. However, minimal data is collected about fathers and their role in their families' lives. The CDC worked with the Georgia Department of Public Health to conduct a pilot survey called "PRAMS for Dads" to collect this data for the first time. The pilot found impactful data, such as mothers being more likely to begin and continue breastfeeding if fathers were supportive, but more support is needed to continue this work and find the best ways this public health data can inform sound policy to improve maternal and infant health.

- What are some ways that HHS and CDC are working to ensure that fathers are taken into account in maternal and infant health data collection?

- Would you work with us to support funding for this survey and public health data collection from fathers going forward?

Response:

CDC's Pregnancy Risk Assessment Monitoring System (PRAMS) is a joint surveillance project between state, territorial, or local health departments and CDC. PRAMS has completed two initiatives focusing on fathers of recently born live infants. In the first initiative, CDC partnered with researchers at Northwestern University and the Georgia Department of Health to look at the feasibility of conducting a PRAMS-like survey with new fathers. The PRAMS for Dads Pilot project was conducted in Georgia in 2018–2019. For example, 55% had a primary care physician, and 49% attended a healthcare visit for themselves during their infant's mother's pregnancy or since their infant's birth. In addition, most fathers were overweight or had obesity (70%) while fewer reported smoking cigarettes (19%), binge drinking (13%) or depressive symptoms (10%) since their infant's birth. The pilot study results quantify public health needs related to fathers' health and healthcare access.

The second initiative occurred as part of the Zika response. A Zika Postpartum Emergency Response Study was conducted using a hospital-based survey among fathers/partners of women with a recent live birth in Puerto Rico. Fathers were initially approached in the hospital shortly after their newborn's birth. This study was conducted between November and December of 2017 and found that, overall, 87.2% of men attended prenatal care visits, with 50.3% reporting attending all visits. Most were present at the birth (83%) and purchased infant supplies (94%). Fewer than one half (48%) of surveyed recent fathers in Puerto Rico had a health care visit for themselves in the 12 months before their newborn's birth.

Additionally, the National Vital Statistics System collects data on maternal and infant health by aggregating birth, fetal death, and death certificates from the 57 vital records jurisdictions (50 states, five US territories, New York City, and Washington, DC). The US Standard Certificate of Birth contains the following data items related to the father of the child: name, date of birth, birthplace (state, territory, or foreign country), race and Hispanic origin, education, mother's marital status at birth, conception, or any time in between, and whether a paternity acknowledgement was signed in the hospital. The US Standard Report of Fetal Death contains the father's name, date of birth, and birthplace.

Question #24

I commend you and the Biden Administration for taking great strides to improve our bioeconomy, as demonstrated by the Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy in September 2022. Can you speak to HHS' efforts to bring the Biotechnology and Biomanufacturing initiative goals to fruition, and how can Congress support the Biden.

Can you speak to HHS' efforts to bring the Biotechnology and Biomanufacturing initiative goals to fruition, and how can Congress support the Biden Administration's goals in furthering this initiative?

Response:
HHS has long supported advancement of biotechnology and biomanufacturing to improve health outcomes. The National Biotechnology and Biomanufacturing Initiative (NBBI) gives HHS an opportunity to accelerate key scientific capabilities to grow the U.S. economy and workforce and improve our quality of life. This bold endeavor is exemplified through the Executive Order's March 2023 Report entitled *Bold Goals for U.S. Biotechnology and Biomanufacturing*, in which HHS outlined goals to further human health leveraging the power of biotechnology and biomanufacturing innovation. HHS continues to invest in these and other NBBI priority areas, including improving access to quality federal data, streamlining regulatory assessment of biotechnology products, advancing biosafety and biosecurity, and increasing domestic manufacturing capacity. We look forward to our continued partnership with you in maintaining global competitiveness in the biotechnology R&D and biomanufacturing sectors.

Question #25

As you know, on February 21st, Change Healthcare, a subsidiary of UnitedHealth Group was a victim of a significant cyberattack. I have heard from providers across my district about the major disruption to care and

significant financial impact this has posed in an already challenging environment.

Please describe HHS's response to the incident, including any efforts to ensure financial stability for providers in the wake of the cyberattack, such as advance payments from Medicare and other payers.

Response:
We recognize the impact the attack on Change Healthcare has had on health care operations across the country. HHS has acted with urgency in responding to this incident and our priority—as it is with any cyber-attack on the Healthcare and Public Health (HPH) sector—has been to coordinate efforts to avoid disruptions to care and protect patient safety. Looking beyond this incident, HHS serves as the Sector Risk Management Agency (SRMA) for the HPH sector with the Administration for Strategic Preparedness and Response (ASPR) coordinating SRMA activities. HHS has recently established a cybersecurity "one-stop shop" within ASPR to manage collaboration and information sharing with other HHS divisions, the healthcare industry, as well as the interagency. Efforts to bolster the sector's cybersecurity will be led from this new office. In December 2023, HHS released a concept paper that outlined the Department's holistic cybersecurity strategy for the health care sector. In January 2024, the department published voluntary HPH Cybersecurity Performance Goals (HPH CPGs), which are intended to help healthcare institutions plan and prioritize implementation of high-impact cybersecurity practices. In the coming weeks and months as we emerge from this attack, we will be focused on developing additional tools, resources, and guidance to help with implementing these HPH CPGs and look forward to working with the sector to help improve its cyber posture.

In terms of CMS involvement, the agency has taken several key actions to support the provider community during this difficult situation. CMS announced the availability of accelerated and advance payments for affected Medicare providers of services and suppliers. Providers and suppliers should reach out to their Medicare Administrative Contractors for more information or visit CMS' website for Frequently Asked Questions and Answers. CMS has also provided flexibility for certain Medicare reporting deadlines. We encourage Medicare Advantage and Medicare Part D plans to offer advance funding to providers, and to remove or relax certain timely filing and prior authorization requirements. We have provided flexibility for certain Medicare reporting deadlines. Similarly, we strongly encourage Medicaid and CHIP managed care plans to remove or relax prior authorization and utilization management requirements, and to consider offering advance funding to providers, to the extent permitted by the state.

To support states and providers who rely on Medicaid, on March 15, 2024, CMS released guidance to help states start making interim payments to Medicaid providers affected by the incident[3]. Subject to certain guardrails to protect program integrity, CMS is encouraging state Medicaid programs to request authority to make certain interim payments.

CMS has maintained frequent communications with United Healthcare and will continue to press them to communicate with the health care sector and to offer assistance to providers and suppliers to ensure continuity of operations for all health care providers and suppliers impacted by the incident.

Rep. Kevin Hern (R-OK)

Question #26

[3] Available at: https://www.medicaid.gov/sites/default/files/2024-03/cib031524.pdf

Do you have an estimation on how many tribes are currently forced to contract with states to get access to the Federal Tax Refund Offset program and how many don't currently have access at all for their families? Likewise, do you know how many tribal families depend on the Tax Refund Offset program to receive their child support?

Response:
There are currently 61 operating tribal child support programs. Thirty-seven tribal child support programs have agreements with states for federal tax refund offset. Twenty-four tribal child support programs have not entered into agreements with states for federal tax refund offset. OCSS does not have a count on the number of tribal families dependent on the tax refund offset program for collections, however in FY 2023 there were 56,124 children served by the tribal child support programs.[4]

Question #27
Congress, patient advocates, and pharmaceutical industry members have all called upon CMS to reconsider their decision based on a plain reading of the law, congressional intent and history of the Orphan Drug Act, and a desire to bring certainty to long-term business planning decisions. Will you commit to working with Congress and direct CMS to review and reconsider their decision to ensure the greatest patient access to these rare disease treatments and instruct the agency to preserve the orphan exemption until the first non-orphan indication is granted?
Will you work with Congress and support the bipartisan and bicameral ORPHAN Cures Act to provide statutory clarity of the timing provision in the IRA's orphan drug exemption should CMS not change its position after a thorough review and reconsideration?

Response:
HHS is always happy to work with Congress and provide technical assistance on legislation.

Regarding the timing component for when a drug would be eligible for negotiation under the Medicare Drug Price Negotiation Program, sections 1192(e)(1)(A)(ii) and (B)(ii) of the Social Security Act require CMS to use the date of the approval or licensure of the drug or biological product to determine whether the product is a qualifying single source drug that may be selected for negotiation if it meets all other Negotiation Program eligibility criteria, regardless of whether the drug or biological product previously qualified for an exclusion under section 1192(e)(3)(A) of the Social Security Act. As such, CMS does not have the statutory authority to change the starting date from which qualifying single source drug status is determined. In June 2023, CMS released revised guidance for Initial Price Applicability Year 2026 to clarify the timing that CMS will use to identify qualifying single source drugs.

Rep. Mike Kelly (R-PA)

Question #28
The National Cancer Institute has predicted almost 10,000 excess deaths over the next decade from breast and colorectal cancer alone because of pandemic-related delays in diagnosing and treating these two cancers, which can often be detected early through screening. The US Preventive Services Task Force (USPSTF) plays an important role in getting new cancer screening tests reviewed and to patients via guideline updates, but they are under-staffed and

[4] Data from Line 3 of the FY 2023 OCSE-75 report.

under-funded, limiting their ability to update recommendations in a timely manner. The President's proposed FY 24 and FY 25 budgets both add $6.5million to the USPSTF budget, for a total of $18million and specifically highlight the need for early action review to give patients access to new screening technologies in a timely manner. What steps can HHS take to ensure timely review of new FDA approved screening tools if Congress does not appropriate additional funding to the Task Force?

Response:
As you know, the USPSTF is a volunteer panel of experts in primary care and prevention that systematically reviews the evidence of the effectiveness of preventive services. The USPSTF's primary mission is to improve the health of people nationwide by making evidence-based recommendations on the use of clinical preventive services. Its recommendations derive from a well-established, transparent, and rigorous assessment of the effectiveness of a preventive service. The panel considers evidence on both the benefits and harms of the service. The Agency for Healthcare Research and Quality (AHRQ) convenes the USPSTF and provides ongoing scientific, administrative, and dissemination support as allocated by Congress in its annual budget.

We know that the USPSTF is constantly surveilling research literature and pays close attention to the status of in-process clinical studies and published new evidence, including studies that might be considered by the FDA as they review submissions involving new screening technology and other preventive interventions. This allows the Task Force to be responsive to changing evidence on clinical preventive services and informs the USPSTF's established prioritization and Early Topic Update processes. If the USPSTF determines that the new evidence should trigger an early update, the Task Force follows its evidence-based methods and processes of developing the research plan, synthesizing and assessing the evidence, and determining the grade of the recommendation.

The USPSTF makes every effort to balance the need to update its recommendations as expeditiously as possible while ensuring a rigorous consideration of the evidence and a comprehensive consideration of stakeholder input and expert feedback to ensure clinicians and their patients have the best information to make decisions about their healthcare. This rigorous and open process makes the USPSTF recommendations trusted by healthcare systems, clinicians, and the public.

Question #29
We were pleased to see since its inception in 2020 in September of 2020, CMS has provided more regular updates of its dashboard of NCD requests under review, requests that had been reviewed but not yet opened (referred to as the NCD Wait List), opened with a national coverage analysis (NCA) underway, or finalized within the previous 12 months. This dashboard represents a positive step forward toward transparency of NCD processes. However, the dashboard did not provide complete details regarding the NCAs that were underway or the NCDs that had been finalized. How can HHS ensure that CMS can provide greater transparency for both requesters and the public regarding the status of NCD requests, prioritization of those requests, and the status of the current waiting list?

Response:
CMS strives to make the National Coverage Determination (NCD) process open, transparent, and accessible to medical innovators and other stakeholders. CMS prioritizes NCD requests based on the magnitude of the potential impact on Medicare program and beneficiaries. CMS has leveraged operational efficiencies to streamline and standardize the evidence review process, and we have augmented our available resources with contractor support to complete the NCD process whenever possible. However, given the ever-increasing

volume of requests and our current level of resources, there are times when CMS must tell requestors that an NCD request is complete and formal, but cannot immediately begin the NCD process.

The NCD Dashboard features alphabetized lists of NCD requests accepted by CMS, open NCDs, and finalized NCDs. Accepted NCD requests on the Wait List are complete and formal based on CMS's review consistent with the NCD Request Process. Opened NCDs are topics currently undergoing a National Coverage Analysis (NCA) with opportunities for public comment on the coverage policy. Finalized NCDs have completed the coverage analysis process and represent current Medicare coverage policy. Both opened and finalized NCDs are available on the CMS Medicare Coverage Database website.

Question #30

CBO said in scoring the Consolidated Appropriations Act, 2024 that investing in Community Health Centers and the primary care workforce would save Medicare and Medicaid more than $700 million over ten years. According to a 2022 analysis of Medicare Shared Savings Plan (MSSP) data, Accountable Care Organizations (ACO) with the largest number of participating Community Health Centers generated the largest per-capita shared savings.
How can CMS incentivize more Accountable Care Organizations to partner with Community Health Centers, which could make Medicare more efficient?

Response:

This year, CMS announced increased participation in CMS' accountable care organization (ACO) initiatives in 2024, which will increase the quality of care for more people with Medicare. Of note, 19 newly formed accountable care organizations (ACOs) in the Medicare Shared Savings Program (Shared Savings Program) are participating in a new, permanent payment option beginning in 2024 that is enabling these ACOs to receive more than $20 million in advance investment payments (AIPs) for caring for underserved populations. An additional 50 ACOs are new to the program in 2024, and 71 ACOs renewed their participation, bringing the total to 480 ACOs now participating in the Shared Savings Program, the largest ACO program in the country. CMS also announced that 245 organizations are continuing their participation in two CMS Innovation Center models — ACO Realizing Equity, Access, and Community Health (ACO REACH) and the Kidney Care Choices (KCC) models.
In summary, for 2024, the Shared Savings Program has 480 ACOs with 634,657 health care providers and organizations providing care to over 10.8 million people with Traditional Medicare. ACOs are delivering care to people with Traditional Medicare in 9,032 Federally Qualified Health Centers, Rural Health Clinics, and critical access hospitals, an increase of 27% from 2023. 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 Traditional Medicare. This model has 1,042 Federally Qualified Health Centers, Rural Health Clinics, and Critical Access Hospitals participating in 2024 — more than a 25% increase from 2023.

For 2024, the KCC model includes 123 Kidney Contracting Entities (KCEs) and CMS Kidney Care First (KCF) Practices, which are accountable for the quality and care of their aligned people with Medicare. The KCC Model has more than 9,227 participating health care providers and organizations, a 10% increase from 2023, serving 282,335 people with Medicare who have chronic kidney disease and end stage renal disease in 2024.

Increasing the number and reach of ACOs in underserved communities will help close disparities that have been identified among people with Traditional Medicare in accountable care relationships and we look forward to increased participation from practitioners, including community health centers.

Question #31

What exactly is "MA risk score trend" and how is it different than coding pattern changes? Why is this a factor included in the fact sheet? If the risk score trend is an average across the industry and varies widely by plan, is it really an accurate figure to communicate in the fact sheet?

Response:

The MA risk score trend is a key factor in estimating overall MA payments. MA risk scores measure the relative risk of a population and are calculated using beneficiaries' demographic information (e.g., age, sex, Medicaid status, among others), and health status, as identified by their diagnoses. CMS calculates the MA risk score trend by using MA risk scores over three prior years and then calculating the average annual change in risk scores across those three years. The MA risk score trend accounts for the average increase in MA risk scores over time and is driven by MA demographics and diagnosis coding patterns. It represents the estimate, based on historical data, for how risk scores will increase for the next year, which results in higher payments to plans. For CY 2025, the MA risk score trend was calculated using MA risk scores from 2018 through 2020 and CMS estimates a blended MA risk score trend of 3.86 percent. CMS blended the MA risk score trends using the same blend proposed to be used to determine CY 2025 risk scores (i.e., 67 percent of the MA risk score trend under the 2024 CMS-HCC model and 33 percent under the 2020 CMS-HCC model).

Like all aspects of the bottom-line table in the 2025 MA Advance Notice Fact Sheet, the risk score trend is an industry-wide average, and thus, individual MA plans may have a different experience. Historically, the risk score trend has steadily increased over time, even in years when CMS implemented updated risk adjustment models. The MA risk score trend is an average estimate of growth, and we have found it to be a reasonable measure of risk score growth.

With respect to the MA coding pattern adjustment, each year, as required by law, CMS makes an adjustment to plan payments to reflect differences in diagnosis coding between MA organizations and FFS providers. The minimum adjustment for coding pattern differences for a year is 5.9% per statute. CMS continually reviews MA coding patterns and continues to assess how we calculate the MA coding pattern adjustment, how best to apply it, and what the appropriate level of the adjustment should be. Ensuring that the coding pattern adjustment policy appropriately addresses differential coding in MA is essential and we will consider these recommendations in the development of future coding pattern adjustment proposals. For CY 2025, CMS proposes to apply the statutory minimum MA coding pattern difference adjustment factor of 5.90 percent.

Question #32

CMS is proposing to set new precedent by changing the Part D normalization factor methodology to separate MA-Part D (integrated plans) from PDP (standalone Part D plans). We understand the proposed policy is intended to address the financial instability caused by the IRA. How do you expect it to impact MA-PDs vs. PDPs and their members?

Response:

CMS has historically used one normalization factor across both PDPs and MA-PD plans. Given the much greater importance of risk adjustment in Part D due to the significant change in the costs for which Part D plans will be at risk ("plan liability") under the IRA redesign of the Part D benefit in 2025, and a trend of growing divergence in risk scores between PDPs and MA-PD plans, CMS proposed in the 2025 Advance Notice to update the Part D normalization methodology to reflect differences between MA-PD plan and stand-alone PDP risk score trends. CMS proposed to maintain the existing linear slope methodology for calculating Part D model normalization factors—which is to calculate a slope using five years of risk scores and then projecting the slope by the number of years between the denominator year to the payment year—but to do this calculation separately for MA-PD plans and PDPs.

Applying separate normalization factors to risk scores used to pay MA-PD plans and PDPs will more accurately reflect Part D costs in each of these two sectors of the Part D market that are driven by a variety of market-based variables, including the overall benefits that they are able to manage, lack of an ability of PDPs to affect the submission of diagnoses in FFS, and available strategies used to manage costs.

Question #33

In speaking with providers and. plans in recent months we continue to hear about increasing levels of utilization from QI to Q4, yet this year's proposed growth rate is just half of what it was two years ago. Can you explain how this number is going down as plans and providers are seeing utilization increase?

Response:

As required by statute, the growth rates used in the calculation of the Medicare Advantage (MA) rates reflect the growth in per capita costs for non-End Stage Renal Disease (non-ESRD) individuals enrolled in either Medicare Fee-for-Service (FFS) or Medicare health plans. The growth rates are based on the expected change in United States Per Capita Costs in Fee-For-Service (FFS USPCC) and in Medicare overall (both FFS and MA) and, as such, are largely driven by trends in per capita costs for individuals in Medicare FFS. The Effective Growth Rate in the Fact Sheet is a national average of expected change in the per capita costs year over year. The main driver of the Effective Growth Rate is the FFS USPCC. The effective growth rate supporting the 2025 Advance Notice reflects the Medicare Fee-for-Service (FFS) experience through the third quarter of 2023. Each year in the Rate Announcement, CMS updates the growth rates to be based on the most current estimate of per capita costs. The growth percentages are based on CMS' best estimate of historical Medicare FFS program experience and projected trends in Medicare FFS program payments using the most up-to-date data available. We continue to consider it best practice to base the growth rates on the most recent data and assumptions available at the time those values are announced. Therefore, for each release of the growth rates, CMS updates historical experience, as well as projection factors, based on the most recent data. The details regarding the data and assumptions supporting the growth rates for the final 2025 Rate Announcement will be included in the Rate Announcement upon its release no later than April 1, 2024. We note that additional data has been incorporated into the growth rates between the Advance Notice and the Rate Announcement in prior years.

Rep. Darin LaHood (R-IL)

Question #34

As we see the population aging and the number of people living with dementia increasing, how will HHS work to ensure workforce readiness and access to treatments and services for people living with dementia?

Response:

Growing the health care workforce and connecting skilled health care providers to communities in need is one of HRSA's highest priorities. The President's Budget for FY 2025 seeks to extend and expand funding for workforce programs essential to maintaining primary care services in underserved and rural communities and building the workforce to deliver these services. The FY 2025 Budget requests $47.2 million for HRSA's Geriatrics Programs to improve health care for older adults by developing a health workforce to provide value-based care for older adults by integrating geriatrics and primary care delivery sites/systems. These programs also support the career development of junior faculty in geriatrics. In Academic Year 2022-2023, the Geriatrics Workforce Enhancement Program and the Geriatrics Academic Career Awards Program (the Geriatrics Programs) trained 67,154 health care professionals, students, patients, and caregivers. A total of 56,716 individuals completed trainings including 24,892 physicians, 5,217 nursing students, and 4,153 medical students.

Question #35

On December 13, 2023, the Centers for Medicare and Medicaid Service (CMS) issued a new Healthcare Common Procedure Coding System (HCPCS) Code for the TriNav Infusion System with an implementation date of 04/01/2024 and a retroactive effective date of 1/1/2024.

I was pleased by CMS's decision, which will ensure that hospitals and physicians are appropriately reimbursed for - and more importantly, patients continue to have access to - this potentially lifesaving device for the treatment of liver and pancreatic tumors. It is my understanding that, to date, hospitals and physicians utilizing the device for the first four months of the year have not had any billing issues with CMS.

Will you commit to working with Congress if there are any health care providers that do have any billing issues due to the retroactive nature of this coverage decision.

Response:

HHS is always happy to work with Congress and provide technical assistance on legislation.
In addition, CMS is committed to working closely with plans, providers, suppliers, and other stakeholders throughout the health care industry to ensure they have the educational tools and resources they need to successfully submit Medicare claims.

Question #36

Many experts have warned that Maximum Fair Price is likely to lead to more restrictive drug coverage in Medicare Part D, resulting in beneficiaries facing fewer choices and more treatment disruptions. In fact, plans also say they will restrict medicines available on formularies and increase actions such as Prior Authorization and Step Therapy. What steps has CMS taken to address the expected shrinking of access and formulary restrictions for Part D drugs?

Response:

CMS continuously works 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 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 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." As CMS reviews Part D plan formularies to ensure they comply with statutory and regulatory requirements, CMS will only approve a Part D plan bid submitted by a Part D plan sponsor if CMS 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. CMS believes this approach will provide Part D sponsors with the flexibility to continue to manage costs through tier placement in a clinically appropriate manner, while allowing CMS to monitor practices that may undermine beneficiary access to selected drugs and inform new requirements for future contract years. Additionally, as required by the IRA, Medicare prescription drug plans, including standalone Part D plans and Medicare Advantage-prescription drug plans, must include in their formularies the selected drugs for which CMS and the participating drug company have agreed to a negotiated price.

CMS also 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.

To help ensure meaningful access to selected drugs, CMS will use its formulary review process to assess: (1) any instances where Part D sponsors place selected drugs on non-preferred tiers, (2) any instances where a selected drug is placed on a higher tier than non-selected drugs in the same class, (3) instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug with an MFP (i.e., step therapy), or (4) instances where Part D sponsors impose more restrictive utilization management (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug in the same class. We will continue to monitor formulary and utilization management changes to assess if such changes have the potential to reduce access to vital medications.

Rep. Nicole Malliotakis (R-NY)

Question #37

Secretary Becerra: Earlier this year, I co-sponsored Restore Protections for Dialysis Patients Act to close the loophole. While we appreciate CMS' work to offer Congressional offices feedback and technical assistance on legislative drafts, it has been more than a year and CMS

has yet to do so on this bill. Can you please provide a timeline for when CMS will provide that assistance as soon as possible?

Response:
HHS agrees that it is critical to preserve and increase access to high quality, affordable health care for Medicare beneficiaries, including services to treat ESRD. As always, HHS appreciates the opportunity to provide technical assistance to Congress on important health care issues, and are working to provide technical assistance as soon as we can.

Rep. Carole Miller (R-WV)

Question #38

Mr. Secretary, the recent Change cyberattack has brought focus on cybersecurity in the healthcare sector into light. Under resourced rural hospitals and clinics are struggling to keep up with required funding, staffing, and connectivity to address growing threats and vulnerabilities. What is HHS doing to ensure rural hospital cybersecurity readiness?

Response
We recognize the impact the attack on Change Healthcare has had on health care operations across the country. HHS has acted with urgency in responding to this incident and our priority—as it is with any cyber-attack on the Healthcare and Public Health (HPH) sector—has been to coordinate efforts to avoid disruptions to care and protect patient safety. Looking beyond this incident, HHS serves as the Sector Risk Management Agency (SRMA) for the HPH sector with the Administration for Strategic Preparedness and Response (ASPR) coordinating SRMA activities. HHS has recently established a cybersecurity "one-stop shop" within ASPR to manage collaboration and information sharing with other HHS divisions, the healthcare industry, as well as the interagency. Efforts to bolster the sector's cybersecurity will be led from this new office. In December 2023, HHS released a concept paper that outlined the Department's holistic cybersecurity strategy for the health care sector. In January 2024, the department published voluntary HPH Cybersecurity Performance Goals (HPH CPGs), which are intended to help healthcare institutions plan and prioritize implementation of high-impact cybersecurity practices. In the coming weeks and months as we emerge from this attack, we will be focused on developing additional tools, resources, and guidance to help with implementing these HPH CPGs and look forward to working with the sector to help improve its cyber posture.

In terms of CMS involvement, CMS recognizes the impact the Change Healthcare cyberattack has had on providers, particularly many small providers and those in rural areas. We are working expeditiously to do our part to ease the impact of the cyberattack.

Specifically, CMS has taken several key actions to support the provider community during this difficult situation. CMS announced the availability of accelerated and advance payments for affected Medicare providers of services and suppliers. Providers and suppliers should reach out to their Medicare Administrative Contractors for more information or visit CMS' website for Frequently Asked Questions and Answers. CMS has also provided flexibility for certain Medicare reporting deadlines. We encourage Medicare Advantage and Medicare Part D plans to offer advance funding to providers, and to remove or relax certain timely filing and prior authorization requirements. We have provided flexibility for certain Medicare reporting deadlines. Similarly, we strongly encourage Medicaid and CHIP managed care plans to remove or relax prior authorization and utilization management requirements, and to consider offering advance funding to providers, to the extent

permitted by the state.

To support states and providers who rely on Medicaid, on March 15, 2024, CMS released guidance to help states start making interim payments to Medicaid providers affected by the incident. [5] Subject to certain guardrails to protect program integrity, CMS is encouraging state Medicaid programs to request authority to make certain interim payments.

CMS has maintained frequent communications with United Healthcare and will continue to press them to communicate with the health care sector and to offer assistance to providers and suppliers to ensure continuity of operations for all health care providers and suppliers impacted by the incident.

Question #39

Mr. Secretary, the new Rural Emergency Hospital designation can serve as a forum to grow rural community-based training opportunities. How is HHS incorporating REHs into training and workforce programs, like the National Health Service Corps? Currently, REHs are not eligible NHSC sites despite the fact that they are outpatient facilities with a focus on keeping emergency and primary care local.

Response:

The Department is incorporating REHs into training and workforce programs by allowing their usage for clinical service and training. For example, National Health Service Corps (NHSC) clinicians may complete part of their service obligations at this provider type by utilizing REHs as approved alternative settings. NHSC physicians may spend up to eight hours per week in approved alternative settings (including REHs), while NHSC behavioral health clinicians may spend up to 20 hours per week in an approved alternative setting. NHSC clinicians may also complete part of their service obligation at REHs by using them for approved teaching activities, which are currently limited to eight hours per week. REHs are not eligible as NHSC sites. See site requirements at **https://nhsc.hrsa.gov/sites/eligibility-requirements** for more information.

Question #40

Mr. Secretary, the proposed minimum staffing standards for long-term care facilities would be disastrous for rural nursing homes, likely leading to more rural facilities closing and threatening access to post-acute care for rural seniors. How is the Administration considering the impact of this rule on rural access?

Response:

Staffing in LTC facilities is a persistent concern, especially among low-performing facilities that are at most risk for providing unsafe care. Numerous studies, including the 2022 Nursing Home Staffing Study,[6] have shown that staffing levels are closely correlated with the quality of care that LTC facility residents receive. CMS believes that national minimum nurse staffing standards in LTC facilities are necessary at this time to protect resident health and safety and ensure residents' needs are met. At the same time, CMS acknowledges the unique challenges that rural LTC facilities face, especially related to staffing, and recognizes the need to strike an appropriate balance that considers the current challenges some LTC facilities are experiencing.

[5] Available at: https://www.medicaid.gov/sites/default/files/2024-03/cib031524.pdf

[6] https://edit.cms.gov/files/document/nursing-home-staffing-study-final-report-appendix-june-2023.pdf

CMS fully expects that LTC facilities will be able to meet the proposed minimum staffing standards. CMS crafted this proposed rule with careful consideration that many LTC facilities will need to recruit, hire, and train new staff. For example, CMS proposed that implementation of the final requirements will occur in three phases over a 3-year period for all non-rural facilities. Rural facilities will have three years to meet the proposed 24/7 RN requirement and five years to meet the proposed minimum staffing requirements. If finalized, the phased-in implementation would be helpful to facilities, which would not have to hire nursing staff all at once. We recognize that in some instances, external circumstances may temporarily prevent a facility from achieving compliance despite the facility's demonstrated best efforts. To that end, the proposed rule would allow a temporary hardship exemption in limited circumstances.

Question #41

Mr. Secretary, over 170 rural hospitals have closed or ceased providing inpatient care since 2010, which makes support for vulnerable hospitals critical. What is the Administration doing to help struggling rural hospitals and ensure that they are able to stay open and care for rural patients?

Response:

HHS recognizes that more than 61 million Americans live in rural areas including rural, Tribal, frontier, and geographically isolated territories. These Americans face several unique challenges in health care that can differ dramatically among the different kinds of rural areas across the country. HHS is dedicated to ensuring that its policies, programs, initiatives, outreach, and local engagement are responsive to the needs of rural, tribal, and geographically isolated communities.

For example, HRSA provides targeted grant dollars and technical support to rural hospitals and Critical Access Hospitals with a focus on supporting rural communities and the hospitals that serve them. HRSA also supports several grants to strengthen the ability of states to serve their rural hospitals and communities by enhancing the capacity of the State Offices of Rural Health, by providing peer learning opportunities and resources for states, by supporting quality improvement in states, and by funding evaluation programs.

In terms of CMS involvement in this area, CMS has engaged with individuals, organizations, and government entities across the nation who have experience receiving health care or supporting health care service delivery in these communities to help shape the CMS Framework for Advancing Health Care in Rural, Tribal, and Geographically Isolated Communities.

In addition, on January 1, 2023, Medicare started paying for Medicare-enrolled rural emergency hospitals (REHs) to deliver emergency hospital, observation, and other services to Medicare patients on an outpatient basis. Section 125 of the Consolidated Appropriations Act, 2021, Division CC defines REHs as facilities that meet certain requirements. As of January 1, 2023, Medicare pays REHs an additional 5% over the payment rate of the Hospital Outpatient Prospective Payment System (OPPS) for REH services as well as additional facility payments, paid in 12 monthly installments. The Health Resources and Services Administration's (HRSA's) REH Technical Assistance Center also offers technical assistance to REHs to make sure rural hospitals and the communities have the information and resources they need to make informed decisions about whether an REH is the best care model for their communities and successfully implement REH requirements for facilities converting to this new provider type.

Medicare payment systems also include a number of payment adjustments to account for the unique circumstances of rural hospitals. These include adjustments through the Medicare Dependent Hospital (MDH) program, the Low-volume Hospital Payment Adjustment, and the Sole Community Hospital (SCH) program.

Question #42

Mr. Secretary, CMS is asking for all community health workers' services to be covered by Medicare beginning in 2026. Community paramedics are another crucial provider type in rural communities that assist with public health, primary care, and preventive services. How is the Administration considering how to pay for community paramedicine services in Medicare?

Response:
Section 1861(s)(7) of the Social Security Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. We have established regulations at 42 C.F.R. § 410.40 that govern Medicare coverage of ambulance services. Under § 410.40(e)(1), Medicare Part B covers ground (land and water) and air ambulance transport services only if they are furnished to a Medicare beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided for the billed services to be considered medically necessary.

Pursuant to authority granted under section 9832 of the American Rescue Plan Act of 2021, CMS could pay for treatment in place by waiving the requirements under section 1861(s)(7) and section 1834(l) of the Social Security Act. This waiver applied in cases where the individual who would have been transported would have met the Medicare criteria for a medically necessary ground ambulance transport to the nearest appropriate facility that could have treated the patient's condition, but such transport did not occur as a result of community-wide emergency medical service protocols due to the COVID-19 public health emergency. This waiver ended with the end of the PHE.

Question #43

Mr. Secretary, an issue of importance to me and my constituents in West Virginia is how we are serving patients with Kidney disease. The challenges these patients face are significantly worse in rural areas, where in addition to having to travel up to 75 miles to see a nephrologist or receive dialysis, studies show reduced access to kidney transplantation, home dialysis training, and renal replacement therapy in less-populated areas. This disproportionate burden on kidney patients in rural communities is a prime example of how geography can contribute to inequalities in healthcare treatment, quality of life, and life expectancy.

To improve care for kidney patients CMS launched a kidney focused model in 2019, called Comprehensive Kidney Care Contracting or "CKCC", which rewards nephrologists who invest in delivering care to their patients proactively where nephrologists capture savings from lower medical spending while improving quality. I am concerned by recent reports from nephrologist and other stakeholders participating in this model that CMS has decided to apply a "retrospective trend adjustment" to retroactively reduce the "benchmarks" for program year 2022 and 2023. This has the potential to drastically reduce participation and thus reverse the important progress we have seen in lowering costs and utilization for seniors. While I am thrilled to see the innovation in

Kidney care including home dialysis, I am equally concerned about CMS actions that could cause these otherwise bipartisan demonstrations to fail our patients, especially those in rural West Virginia.

Will you commit to engaging with CMS to re-evaluate the application of this "RTA" for 2022 and 2023, including applying risk corridors to limit the impact, taking into account the wide discrepancy in we have seem om the 2025 MA advanced rate notice for ESRD and Traditional Medicare patients?

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 #44

Mr. Secretary, CMS is proposing to set new precedent by changing the Part D normalization factor methodology to separate MA-Part D (integrated plans) from PDP (standalone Part D plans). We understand the proposed policy is intended to address the financial instability caused by the IRA. How do you expect it to impact MA-PDs vs. PDPs and their members? We are hearing it will cut MA-PDs and shift dollars to standup PDPs.

Does CMS believe this proposed policy would create an unintended incentive for MA-PD plans to split MA and Part D benefits? I would think CMS would value integrating MA and Part D since integrated health plans enable improved member experience and quality. Has CMS considered the impact of the inclusion of SNPs in the Part D normalization factor, yet exclusion from the national average monthly bid amount (NAMBA)? And has CMS considered whether this methodological inconsistency will be exacerbated by having two separate normalization factors?

Response:
CMS has historically used one normalization factor for Part D risk adjustment across both PDPs and MA-PD plans. Given the much greater importance of risk adjustment in Part D in 2025 due to the significant change in the costs for which Part D plans will be at risk ("plan liability") under the IRA redesign of the Part D benefit in 2025, and a trend of growing divergence in risk scores between PDPs and MA-PD plans, CMS proposed in the 2025 Advance Notice to update the Part D normalization methodology to reflect differences between MA-PD plan and stand-alone PDP risk score trends. CMS proposed to maintain the existing linear slope methodology for calculating Part D model normalization factors—which is to calculate a slope using five years of risk scores and then projecting the slope by the number of years between the denominator year to the payment year—but to do this calculation separately for MA-PD plans and PDPs.

Applying separate normalization factors to risk scores used to pay MA-PD plans and PDPs will more accurately reflect Part D costs in each of these two sectors of the Part D market that are driven by a variety of market-based variables, including the overall benefits that they are able to manage, lack of an ability of PDPs to affect the submission of diagnoses in FFS, and available strategies used to manage costs.

Question #45

Mr. Secretary, how did HHS calculate the impact across the broad community of MA plans and providers? Have you calculated how this impacts physicians participating in capitated care models, SNPs or entities participating in CMMI models like ACO reach, or Comprehensive Kidney Care Contracting (CKCC)?

In speaking with providers and plans in recent months we continue to hear about increasing levels of utilization from Q1 to Q4, yet this year's proposed growth rate is just half of what it was two years ago. Can you explain how this number is going down as plans and providers are seeing utilization increase?

Response:
CMS's release of the Calendar Year (CY) 2025 Advance Notice continues to build on our actions to keep the MA program strong while improving MA payment accuracy. Medicare Advantage payments from the government to MA plans are expected to increase by 3.7 percent on average from 2024 to 2025, as proposed. This is over a $16 billion increase in expected MA payments for the next year. This expected increase includes consideration of various elements that impact MA payment, such as growth rates of underlying costs, 2024 Star Ratings for 2025 quality bonus payments, continued phase-in of risk adjustment model updates that were implemented in CY 2024, and increases to risk scores because of MA risk score trend, which can be driven by a number of factors including MA demographics and coding patterns. This increase represents the average expected payment update across plans, and thus, there will be variation among plans in terms of their plan-specific payment impacts, including plans that would see a larger or smaller impact year over year.

As required by statute, the growth rates used in the calculation of the Medicare Advantage (MA) rates reflect the growth in per capita costs for non-End Stage Renal Disease (non-ESRD) individuals enrolled in either Medicare Fee-for-Service (FFS) or Medicare health plans. The growth rates are based on the expected change in United States Per Capita Costs in Fee-For-Service (FFS USPCC) and in Medicare overall (both FFS and MA) and, as such, are largely driven by trends in per capita costs for individuals in Medicare FFS. The Effective Growth Rate in the Fact Sheet is a national average of expected change in the per capita costs year over year. The main driver of the Effective Growth Rate is the FFS USPCC. The effective growth rate supporting the 2025 Advance Notice reflects the Medicare Fee-for-Service (FFS) experience through the third quarter of 2023. Each year in the Rate Announcement, CMS updates the growth rates to be based on the most current estimate of per capita Medicare Fee-for-Service (FFS) costs. The growth percentages are based on CMS's best estimate of historical Medicare FFS program experience and projected trends in Medicare FFS program payments using the most up-to-date data available. Therefore, for each release of the growth rates, CMS updates historical experience, as well as projection factors, based on the most recent data. The details regarding the data and assumptions supporting the growth rates for the final 2025 Rate Announcement will be included in the Rate Announcement upon its release no later than April 1, 2024. We note that additional data has been incorporated into the growth rates between the Advance Notice and the Rate Announcement in prior years.

If finalized, CMS anticipates stable premiums and benefits for individuals for CY 2025, as was the case for offerings in CY 2024, which was the first year of the updated risk adjustment model implementation. For CY 2024, average premiums and benefits for MA remained stable. The CY 2024 MA average monthly plan premium remained stable with an increase of less than one dollar on average, while plan choice and average supplemental benefit offerings across MA plans increased.

Question #46
Last year, HHS proposed a new method of calculating the best price which is significantly different from how the best price has been calculated since the start of the program. Best Price has been understood to be the lowest price available on a drug unit to any individual entity. The new policy, however, is suggesting that when the same drug unit goes through multiple different entities, the multiple concessions be added up. I am greatly concerned this policy will greatly reduce access to low-cost medications for medically underserved individuals. It appears like you're playing politics with the lives of my constituents, and Congress agrees, as last fall the House bipartisanly passed my amendment by voice vote to withhold funds from enacting the new rule. How can CMS rewrite a policy like this when the statute is clear on what best price is, and will you commit to me today to revisit this policy and to study the unintended consequences it will have on patient access and cost to medications?

Question #47
We are concerned that this proposed rule would dramatically change the way the drug rebate program works with no direct benefit for patients. Can you follow up and send me the studies you have that led you to believe you should pursue this change?

Question #48
Has CMS fully considered the unintended consequences of this policy? CBO has said in past reports that changes in pricing regulations would likely change prices to other purchasers. Do you see some unintended consequences where patients may be adversely affected? My concern is that manufacturers may pull back discounts from certain entities to mitigate the "stacking" effect. Won't that result in patients' paying more out of pocket?

Question #49
If I understand correctly, the calculation is derived by aggregating (or "stacking") the discounts across the supply chain – across many different entities. Is there a system that exists today that can interface across the supply chain and track and add all of these discounts and price concessions? If not, how do you think this can be operationalized?

Response (46-49):
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.

Question #50
Medicare accounts for 71% of all GME funding. DO and MD requirements are parallel, both leading to unrestricted physician licenses. Yet, National Resident Matching Program data shows that 32% of Residency Program Directors said that they never or seldom interview DO seniors, and of those PDs that do interview DOs, 56% require the MD licensure exam, the USMLE. What has the Center for Medicare and Medicaid Services done to ensure that residency programs receiving Medicare Graduate Medical Education funding do not exclude DOs or require them to take the medical examination for allopathic physicians (United State Medical Licensing Examination)?

Response:
Through the Graduate Medical Education program, Medicare makes payments to participating hospitals and hospital-based providers for the costs of approved residency programs. The number of available GME slots and the payment calculations are determined by law. CMS assigns GME slots to eligible providers through an application process, and the provider selects a resident for each slot. While residents must meet certain eligibility criteria, such as participating in an accredited residency program in medicine, osteopathy, dentistry, or podiatry, the teaching programs themselves establish the application process for their individual assigned GME slots.

Rep. Blake Moore (R-UT)

Question #51

Analyses from the Kaiser Family Foundation, Avalere, and Milliman suggest that there may be disruption in the Part D market in 2024 and beyond due to changes in the IRA. CMS states that overall average predicted annual plan liability will increase 99% between the pre-IRA update and post-IRA update. Given that these trends could affect seniors' access to Part D plans and covered medicines in Utah and across the country, please respond to the following questions related to the implementation of the IRA:

i. Avalere's analysis found that over 8 million beneficiaries in standalone PDPs could see an increase of more than 25% in their 2024 premium. Given the increasing plan liability as well, does CMS expect that plans will exit the market or offer fewer plans, particularly in the standalone PDP market, because of changes in the IRA?
ii. How is CMS monitoring changes in formulary design? Please describe the current process for monitoring changes, as well as any changes the agency expects to make to this process, providing specific examples.
iii. How is CMS monitoring changes in utilization management to ensure that beneficiaries maintain timely access to appropriate therapies? Please describe the current process for monitoring changes, as well as any changes the agency expects to make to this process, providing specific examples.
iv. Will you commit to working with Congress on a bipartisan basis going forward to ensure the stability of the Part D program for both patients and the Supplementary Medical Insurance trust fund?

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.

Average premiums, benefits, and plan choices for Medicare Advantage and the Medicare Part D prescription drug program have remained stable in 2024. Improvements adopted in the 2024 Rate Announcement, as well as the 2024 Medicare Advantage and Part D Final Rule, support this stability. Plan choice also increased. The average total monthly premium for Medicare Part D coverage is approximately $55.50 in 2024. This amount is a decrease of 1.8% from $56.49 in 2023. Stable premiums for Medicare Part D prescription drug coverage in 2024 are accompanied by improvements to the Part D program that allow people with Medicare to benefit from reduced costs in 2024.

Additionally, 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 impermissibly 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.

Question #52

What is CMS doing internally to ensure there is a separate, meaningful pathway for expedited Medicare coverage of new devices with existing sound data that does not require additional evidence generation? If CMS is not acting on this issue, please explain why.

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 #53

Can you outline what current interactions FDA and CMS have as innovative therapies and treatments go through the FDA approval/clearance process?
Has CMS utilized authorities granted by Section 3630 of the Consolidated Appropriations Act, 2023 (P.L. 117-328), to consider certain clinical and economic information provided by developers of new therapies and devices prior to FDA approval/clearance? If not, please explain why.

Response:

Ensuring the availability of innovative interventions for people is a shared priority for both CMS and FDA. HHS recognizes the important and related – but different – roles of these respective agencies and know that

CMS and FDA decisions have an outsized impact on the U.S. health care system, as well as implications for the rest of the world.

Underpinning both of these agencies' work is the unwavering commitment to use reliable data to ensure that effective treatments are made available to patients. The FDA's decision to approve a new drug or biological product is based on a careful evaluation of the available data and a determination that the medical product is safe and effective for its intended use. In some instances, the FDA has the authority to require additional studies after approval to provide additional information regarding the anticipated clinical benefit for the medical product. CMS can conduct its own independent review to determine whether an item or service should be covered nationally by Medicare, including examining whether it is reasonable and necessary for the diagnosis or treatment of an illness or injury for individuals in the Medicare population. The work of both of these agencies is critical to ensure that medical products are available to people across the country.

One example of CMS and FDA collaboration is the parallel review program for medical devices, in which both agencies collaboratively engage with manufacturers regarding evidence development for FDA premarket review decisions and the reasonable and necessary coverage criteria of CMS. Early feedback can assist manufacturers in designing pivotal trials and collecting evidence that can answer evidentiary questions from both agencies. If there are insufficient data that are relevant to the statutory requirements of CMS, it is difficult for the agency to make a favorable evidence-based decision regarding whether a device meets the legal criteria to be reasonable and necessary

HHS recognizes the impact these decisions have on people with serious and life-threatening conditions and their loved ones. We share a common goal of wanting to advance the development and availability of innovative medical products. CMS and FDA remain committed to using their distinct sets of authorities to ensure the continued availability of medical products that meet their respective standards to care for the people they serve.

Rep. Gwen Moore (WI-D)

Question #54

I have questions about a request for information included in the proposed rule (Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program (RIN 0938-AU28) related to requiring *a diagnosis to be included on Medicaid prescriptions***.**

a. While I understand CMS has argued that it can be "difficult to determine whether a drug is being used for a medically accepted indication, and if it therefore satisfies the definition of a [Covered Outpatient Drug] COD, and is rebate eligible," I have deep concerns about the implications should such a policy be implemented and ask that you provide an understanding of your timeline for moving forward with this particular part of this proposal.

b. Are you aware that requiring a diagnosis code on Medicaid prescriptions raises serious concerns about patient privacy, especially when it comes to birth control and other reproductive health matters that are already under attack in our country?

c. Will the Department, as it considers the information it receives, weigh the impact on access to medication, especially family planning related medications, which some believe would become more difficult for individuals to access as a result of such a proposal? I share concerns that requiring a diagnosis on Medicaid prescriptions may only lead individuals to delay or not seek some medications and that requiring a diagnosis on a prescription could be used, especially for reproductive health, against the individual seeking care especially in today's environment in some states where we are already seeing efforts to criminalize people for accessing needed health care.

d. Please also explain to me the intention behind the Administration's proposal regarding the "stacking" of Medicaid rebates in the best price calculation, including what benefits to the federal government, states, and Medicaid beneficiaries the Administration sees arising from implementing that proposal. On the other hand, what were or are some of the unintended consequences or drawbacks that the Administration has considered would arise from implementing this proposal?

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.

Question #55
The budget notes that the number of Federal SSI recipients has decreased from 7.9 million in FY 2020 to an estimated 7.3 million in FY 2025. Have you explored the reasons for this decline, and do you anticipate it continuing to decline?

Response:
The Department defers to other agencies to respond to this question.

Rep. Gregory Murphy (R-NC)

Question #56
It is my understanding that insurers are still not complying with the No Surprises Act requirement to issue an initial payment or denial within 30 calendar days of the transmittal of a bill by a provider. I have heard that providers are still waiting months for both the initial payment and for payments due following IDR determination.

- Can you please update me on what HHS is doing to enforce both the law, and the court's ruling? If the Government's appeal of the District Court's decision fails, will HHS move aggressively to enforce the 30-day timeline as written in statute?

Response:
We are actively investigating these complaints and we take the issues of late initial payments or notices of denials of payment and late payments after IDR payment determinations very seriously.

Through the CMS investigation process, as of October 31, 2023, CMS has directed numerous 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 $3,018,432 in monetary relief paid to consumers or providers. To provide transparency into our processes, CMS has begun to publish data on the resolution of certain consumer complaints, including complaints related to NSA (see: https://www.cms.gov/files/document/enforcement-report-11-23.pdf). CMS intends to update this chart regularly. Most consumer submissions involve requests for basic information about the NSA, complaints related to potential balance billing in cases of non-emergency or emergency services, or complaints that a good faith estimate was not provided for scheduled care or upon request.

The Departments continue to receive provider complaints alleging that payers are not complying with the Federal IDR process requirements. Most provider complaints allege that payers have failed to abide by the requirement to pay the prevailing party within 30 days of a payment determination by a certified IDR entity, or that payers incorrectly calculated QPAs. The Departments take the issue of late payments and failures to pay after IDR payment determinations very seriously. In general, the Departments have seen progress in payers processing IDR payments when reaching out in response to complaints. Additionally, based on our investigations, we have made operational changes to help mitigate issues we have identified. These changes include developing a new payment determination template for certified IDR entities to use which includes claim line-level details and developing a process for sending these templates through the Federal IDR portal. While we believe these operational enhancements should help mitigate some of the identified issues related to missing information, we continue to investigate complaints as they are received. It is important to note that to date, most complaints have come from a few distinct provider groups that allege violations from a few distinct plans and issuers. However, to ensure that the Departments are aware of all issues related to timely payment, the Departments continue to strongly encourage parties who use the Federal IDR process to submit complaints to the No Surprises Help Desk (NSHD).

CMS is actively investigating and addressing complaints under its jurisdiction and we take the issues of late initial payments or notices of denials of payment and late payments after IDR payment determinations very seriously. If a violation is found, CMS will explore ways to enforce the requirement.

Question #57

The Comprehensive Kidney Care Choices model received bipartisan support and aims to enhance outcomes, particularly among minority and underserved populations. However, recent decisions to retroactively adjust the benchmark for CY22 and CY23 have put this successful model at risk.

- 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. KCC 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 #58

AI and ML-enabled devices have the potential to enhance clinical care and yield significant cost savings through administrative cost reductions, rooting out inappropriate medical care, and increasing labor productivity. However, appropriate Medicare reimbursement for providers will be crucial to ensure patient access to these technologies.

- Is CMS actively examining reimbursement pathways for AI/ML-enabled devices?
- What can Congress do to ensure adequate access to these teclu1ologies?

Response:

CMS recognizes that Software as a Service (SaaS) procedures are a heterogenous group of services, which presents challenges when it comes to adopting payment policy for SaaS procedures as a whole. Due to the novel and evolving nature of these technologies, it has been challenging to compare some SaaS procedures to existing

medical services for purposes of determining clinical and resource similarity. We recognize that certain clinical decision support software, including machine learning or "AI," has been available for many years. In the past ten years, clinical decision support software has been commonly used alongside electronic medical records by medical practitioners. Nonetheless, the number of FDA approved or cleared "machine learning" or "AI" clinical software programs has rapidly increased in the past few years. CMS solicited comments in the CY 2023 OPPS/ASC proposed rule on a payment approach that would broadly apply to SaaS procedures and the specific payment approach we might use for these services under the OPPS, and we stated that we would consider this input for future rulemaking.

Rep. Jimmy Panetta (D-CA)

Question #59

My constituents have been directly impacted by the Change Healthcare cyberattack.

a. What ongoing support will HHS provide to individual providers to ensure they are compensated for their work?
b. How is HHS helping providers that are not paid directly by CMS, like those serving MediCal patients or accepting private insurance?
c. What steps are being taken to secure U.S. healthcare from future attacks?
d. What additional support do you need from Congress in this effort?

Response:
We recognize the impact the attack on Change Healthcare has had on health care operations across the country. HHS has acted with urgency in responding to this incident and our priority—as it is with any cyber-attack on the Healthcare and Public Health (HPH) sector—has been to coordinate efforts to avoid disruptions to care and protect patient safety. Looking beyond this incident, HHS serves as the Sector Risk Management Agency (SRMA) for the HPH sector with the Administration for Strategic Preparedness and Response (ASPR) coordinating SRMA activities. HHS has recently established a cybersecurity "one-stop shop" within ASPR to manage collaboration and information sharing with other HHS divisions, the healthcare industry, as well as the interagency. Efforts to bolster the sector's cybersecurity will be led from this new office. In December 2023, HHS released a concept paper that outlined the Department's holistic cybersecurity strategy for the health care sector. In January 2024, the department published voluntary HPH Cybersecurity Performance Goals (HPH CPGs), which are intended to help healthcare institutions plan and prioritize implementation of high-impact cybersecurity practices. In the coming weeks and months as we emerge from this attack, we will be focused on developing additional tools, resources, and guidance to help with implementing these HPH CPGs and look forward to working with the sector to help improve its cyber posture.

In terms of CMS involvement, the agency has taken several key actions to support the provider community during this difficult situation. CMS announced the availability of accelerated and advance payments for affected Medicare providers of services and suppliers. Providers and suppliers should reach out to their Medicare Administrative Contractors for more information or visit CMS' website for Frequently Asked Questions and Answers. CMS has also provided flexibility for certain Medicare reporting deadlines. We encourage Medicare Advantage and Medicare Part D plans to offer advance funding to providers, and to remove or relax certain timely filing and prior authorization requirements. We have provided flexibility for certain Medicare reporting deadlines. Similarly, we strongly encourage Medicaid and CHIP managed care plans

to remove or relax prior authorization and utilization management requirements, and to consider offering advance funding to providers, to the extent permitted by the state.

To support states and providers who rely on Medicaid, on March 15, 2024, CMS released guidance to help states start making interim payments to Medicaid providers affected by the incident. [7] Subject to certain guardrails to protect program integrity, CMS is encouraging state Medicaid programs to request authority to make certain interim payments.

CMS has maintained frequent communications with United Healthcare and will continue to press them to communicate with the health care sector and to offer assistance to providers and suppliers to ensure continuity of operations for all health care providers and suppliers impacted by the incident.

Rep. Bill Pascrell, Jr. (D-NJ)

Question #60

You know my long interest in the safety and costs of medical devices. I have been demanding unique device identifiers be included on Medicare claims forms for ages. The process is interminable. I have been working on this issue for a decade and we are still not there. Secretary Becerra, what is the status of HHS's implementation to include medical devices' unique device identifier (UDI) in Medicare claims?

Response:

While the benefits of UDI adoption in health care are well known, as you noted, for any portion of the UDI to be included in Medicare claims, the American National Standard Institute's Accredited Standards Committee (X12) must first submit formal recommendations on the proposed health care claims transaction standards to the National Committee on Vital and Health Statistics (NCVHS). NCVHS must then, after assessing the recommendations, officially recommend to the Department that it should adopt the standards. Finally, the Department's adoption of new standards would still have to be completed through notice and comment rulemaking. The X12 committee has made recommendations to include collection of the DI for high-risk implantable devices, between willing trading partners, in the next version of the claim transactions standards. The Department will have the opportunity to address this issue after we receive the NCVHS recommendations for the next version of the standard transactions.

Question #61

Secretary Becerra, I am concerned about private equity firms growing control in health care. In 2021 alone, private equity tycoons spent more than $200 billion on health care acquisitions, and $1 trillion in the past decade. Your agency's recent announcement with DOJ and FTC was an exciting step. Please elaborate about your timeline. Also, what guardrails is HHS implementing to address costs, quality, and access related to private equity control?

Response:

HHS is an active and committed member of the President's Competition Council, and has been continuing efforts to create as much transparency and competition as possible in health care markets. For example, HHS

[7] Available at: https://www.medicaid.gov/sites/default/files/2024-03/cib031524.pdf

has taken unprecedented action to shed light on ownership trends in health care, including – for the first time – making ownership data on hospitals, nursing homes, hospice providers, and home health agencies publicly available on data.cms.gov.

Comments on the request for information are due on May 6. HHS is committed to reviewing comments expeditiously with our Departmental partners, and crafting policy solutions based on the feedback we receive. We welcome partnership in the effort to increase transparency and competition in health care.

HHS has taken several important steps to increase transparency around private equity:

- CMS released ownership data publicly — for the first time ever — for all Medicare-certified hospitals.
- Last fall, CMS began requiring the disclosure of certain ownership, managerial, and other information regarding Medicare skilled nursing facilities (SNFs) and nursing homes.
- CMS also has released data publicly on mergers, acquisitions, consolidations, and changes of ownership from 2016-2022 for nursing homes enrolled in Medicare.

Question #62

Mr. Secretary, there are hospitals and providers in my district that have been impacted by Change Healthcare's cybersecurity incident last month. Will there be aid or other offsets to assist providers with this administrative and financial burden?

Response:

HHS recognizes the impact the attack on Change Healthcare has had on health care operations across the country. HHS has acted with urgency in responding to this incident and our priority—as it is with any cyber-attack on the Healthcare and Public Health (HPH) sector—has been to coordinate efforts to avoid disruptions to care and protect patient safety. Looking beyond this incident, HHS serves as the Sector Risk Management Agency (SRMA) for the HPH sector with the Administration for Strategic Preparedness and Response (ASPR) coordinating SRMA activities. HHS has recently established a cybersecurity "one-stop shop" within ASPR to manage collaboration and information sharing with other HHS divisions, the healthcare industry, as well as the interagency. Efforts to bolster the sector's cybersecurity will be led from this new office. In December 2023, HHS released a concept paper that outlined the Department's holistic cybersecurity strategy for the health care sector. In January 2024, the department published voluntary HPH Cybersecurity Performance Goals (HPH CPGs), which are intended to help healthcare institutions plan and prioritize implementation of high-impact cybersecurity practices. In the coming weeks and months as we emerge from this attack, we will be focused on developing additional tools, resources, and guidance to help with implementing these HPH CPGs and look forward to working with the sector to help improve its cyber posture.

In terms of CMS involvement, CMS recognizes the impact the Change Healthcare cyberattack has had on providers, particularly many small providers and those in rural areas. We are working expeditiously to do our part to ease the impact of the cyberattack.

Specifically, CMS has taken several key actions to support the provider community during this difficult situation. CMS announced the availability of accelerated and advance payments for affected Medicare providers of services and suppliers. Providers and suppliers should reach out to their Medicare Administrative Contractors for more information or visit CMS' website for Frequently Asked Questions and Answers. CMS has also provided flexibility for certain Medicare reporting deadlines. We encourage Medicare Advantage and Medicare Part D plans to offer advance funding to providers, and to remove or relax certain timely filing and

prior authorization requirements. We have provided flexibility for certain Medicare reporting deadlines. Similarly, we strongly encourage Medicaid and CHIP managed care plans to remove or relax prior authorization and utilization management requirements, and to consider offering advance funding to providers, to the extent permitted by the state.

To support states and providers who rely on Medicaid, on March 15, 2024, CMS released guidance to help states start making interim payments to Medicaid providers affected by the incident. [8] Subject to certain guardrails to protect program integrity, CMS is encouraging state Medicaid programs to request authority to make certain interim payments.

CMS has maintained frequent communications with United Healthcare and will continue to press them to communicate with the health care sector and to offer assistance to providers and suppliers to ensure continuity of operations for all health care providers and suppliers impacted by the incident.

Question #63

Lastly, Secretary Becerra, Dr. Murphy, Dr. Wenstrup and dozens of our colleagues sent you a bipartisan letter this week on, ***'No Surprises Act'*** implementation. What is HHS doing to address the long outstanding issues with qualified payment amounts, compliance, and payment timelines? We need your leadership here. A change in direction is essential.

Response:

We are actively investigating these complaints and we take the issue of late payments after IDR payment determinations very seriously.

Through the CMS investigation process, as of October 31, 2023, CMS has directed numerous 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 $3,018,432 in monetary relief paid to consumers or providers. To provide transparency into our processes, CMS has begun to publish data on the resolution of certain consumer complaints, including complaints related to NSA (see: https://www.cms.gov/files/document/enforcement-report-11-23.pdf). CMS intends to update this chart regularly. Most consumer submissions involve requests for basic information about the NSA, complaints related to potential balance billing in cases of non-emergency or emergency services, or complaints that a good faith estimate was not provided for scheduled care or upon request.

The Departments continue to receive provider complaints alleging that payers are not complying with the Federal IDR process requirements. Most provider complaints allege that payers have failed to abide by the requirement to pay the prevailing party within 30 days of a payment determination by a certified IDR entity, or that payers incorrectly calculated QPAs. The Departments take the issue of late payments and failures to pay after IDR payment determinations very seriously. In general, the Departments have seen progress in payers processing IDR payments when reaching out in response to complaints. Additionally, based on our investigations, we have made operational changes to help mitigate issues we have identified. These changes include developing a new payment determination template for certified IDR entities to use which includes claim line-level details and developing a process for sending these templates through the Federal IDR portal. While we believe these operational enhancements should help mitigate some of the identified issues related to missing

[8] Available at: https://www.medicaid.gov/sites/default/files/2024-03/cib031524.pdf

information, we continue to investigate complaints as they are received. It is important to note that to date, most complaints have come from a few distinct provider groups that allege violations from a few distinct plans and issuers. However, to ensure that the Departments are aware of all issues related to timely payment, the Departments continue to strongly encourage parties who use the Federal IDR process to submit complaints to the No Surprises Help Desk (NSHD).

With regard to the QPA calculation, as required by the statute, the Departments established a process under which payers are audited by the applicable Secretary or applicable state authority to ensure that such payers comply with the requirement that they apply a QPA that satisfies the NSA's definition of the term with respect to the year involved. This audit process is important to ensure that payers are calculating and disclosing the QPA correctly. CMS conducts market conduct exams, including QPA audits, of issuers of individual or group health insurance coverage in states where we have enforcement authority, non-Federal governmental plans in all states, and states with a collaborative enforcement agreement at the request of the state, to verify compliance with specific market-wide PHS Act requirements. As of October 2023, CMS (on behalf of HHS) is conducting 23 QPA audits. As we complete audits, we intend to post our findings on the CMS website and report our findings to Congress as required by the NSA. CMS anticipates making audit results available on a rolling basis as audits are completed.

Rep. Bradley Schneider (D-IL)

Question #64

As of February 2024, the FDA has cleared more than 600 Al/ML medical devices, the majority of which are medical imaging devices. At the same time, fewer than IO of these medical devices have received hospital outpatient payment assignments through Medicare. Without appropriate reimbursement for providers, patient access to these transformational technologies, especially for patients in rural and underserved communities, will remain limited.

How is CMS working to streamline the process for reviewing and issuing payment assignments for Al/ML medical devices?

What steps are being taken to ensure existing Medicare payment pathways adequately support innovation, provider adoption, and beneficiary access to AI healthcare services?

New innovations are improving the potential for better health care outcomes, but they will only be effective if people have access to them. What is CMS doing to ensure access to medical imaging devices, including Al/ML devices, in underserved populations?

How can Congress better support increased access to medical imaging devices, including AI/ML device, while also ensuring patient safety?

Response:

Medicare payment policy is set by Congress, and CMS works within the confines of the law to establish payment policies. The Hospital Outpatient Prospective Payment System (OPPS) pass-through and Inpatient Prospective Payment System (IPPS) New Technology Add-on Payment (NTAP) collectively incentivize hospitals to quickly adopt and promote beneficiary access to innovative technologies through additional payments. Section 1886(d)(5)(K) of the Act requires the Secretary to establish a mechanism to recognize the

costs of new medical services and technologies under the IPPS. The OPPS transitional pass-through provisions are established under section 1833(t)(6) of the Act. The intent of the OPPS transitional device pass-through payment is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the overall procedure payment rate (66 FR 55861). A criterion for both NTAP and OPPS pass-through is that the device represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In the CY 2020 and FY 2021 annual rulemaking processes for the OPPS and IPPS, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation, under which these devices are not evaluated in terms of the current substantial clinical improvement criterion for the purposes of determining device pass-through status or NTAP.

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.

In addition, CMS solicited comments in the CY 2023 OPPS/ASC proposed rule (87 FR 44688) on a payment approach that would broadly apply to Software as a Service (SaaS) procedures and the specific payment approach we might use for these services under the OPPS. In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72036), we summarized the comments and stated that we would consider that input for future rulemaking.

Rep. Adrian Smith (R-NE)

Question #65

In December of last year, I joined several Members in writing to CMS Administrator Brooks-LaSure raising concerns that CMS has not yet added either the National Healthcare Safety Network's blood culture contamination measure or the CDC's hospital onset bacteremia measure to the Hospital-Acquired Conditions reduction program. False positive blood cultures due to contaminated samples affect more than 800,000 Americans every year, placing them at risk for serious complications and even death. These false-positive tests also result in $8.5 billion being spent on unnecessary treatments and exacerbate the antibiotic resistant infection crisis. Previously Administrator Brooks-LaSure responded that despite these measures being endorsed as valid and reliable by independent, consensus-based health care monitoring organizations, CMS is waiting for CDC to conduct yet another round of testing after which the measures will have to go through at least another year of rulemaking before they can be adopted into the program. Blood culture contamination is a serious patient safety issue and more needs to be done to protect patients from this entirely preventable medical error. Each

year of delay means more patients are unnecessarily placed at risk for serious complications, including death.

Can you describe how the Department could expedite the adoption of one or both of these measures so that hospitals are incentivized to address the issue and meet the CDC's standard of having a one percent or less blood culture false positive rate?

Response:
CMS is committed to patient safety and healthcare quality. The Hospital-Acquired Condition (HAC) Reduction Program is one of the quality programs aimed at fulfilling this commitment. In the FY 2023 IPPS/LTCH PPS final rule, CMS described the Request for Comment (RFC) on the potential future adoption of the digital National Healthcare Safety Network (NHSN) Healthcare-associated *Clostridioides difficile* Infection Outcome measure and the digital NHSN Hospital-Onset Bacteremia (HOB) Fungemia Outcome measure. We received public input in support of the adoption of these two electronic clinical quality measures (eCQMs). However, a few commenters stated concern regarding baseline data testing, measure definitions, and the risk adjustment methodology for both eCQMs. Both measures are currently undergoing advanced testing by the CDC, including one year of real-world data collection necessary to set performance benchmarks that hospitals would be assessed against when the measure is proposed for use in any CMS quality programs. CMS is coordinating with the CDC in evaluating these measure tests.

Lloyd Smucker (R-PA)

Question #66
I along with my colleague, Rep. Brad Wenstrup (OH-02) introduced H.R. 7446, the *Reduce Duplication and Improve Access to Work Act.* This legislation would grant states flexibility to devote a portion of funds received from TANF program to workforce training programs organized under WIOA. This policy allows states to direct TANF toward getting more individuals into the workforce while also reducing duplication.

Do you support reforming TANF in this way to ensure we reduce duplication and better integrate our programs to help individuals enter the workforce and build self-sufficiency?

Are you willing to work with me to reform TANF and put these necessary financial guardrails in place?

Response:
The Department supports and provides technical assistance to Congress on the use of TANF funds to assist parents entering the workforce and increasing their economic mobility and encourages collaboration between TANF and WIOA partners.

Rep. Michelle Steele (R-CA)

Question #67
How is the Administration working with jurisdictions and tribes to improve the well- being of families, so that the child protection involvement is only when there is a safety concern?

Response:
Child and family well-being and primary prevention are core priorities of the Administration. The President's FY 2025 budget includes a suite of proposals to enhance the scale and scope of prevention services to reduce child protection involvement and placements into foster care in cases when families can remain safely together. The FY 2025 budget builds on bipartisan progress from the 2018 Family First Prevention Services Act (FFPSA) by enhancing the title IV-E Prevention Services and Kinship Navigator programs. This proposal would allow states and tribes more flexibility to provide a wider array of services that best meet a families' needs and reduce the need for child protective and foster care services in cases where children and families can remain safely together. Specifically, the proposal would:

- Increase federal reimbursement rates for the title IV-E Prevention Services Program and title IV-E Kinship Navigator Programs as follows: 90 percent for FYs 2025-2028; and thereafter, the greater of 75 percent or the state/tribe's Federal Medical Assistance Percentage (FMAP) rate plus 10 percentage points;
- Under the Prevention Services Program, makes permanent the current policy requiring states to spend at least 50 percent for services with a Title IV-E Prevention Services Clearinghouse rating of "supported" or "well-supported;"
- Allows up to 15 percent of a state's Prevention Services funding to be spent on emerging or developing services that do not currently meet the ratings criteria, but states must evaluate the services and either modify or cease using title IV-E funding if the evaluation shows the service to be ineffective; and
- Allows for increased tribal and cultural adaptations of approved prevention services programs.
- Allows Tribes that participate in the title IV-B, subpart 1 Child Welfare Services program, but do not currently participate in the title IV-E foster care and adoption assistance programs to submit a plan to directly operate the title IV-E Prevention Services program.

The budget also includes two proposals to provide resources through the Community Based Child Abuse Prevention Program (CBCAP) that prevent children's removal into foster care.

The first is a request for $90 million, an increase of $19.3 million from FY 2024 appropriations, which funds primary prevention programs designed to strengthen families and prevent their coming to the attention of child welfare systems.

The increased funding level will allow CBCAP state lead agencies to continue to develop and coordinate effective community-based family support and prevention services:

- Funding will support ongoing efforts to build the capacity of states to authentically engage individuals with lived experiences in planning and decision-making processes of their CBCAP program.
- Funding will further expand training and technical assistance provided by CBCAP State lead agencies to build and improve the capacities of community-based agencies to secure and effectively implement culturally responsive services and resources.
- Funding will bolster family supports and prevention services to reduce the likelihood of child abuse and placements in foster care for all families and may help to reduce disparities in the child welfare system and prevent further trauma exposure.
- Funding will also be used to provide increased support for the CBCAP workforce at the state and local levels. Similar to other areas of child and family support, CBCAP State lead agencies are experiencing

significant turnover, staffing shortages, and concerns of low morale among remaining personnel that are affecting their abilities to implement and maintain CBCAP programs as planned.

The FY 2025 budget also includes a legislative proposal to replace the one percent reservation with a $5 million set-aside for CBCAP grants to Tribes, tribal organizations, and migrant programs. Under the existing reservation of funds, a total of three grant recipients were awarded funds under this program.

Finally, the FY 2025 budget includes a legislative proposal to increase the minimum state allocation for CBCAP formula grants from $175,000 to $225,000. The proposed increase in the minimum award would allow states to maintain family support and prevention services and ensure that smaller States, some of which did not qualify for an increase of funding in recent years, benefit from the proposed increase in appropriations at the national level.

Question #68

We can learn a great deal about the needs of families through those with lived experience with involvement with the child welfare system. What is the Administration doing to encourage efforts by states, territories and tribes to include those individuals with lived experience in the work to support families?

Response:

Engaging the voices of lived experience in formulating policy priorities and service delivery is a cornerstone of every one of the Administration's priorities and has been incorporated in the implementation of programming across federal child welfare funding streams.

The President's FY 2025 budget request for the Child Welfare, Research, Training and Demonstration program includes, among other things, an increase of $5 million for a National Child Welfare Lived Experience Institute to engage organizations with relevant experience through a competitive grant program to address racial inequities in child welfare, reduce overrepresentation of children and families of minority heritage in the foster care system, and reorient systems towards a prevention-first model. The grant recipient would support State, local, and Tribal child welfare agencies to partner with other government and community stakeholders across the education, health, human services, and early childhood sectors to advance comprehensive policy and practice reforms. These reforms would focus on advancing racial equity and safely reducing the number of children entering foster care, particularly in communities over-represented in the child welfare system.

Question #69

Recent changes to Medicare Advantage and Part D are having a disproportionate effect on small and non-profit plans who serve low-income and vulnerable populations.

For instance:

- After CMS implemented the "Tukey outlier policy" in the MA quality rating system, one in every five non-profit plans lost 4-star status in 2024 compared to only 7% of for-profit plans.
- CMS's proposed 2024 MA Risk Adjustment Model cuts payment to D-SNPs. According to Milliman, under CMS's proposal, "the median change to average risk scores for D-SNPs…is -0.3%...under the 2024 model whereas the median change to average risk score for non-SNPs is +2.1%."
- The Inflation Reduction Act will substantially increase costs to plans for Low-Income

Subsidy (LIS) enrollees. According to Milliman, under the IRA, gross plan liability will increase by 111% for LIS enrollees, compared to an increase of 58% for non-LIS enrollees.

Taken together, policy changes made and proposed by CMS and/or Congress are making it difficult for the Medicare Advantage program to serve populations who need high-quality coordinated care the most.

Will CMS take into account the cumulative impact of policies on different types of plans when finalizing the 2025 Rate Notice?

Question #70

One way to prevent cuts to benefits received by vulnerable populations is to reform CMS's Total Beneficiary Cost (TBC) policy. The current TBC policy arbitrarily limits the amount of changes a plan can make in its benefits, premiums, and cost-sharing compared to the prior year.

TBC does not take into account changes in risk scores when determining if a plan is meeting the TBC requirements. TBC also does not allow for multi-year comparisons of plan design.

Given the high volatility in policies affecting plans, CMS should revise the current TBC policy in two critical ways:

A. Allow for permitted changes in benefits to be applicable across two years rather than the current one-year comparison
B. Incorporate changes in risk scores due to policy decisions in the same way changes in star ratings and QBPs are currently incorporated

Question #71

Will CMS consider these changes prior to the CY2025 bid submission deadline in June?

Response (69-71):

CMS agrees it is imperative to protect Medicare coverage for vulnerable beneficiaries and those plans providing care to them. Each year, CMS is required to update MA payment rates and regularly conducts technical updates to make improvements needed to keep MA payments up-to-date and accurate. CMS makes technical updates and improvements through the Advance Notice and Rate Announcement process for this purpose. CMS's release of the Calendar Year (CY) 2025 Advance Notice continues to build on our actions to keep the MA program strong while improving MA payment accuracy. Overall, payments from the government to MA plans are expected to increase on average by more than $16 billion as proposed, from 2024 to 2025. CMS also is proposing policies in the CY 2025 Advance Notice that continue to phase in common sense, routine technical updates so that MA plan payments better reflect the costs of care for people enrolled in MA.

When contemplating the continued phase-in of the updated model for CY 2025, CMS carefully considered and analyzed impacts on dually eligible enrollees and special needs plans that serve dually eligible individuals (D-SNPs). CMS has concluded that continuing to implement the 2024 CMS-HCC model is necessary and appropriate and increases predictive accuracy of the risk adjustment model for these individuals. As CMS explained in the CY 2024 Rate Announcement, the updates to the model improved the model's predictive accuracy and helped to ensure that higher payments are available to plans that serve enrollees with more costly health care needs.

Additionally, the updates in the 2024 CMS-HCC model did not change protective features in the CMS-HCC risk adjustment model, first implemented in CY 2017, that ensures plans that care for dually eligible individuals are paid more to reflect the expected cost of care for peoples' health conditions. In addition to internally analyzing potential impacts of policy changes on Medicare Part C and Part D plans, providers, and beneficiaries, CMS relies heavily on feedback received during the 60-day public comment period to inform our final decisions.

Under section 1854(a)(5)(C)(ii) of the Social Security Act, CMS may deny a bid submitted by an MA organization for an MA plan if it proposes significant increases in cost sharing or decreases in benefits offered under the plan. A plan's Total Beneficiary Cost (TBC) is the sum of plan-specific Part B premium, plan premium, and estimated beneficiary out-of-pocket costs. The change in TBC from one year to the next captures the combined financial impact of premium changes and benefit design changes (i.e., cost-sharing changes) on plan enrollees. By limiting excessive increases in the TBC from one year to the next, CMS is able to ensure that beneficiaries who continue enrollment in the same plan are not exposed to significant cost increases.

Regarding the Tukey outlier deletion, CMS proposed the Tukey outlier deletion policy in the Contract Year 2021 and 2022 Parts C and D proposed rule, which was issued in February 2020. After review of the comments received, CMS finalized the proposed policies, with the only modification being to delay the implementation of the Tukey outlier deletion until the 2024 Star Ratings.

Question #72

Do you believe the administration's recent attacks on private sector collaboration via its march-in proposal and other policies that would weaken U.S. intellectual property protections will help bolster our nation's ability to compete against countries like China?

Response:

The Bayh-Dole Act was designed to promote the commercialization of research results, maximize the potential for federally-funded technologies to become products, and serve the broader interest of the American public.

HHS is fully committed to implementing the law to uphold these aims and support the innovation needed to deliver new safe and effective drugs to patients. To that end, HHS has continued to engage with the Department of Commerce through an interagency working group on non-binding guidance for agencies considering the use of march-in rights. .

Question #73

The comment period for the Transitional Coverage for Emerging Technologies (TCET) procedural notice concluded on August 28, 2023. However, the HHS Fall 2023 Unified Agenda lists the TCET procedural notice as a "completed action" and does not provide any further update as to when CMS may issue the final TCET policy. Given that roughly 7 months has passed since the TCET comment period ended, can you assure us that CMS will issue the final TCET policy soon this spring or early summer?

Question #74

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

Question #75

CMS's approach for TCET as proposed limits coverage to only up to 5 devices annually with "breakthrough" designation from the FDA. That leaves the many other new devices and technologies not eligible for TCET subject to the LCD and NCD processes. However, both of those existing coverage processes have extensive backlogs. What is the Administration planning to do to address the extensive NCD and LCD backlogs – especially given that this seems to be the default approach for coverage for the many new and innovative devices and technologies that will not be eligible for TCET as it is currently envisioned? Without reforms, patients will continue to experience barriers and delays in treatment – which is exactly what TCET was supposed to address but does not seem to be doing so as currently laid out.

Question #76

Medicare has created all sorts of barriers and delays in accessing the treatments they need. My understanding is that, even though there was an FDA-approved medical device available that has been shown in clinical trials to extend the life of these patients by 5 months, where unfortunately they typically only live 12 to 18 months, Medicare did not cover and adequately reimburse for the device for a number of years due to needlessly burdensome coverage processes. Can you assure me that TCET will stop cases like the one I just described from happening to patients and their families anymore? Can you give me confidence me that TCET will provide Medicare coverage for innovative medical technologies like this one that extends survival by 5 months for patients with brain cancer so Medicare beneficiaries and their families do not have to endure needless barriers and delays in treatment when there are innovative treatments and technologies that are available that can help them get better and live longer? If you cannot assure me that TCET will stop cases like this one from happening, can you address how patients seeking to access new devices with sound clinical evidence and safety data will not continue to face significant delays in coverage and access due to existing the LCD and NCD approval backlogs?

Response (73-76):

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). In the notice, we noted that CMS anticipates accepting up to five TCET candidates annually due to CMS resource constraints; given the volume of National Coverage Determination (NCD) requests and our current level of resources, there are times when CMS must tell requestors that the NCD request is complete and formal, but CMS cannot immediately begin the NCD process.

In addition to the proposed TCET procedural notice, CMS issued an updated proposed 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 #77

One of the challenges to me in patients not being able to get access to innovative treatments and technologies is that FDA and CMS do not seem to be talking to each other as much as they could. It just seems that if there were better communications between the two agencies there might not be significant delays between when FDA approves a device or drug and when Medicare beneficiaries can actually get access to the new treatment. Do you have a sense of why that is? Do you believe that earlier interactions between the FDA and CMS could foster better patient access to innovative treatments and therapies? If so, what efforts are you considering for FDA and CMS to work together more effectively and efficiently so that patients can get these new treatments without barriers and delays? For example, would it be helpful for CMS to communicate with FDA at an early development stage important issues that should be addressed in clinical trials to help facilitate timely Medicare coverage upon market entry? Should a formal process be established for FDA and CMS to routinely discuss with manufacturers the clinical data and other information necessary to support simultaneous FDA approval or clearance and Medicare coverage for a new medical device? What steps can FDA and CMS put in place to stop the need for CMS to collect additional post-market data so that Medicare beneficiaries do not experience further burden in accessing innovative treatments and technologies?

Response:

Ensuring the availability of innovative interventions for people is a shared priority for both CMS and FDA. HHS recognizes the important and related – but different – roles of these respective agencies and know that CMS and FDA decisions have an outsized impact on the U.S. health care system, as well as implications for the rest of the world.

Underpinning both of these agencies' work is the unwavering commitment to use reliable data to ensure that effective treatments are made available to patients. The FDA's decision to approve a new drug or biological product is based on a careful evaluation of the available data and a determination that the medical product is safe and effective for its intended use. In some instances, the FDA has the authority to require additional studies after approval to provide additional information regarding the anticipated clinical benefit for the medical product. CMS can conduct its own independent review to determine whether an item or service should be covered nationally by Medicare, including examining whether it is reasonable and necessary for the diagnosis or treatment of an illness or injury for individuals in the Medicare population. The work of both of these agencies is critical to ensure that medical products are available to people across the country.

One example of CMS and FDA collaboration is the parallel review program for medical devices, in which both agencies collaboratively engage with manufacturers regarding evidence development for FDA premarket review decisions and the reasonable and necessary coverage criteria of CMS. Early feedback can assist manufacturers in designing pivotal trials and collecting evidence that can answer evidentiary questions from both agencies. If there are insufficient data that are relevant to the statutory requirements of CMS, it is difficult for the agency to make a favorable evidence-based decision regarding whether a drug or medical device meets the legal criteria to be reasonable and necessary.

In addition, the TCET proposed notice notes that "After CMS initiates review of a complete, formal nomination, representatives from CMS will meet with their counterparts at FDA to learn more information about the technology in the nomination to the extent the Agencies have not already done so. These discussions may help CMS gain a better understanding of the device and potential FDA review timing."

HHS recognizes the impact these decisions have on people with serious and life-threatening conditions and their loved ones. We share a common goal of wanting to advance the development and availability of innovative medical products. CMS and FDA remain committed to using their distinct sets of authorities to ensure the continued availability of medical products that meet their respective standards to care for the people they serve.

Question #78

I am a proud co-sponsor of bipartisan legislation, which has been introduced in multiple sessions of Congress that would establish a transitional pathway for Medicare coverage of innovative technologies and devices. The "breakthrough bill" as it is often referred to – H.R. 1691 – is simply critical for patients. The bill will make sure that Medicare beneficiaries have access to the treatments they need to live longer and healthier lives. Can you commit to supporting our legislation, which has strong bipartisan support and the backing of so many patient organizations?

Response:

CMS strives to improve patient care and innovation while maintaining robust safeguards for the Medicare population. The TCET pathway discussed above is intended to offer more timely and predictable access to new medical technologies for people with Medicare. HHS is always happy to work with Congress and provide technical assistance on legislation.

Question #79

Will guidance specific to alcohol consumption be included in the 2025 Dietary Guidelines?

Response:
Yes, guidance specific to alcohol consumption will be included in the 2025 Dietary Guidelines. This guidance will come from USDA and HHS as the authors of the Dietary Guidelines. The ICCPUD Technical Review Subcommittee's (TRS) work to assess the scientific evidence on adult alcohol consumption and health will be finalized in 2025 after completion of the evidence reviews by ICCPUD's Scientific Review Panel (below) and the NASEM committee, which are both slated to conclude by December 2024. The TRS will review the findings from both studies and provide a synthesis of the data and conclusions to USDA and HHS for consideration during the Dietary Guideline development process.

In this current phase, with ICCPUD and NASEM external scientific committees' work under way, USDA and HHS Dietary Guidelines staff serve in a liaison role, providing information, as needed, as subject matter experts on the needs for development of the next edition of Dietary Guidelines.

Question #80
Congress appropriated $1.3 million through USDA for the National Academies of Science, Engineering and Medicine to assess research on alcohol consumption and health outcomes that were not addressed in the 2020 Dietary Guidelines. Please explain why HHS supports two separate work streams to serve the same purpose in developing recommendations specific to alcohol consumption – one by the National Academies and a second by the SAMHSA-led interagency working group.

Response:
While both NASEM's study and ICCPUD's alcohol intake and health study will assess 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. The NASEM study will yield graded conclusion statements, not recommendations for adult alcohol consumption. The alcohol intake and health study will use risk modeling to generate evidence on the health risks of weekly drinking thresholds as well as risk modelling to estimate the lifetime risk of death and disability for different levels of average alcohol consumption. Given that these two distinct studies have different outcomes and methodologies, they will both provide important findings on the relationship between alcohol intake and health, making them complementary rather than redundant. Finally, neither study will provide specific recommendations on alcohol consumption by adults

Question #81
How will HHS ensure that any recommendations developed by the SAMHSA-led working group are developed free of conflicts of interest?

Response:
SAMHSA and/or any working group led by SAMHSA is not developing the recommendations, the ICCPUD will be conducting an independent study on alcohol consumption and health outcomes**.** The ICCPUD will use its existing structure and procedures as outlined in the 2023 ICCPUD Comprehensive Plan to create a balanced subcommittee that includes a full assessment of conflicts of interest to minimize bias. All Technical Review Subcommittee members have been sought with a disease prevention and public health orientation and include scientists from diverse backgrounds representing a range of career levels including mid-career researchers.

All Technical Review Subcommittee members and external subject matter experts will be 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.

The Scientific Review Panel (SRP) was selected through an ICCPUD nominations process. The Associate Administrator for Alcohol Prevention and Treatment Policy oversees the operational aspects of ICCPUD and put together the initial list of potential experts for consideration, based on their scientific expertise, publications, and a review of conflicts of interest. This list was shared with the ICCPUD agency representatives, who provided additional recommendations and feedback. Once the list was condensed to less than ten potential experts by the ICCPUD members, potential external experts were invited to the SRP by the Associate Administrator. Ultimately six external experts were included on the panel. In addition to the six external experts on the SRP, which have disclosed any potential conflicts of interest, the study methodology includes the use of a nominal group interview process. Consistent with best-practice research, this scientific process will engage additional experts in six distinct areas ((i) cancer, (ii) cardiovascular diseases, (iii) digestive conditions, (iv) neurological disorders, (v) infectious diseases, and (vi) injuries). Selection of these additional experts for participation in the nominal group process will be based on the authors who have published the largest number of first and last author publications concerning the above-noted disease areas (as determined by performing a PubMed Search) in the past 10 years. These authors will be asked to participate in the nominal group interview panels to determine the most appropriate meta-analyses to use in the study. The nominal group interview allows for the selection of meta-analyses avoiding group think and reduces random error in decision making by increasing the number of people whose opinions are considered in the scientific process.

Question #82

Federal law requires that the preponderance of scientific and medical knowledge must support changes to the existing Dietary Guidelines recommendations. No changes can be made without clearly showing that the preponderance of scientific and medical knowledge supports each change. How is the SAMHSA-led technical committee ensuring that this mandate by Congress is followed as it reviews research and drafts recommendations?

Response:

SAMHSA and/or any working group led by SAMHSA is not developing the recommendations, the ICCPUD will be conducting an independent study on alcohol consumption and health outcomes**.** The ICCPUD Alcohol Intake and Health study and the NASEM study will conduct complementary assessments of the relationship between alcohol consumption and various health outcomes. The synthesis of these findings will be provided to HHS and USDA for consideration as they develop guidelines for alcohol consumption as part of the Dietary Guideline development process.

Analyses will be conducted by experts in disease prevention and public health and include scientists from diverse backgrounds representing a range of career levels including experts and mid-career researchers. Methodological approaches will be grounded in rigorous scientific evidence and follow best practices for conducting systematic reviews and reviewing meta-analyses. The findings will undergo a rigorous review process that will include scientific peer review and opportunities for public comment.

Question #83
How is HHS ensuring that the scientific review process underway by the SAMHSA-led working group mirrors the Dietary Guidelines Advisory Committee process in its research procedures and protocols, commitment to transparency, preclusion of conflicts of interest and willingness to invite comment from interested public stakeholders?

Response:
The findings will undergo a rigorous review process that will include scientific peer review and opportunities for public comment.
The Alcohol Intake and Health study will undergo two opportunities for written formal feedback and public comment via Request for Information: one in the summer of 2024 to specifically solicit feedback on the scientific methodology to be used by the ICCPUD TRS and SRP to assess the relationship between alcohol intake and health, and the second in the summer of 2025 to solicit public comment on the findings of the study. Feedback will be taken under consideration and shared with the Subcommittee and SRP for potential inclusion and revision. The public comment opportunities will ensure transparency in the methodology and that the broadest evidence base is considered in this study. In conjunction with the caliber of experts conducting the study, this process will ensure that the findings presented to the Subcommittee will be based on the latest science and medical knowledge.

Additionally, there will be three opportunities for public engagement over the course of the study:

1. In August 2024, the ICCPUD Annual Stakeholders Meeting for interested parties including the alcohol beverage industry; medical, public health, consumer, and parent groups; law enforcement; institutions of higher education; community-based organizations and coalitions; and other relevant stakeholders to engage and provide input on this effort;
2. In August 2025, the ICCPUD Annual Stakeholders Meeting for interested parties; and
3. Additionally, in September 2025, a public meeting will be held on the findings of the Alcohol Intake and Health study

Question #84
Will the work of the National Academies and recommendations developed by the SAMHSA-led interagency group be considered for inclusion in the 2025 Dietary Guidelines? If not, please explain how any alcohol policies will be reported to consumers, the medical community and interested stakeholders.

Response:
HHS and USDA are required by statute to jointly publish the Dietary Guidelines every 5 years. The next edition of the Dietary Guidelines, the 2025-2030 edition, will be released by the end of 2025. HHS is serving as the administrative lead for the 2025-2030 edition. As a part of this effort, HHS and USDA requested that the ICCPUD, as the interagency coordinating committee dedicated to alcohol use and health, support a synthesis of the current science on health risks associated with alcohol use. The Alcohol Intake and Health Study is the primary mechanism ICCPUD will use to assess the current state of the science. The ICCPUD Alcohol Intake and Health study and the NASEM study will conduct complementary assessments of the relationship between alcohol consumption and various health outcomes. The synthesis of these findings will be provided to HHS and

USDA for consideration as they develop guidelines for alcohol consumption as part of the Dietary Guideline development process.

Question #85

Please provide the names of those appointed by the SAMHSA-led working group to the Technical and Scientific Committees who are reviewing research and drafting recommendations.
Please provide a list of staff from each agency who are participating in the SAMHSA-led interagency working group.

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.

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

Question #86

Will the research reviewed by the National Academies and SAMHSA-led working group include potential risks as well as potential harm from moderate consumption of alcohol? Please outline and list all protocols that each working group is utilizing to assess research and develop recommendations.

Response:

While both NASEM's study and ICCPUD's alcohol intake and health study will assess 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.
These studies will assess the relationship between alcohol intake and health; the findings may include related risks, harms, and benefits, depending on the best available science and findings of the analyses.

The table below provides a comparison of the two studies.

Study	Purpose	Methods and Product
NASEM – Review of evidence on alcohol and health https://www.nationalacademies.org/our-work/review-of-evidence-on-alcohol-and-health	To review, evaluate, and report on the current scientific evidence on the relationship between alcohol consumption and the following health outcomes: 1. growth, size, body composition, and risk of overweight and obesity 2. risk of certain types of cancer 3. risk of cardiovascular disease	The NASEM study involves the conduct of systematic reviews. The NASEM study will yield graded conclusion statements, not recommendations for adult alcohol consumption. This study is scheduled to be completed in time for inclusion in the ICCPUD process that will assess the scientific evidence on adult alcohol

	4. neurocognitive health 5. risk of all-cause mortality 6. post-partum weight loss 7. human milk composition and quantity 8. Infant development milestones, including neurocognitive development	consumption. USDA and HHS will also consider the findings from the NASEM study as the Departments review the findings from ICCPUD and develop the Dietary Guidelines.
ICCPUD - Alcohol intake and health study	To generate risk estimates for weekly thresholds to minimize health risks by modelling cause-specific absolute risk curves based on disease-, injury-, and condition-specific relative risk curves from cohort studies from conditions that are thought to be causally related to alcohol use (e.g., liver cirrhosis and cancer). This approach aligns with the current practices of the Centers for Disease Control and Prevention, the World Health Organization, and the Institute for Health Metrics and Evaluation, when estimating the burden of disease attributable to alcohol use.	The alcohol intake and health study will use the following methods to generate evidence on weekly drinking thresholds to minimize health risks: • Lifetime risk modelling to estimate the lifetime risk of death and disability for different levels of average alcohol consumption. • Model cause-specific absolute risk curves based on disease-, injury-, and condition-specific relative risk curves. • Cohort studies from conditions that are thought to be causally related to alcohol use (e.g., liver cirrhosis and cancer) The ICCPUD study will be considered with the NASEM systematic reviews by the ICCPUD Technical Review Subcommittee as the Subcommittee provides a synthesis of the data and summarizes the science on adult alcohol consumption. The end product of the ICCPUD alcohol and intake study will be a synthesis of the science, not recommendations on alcohol consumption.

Question #87

Will alcohol policies and recommendations remain part of future Dietary Guidelines or will they be part of a separate process and which agency will lead that effort?

Response:
Guidance specific to alcohol consumption will be included in the 2025-2030 Dietary Guidelines. For the process to update the next edition, HHS and USDA determined the topic requires a comprehensive review with significant, specific expertise. HHS and USDA are addressing the scientific reviews on this topic through efforts. The scientific reviews on adult alcohol consumption and health are being conducted by a Department of Health and Human Services (HHS) Committee and the National Academies of Sciences, Engineering and Medicine (NASEM) working on complementary tracks. Both projects will include opportunities for public participation and will include external scientific peer review. These efforts are under way and slated to be completed by the end of December 2024. Each will result in a report with findings, not recommendations on alcohol consumption. These findings will be considered by HHS and USDA as the Departments develop the next edition of the Dietary Guidelines.
While both evidence reviews will address the relationship between alcohol and health, there are key distinctions between the two, including some of the outcomes being examined and the methods being used to conduct the studies.

Question #88
Mr. Secretary, how will you work with this board to ensure the administration produces results to support our bioeconomy?

Question #89
Additionally, beyond the creation of this board, is the administration on track to meet its deadlines for the purposes of this executive order? Can you commit to providing regular updates on these efforts?

Response 88-89:
USDA and HHS are required by statute to jointly publish the Dietary Guidelines every 5 years. The next edition of the Dietary Guidelines, the 2025-2030 edition, will be released by the end of 2025. HHS is serving as the administrative lead for the 2025-2030 edition. More information on the dietary guidelines' development process is available here: https://www.dietaryguidelines.gov/usda-hhs-development-dietary-guidelines.
A Nutrition Evidence Systematic Review (NESR) is the gold-standard evidence-based synthesis project that answers a nutrition question of public health importance using systematic, transparent, rigorous, and protocol-driven methods to search for, evaluate, synthesize, and grade the strength of the eligible body of evidence. The DGAC has access to systematic reviews conducted by previous Committees. For proposed questions that could be answered by a systematic review, USDA staff identified existing systematic reviews that had been conducted by a previous Committee or expert group to address the same scientific question. The Committee then determines whether to update the existing NESR systematic reviews based on whether the existing review still reflects the state of the science, or if newly published evidence could result in changes to the conclusions and strength of the evidence. In connection with the current Dietary Guidelines, the DGAC has discussed prioritization of the scientific questions in public meetings, and the systematic review protocols have been made publicly available.

The DGAC includes nationally recognized scientific experts in nutrition and medicine appointed by HHS and USDA. The 2025 DGAC is formed under and governed by the Federal Advisory Committee Act (FACA), which provides legal requirements for forming and using Federal advisory committees. According to FACA, a charter must be filed with Congress before a Federal advisory committee can meet or take any action. The

charter for the 2025 DGAC was filed on December 9, 2022. HHS and USDA accepted Committee nominations from the public and reviewed all complete nomination packages, including to ensure that the interests and affiliations of Committee members were reviewed for conformance with applicable conflicts-of-interest statutes and regulations and to ensure that Committee membership was fairly balanced in terms of the points of view represented and functions to be performed. As suggested in the NASEM recommendation, HHS and USDA developed publicly shared criteria against which nominees were screened: professional experience, educational background, demonstrated scientific expertise, and balanced and diverse membership.

The members of the DGAC are appointed as special government employees (SGEs). All SGEs have a fiduciary responsibility to the federal government and must follow comprehensive federal ethics laws, including the criminal conflicts of interest and financial disclosure reporting laws, and the Standards of Ethical Conduct for Employees of the Executive Branch. All SGEs must comply with the financial disclosure requirements found in U.S. Office of Government Ethics (OGE) regulations. Each Committee member was also provided SGE-specific ethics training as required by statute, regulation, and HHS policies upon appointment and will continue to do so annually throughout their service on the Committee.

The vetting process for potential members of the Committee includes a background check to determine if any candidates have a financial conflict of interest or impartiality concerns that would prohibit them from serving on the Committee. HHS ethics officials ensure interests and affiliations of proposed Committee members complied with applicable conflicts of interest statutes, regulations issued by OGE, additional agency requirements, and other applicable Federal ethics rules.

To demonstrate their commitment to transparency, the members of the DGAC have further voluntarily agreed to disclose relationships, activities, and interests that may potentially be related to the content of the Committee's scientific review, as defined by the International Committee of Medical Journal Editors. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the Committee's report. The decisions of the Committee are collective, and therefore, the Committee has provided public disclosures reflective of the last 12 months collectively. This voluntary action on the part of the 2025 Committee is the first time a DGAC has disclosed such information publicly and represents a commitment to transparency that goes beyond what is required of federal advisory committees.

Each step of the process for developing the Dietary Guidelines includes opportunities for public participation. The DGAC public comment period has been open since January 19, 2023, and will remain open throughout the Committee's work to allow for public comment on the Committee's scientific review throughout the entire process. In addition, during the DGAC's evidence review, the public is regularly encouraged to submit written comments to the DGAC related to the scientific questions being examined. HHS and USDA encourage public comments through Federal Register notices, blogs, GovDelivery notifications, in social media posts, and during public meetings. All public comments will be taken into consideration by the Committee during its evidence review and in the development of its final report.

Meetings of the DGAC are open to the public in accordance with FACA and guidelines within the Government in the Sunshine Act at 5 U.S.C.552b. Notice of all Committee meetings are provided to the public through the Federal Register and at www.DietaryGuidelines.gov. All Committee meetings can be viewed by the public online. Meeting recordings, slides and summaries are posted online for each meeting. During these meetings, the Committee reviews the scientific questions it will address in its evidence review. In general, meetings include presentations by subcommittees and deliberation by the full Committee to detail progress made since previous meetings, including protocol development, evidence review and synthesis, draft conclusion statements, plans for upcoming work, and the development of the Committee's scientific report. Members of the public

provided virtual oral comments to the DGAC at the DGAC's third public meeting.

Regarding alcohol consumption, in early 2022, the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD) asked the HHS Substance Abuse and Mental Health Services Administration (SAMHSA), as the convenor of the ICCPUD, to support a technical subcommittee with expertise on adult alcohol consumption to review evidence on adult alcohol intake and health. Additionally, in the 2023 Consolidated Appropriations Act, 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 health.

The ICCPUD and NASEM reviews are complementary. Both projects will include opportunities for public comment and engagement and will include external scientific peer review. These efforts are underway and slated to be completed 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.

Rep. Gregory Steube (R-FL)

Question #90

In the Contract Year 2025 Medicare Advantage (MA) and Part D proposed rule, the Centers for Medicare and Medicaid Services (CMS) proposes certain changes to agent and broker compensation for enrolling individuals in MA plans. The proposed rule has implications for Medicare beneficiaries, field marketing organizations (FMOs), and agents and brokers who all play important roles in helping seniors select and enroll in the MA plan that best meets their needs, and it is important that there not be any unintended consequences that could adversely impact beneficiaries.

I led a letter with most Republicans on this committee to CMS trying to get clarification and answers. Unfortunately, your agency sent the rule to OMB for final review before responding to our letter almost two months later with a less than satisfactory response.

Why did CMS move forward with sending the rule to OMB before replying to the members of the committee?

What is the average response time for CMS and HHS to congressional letters while you have been Secretary?

The response letter says "the proposed single compensation rate is based on calculations that we described in detail in the proposed rule." Please describe them for better awareness for both the committee and the public.

Some stakeholders have told me that they believe the letter supports the interpretation that the administrative fee provision and the $31 cap applies only to agents and brokers, not FMOs. To date, CMS has refused to confirm this explicitly. Under the rule, are FMOs subject to the $31 cap?

Will you commit to engaging FMOs and other relevant stakeholders prior to issuing any future

rulemaking that could affect the FMO business model and FMOs' ability to enter in services contracts with carriers to ensure there are no adverse impacts to our nation's seniors?

Question #91

What data did CMS review to inform the decision to establish the $31 administrative payment? How did you come up with this number?

Will CMS share the data that forms the methodological basis to determine the proposed, new administrative payment of $31 as we requested in our letter?

Does CMS intend the $31 to cover all administrative costs, including costs provided by a third party, such as an FMO? And if yes, on what basis did CMS calculate that $31 would be sufficient to compensate the services covered by administrative payments?

If CMS anticipates regulating field marketing organization (FMO) costs, please provide the statutory basis for this regulation.

Question #92

Why did you propose changes to the agent and broker compensation regulations that would eliminate Field Management Organizations?

How many Field Management Organizations are there?

What impact did you consider the removal of the FMO/broker resource would have on the dual eligible population?

What impact would the removal of the management and oversight organization have on Medicare beneficiary access to care and resources, such as Medicaid eligibility determination/redetermination?

What are the essential services that Field Management Organizations provide to Medicare Beneficiaries?

Who will provide the highly specialized administrative services given the removal of Field Management Organizations?

Have you researched what organizations the Medicare complaints have originated from?

And have you seen that most of the complaints are concentrated among a few brokers, organizations, and/or organization types?

How do you differentiate between a community-based broker management organization and a third-party lead-generating organization?

What is the impact of unsupervised brokers due to the elimination of their management organization?

Question #93

When CMS required all agent calls with beneficiaries to be recorded and kept for 10 years, insurance plans offloaded this responsibility to FMOs because they could not comply. If FMOs are no longer in business, are plans ready to handle the compliance costs FMOs were handling?

How much will this cost?

Will there be a compliance difference between regional plans and national plans who may be better positioned to carry the cost?

Question #94

I am concerned about bad actors who may sign beneficiaries up for a plan that doesn't meet their needs, and probably as a result of aggressive sales tactics.

Do you know the number of beneficiaries that disenroll from MA plans within three months of enrollment?

Do you know of those who disenroll, how many were assisted in their enrollment and the nature of their assisting entity (third-party marketing organizations, field marketing organizations, e-brokers, etc.)?

Has CMS found a correlation between compensation paid to agents and brokers and beneficiary complaints or rapid disenrollment (disenrolling in a plan within 3 months of enrollment)?

I am told regional plans are having a very good enrollment year – they showed up with lower premiums and more robust benefits than national plans. Have you found a correlation between higher payments to agents and enrollment in specific plans?

Response (90-94):
HHS agrees that it is critical to ensure that as the MA and Part D Programs continue to grow, it remains viable and that seniors and individuals with disabilities eligible for Medicare can make informed decisions about their health care coverage, and, when appropriate, enroll in the plan that is best suited to their personal health care needs. As discussed in the CY 2025 MA and Part D proposed rule, section 1851(j) of the Social Security Act requires that CMS develop guidelines to ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the MA plan that is intended to best meet their health care needs. We have learned, however, that many MA and stand-alone Prescription Drug Plans (PDP), as well as third-party entities with which they contract (such as Field Marketing Organizations (FMO)), have structured payments to agents and brokers that have the effect of circumventing existing CMS regulations that limit agent and broker compensation to specified fair market value (FMV) levels. CMS has also received complaints from different organizations, including state partners, beneficiary advocacy organizations, and MA plans, to this effect. A common thread to the complaints is that agents and brokers are being paid, typically through various purported administrative and other add-on payments, amounts that cumulatively exceed the maximum compensation allowed under the current regulations. Moreover, CMS has observed that such payments have created an environment, not dissimilar to what originally prompted us to set limits on agent and broker compensation in 2008, where the amounts being paid for activities that do not fall under the umbrella of "compensation," are rapidly increasing.

We understand that FMOs help millions of Medicare beneficiaries to learn about and enroll in Medicare, Medigap, MA plans, and PDP plans by providing guidance on plan options, including comparisons of relative costs and coverage, as well as assisting beneficiaries with applying for financial assistance.

In our proposed rule, CMS is focused on current payment structures among MA organizations, agents, brokers, and Third-Party Marketing Organizations (TMPO), including FMOs, that may incentivize agents or brokers to emphasize or prioritize one plan over another, irrespective of the beneficiary's needs, leading to enrollment in a plan that does not best fit the beneficiary's needs and a distortion of the competitive process. In this rule, CMS has proposed to: (1) generally prohibit contract terms between MA organizations and agents, brokers, or other TMPOs that may interfere with the agent's or broker's ability to objectively assess and recommend the plan which best fits a beneficiary's health care needs; (2) set a single agent and broker compensation rate for all plans, while revising the scope of what is considered "compensation;" and (3) eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services.

CMS is committed to collaborating and engaging with stakeholders and interested parties in the policy-making process. The comment period for the CY 2025 MA and Part D proposed rule closed on January 5, 2024. CMS sought comment on these proposals to further inform our calculations and policy direction. We have received feedback from many interested parties on our proposed policy, and we will carefully consider these comments throughout this rulemaking process.

Question #95

In your proposed rule, "Strengthening TANF as a Safety Net and Work Program," the Administration carries this attack by singling out crisis pregnancy centers and preemptively suggests they cannot be "reasonably calculated to accomplish a TANF purpose," and therefore TANF spending to support these vital centers would no longer be allowable should the proposed rule become final. Alarmingly, the rule goes further and appears to suggest TANF should instead be steered toward family planning programs similar to the business model of Planned Parenthood because they meet the TANF purpose of "preventing out of wedlock births."

Are you aware that over 2,700 crisis pregnancy centers served over two million people in 2019 with services such as pregnancy testing, testing for sexually transmitted diseases, prenatal and pregnancy education, ultrasounds, adoption referrals, diapers, baby clothes, linkages to housing, and other material supports?

Could prenatal and pregnancy education services, including pregnancy testing and ultrasounds, be "reasonably calculated" to "encourage the formation and maintenance of two-parent families?" If not, why not?

Could adoption referral services be "reasonably calculated" to "encourage the formation and maintenance of two-parent families?" If not, why not?

Would services that provide necessary products such as diapers and baby clothes be "reasonably calculated" to "provide assistance to needy families so that children may remain in their homes" and/or "encourage the formation and maintenance of two-parent families?" If not, why not?

Response:

The Strengthening TANF Notice of Proposed Rulemaking NPRM proposes to improve the effectiveness and integrity of the TANF regulations. One proposed provision in the NPRM sets forth the reasonable person standard for assessing whether an expenditure is "reasonably calculated to accomplish a TANF purpose." Some of the services offered by pregnancy centers may be allowable if they are reasonably calculated to accomplish a TANF purpose. Fact-specific analysis must determine the connection to a TANF purpose. The NPRM preamble proposes several forms of evidence that a State might provide to support its justification for a TANF expenditure. We note that 42 U.S.C. 608(a)(6) prohibits TANF funds for being used to provide medical services.

Question #96

Your agency expanded abortion by approving abortion pills to be sent in the mail - likely in violation of federal law. HHS has enabled providers to prescribe abortion drugs without examining the patient, being physically present for the abortion, and without follow up visits. These horrific practices are obviously unsafe for the child - as it results in their death - but it is unsafe for the mother as well.

In a press release from April 2023, you stated that abortion pills are "safe and effective."

Mr. Secretary, do you have any medical training or experience that informs your position that these drugs are "safe and effective?"

Are you aware that as many as 15% of women taking abortion drugs suffer hemorrhage?

Response:

FDA's regulatory decisions, including decisions regarding the safety and effectiveness of medical products, are based on the best available science and data. FDA stands by its evidence-based approval of mifepristone for medical termination of early pregnancy. FDA's regulatory decisions regarding mifepristone for medical termination of early pregnancy are the subject of pending litigation; given the pending litigation, I decline to comment further.

Question #97

Can you explain the process the Office of Refugee Resettlement (ORR) uses to find placements and shelter for unaccompanied migrant children as it relates to the availability of state licensed homes and placements for children in foster care?

Does HHS report on the number of state-licensed foster care parents or congregate care providers who are caring for unaccompanied children? If not, can you commit to working with the Committee to provide that information?

Some news reports have found that HHS is looking for placements for migrant children by recruiting from limited foster homes available to provide care to the nearly 400,000 children and youth already in America's child welfare system. For example, Governor Pete Ricketts (R-NE), Governor Kristi Noem (R-SD), Governor Kim Reynolds (R-IA), and Governor Henry McMaster (R-SC) have all publicly declined the Administration's requests due to existing pressures on the foster care system. To what extent is HHS relying on state child welfare agencies to find

placements to accommodate migrant children?

Rep. Claudia Tenney (NY-R)

Question #98
As you are aware CMS now requires all hospitals to make public their standard charges for items and services they provide. However, a Patient Rights Advocate report released last month found that only 34.5% of the 2,000 hospitals it reviewed were in full compliance. In addition, CMS has issues notices to only 14 hospitals for a lack of compliance. Does CMS plan to increase its enforcement of hospital price transparency standards and when should we expect that improvement by?

Response:
CMS is committed to ensuring that hospitals make public clear, accessible standard charge information online about the items and services they provide in accordance with the hospital price transparency (HPT) regulations. We expect hospitals to comply with these requirements and are actively enforcing these rules to make sure Americans know in advance what hospitals charge for the items and services they provide. CMS enforces the HPT regulations by conducting comprehensive compliance reviews through monitoring and assessing hospitals' noncompliance with the requirements. These reviews consist of evaluating complaints made by the public, reviewing individuals' or entities' analysis of noncompliance, and internally auditing hospitals' websites. CMS prioritizes hospitals for comprehensive reviews based on the degree to which the hospital appears to be out of compliance with the HPT regulation. When initially evaluating complaints, if egregious violations have been alleged against a hospital, such as failure to publish any machine-readable file (MRF), that case is prioritized.

Since January 1, 2021, the effective date of the HPT regulation, CMS has taken steps to increase compliance by strengthening the enforcement process. For example, beginning January 1, 2022, and with respect to violations on or after that date, CMS increased penalties for hospitals that do not comply. In April 2023, we updated enforcement processes by requiring corrective action plan completion deadlines, imposing civil monetary penalties earlier and automatically, and streamlining the compliance process. These enforcement updates shorten the average time by which hospitals must come into compliance with the HPT requirements after a deficiency is identified and will complement future efforts. Finally, in the calendar year (CY) 2024 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center (OPPS/ASC) Payment System final rule, we finalized several proposals to improve enforcement, including:

- Publicizing compliance assessments, actions, and outcomes;
- Requiring submission of certification by an authorized hospital official as to the accuracy and completeness of the data in the machine-readable file;
- Requiring hospitals to acknowledge receipt of a warning notice;
- Notifying the health system's leadership of noncompliance enforcement actions and CMS may work with health system leadership to address similar deficiencies for hospitals across the health system.

Enforcing the hospital price transparency requirements is a high priority for CMS in order to increase competition and bring down costs. It is imperative that consumers can access cost information to shop for care and save money and for employers to use data to negotiate more competitive rates.

Question #99

As you may be aware, last year CMS made a adjustment to the wage index for Upstate hospitals, treating geographically rural and rural reclassified hospitals the same. This change resulted in wage index increases of between 20-40 percent throughout Upstate. While this produced relief for hospitals that had been severely underpaid by the fee for service program, it had the inadvertent effect of putting enormous financial pressure on Upstate MA plans, which are largely regional not for profit plans. Because the 2024 benchmarks did not capture these new costs, plans are facing losses in excess of $220 million for the 5 not for profit plans over the past year. We are also concerned that existing CMS policy (such as the pre-ACA cap) will prevent the 2025 benchmark rate from fully capturing the wage index increase going forward. I understand that the Upstate MA plan community has been in communication with CMS to try to find a solution that protects beneficiaries from the dramatic reductions in access and benefits that will occur if the benchmark problem is not solved. Would you be willing to weigh in with CMS to encourage a prompt resolution?

Response:

CMS shares your commitment to a strong MA program that meets the needs of New York beneficiaries. We have heard from the upstate New York plans about their concerns. We carefully looked at the statute and regulations for what MA payment adjustments could be made. We concluded that we do not have the discretion or flexibility to revise or amend the 2024 MA payments for policies that were finalized after March 31, 2023 when the 2024 Rate Announcement was released. The FY 2024 IPPS final rule was finalized several months later in August 2023. With respect to concerns about 2025 MA payments, we solicited public comments on the 2025 Advance Notice. We will consider the comments received, including any submitted by the upstate New York plans, before issuing the 2025 Rate Announcement by April 1, 2024.

Question #100 A.

Currently, deliberations over the 2025 Dietary Guidelines are well underway, and review of alcohol policies will be addressed through a separate process. The Committee has learned that the SAMHSA-led interagency working group began meeting last year but many questions have arisen as to who, how and when recommendations developed by this group will be released and whether its recommendations will be reviewed by both HHS and USDA for inclusion in the 2025 Dietary Guidelines. The Committee is seeking answering to the following questions:

> A. Will guidance specific to alcohol consumption be included in the 2025 Dietary Guidelines?

Response:

USDA and HHS are required by statute to jointly publish the Dietary Guidelines every 5 years. The next edition of the Dietary Guidelines, the 2025-2030 edition, will be released by the end of 2025. The ICCPUD Alcohol Intake and Health study and the NASEM study will conduct complementary assessments of the relationship between alcohol consumption and various health outcomes. Both projects will include opportunities for public comment and engagement and will include external scientific peer review. These efforts are underway

and slated to be completed by the end of December 2024. Each will result in a report with scientific findings, not recommendations, on alcohol consumption. The synthesis of these findings will be provided to HHS and USDA for consideration as they develop guidelines for alcohol consumption as part of the Dietary Guideline development process.

Question #100 B

B. Congress appropriated $1.3 million through USDA for the National Academies of Science, Engineering and Medicine to assess research on alcohol consumption and health outcomes that were not addressed in the *2020 Dietary Guidelines.* Please explain why HHS supports two separate work streams to serve the same purpose in developing recommendations specific to alcohol consumption - one by the National Academies and a second by the SAMHSA-led interagency working group.

Response:

While both NASEM's study and ICCPUD's alcohol intake and health study will assess 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. The NASEM study will yield graded conclusion statements, not recommendations for adult alcohol consumption. The alcohol intake and health study will use risk modeling to generate evidence on the health risks of weekly drinking thresholds as well as risk modelling to estimate the lifetime risk of death and disability for different levels of average alcohol consumption. Given that these two distinct studies have different outcomes and methodologies, they will both provide important findings on the relationship between alcohol intake and health, making them complementary rather than redundant. Finally, neither study will provide specific recommendations on alcohol consumption by adults.

Question #100 C

C. How will HHS ensure that any recommendations developed by the SAMHSA-led working group are developed free of conflicts of interest?

Response:

The ICCPUD will use its existing structure and procedures as outlined in the 2023 ICCPUD Comprehensive Plan to create a balanced subcommittee that includes a full assessment of conflicts of interest to minimize bias. All Technical Review Subcommittee members have been sought with a disease prevention and public health orientation and include scientists from diverse backgrounds representing a range of career levels including mid-career researchers. All potential internal and external subject matter experts will be free from conflicts of interest.

All Technical Review Subcommittee members and external subject matter experts will be 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.

The Scientific Review Panel (SRP) was selected through an ICCPUD nominations process. The Associate Administrator for Alcohol Prevention and Treatment Policy oversees the operational aspects of ICCPUD and put together the initial list of potential experts for consideration, based on their scientific expertise, publications, and a review of conflicts of interest. This list was shared with the ICCPUD agency representatives, who provided additional recommendations and feedback. Once the list was condensed to less than ten potential experts by the ICCPUD members, potential external experts were invited to the SRP by the Associate Administrator. Ultimately six external experts were included on the panel. In addition to the six external experts on the SRP, which have disclosed any potential conflicts of interest, the study methodology includes the use of a nominal group interview process. Consistent with best-practice research, this scientific process will engage additional experts in six distinct areas ((i) cancer, (ii) cardiovascular diseases, (iii) digestive conditions, (iv) neurological disorders, (v) infectious diseases, and (vi) injuries). Selection of these additional experts for participation in the nominal group process will be based on the authors who have published the largest number of first and last author publications concerning the above-noted disease areas (as determined by performing a PubMed Search) in the past 10 years. These authors will be asked to participate in the nominal group interview panels to determine the most appropriate meta-analyses to use in the study. The nominal group interview allows for the selection of meta-analyses avoiding group think and reduces random error in decision making by increasing the number of people whose opinions are considered in the scientific process.

The ICCPUD Alcohol Intake and Health study and the NASEM study will conduct complementary assessments of the relationship between alcohol consumption and various health outcomes. Both projects will include opportunities for public comment and engagement and will include external scientific peer review. These efforts are underway and slated to be completed by the end of December 2024. Each will result in a report with scientific findings, not recommendations, on alcohol consumption. The synthesis of these findings will be provided to HHS and USDA for consideration as they develop guidelines for alcohol consumption as part of the Dietary Guideline development process.

Question #100 D

D. Federal law requires that the preponderance of scientific and medical knowledge must support changes to the existing *Dietary Guidelines* recommendations. No changes can be made without clearly showing that the preponderance of scientific and medical knowledge supports each change. How is the SAMHSA-led technical committee ensuring that this mandate by Congress is followed as it reviews research and drafts recommendations?

Response:
Analyses will be conducted by experts in disease prevention and public health and include scientists from diverse backgrounds representing a range of career levels including experts and mid-career researchers. Methodological approaches will be grounded in rigorous scientific evidence and follow best practices for conducting systematic reviews and reviewing meta-analyses. The findings will undergo a rigorous review process that will include scientific peer review and opportunities for public comment.

The ICCPUD Alcohol Intake and Health study and the NASEM study will conduct complementary assessments of the relationship between alcohol consumption and various health outcomes. Both projects will include

opportunities for public comment and engagement and will include external scientific peer review. These efforts are underway and slated to be completed by the end of December 2024. Each will result in a report with scientific findings, not recommendations, on alcohol consumption. The synthesis of these findings will be provided to HHS and USDA for consideration as they develop guidelines for alcohol consumption as part of the Dietary Guideline development process.

Question #100 E

E. How is HHS ensuring that the scientific review process underway by the SAMHSA-led working group mirrors the Dietary Guidelines Advisory Committee process in its research procedures and protocols, commitment to transparency, preclusion of conflicts of interest and willingness to invite. comment from interested public stakeholders?

Response:

The findings will undergo a rigorous review process that will include scientific peer review and opportunities for public comment.

The Alcohol Intake and Health study will undergo two opportunities for written formal feedback and public comment via Request for Information: one in the summer of 2024 to specifically solicit feedback on the scientific methodology to be used by the ICCPUD TRS and SRP to assess the relationship between alcohol intake and health, and the second in the summer of 2025 to solicit public comment on the findings of the study. Feedback will be taken under consideration and shared with the Subcommittee and SRP for potential inclusion and revision. The public comment opportunities will ensure transparency in the methodology and that the broadest evidence base is considered in this study. In conjunction with the caliber of experts conducting the study, this process will ensure that the findings presented to the Subcommittee will be based on the latest science and medical knowledge.

Additionally, there will be three opportunities for public engagement over the course of the study: In August 2024 and 2025, the ICCPUD Annual Stakeholders Meeting for interested parties including the alcohol beverage industry; medical, public health, consumer, and parent groups; law enforcement; institutions of higher education; community-based organizations and coalitions; and other relevant stakeholders to engage and provide input on this effort. Additionally, in September 2025, a public meeting will be held on the findings of the Alcohol Intake and Health study.

Question #100 F

F. Will the work of the National Academies and recommendations developed by the SAMHSA-led interagency group be considered for inclusion in the *2025 Dietary Guidelines?* If not, please explain how any alcohol policies will be reported to consumers, the medical community and interested stakeholders.

Response:

HHS and USDA are required by statute to jointly publish the Dietary Guidelines every 5 years. The next edition of the Dietary Guidelines, the 2025-2030 edition, will be released by the end of 2025. HHS is serving as the administrative lead for the 2025-2030 edition. As a part of this effort, HHS and USDA requested that the

ICCPUD, as the interagency coordinating committee dedicated to alcohol use and health, support a synthesis of the current science on health risks associated with alcohol use. The Alcohol Intake and Health Study is the primary mechanism to assess the current state of the science. Based on this request, findings from the Alcohol Intake and Health study as well as the NASEM study will be provided to HHS and USDA for consideration as they develop the 2025-2030 Dietary Guidelines.
The ICCPUD Alcohol Intake and Health study and the NASEM study will conduct complementary assessments of the relationship between alcohol consumption and various health outcomes. The synthesis of these findings will be provided to HHS and USDA for consideration as they develop guidelines for alcohol consumption as part of the Dietary Guideline development process.

Question #100 G

G. Please provide the names of those appointed by the SAMHSA-led working group to the Technical and Scientific Committees who are reviewing research and drafting recommendations. Please provide a list of staff from each agency who are participating in the SAMHSA-led interagency working group.

Response:
HHS and USDA will update guidance on alcohol consumption, as the authors of the Dietary Guidelines. The ICCPUD will not make recommendations on alcohol consumption.

a. The Technical Review Subcommittee includes representatives designated by their agency Principal from the following agencies:
   - Office of the Assistant Secretary for Health
   - U.S. Department of Agriculture
   - 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 Institute on Alcohol Abuse and Alcoholism
   - National Institutes of Health, National Cancer Institute
   - Substance Abuse and Mental Health Services Administration

b. 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

Question #100 H

H. Will the research reviewed by the National Academies and SAMHSA-led working group include potential risks as well as potential harm from moderate consumption of alcohol? Please outline and list all protocols that each working group is utilizing to assess research and develop recommendations.

Response:
The NASEM study will use systematic reviews to examine evidence on the relationship between alcohol consumption and health outcomes, while the ICCPUD 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 as one of many inputs for their consideration as the Departments develop the next edition of the Dietary Guidelines. More information about the ICCPUD study methodology, including the study's approach to assessing risk at various levels of alcohol consumption, is available online: Alcohol Intake and Health Methodology for Public Comment pdf

Question #100 I.

I. Will alcohol policies and recommendations remain part of future *Dietary Guidelines* or will they be part of a separate process and which agency will lead that effort?

Response:
HHS and USDA are required by statute to jointly publish the Dietary Guidelines every 5 years. The next edition of the Dietary Guidelines, the 2025-2030 edition, will be released by the end of 2025 and will include guidance on alcohol consumption. HHS is serving as the administrative lead for the 2025-2030 edition. As a part of this effort, HHS and USDA requested that the ICCPUD, as the interagency coordinating committee dedicated to alcohol use and health, support a synthesis of the current science on health risks associated with alcohol use. The Alcohol Intake and Health Study is the primary mechanism ICCPUD will use to assess the current state of the science. Based on this request, findings from the Alcohol Intake and Health study as well as the NASEM study will be provided to HHS and USDA for consideration as they develop the 2025-2030 Dietary Guidelines.
The ICCPUD Alcohol Intake and Health study and the NASEM study will conduct complementary assessments of the relationship between alcohol consumption and various health outcomes. The synthesis of these findings will be provided to HHS and USDA for consideration as they develop guidelines for alcohol consumption as part of the Dietary Guideline development process.

Question #101
With the federal proposed HHS rule titled "Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting" there are significant differences between these new federal standards and those already established in states such as

New York. In New York State, nursing homes are required to provide more direct care than the federal proposal. However, the federal proposal would require more of this care to come from an RNA and leaves LPNs out completely. Finally, the federal proposal would require an RN on call 24 hours a day, which the New York law does not. This discrepancy will be an enormous burden in nursing homes across New York, and especially in rural communities with less access to staff, potentially leading to closures and less access to nursing home care. It is important to point out that when NY DOH began implementing and monitoring compliance last year with the state regulations it discovered that 80% of nursing homes were not able to comply with the regulations. That number has not dramatically changed given the staffing shortages that exist, and it is feared that should CMS finalize its rule it will add more requirements which cannot be met. It is also concerning that LPNs would not be able to help with compliance under the federal proposal and they are a major part of the healthcare workforce. Is HHS planning on adjusting the final rule to incorporate the experience of New York in its minimum staffing requirements?

Response:
Staffing in LTC facilities is a persistent concern, especially among low-performing facilities that are at most risk for providing unsafe care. Numerous studies have shown that staffing levels are closely correlated with the quality of care that LTC facility residents receive. CMS believes that national minimum nurse staffing standards in LTC facilities are necessary at this time to protect resident health and safety and ensure residents' needs are met. At the same time, CMS acknowledges the unique challenges that rural LTC facilities face, especially related to staffing, and recognizes the need to strike an appropriate balance that considers the current challenges some LTC facilities are experiencing.

With respect to the impact of this proposal on long-term care providers, CMS fully expects that LTC facilities will be able to meet the proposed minimum staffing standards. CMS crafted this proposed rule with careful consideration that many LTC facilities will need to recruit, hire, and train new staff. For example, CMS proposed that implementation of the final requirements will occur in three phases over a 3-year period for all non-rural facilities. Rural facilities will have three years to meet the proposed 24/7 RN requirement and five years to meet the proposed minimum staffing requirements. If finalized, the phased-in implementation will be helpful in that facilities may not have to hire nursing staff all at once. We recognize that in some instances, external circumstances may temporarily prevent a facility from achieving compliance despite the facility's demonstrated best efforts. To that end, we proposed to allow for a hardship exemption in limited circumstances. If finalized, LTC facilities could qualify for a temporary hardship exemption from the minimum.

Question #102A
The Change Healthcare cyberattack is the most significant cyberattack the United States health care industry has ever experienced. Systems like Change Healthcare are the underbelly of many health care providers' financial operations. Many providers had no choice but to disconnect from Change Healthcare systems to avoid security breaches in their own networks. This has resulted in forcing them to exert enormous manpower implementing workarounds to sustain their operations and continue patient care delivery. In addition, the event has created a significant performance risk for Medicare Stars and NCQA Accreditation in New York markets.

A. How is HHS working with other agencies such as CISA to prepare for and address health care-specific cyber threats?

Response:
HHS serves as the Sector Risk Management Agency (SRMA) for the HPH sector with the Administration for Strategic Preparedness and Response (ASPR) coordinating HHS SRMA activities. HHS has recently established a cybersecurity "one-stop shop" within ASPR to manage collaboration and information sharing with other HHS divisions, the healthcare industry, as well as the interagency. In this role, ASPR coordinates daily with CISA and other interagency partners as events emerge to prevent the impacts of attacks and restore services if and when impacted. In December 2023, HHS released a concept paper that outlined the Department's holistic cybersecurity strategy for the health care sector. In January 2024, the department published voluntary HPH Cybersecurity Performance Goals (HPH CPGs), which are intended to help healthcare institutions plan and prioritize implementation of high-impact cybersecurity practices. Among other things, the HPH CPGs focus on developing response plans for potential future cyber-attacks on the HPH sector. In the coming weeks and months as we emerge from this attack, we will be focused on developing additional tools, resources, and guidance to help with implementing these HPH CPGs and look forward to working with the sector to help improve its cyber posture.

Question #102B

B. Is HHS helping providers to develop contingency plans for future outages?

Response:
We recognize the impact the attack on Change Healthcare has had on health care operations across the country. HHS has acted with urgency in responding to this incident and our first priority—as it is with any cyber-attack on the Healthcare and Public Health (HPH) sector—has been to coordinate efforts to avoid disruptions to care and protect patient safety. We coordinated daily with CISA and other interagency partners to ensure all our response was as effective as possible in preventing patient impacts and restoring services. HHS is not the lead investigator for this incident but is working closely with USG colleagues on the general response.

Questions #102 Cand D

C. Can you provide any updates on the OCR investigation into Change Healthcare?
D. Is CMS and NCQA planning to hold plans using the CHC HEDIS calculation tool harmless for Measurement Year (MY) 2024 HEDIS submission or provide any other form of relief?

Response:
CMS has heard from some plans about this issue and has been in close contact with NCQA on it as well. Should the need arise, we will release guidance in the future about the submission of HEDIS data.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Breach Notification Rule requires that if a HIPAA covered entity or its business associate experiences a breach of unsecured protected health information (PHI) that affects 500 or more individuals, the HIPAA covered entity must notify the Department, affected individuals, and where applicable the media without unreasonable delay and in no case later than 60 calendar days following discovery of the breach by the covered entity.

Given the unprecedented magnitude of this cyberattack and in the interest of patients and health care providers, OCR initiated investigations of Change Healthcare and UHG in March 2024. The investigations are primarily focused on whether a breach of unsecured PHI occurred and UHG's and Change Healthcare's compliance with the HIPAA Rules. OCR also issued a Dear Colleague letter (available at https://www.hhs.gov/about/news/2024/03/13/hhs-office-civil-rights-issues-letter-opens-investigation-change-healthcare-cyberattack.html) to the health care industry to:

- Announce OCR's priority in investigating UHG and Change Healthcare's compliance with the HIPAA Rules.
- Remind entities that have partnered with UHG and Change Healthcare of their HIPAA obligations to ensure business associate agreements are in place and that timely breach notification to HHS and affected individuals occurs.
- Clarify that partner entities are not the priority in enforcement, which is focused on UHG and Change Healthcare.
- Provide resources for the health care community on the HIPAA Security Rule and cybersecurity .

OCR and other HHS agencies will work with federal and state law enforcement in support of these interests.

Question #103

As you know, many federal grants from HHS and other agencies have requirements that the federal funds provided be used to supplement current state and local funding and programs. Unfortunately, the Temporary Assistance for Needy Families program has no such requirement. To address this issue, last month I introduced the Protect TANF Resources for Families Act to prevent states from misusing TANF funds to fill gaps in state budgets. Do you support reforming TANF in this way to ensure TANF dollars are being used to supplement, not supplant state funding? Are you willing to work with me to reform TANF and put these necessary financial guardrails in place?

Response:

The Department supports and provides technical assistance to Congress and is committed to working with states and partners to maximize the effective use of state and federal dollars to achieve TANF purposes.

Rep. Mike Thompson (D-CA)

I firmly support dietary guidelines that follow the best available science, are rigorously reviewed and updated, and encourage healthy habits for American adults and children. As you and your colleagues continue to develop the next round of updates to the guidelines, I would like to know:

Question #104 A

Can you confirm that the *Guidelines* will be updated in 2025?

Question #104 B

If the *Guidelines* are indeed to be updated next year, can you confirm that the forthcoming version will include guidance related to alcohol consumption? If not, does HHS intend to promulgate guidance related to alcohol consumption in another form or through another channel?

Response 104 A-B:
USDA and HHS are required by statute to jointly publish the Dietary Guidelines every 5 years. The next edition of the Dietary Guidelines, the 2025-2030 edition, will be released by the end of 2025. HHS is serving as the administrative lead for the 2025-2030 edition.

Question #104 C
How do SAMHSA and any other agency working on this matter intend to ensure that alcohol consumption-related additions to the updated *Guidelines* are (a) free from conflicts of interest, (b) crafted transparently, and (c) reflective of the preponderance of scientific evidence?

Response 104 C:
The ICCPUD will use its existing structure and procedures as outlined in the 2023 ICCPUD Comprehensive Plan to create a balanced subcommittee that includes a full assessment of conflicts of interest to minimize bias. All Technical Review Subcommittee members have been sought with a disease prevention and public health orientation and include scientists from diverse backgrounds representing a range of career levels including mid-career researchers. All potential internal and external subject matter experts will be free from conflicts of interest.
All Technical Review Subcommittee members and external subject matter experts will be 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.

The Scientific Review Panel (SRP) was selected through an ICCPUD nominations process. The Associate Administrator for Alcohol Prevention and Treatment Policy oversees the operational aspects of ICCPUD and put together the initial list of potential experts for consideration, based on their scientific expertise, publications, and a review of conflicts of interest. This list was shared with the ICCPUD agency representatives, who provided additional recommendations and feedback. Once the list was condensed to less than ten potential experts by the ICCPUD members, potential external experts were invited to the SRP by the Associate Administrator. Ultimately six external experts were included on the panel. In addition to the six external experts on the SRP, which have disclosed any potential conflicts of interest, the study methodology includes the use of a nominal group interview process. Consistent with best-practice research, this scientific process will engage additional experts in six distinct areas ((i) cancer, (ii) cardiovascular diseases, (iii) digestive conditions, (iv) neurological disorders, (v) infectious diseases, and (vi) injuries). Selection of these additional experts for participation in the nominal group process will be based on the authors who have published the largest number of first and last author publications concerning the above-noted disease areas (as determined by performing a PubMed Search) in the past 10 years. These authors will be asked to participate in the nominal group interview panels to determine the most appropriate meta-analyses to use in the study. The nominal group interview allows

for the selection of meta-analyses avoiding group think and reduces random error in decision making by increasing the number of people whose opinions are considered in the scientific process.

Question #104 D
Does the Department intend to assess any possible benefits to, in addition to risks of, moderate alcohol consumption?

Response 104 D:
Neither the ICCPUD and NASEM studies are designed to assess possible benefits to moderate alcohol consumption.

Question #104 E
Assuming updated *Guidelines* are released in 2025, and assuming those guidelines include guidance related to alcohol consumption, does the Department intend to differentiate between different types of alcohol in the updated *Guidelines?*

Response:
USDA and HHS are required by statute to jointly publish the Dietary Guidelines every 5 years. The next edition of the Dietary Guidelines, the 2025-2030 edition, will be released by the end of 2025. HHS is serving as the administrative lead for the 2025-2030 edition.

The step in which Dietary Guidelines are updated has not begun since scientific reports that will inform updates are still in progress. HHS and USDA will review the available scientific evidence in advance of updating guidance.

Rep. Beth Van Duyne (TX-R)

Question #105
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? What administrative actions will the Administration take to ensure that Medicare beneficiaries can access the life-saving treatments they need? Furthermore, given that roughly 7 months has passed since the TCET comment period ended, can you assure us that CMS will issue the final TCET policy soon this spring or early summer?

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).

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 CMS anticipates accepting up to five TCET candidates annually due to CMS resource constraints; given the volume of National Coverage Determination (NCD) requests and our current level of resources, there are times when CMS must tell requestors that the NCD request is complete and formal, but CMS cannot immediately begin the NCD process. If so inclined, Congress can provide additional resources to CMS so that CMS can review a greater number of applications per year.

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 #106

The intent of the No Surprises Act was not only to protect patients from "surprise" medical bills but also to ensure fair and reasonable reimbursement rates to out-of-network physicians. I've heard from emergency providers in my district that they are being offered unreasonably low Qualifying Payment Amounts (QPAs) from insurers for their services, which has resulted in the IDR system being flooded with claims. These low QPA rates are not reflective of historical payment rates and the QPA calculation provisions in NSA rules released by the Administration over the last few years have allowed for the QPA to be skewed unfairly downward and the Departments have done little to audit the IDR process. What steps do HHS and the other Departments plan on taking to address these QPA calculation issues and how will you ensure that providers are being offered reasonable and fair reimbursement rates?

Response:

The Departments have established a process to audit or investigate the appropriate parties for compliance with the NSA. With regard to the QPA calculation, CMS established a process under which payers are audited by the Secretary or applicable state authority to ensure that such payers comply with the requirement that they apply a QPA that satisfies the NSA's definition of the term with respect to the year involved. This audit process is important to ensure that payers are calculating and disclosing the QPA correctly. CMS conducts market conduct exams, including QPA audits, of issuers of individual or group health insurance coverage in states where we have enforcement authority, non-Federal governmental plans in all states, and states with a collaborative enforcement agreement at the request of the state, to verify compliance with specific market-wide PHS Act requirements. As we complete audits, we intend to post our findings on the CMS website and report our findings to Congress as required by the NSA. CMS anticipates making audit results available on a rolling basis as audits are completed.

CMS is actively investigating and addressing complaints under its jurisdiction. If a violation is found, CMS will explore ways to enforce the requirement.

The NSA specifies that a plan or issuer must issue an initial payment, or notice of a denial of payment, to a provider or facility within 30 calendar days after the provider or facility transmits a bill to the plan or issuer for an out-of-network service. 42 U.S.C. §§ 300gg-111(a)(1)(C)(iv), (b)(1)(C), 300gg-112(a)(3)(A). When the plan or issuer issues this initial payment, or notice of denial of payment, it must disclose the QPA, defined as "the median of the contracted rates recognized by the plan or issuer on January 31, 2019, for the same or similar item or service that is provided by a provider in the same or similar specialty and provided in a geographic region in which the item or service is furnished, increased for inflation." But the plan or issuer is not required by statute or regulation to make an initial offer of payment that is equal to or reflective of the QPA. If the provider or facility is not satisfied with the initial payment or denial, either party may initiate a 30-day period of open negotiation over the claim. *Id*. §§ 300gg-111(c)(1)(A), 300gg-112(b)(1)(A). If those negotiations do not resolve the dispute, the parties may then proceed to an independent dispute resolution process; during that process, the arbitrator must consider the QPA in selecting the appropriate payment amount. *Id*. §§ 300gg-111(c)(1)(B), 300gg-112(b)(1)(B).

Question #107

Your department has cleared a CMS rule that is waiting for White House approval that would overhaul the Medicare Advantage enrollment process. With a choice of 44 different plans, and considering the disruption in Medicare plans caused by the Inflation Reduction Act, do you believe now is the time to reduce resources to help seniors pick a plan that works for them?

Response:

We agree that it is critical to ensure that as the MA and Part D Programs continue to grow, it remains viable and that seniors and individuals with disabilities eligible for Medicare can make informed decisions about their health care coverage, and, when appropriate, enroll in the plan that is best suited to their personal health care needs. As discussed in the CY 2025 MA and Part D proposed rule, section 1851(j) of the Social Security Act requires that CMS develop guidelines to ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the MA plan that is intended to best meet their health care needs. We have learned, however, that many MA and stand-alone Prescription Drug Plans (PDP), as well as third-party entities with which they contract (such as Field Marketing Organizations (FMO)), have structured payments to agents and brokers that have the effect of circumventing existing CMS regulations that limit agent and broker compensation to specified fair market value (FMV) levels. CMS has also received complaints from different organizations, including state partners, beneficiary advocacy organizations, and MA plans, to this effect. A common thread to the complaints is that agents and brokers are being paid, typically through various purported administrative and other add-on payments, amounts that cumulatively exceed the maximum compensation allowed under the current regulations. Moreover, CMS has observed that such payments have created an environment, not dissimilar to what originally prompted us to set limits on agent and broker compensation in 2008, where the amounts being paid for activities that do not fall under the umbrella of "compensation," are rapidly increasing.

We understand that FMOs help millions of Medicare beneficiaries to learn about and enroll in Medicare, Medigap, MA plans, and PDP plans by providing guidance on plan options, including comparisons of relative costs and coverage, as well as assisting beneficiaries with applying for financial assistance.

In our proposed rule, CMS is focused on current payment structures among MA organizations, agents, brokers, and Third-Party Marketing Organizations (TMPO), including FMOs, that may incentivize agents or brokers to emphasize or prioritize one plan over another, irrespective of the beneficiary's needs, leading to enrollment in a plan that does not best fit the beneficiary's needs and a distortion of the competitive process. In this rule, CMS has proposed to: (1) generally prohibit contract terms between MA organizations and agents, brokers, or other

TMPOs that may interfere with the agent's or broker's ability to objectively assess and recommend the plan which best fits a beneficiary's health care needs; (2) set a single agent and broker compensation rate for all plans, while revising the scope of what is considered “compensation;” and (3) eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services.

CMS is committed to collaborating and engaging with stakeholders and interested parties in the policy-making process. The comment period for the CY 2025 MA and Part D proposed rule closed on January 5, 2024. CMS sought comment on these proposals to further inform our calculations and policy direction. We have received feedback from many interested parties on our proposed policy, and we will carefully consider these comments throughout this rulemaking process.

Question #108

I understand HHS has received over $10 million per year in Congressional appropriations since FY20 to support the CDC Epilepsy Program. According to the CDC website, the Epilepsy Program uses these funds to "work with partners to research, test, and share strategies and programs to improve the lives of people with epilepsy." The CDC also acknowledges on its website that "more than one-third of people with epilepsy continue to have seizures despite treatment." Patients who suffer from epilepsy that fails to respond to pharmaceutical treatment - also known as drug-resistant epilepsy (DRE) - are more likely to experience negative outcomes such as developmental challenges, physical injury, occupational limitations, and diminished quality of life. Does the CDC currently deploy any of the Epilepsy Program appropriations to fund activities specifically aimed at increasing awareness of FDA-approved therapies for DRE?

Response:

CDC’s Epilepsy Program funds nine organizations through two cooperative agreements to increase awareness, reduce stigma, and enhance care and safety for people with epilepsy, inclusive of those with drug-resistant epilepsy. As of March 2024, CDC recipients have referred over 27,000 people with epilepsy to community-based services. Recipients reported 14 health systems that are monitoring and tracking epilepsy clinical data to improve outcomes, with nine epilepsy centers in the Epilepsy Learning Healthcare System using standardized questions on seizure control for their patients. Such screening could identify drug-resistant patients or those with uncontrolled seizures due to other reasons. Preliminary screening findings demonstrate that medication adherence is a major challenge and breakthrough seizures are often due to non-adherence. In response to this finding, eight of the epilepsy centers have implemented standardized screening for barriers to medication adherence and provide resources and referrals to overcome these barriers. In FY 2025, CDC will continue surveillance and prevention research, program implementation, and provider education in more communities to expand epidemiologic studies of epilepsy and improve epilepsy diagnosis and management. These activities are inclusive of population efforts to identify and support all people with epilepsy with uncontrolled seizures, including those with drug-resistant epilepsy.

Question #109 A

I am aware that deliberations over the 2025 Dietary Guidelines are well underway, and review of alcohol policies will be addressed through a separate process. I have also learned that the SAMHSA-led interagency working group began meeting last year but many questions have arisen as to who, how and when recommendations developed by this group will be released and whether its recommendations will be

reviewed by both HHS and USDA for inclusion in the 2025 Dietary Guidelines. I am seeking answering to the following questions:

a. Will guidance specific to alcohol consumption be included in the 2025 Dietary Guidelines?

Response 109 A:
The ICCPUD Technical Review Subcommittee's (TRS) work to assess the scientific evidence on adult alcohol consumption and health will be finalized in 2025 after completion of the evidence reviews by ICCPUD's Scientific Review Panel (below) and the NASEM committee, which are both slated to conclude by December 2024. The TRS will review the findings from both studies and provide a synthesis of the data and conclusions to USDA and HHS for consideration during the Dietary Guideline development process.

Question #109 B
In this current phase, with ICCPUD and NASEM external scientific committees' work under way, USDA and HHS Dietary Guidelines staff serve in a liaison role, providing information, as needed, as subject matter experts on the needs for development of the next edition of Dietary Guidelines.
Congress appropriated $1.3 million through USDA for the National Academies of Science, Engineering and Medicine to assess research on alcohol consumption and health outcomes that were not addressed in the 2020 Dietary Guidelines. Please explain why HHS supports two separate work streams to serve the same purpose in developing recommendations specific to alcohol consumption - one by the National Academies and a second by the SAMHSA-led interagency working group.

Response 109 B:
While both NASEM's study and ICCPUD's alcohol intake and health study will assess 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. The NASEM study will yield graded conclusion statements, not recommendations for adult alcohol consumption. The alcohol intake and health study will use risk modeling to generate evidence on the health risks of weekly drinking thresholds as well as risk modelling to estimate the lifetime risk of death and disability for different levels of average alcohol consumption. Given that these two distinct studies have different outcomes and methodologies, they will both provide important findings on the relationship between alcohol intake and health, making them complementary rather than redundant. Finally, neither study will provide specific recommendations on alcohol consumption by adults.

Question #109 C
How will HHS ensure that any recommendations developed by the SAMHSA-led working group are developed free of conflicts of interest?

Response 109 C:
The ICCPUD will use its existing structure and procedures as outlined in the 2023 ICCPUD Comprehensive Plan to create a balanced subcommittee that includes a full assessment of conflicts of interest to minimize bias. All Technical Review Subcommittee members have been sought with a disease prevention and public health orientation and include scientists from diverse backgrounds representing a range of career levels including mid-

career researchers. All potential internal and external subject matter experts will be free from conflicts of interest.

All Technical Review Subcommittee members and external subject matter experts will be 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.

The Scientific Review Panel (SRP) was selected through an ICCPUD nominations process. The Associate Administrator for Alcohol Prevention and Treatment Policy oversees the operational aspects of ICCPUD and put together the initial list of potential experts for consideration, based on their scientific expertise, publications, and a review of conflicts of interest. This list was shared with the ICCPUD agency representatives, who provided additional recommendations and feedback. Once the list was condensed to less than ten potential experts by the ICCPUD members, potential external experts were invited to the SRP by the Associate Administrator. Ultimately six external experts were included on the panel. In addition to the six external experts on the SRP, which have disclosed any potential conflicts of interest, the study methodology includes the use of a nominal group interview process. Consistent with best-practice research, this scientific process will engage additional experts in six distinct areas ((i) cancer, (ii) cardiovascular diseases, (iii) digestive conditions, (iv) neurological disorders, (v) infectious diseases, and (vi) injuries). Selection of these additional experts for participation in the nominal group process will be based on the authors who have published the largest number of first and last author publications concerning the above-noted disease areas (as determined by performing a PubMed Search) in the past 10 years. These authors will be asked to participate in the nominal group interview panels to determine the most appropriate meta-analyses to use in the study. The nominal group interview allows for the selection of meta-analyses avoiding group think and reduces random error in decision making by increasing the number of people whose opinions are considered in the scientific process.

The ICCPUD Alcohol Intake and Health study and the NASEM study will conduct complementary assessments of the relationship between alcohol consumption and various health outcomes. The synthesis of these findings will be provided to HHS and USDA for consideration as they develop guidelines for alcohol consumption as part of the Dietary Guideline development process.

Question #109D

Federal law requires that the preponderance of scientific and medical knowledge must support changes to the existing Dietary Guidelines recommendations. No changes can be made without clearly showing that the preponderance of scientific and medical knowledge supports each change. How is the SAMHSA-led technical committee ensuring that this mandate by Congress is followed as it reviews research and drafts recommendations?

Response 109 D:

Analyses will be conducted by experts in disease prevention and public health and include scientists from diverse backgrounds representing a range of career levels including experts and mid-career researchers. Methodological approaches will be grounded in rigorous scientific evidence and follow best practices for conducting systematic reviews and reviewing meta-analyses. The findings will undergo a rigorous review process that will include scientific peer review and opportunities for public comment.

The ICCPUD Alcohol Intake and Health study and the NASEM study will conduct complementary assessments of the relationship between alcohol consumption and various health outcomes. The synthesis of these findings will be provided to HHS and USDA for consideration as they develop guidelines for alcohol consumption as part of the Dietary Guideline development process.

Question #109 E

How is HHS ensuring that the scientific review process underway by the SAMHSA-led working group mirrors the Dietary Guidelines Advisory Committee process in its research procedures and protocols, commitment to transparency, preclusion of conflicts of interest and willingness to invite comment from interested public stakeholders?

Response 109 E:

The findings will undergo a rigorous review process that will include scientific peer review and opportunities for public comment.

The Alcohol Intake and Health study will undergo two opportunities for written formal feedback and public comment via Request for Information: one in the summer of 2024 to specifically solicit feedback on the scientific methodology to be used by the ICCPUD TRS and SRP to assess the relationship between alcohol intake and health, and the second in the summer of 2025 to solicit public comment on the findings of the study. Feedback will be taken under consideration and shared with the Subcommittee and SRP for potential inclusion and revision. The public comment opportunities will ensure transparency in the methodology and that the broadest evidence base is considered in this study. In conjunction with the caliber of experts conducting the study, this process will ensure that the findings presented to the Subcommittee will be based on the latest science and medical knowledge.

Additionally, there will be three opportunities for public engagement over the course of the study: In August 2024 and 2025, the ICCPUD Annual Stakeholders Meeting for interested parties including the alcohol beverage industry; medical, public health, consumer, and parent groups; law enforcement; institutions of higher education; community-based organizations and coalitions; and other relevant stakeholders to engage and provide input on this effort. Additionally, in September 2025, a public meeting will be held on the findings of the Alcohol Intake and Health study.

Question #109F

Will the work of the National Academies and recommendations developed by the SAMHSA-led interagency group be considered for inclusion in the 2025 Dietary Guidelines? If not, please explain how any alcohol policies will be reported to consumers, the medical community and interested stakeholders.

Response 109 F:

HHS and USDA are required by statute to jointly publish the Dietary Guidelines every 5 years. The next edition of the Dietary Guidelines, the 2025-2030 edition, will be released by the end of 2025. HHS is serving as the administrative lead for the 2025-2030 edition. As a part of this effort, HHS and USDA requested that the ICCPUD, as the interagency coordinating committee dedicated to alcohol use and health, support a synthesis of the current science on health risks associated with alcohol use. The Alcohol Intake and Health Study is the primary mechanism ICCPUD will use to assess the current state of the science. Based on this request, findings

from the Alcohol Intake and Health study as well as the NASEM study will be provided to HHS and USDA for consideration as they develop the 2025-2030 Dietary Guidelines.
The ICCPUD Alcohol Intake and Health study and the NASEM study will conduct complementary assessments of the relationship between alcohol consumption and various health outcomes. The synthesis of these findings will be provided to HHS and USDA for consideration as they develop guidelines for alcohol consumption as part of the Dietary Guideline development process.

Question #109 G

Please provide the names of those appointed by the SAMHSA-led working group to the Technical and Scientific Committees who are reviewing research and drafting recommendations. Please provide a list of staff from each agency who are participating in the SAMHSA-led interagency working group.

Response 109 G:

HHS and USDA will update guidance on alcohol consumption, as the authors of the Dietary Guidelines. The ICCPUD will not make recommendations on alcohol consumption.
The Technical Review Subcommittee includes representatives designated by their agency Principal from the following agencies:

- Office of the Assistant Secretary for Health
- U.S. Department of Agriculture
- 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 Institute on Alcohol Abuse and Alcoholism
- National Institutes of Health, National Cancer Institute
- Substance Abuse and Mental Health Services Administration

c. 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

Question #109 H

Will the research reviewed by the National Academies and SAMHSA-led working group include potential risks as well as potential harm from moderate consumption of alcohol?

Please outline and list all protocols that each working group is utilizing to assess research and develop recommendations.

Response 109 H:

While both NASEM's study and ICCPUD's alcohol intake and health study will assess 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.

These studies will assess the relationship between alcohol intake and health; the findings may include related risks, harms, and benefits, depending on the best available science and findings of the analyses.

The table below provides a comparison of the two studies.

Study	Purpose	Methods and Product
NASEM – Review of evidence on alcohol and health https://www.nationalacademies.org/our-work/review-of-evidence-on-alcohol-and-health	To review, evaluate, and report on the current scientific evidence on the relationship between alcohol consumption and the following health outcomes: 9. growth, size, body composition, and risk of overweight and obesity 10. risk of certain types of cancer 11. risk of cardiovascular disease 12. neurocognitive health 13. risk of all-cause mortality 14. post-partum weight loss 15. human milk composition and quantity 16. Infant development milestones, including neurocognitive development	The NASEM study involves the conduct of systematic reviews. The NASEM study will yield graded conclusion statements, not recommendations for adult alcohol consumption. This study is scheduled to be completed in time for inclusion in the ICCPUD process that will assess the scientific evidence on adult alcohol consumption. USDA and HHS will also consider the findings from the NASEM study as the Departments review the findings from ICCPUD and develop the Dietary Guidelines.
ICCPUD - Alcohol intake and health study	To generate risk estimates for weekly thresholds to minimize health risks by modelling cause-specific absolute risk curves based on disease-, injury-, and condition-specific relative risk curves from cohort studies from conditions that are thought to be causally related to alcohol use (e.g., liver cirrhosis and cancer). This approach aligns with the current practices of the Centers for Disease Control and Prevention, the World Health Organization,	The alcohol intake and health study will use the following methods to generate evidence on weekly drinking thresholds to minimize health risks: • Lifetime risk modelling to estimate the lifetime risk of death and disability for different levels of average alcohol consumption. • Model cause-specific absolute risk curves based on disease-, injury-, and condition-specific relative risk curves.

	and the Institute for Health Metrics and Evaluation, when estimating the burden of disease attributable to alcohol use.	• Cohort studies from conditions that are thought to be causally related to alcohol use (e.g., liver cirrhosis and cancer). The ICCPUD study will be considered with the NASEM systematic reviews by the ICCPUD Technical Review Subcommittee as the Subcommittee provides a synthesis of the data and summarizes the science on adult alcohol consumption. The end product of the ICCPUD alcohol and intake study will be a synthesis of the science, not recommendations on alcohol consumption.

Question #109 I

Will alcohol policies and recommendations remain part of future *Dietary Guidelines* or will they be part of a separate process and which agency will lead that effort?

Response 109 I:

USDA and HHS are required by statute to jointly publish the Dietary Guidelines every 5 years. The next edition of the Dietary Guidelines, the 2025-2030 edition, will be released by the end of 2025. HHS is serving as the administrative lead for the 2025-2030 edition.

Question #110

There remain concerns about the continued increase in Medicare-enrolled hospices in states where there has been a pattern of explosive growth and subsequent media and policymaker focus on potentially fraudulent activity, namely California, Texas, Arizona, & Nevada. As of April 1, 2024, CMS' QCOR data website indicates that the agency enrolled 418 new hospices into Medicare during 2023, almost 70 percent of which were added in the enhanced oversight states:

- 130 hospices in California
- 98 hospices in Texas
- 34 hospices in Nevada
- 27 hospices in Arizona.

Further, many of these hospices were enrolled in specific counties well-known to be at high-risk for fraud. For example, 98 hospices were added in Los Angeles County, CA, where reporting and state data has indicated there are already over 1000 hospices in operation. Even more concerning, 20 of these 94 hospices enrolled in Los Angeles County were located at 14545 Friar St. in the Van Nuys neighborhood, a small building which, according to high

profile reporting, houses over 100 hospices already, including many that have characteristics reflective of fraud and abuse.

Why does CMS continue to enroll hospice providers in areas it is aware are at very high risk for Medicare fraud and abuse?

Question #111

Why is CMS not considering a temporary targeted moratorium on Medicare hospice certification in these areas that are oversaturated with providers and likely engaged in fraud, waste, and abuse of the Medicare program that could be leading to beneficiary harm, and what authorities or flexibilities that it may not have would CMS need in order to implement such a targeted moratoria?

Question #112

CMS has indicated that they have taken action and made some policy changes in order to address the heightened fraud, waste and abuse challenges in the Medicare hospice program. Examples include a site visit project during which CMS has stated that over 7000 hospice locations were visited over the course of 2023, and a Provisional Period of Enhanced Oversight (PPEO) for new hospices and those undergoing ownership changes in California, Texas, Arizona and Nevada. Reporting indicates that, in relation to the site visits, *"Following the tour, the Medicare billing privileges for 46 nonoperational hospices were revoked."* There are no public- facing updates regarding the PPEO process.

How specifically is CMS measuring the impact and success or failure of the various actions it has taken in the last two years that it claims are addressing high-risk hospice fraud? Does CMS plan to make data on these actions (process and outcome) available to the public? If not, what justification does CMS have for not releasing such data?

Question #113

In 2023, CMS enrolled 418 new hospices, almost 70 percent of which were in these four states. While CMS has taken some action during the last year to address these challenges, more is clearly needed. CMS is quoted in the article as saying that it does not have the authority to deny Medicare enrollment without "evidence of sanctions.":

b. Please explain further what you mean by "evidence of sanctions"-what specific evidence is needed under current law to deny Medicare enrollment?
c. What authority do you need in order to deny enrollment or conduct additional scrutiny prior to enrollment?

Question #114

Has CMS identified a process for ensuring that hospices identified for Inclusion in the Special Focus Program (SFP) will Include the potential fraudulent actors in AZ, CA, NV, and TX?

Question #115

Can you please confirm the dates that CMS was in full compliance with the requirements under Section 1822(a) of the Social Security Act, specifically:

- Standard survey not less frequently than once every 36 months at SSA 1822(a)(l)
- Requirement for AOs to begin use of the Form CMS-2567 to document survey findings at SSA l822(a)(2)(A)(ii).
- Public disclosure of survey information at SSA 1822(a)(2)(B)
- Improvement of the consistency of surveys at SSA 1822(a)(3)
- Requirements for use of multidisciplinary survey teams SSA I 822(a)(4)(A)
- Prohibition of conflicts of interest of at surveyors at SSA 1822(a)(4)(B)
- Expanding CMS-based surveyor training to Accrediting Organizations at SSA 1822(a)(4)(C)

Please provide the exact date the agency was in compliance with the requirements under Section 1822(a), as well as how the agency intends to ensure compliance with the requirements that the agency stated will require surveyor attestation.

Response (111-115):
In response to concerns about Medicare fraud in the hospice industry, CMS revisited and revitalized its hospice program integrity strategy. As part of this strategy, CMS completed a nationwide hospice site visit project in 2023, making unannounced site visits to every Medicare-enrolled hospice to verify that each hospice is operational at the address listed on their enrollment form. If a hospice was not operational at the address listed on their Medicare enrollment form, CMS exercised its authority to either deactivate the hospice's Medicare billing privileges or revoke the hospice's enrollment in Medicare.

Because of the noted rapid growth in the number of potentially fraudulent hospices in Arizona, California, Nevada, and Texas, CMS has implemented a provisional period of enhanced oversight in these states for newly enrolling hospices. During this period, CMS is conducting a medical review before making payments on claims submitted by newly enrolling hospices. This additional oversight will help ensure that the newly enrolled hospices are treating only patients who truly need hospice care.

With the same goal in mind, CMS initiated a pilot project to review hospice claims following an individual's first 90 days of hospice care. Doing this earlier during a patient's length of stay will help inform future medical review activities aimed at determining whether hospices are submitting claims to Medicare for patients that are eligible for the benefit. This pilot is not limited to Arizona, California, Nevada, and Texas.

In addition, CMS finalized several regulatory changes as part of the Calendar Year 2024 Home Health Prospective Payment System final rule to better address hospice fraud, some of which were suggested by the hospice industry. This includes policies that:

- Prohibit the transfer of the provider agreement and Medicare billing privileges of a hospice that undergoes a change in majority ownership by sale within 36 months after its initial enrollment or after its most recent change in majority ownership, similar to how CMS treats transfers of Home Health Agency provider agreements;
- Clarify that the definition of "Managing Employee" on the Medicare enrollment application form includes the administrator and medical director of a hospice;
- Subject newly-enrolling hospices to the highest level of provider enrollment application screening, which includes fingerprint background checks for all 5 percent or greater owners of hospices; and
- Reduce the period of Medicare non-billing for which a provider or supplier can be deactivated from 12 months to 6 months.

CMS also finalized a requirement as part of the Fiscal Year 2024 Hospice Payment Rate Update Final Rule to screen hospice certifying physicians to ensure they are qualified to treat Medicare beneficiaries, including making sure they have active licenses and do not have felony conviction records.
CMS continues to review and revise our health and safety requirements and survey processes to ensure that they are effective in driving quality of care for hospice programs. The Consolidated Appropriations Act, 2021 (CAA, 2021) added section 1822 to the Social Security Act. Section 1822 enhanced the hospice program survey process and established new authorities for imposing enforcement remedies for noncompliant hospice programs. CMS has been hard at work implementing the new survey and enforcement requirements, with a goal of making sure that hospices enrolled in Medicare are fully able to provide high quality care.

In the calendar year 2022 Home Health final rule, CMS finalized policies to implement the survey and enforcement provisions of the CAA, 2021 that increase and improve transparency, oversight, and enforcement of health and safety requirements for hospice programs. These policies include requiring surveyors to use multidisciplinary survey teams, prohibiting surveyor conflicts of interest (such as prohibiting surveyors from performing a survey of a provider where they have an ownership interest or are employed), and requiring surveyors from accrediting organizations (AOs) to complete CMS-sponsored comprehensive training and testing (rather than training provided by the AOs).

In addition, CMS has established a special focus program (SFP), as required in the CAA, 2021, to provide enhanced oversight of the poorest-performing hospices that have repeated cycles of serious health and safety deficiencies, to enable continuous improvement, building on similar oversight and enforcement programs focused on nursing homes.

CMS is happy to keep your office informed on the progress of these efforts.

Brad Wenstrup (OH-R)

Question #116
I am concerned that the TCET proposal limits coverage to only 5 breakthrough devices per year - can you commit to establishing a separate pathway for Medicare coverage that does not restrict eligibility to just a few breakthrough devices per year?

Response:
Medicare payment policy is set by Congress, and CMS works within the confines of the law to establish payment polices. The Hospital Outpatient Prospective Payment System (OPPS) pass-through and Inpatient Prospective Payment System (IPPS) New Technology Add-on Payment (NTAP) collectively incentivize hospitals to quickly adopt and promote beneficiary access to innovative technologies through additional payments. Section 1886(d)(5)(K) of the Act requires the Secretary to establish a mechanism to recognize the costs of new medical services and technologies under the IPPS. The OPPS transitional pass-through provisions are established under section 1833(t)(6) of the Act. The intent of the OPPS transitional device pass-through payment is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the overall procedure payment rate (66 FR 55861). A criterion for both NTAP and OPPS pass-through is that the device represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In the CY 2020 and FY 2021 annual rulemaking processes for the OPPS and IPPS, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation, under which these devices are not evaluated in terms of the

current substantial clinical improvement criterion for the purposes of determining device pass-through status or NTAP.

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 CMS anticipates accepting up to five TCET candidates annually due to CMS resource constraints; given the volume of National Coverage Determination (NCD) requests and our current level of resources, there are times when CMS must tell requestors that the NCD request is complete and formal, but CMS cannot immediately begin the NCD process.

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 #117

Mr. Secretary, the United States' manufacturing capacity for essential medical devices is at serious risk due to organized efforts by Chinese manufacturers to enter the U.S. market in response to inflationary pressures faced by U.S.-based manufacturers, distributors, and providers. The current shift toward purchasing Chinese-made medical devices is drastic and occurring at a pace that will leave U.S. hospitals dependent on Chinese supplied devices.

How does CMS plan to help address the manufacturing imbalance for essential medical devices and ensure access to these products for Medicare beneficiaries?

Response:

The COVID-19 pandemic has illustrated how overseas production shutdowns, foreign export restrictions, and shipping delays can jeopardize the availability of raw materials and components needed to make critical public health supplies. CMS is committed to strengthening the Medicare program using the lessons learned from the COVID-19 PHE and ensuring beneficiaries have access to the care and medical devices they need. We look forward to continuing to engage with the public and Congress on this issue, including potential payment policies.

Question #118 A

There are safe and effective FDA-approved medications that are helping patients with obesity, type II diabetes, and now cardiovascular disease. Every federal health care program - except Medicare- covers these medications for obesity, including the VA, DoD, FEHBP, Indian Health

Service, and state Medicaid programs. As you know, CMS is enforcing a policy prohibiting Medicare from covering Medications for weight loss. Right now, seniors taking prescriptions to treat obesity are entering Medicare and losing access to their prescriptions. We know obesity and its comorbidities caused $5,155 in average excess medical costs per person suffering from the condition in 2023, which corresponded to roughly $520 billion in additional healthcare costs in 2023 alone. Over 2024-2033, JEC economists project that the combined Medicare and Medicaid spending on obesity and obesity-related diseases will total $4.1 trillion.

A. Can you clarify for the committee the distinction between medications used for weight loss compared to those used to treat obesity as a chronic medical condition?

Response 118 A:

Anti-obesity drugs that receive FDA approval for additional medically-accepted indications, such as diabetes or cardiovascular risk, would be considered a Part D drug for those specific uses.

Further, the FDA considers has approved products for chronic weight management or to reduce excess weight and maintain weight reduction long-term in patients with obesity (or patients with overweight who have weight-related medical problems). The purpose of these products is weight reduction that is sustained long-term to improve cardiovascular and metabolic risk factors associated with obesity.

FDA has not approved any drugs for "weight loss" in people without obesity or overweight.

Question #118 B

How is this Administration investing in the treatment and prevention of obesity?

Response 118 B:

Administration Investments in Treatment and Prevention of Obesity

HHS, led by the Office of the Assistant Secretary for Health (OASH), is in the process of developing the first federal tool kit and implementation guidance to help advance Food is Medicine and develop and implement a federal strategy to reduce nutrition-related chronic diseases and food insecurity. This includes diet-related research and programmatic efforts that will increase access to Food is Medicine interventions. On January 31, 2024, HHS hosted its first-ever Food is Medicine summit in Washington, D.C., an all-day summit for stakeholders at the intersection between food and health.

Integrating nutrition and health can optimize Americans' well-being and reduce healthcare costs. The President's FY 25 budget includes a proposal to expand access to Medicare benefits for nutrition and obesity counseling services to additional beneficiaries with nutrition or obesity-related chronic diseases and making additional providers eligible to furnish services. The budget also includes a new Medicare pilot project on medically-tailored meals for beneficiaries with a diet-impacted disease. The budget also includes $3 million for the Indian Health Service (IHS) Produce Prescription Pilot Program. First appropriated in FY 2022, the program addresses the disproportionate impacts of food insecurity for American Indians/Alaska Natives by increasing access to healthy, fresh foods as part of a provider's overall treatment plan to improve patient health outcomes.

Health Insurance Coverage of Services to Prevent and Treat Obesity

HHS recognizes the devastating impact obesity 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. Part D sponsors wishing to provide coverage of prescription weight loss drugs may do so as a supplemental benefit of an enhanced alternative Part D plan. Medicare covers, under Part B, specific services that aim to address obesity. For example, obesity screenings, intensive obesity behavioral therapy, bariatric surgical procedures, and diabetes screenings and participation in a diabetes prevention program are covered under Medicare in certain cases. These services can be furnished via telehealth in certain cases as well.

Medicaid and CHIP programs can cover a range of services to prevent and reduce obesity, including Body Mass Index screening, education and counseling on nutrition and physical activity, prescription drugs that promote weight loss, and, as appropriate, bariatric surgery. For eligible children enrolled in Medicaid and Medicaid-expansion CHIP, the Early and Periodic Screening, Diagnostic and Treatment benefit covers medically necessary services described in section 1905(a) of the Social Security Act whether or not a state includes them in the Medicaid state plan, including obesity-related services that can be covered under section 1905(a). For adults enrolled in Medicaid and beneficiaries in separate CHIPs, states have greater flexibility regarding which services to cover. All Marketplace plans, and many other group health plans and group and individual health insurance plans, are required to cover a number of preventive services without charging any copay or coinsurance. This includes obesity screening and counseling.

Question #119

While step therapy protocols are designed to help manage drug costs, they may also impact medication adherence, block or delay access to medication, or limit treatment options which can result in negative outcomes for patients. As the lead sponsor of the *Safe Step Act,* I have heard many stories from patients at home and across the country who have suffered irreversible harm from insurance-mandated step therapy protocols.

Can you and your agency commit to working with Congress to ensure that utilization management tools like step therapy do not impact a provider's ability to treat their patient?

Question #120

Centers for Medicare and Medicaid Services (CMS) has said that Medicare Advantage plans must establish a Utilization Management Committee to review all utilization management policies annually and ensure they are consistent with the coverage requirements, including current, traditional Medicare's national and local coverage decisions and guidelines. It is not clear what CMS is doing for patients who are denied their medication due to utilization management protocols.

Can you detail what recourse a patient has if their medication is denied due to utilization management, and they need immediate treatment?

Response 119-120:

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.

With respect to Medicare Advantage, in the CY 2024 Medicare Advantage (MA) and Part D final rule, CMS clarified rules requiring that MA plans must comply with national coverage determinations, applicable local coverage determinations, and general coverage and benefit conditions included in Traditional Medicare regulations and adopted new requirements for how and when MA plans may adopt and use additional internal coverage criteria for Part A and B benefits (called basic benefits), including Part B drugs. CMS finalized that when 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.

The final rule also streamlined and improved 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. Second, 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. Third, to ensure prior authorization is being used appropriately, CMS required all MA plans establish a Utilization Management Committee to review policies annually and ensure consistency with Traditional Medicare's national and local coverage decisions and guidelines. Finally, the final rule required that approval of a prior authorization request for a course of treatment must be valid for as long as medically reasonable and necessary to avoid disruptions in care in accordance with applicable coverage criteria, the patient's medical history, and the treating provider's recommendation.

In addition, Medicare Advantage regulations have required for several years that prior authorization decisions for Part B drugs by MA organizations must be made as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request in the case of standard (i.e., non-expedited) requests. An enrollee or physician may request that the MA organization expedite a prior authorization decision for a Part B drug, in which case, the decision must be made as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request. If the prior authorization decision is unfavorable, the decision may be appealed through the appeals process, which has 5 levels of appeal—reconsideration by the MA organization, independent review entity (IRE) reconsideration, an administrative law judge hearing under the Office of Medicare Hearings and Appeals, review by the Medicare Appeals Council, and Federal District Court review. For both the reconsideration by the MA plan and the IRE reconsideration levels of appeals for Part B drugs, decisions must be made as expeditiously as the enrollee's health condition requires, but no later than 7 days after receiving a standard request and 72 hours after receiving an expedited request.

With respect to Part D, 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 based in part on 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.

In addition, prior authorization decisions for Part D drugs by Part D plan sponsors must be made as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request in the case of standard (i.e., non-expedited) requests. An enrollee or prescribing physician may request that the Part D plan sponsor expedite a prior authorization decision for a Part D drug, in which case, the decision must be made as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request. If the prior authorization decision is unfavorable, the decision may be appealed through the appeals process, which has 5 levels of appeal—reconsideration by the Part D plan sponsor, IRE reconsideration, an administrative law judge hearing under the Office of Medicare Hearings and Appeals, review by the Medicare Appeals Council, and Federal District Court review. For both the reconsideration by the Part D plan sponsor and the IRE reconsideration levels of appeals for Part D drugs, decisions must be made as expeditiously as the enrollee's health condition requires, but no later than 7 days after receiving a standard request and 72 hours after receiving an expedited request.

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

Question #121

I remain concerned by the increased challenges rural providers across the country are facing. Workforce shortages met with arbitrary nursing staff ratio mandates and growing medical inflation rates continue to exacerbate these challenges. Over 170 rural hospitals have closed or ceased providing inpatient care since 2010, which makes support for vulnerable hospitals critical. The proposed minimum staffing standards for long-term care facilities would be

disastrous for rural nursing homes, likely leading to more rural facilities closing and threatening access to post-acute care for rural seniors. How is the Administration considering the impact of this rule on rural access?

Response:
Staffing in LTC facilities is a persistent concern, especially among low-performing facilities that are at most risk for providing unsafe care. Numerous studies have shown that staffing levels are closely correlated with the quality of care that LTC facility residents receive. CMS believes that national minimum nurse staffing standards in LTC facilities are necessary at this time to protect residents' health and safety and ensure their needs are met. We intend to promote safe, high-quality care for all residents regardless of location. At the same time, CMS recognizes the need to strike an appropriate balance that considers the current challenges some LTC facilities are experiencing, particularly in rural areas.

Given the challenges rural communities face, CMS proposed later implementation dates for rural facilities. Under the proposed rule, rural facilities would have three years to meet the proposed 24/7 Registered Nurse (RN) requirement and five years to meet the proposed minimum staffing standards for RNs and nurse aides (NAs). CMS sought feedback on the appropriateness of this implementation time frame, and possible alternative implementation approaches. In addition, CMS proposed to maintain the current statutory waiver process for facilities for RN onsite requirements under qualifying circumstances. Facilities seeking relief from the proposed 24/7 RN requirement in the proposed rule would follow the applicable existing waiver process, as required by statute, and set out in the current regulations. We believe that the proposed standards take into consideration local realities in rural and underserved communities and will carefully review the comments received.

While CMS fully expects LTC facilities would be able to meet our proposed minimum staffing standards, we recognize that in some instances, external circumstances may temporarily prevent a facility from achieving compliance despite the facility's demonstrated best efforts. Therefore, CMS proposed a hardship exemption. If finalized, LTC facilities could qualify for a hardship exemption from the minimum nurse staffing standards if they met specific criteria, which are discussed in the proposed rule. The facility would have to be located either in an area where the supply of health care personnel was insufficient, or at least 20 miles away from another LTC facility. Facilities also would have to meet other criteria including demonstrating good faith efforts to hire and retain staff. Facilities also would be surveyed for compliance with the minimum staffing standards prior to being considered for an exemption.

Question #122

What is the Administration doing to help struggling rural hospitals and ensure that they can stay open and care for rural patients?

Response:

HHS recognizes that more than 61 million Americans live in rural areas including rural, Tribal, frontier, and geographically isolated territories. These Americans face several unique challenges in health care that can differ dramatically among the different kinds of rural areas across the country. HHS is dedicated to ensuring that its policies, programs, initiatives, outreach, and local engagement are responsive to the needs of rural, tribal, and geographically isolated communities.

For example, HRSA provides targeted grant dollars and technical support to rural hospitals and Critical Access Hospitals with a focus on supporting rural communities and the hospitals that serve them. HRSA also supports several grants to strengthen the ability of states to serve their rural hospitals and communities by enhancing the capacity of the State Offices of Rural Health, by providing peer learning opportunities and resources for states, by supporting quality improvement in states, and by funding evaluation programs.

In terms of CMS involvement in this area, CMS has engaged with individuals, organizations, and government entities across the nation who have experience receiving health care or supporting health care service delivery in these communities to help shape the CMS Framework for Advancing Health Care in Rural, Tribal, and Geographically Isolated Communities.

In addition, on January 1, 2023, Medicare started paying for Medicare-enrolled rural emergency hospitals (REHs) to deliver emergency hospital, observation, and other services to Medicare patients on an outpatient basis. Section 125 of the Consolidated Appropriations Act, 2021, Division CC defines REHs as facilities that meet certain requirements. As of January 1, 2023, Medicare pays REHs an additional 5% over the payment rate of the Hospital Outpatient Prospective Payment System (OPPS) for REH services as well as additional facility payments, paid in 12 monthly installments. The Health Resources and Services Administration's (HRSA's) REH Technical Assistance Center also offers technical assistance to REHs to make sure rural hospitals and the communities have the information and resources they need to make informed decisions about whether an REH is the best care model for their communities and successfully implement REH requirements for facilities converting to this new provider type.

Question #123

I continue to hear from providers across the country who are closing their doors or walking away from providing care to their patients every day because of challenges like continued cuts to physician reimbursement, workforce shortages, growing inflation rates, and government red tape. If these challenges continue - healthcare providers, especially those who are operating under thin margins in rural and urban underserved communities, will no longer be able to afford to see their patients.

Mr. Secretary, can you commit to working with Congress on addressing some of these issues so that we can focus on policies that put the patient first and make the United States the healthiest nation on the planet?

Response:

CMS recognizes that more than 61 million Americans live in rural areas including rural, Tribal, frontier, and geographically isolated territories. These Americans face several unique challenges in health care that can differ dramatically among the different kinds of rural areas across the country. And CMS is dedicated to ensuring that its policies, programs, initiatives, outreach, and local engagement are responsive to the needs of rural, tribal, and geographically isolated communities. To ensure that the Agency's approach is responsive to the unique needs of these communities, CMS has engaged with individuals, organizations, and government entities across the nation who have experience receiving health care or supporting health care service delivery in these communities to help shape the CMS Framework for Advancing Health Care in Rural, Tribal, and Geographically Isolated Communities.

In addition, on January 1, 2023, Medicare started paying for Medicare-enrolled rural emergency hospitals (REHs) to deliver emergency hospital, observation, and other services to Medicare patients on an outpatient basis. Section 125 of the Consolidated Appropriations Act, 2021, Division CC defines REHs as facilities that meet certain requirements. As of January 1, 2023, Medicare pays REHs an additional 5% over the payment rate of the Hospital Outpatient Prospective Payment System (OPPS) for REH services as well as additional facility payments, paid in 12 monthly installments. The Health Resources and Services Administration's (HRSA's) REH Technical Assistance Center also offers technical assistance to REHs to make sure rural hospitals and the communities have the information and resources they need to make informed decisions about whether an REH is the best care model for their communities and successfully implement REH requirements for facilities converting to this new provider type.