HEARING WITH HEALTH AND HUMAN SERVICES SECRETARY BECERRA

HEARING

BEFORE THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTEENTH CONGRESS

SECOND SESSION

MARCH 20, 2024

Serial No. 118–FC23

Printed for the use of the Committee on Ways and Means

U.S. GOVERNMENT PUBLISHING OFFICE
55–927 WASHINGTON : 2025

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PUBLIC SUBMISSIONS FOR THE RECORD

United States House Committee on
Ways & Means
CHAIRMAN JASON SMITH

FOR IMMEDIATE RELEASE
March 13, 2024
No. FC-22

CONTACT: 202-225-3625

Chairman Smith Announces Hearing with Health and Human Services Secretary Becerra

House Committee on Ways and Means Chairman Jason Smith (MO-08) announced today that the Committee will hold a hearing on the President's Fiscal Year 2025 Budget Request with Health and Human Services Secretary Xavier Becerra. The hearing will take place on **Wednesday, March 20, 2024, at 2:00 PM in 1100 Longworth House Office Building.**

In view of the limited time available to hear the witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit written comments for the hearing record can do so here: WMSubmission@mail.house.gov.

Please ATTACH your submission as a Microsoft Word document in compliance with the formatting requirements listed below, **by the close of business on Wednesday, April 3, 2024**. For questions, or if you encounter technical problems, please call (202) 225-3625.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission but reserves the right to format it according to guidelines. Any submission provided to the Committee by a witness, any materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission not in compliance with

these guidelines will not be printed but will be maintained in the Committee files for review and use by the Committee.

All submissions and supplementary materials must be submitted in a single document via email, provided in Word format and must not exceed a total of 10 pages. Please indicate the title of the hearing as the subject line in your submission. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record. All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears. The name, company, address, telephone, and fax numbers of each witness must be included in the body of the email. Please exclude any personal identifiable information in the attached submission.

Failure to follow the formatting requirements may result in the exclusion of a submission. All submissions for the record are final.

ACCOMMODATIONS:

The Committee seeks to make its facilities accessible to persons with disabilities. If you require accommodations, please call 202-225-3625 or request via email to WMSubmission@mail.house.gov in advance of the event (four business days' notice is requested). Questions regarding accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Note: All Committee advisories and news releases are available on the Committee website at http://www.waysandmeans.house.gov/.

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HEARING WITH HEALTH AND HUMAN SERVICES SECRETARY BECERRA

WEDNESDAY, MARCH 20, 2024

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
Washington, DC.

The Committee met, pursuant to call, at 2:23 p.m., in Room 1100, Longworth House Office Building, Hon. Jason T. Smith [Chairman of the Committee] presiding.

Chairman SMITH. The committee will come to order.

Thank you all for joining us today, thank you, Secretary Becerra. This hearing provides an opportunity to examine the policy proposals outlined in President Biden's fiscal year 2025 budget request for the Department of Health and Human Services.

HHS is an incredibly important agency responsible for running Medicare and many of our health programs, and critical in responding to unexpected events such as the recent cyber attack of Change Healthcare. But today we seek your commitment to leverage your resources to ensure patients and providers have access to timely care.

Turning to the budget request, I have serious concerns that these policies continue to prioritize politics over the health of the American people, and will harm access to quality, affordable health care. The Biden Administration's continued pursuit of a harmful agenda, combined with your department's failure to address its own shortcomings, has required this committee to take action on multiple occasions to force your hand.

All across the country in districts like mine, rural and underserved patients struggle with access to care, which has been worsened by hospital closures and provider shortages in recent years. One-size-fits-all mandates, such as the proposed rule regarding nursing home staffing that was rejected by this committee, will further fuel that crisis and result in the closure of more facilities.

You failed to follow congressional intent when implementing health care policies like the bipartisan surprise medical billing protections. During Ways and Means Committee hearings this past year, and as recent as Monday down in Denton, Texas, we have heard consistently how this has resulted in less access and reduced in-network, affordable care for patients.

You neglected to hold hospitals accountable for non-compliance with price transparency requirements until this committee and Congress placed intense pressure on you to do so. Earlier this year, the House of Representatives stood up for patients again in a bipartisan manner and passed the Lower Cost More Transparency

Act to enshrine these requirements into law. I hope this action signals to your department how important price transparency is to the American people and will guide your decisions going forward.

The budget also doubles down on the Biden Administration's scheme to expand Washington price controls on drugs. We heard from witnesses at hearings last summer that these price controls will decimate critical research into diseases like cancer and Alzheimer's, depriving patients of lifesaving treatments, and killing up to 1.2 million jobs in the United States.

Equally troubling is the allocation of $272 billion in new Obamacare subsidies to wealthy households making nearly $600,000 per year. Our Health Subcommittee's first hearing this Congress examined the high cost of health care driven by Obamacare's mandates, and I am disappointed to see the budget propose bailouts to private health insurance companies as their only solution.

In January the House was forced to pass legislation from this committee blocking a misguided HHS rule to eliminate funding for pregnancy resource centers which play a vital role in supporting maternal health and prenatal care. Again, this does not line up with the Administration's stated goal of improving access to care. You claim to support a woman's right to choose their own health care, but then you make it harder for moms to choose life for their unborn child.

Recent reports also indicate the crisis at our southern border, and the staggering influx of illegal immigrants has placed strain on an already overburdened foster care system, as well as access to care for U.S. patients at vital safety net hospitals. We are eager to hear your plan to address the impact of the border crisis on these services because your budget suggests there is not one. Words like "diversity," "discrimination," "racial justice," and "gender" all appear in your budget far more than the border.

Fentanyl, the number-one killer of Americans age 18 to 45, is mentioned only once in a footnote in the budget.

I hope recent committee activity has made clear to you that we are demanding accountability and transparency at your department, as well as solutions that will actually improve the health and well-being of the American people. It is imperative that health care policy prioritize patient outcomes over political agendas, particularly in the face of urgent public health crisis.

Thank you again for being here today, Secretary Becerra, and I look forward to discussing these important issues.

Chairman SMITH. And I am pleased to recognize Ranking Member Neal for his opening statement.

Mr. NEAL. Thank you, Chairman. It is always a pleasure to welcome back one of our own alums, and we are delighted to have Secretary Becerra before this storied committee today.

I appreciate you being here, Mr. Secretary.

Democrats have transformed our nation by prioritizing the well-being and wallets of the American people, rebuilding our economy from the bottom up and the middle out, and the results are indeed record-breaking: 15 million jobs created under President Biden; back-to-back, record-breaking open enrollment; and strides in finally holding many of our drug companies accountable. Truly an

unbelievable transformation between now and, indeed, your first budget hearing, Mr. Chairman.

The timing of this meeting is especially sweet, since later this week we will celebrate the 14th anniversary of the Affordable Care Act. Back then, on this very dais, we moved with the dream of what could be. And thanks to the investments and commitment from the Biden Administration, the ACA is alive, strong, and quite well. More Americans have health coverage than ever before, with 21.3 million Americans signing up for the last open enrollment. Four out of five Americans can access high quality plans for less than ten dollars per month. Seniors are saving on their out-of-pocket costs, which will be capped at $2,000 per year starting next year. They are also saving on insulin, which we capped at $35 a month, and I look forward to bringing this savings to the American family at large.

The ACA is now firmly the law of the land. It is polling quite well, standing proudly as a beacon of what is possible when the government does what is best for its people. Our nation's teenagers don't even know what life is without the ACA. We have taken away the fear of the insurance company discriminating against those with pre-existing conditions. Even women are cutting off coverage or being denied coverage due to cost. For 14 years, the American people have had peace of mind and the only path forward, never once backward.

While accomplishments have been superb, President Biden's budget shows what we can build through this progress and how we might finish the job for the American family. Ways and Means Democrats share the view that when we invest in our health and caregiving, we are investing in the nation's children, families, and the economy of tomorrow. From the Affordable Care Act to the expanding Medicare's power to lower drug prices to permanently extending this committee's premium tax credits, we are putting the needs of the American people first and taking our cues from them.

Ninety-six percent of Americans agree that lowering drug prices is an important way to help people afford the cost of living: another reason we intend to continue to expand these savings.

All, while our progress has never been more popular, our colleagues on the other side have not demonstrated many plans of their own, and they unite around what they don't like about ours. Recently, the former President said, as he re-ignited attacks on not only the Affordable Care Act but also on Medicare, two wildly popular programs that the American family depend on, uprooting settled popular laws of the land, including the ACA and the Inflation Reduction Act, which was a superb piece of work that came right from this committee, will send our nation backwards while all putting lives and livelihoods at risk.

We are delighted, Mr. Secretary, that you are with us today. It is a privilege to share this progress with you, as I am sure you will remind all of us in the coming minutes.

Nice to have you here, Mr. Secretary.

Chairman SMITH. Thank you, Ranking Member Neal.

Today's sole witness is Department of Health and Human Services Secretary Becerra.

The committee has received your written statement, and it will be made part of the formal hearing record. Secretary Becerra, you may begin when you are ready.

STATEMENT OF XAVIER BECERRA, UNITED STATES SECRETARY OF HEALTH AND HUMAN SERVICES

Mr. BECERRA. Chairman Smith, Ranking Member Neal, and members of the committee, it is great to be with you again. Thank you for giving me an opportunity to speak about the President's fiscal year 2025 budget for the Department of Health and Human Services.

If we could go back to January 2021, when President Biden first took office, if you recall, COVID was ravaging our families and our economy, and Americans were dying at the rate of 2 to 3 9/11s every day. Let me repeat that again. Every single day, not one 9/11, not just 2, but often times 3 9/11s were occurring every day in America as we were losing so many of our loved ones.

When President Biden took office in January 2021, COVID was not just hurting our economy, it was hurting the way we did business. In January 2021 the number of Americans with health insurance was, like our jobs and our economy, down and on the canvas. In January 2021 prescription drug prices were skyrocketing, with patients and their pocketbooks at the mercy of Big Pharma and its profits. Today, 3 years later, nearly 700 million shots of COVID vaccines have gone into the arms of Americans, and we can now manage COVID like the flu.

Today more than 300 million Americans, a record number, can go to the doctor or hospital and not go bankrupt because they have their own health insurance. More than 21 million of those Americans count on the Affordable Care Act marketplace for their insurance, another record.

Today, while Big Pharma—well, they are still big—the President's new prescription drug law has brought down the price of insulin to $35 per month for Americans with Medicare. And as we speak, we are negotiating with drug companies to lower the prices of even more prescription drugs, even as they sue us to stop us.

The President's budget doubles down on the investments that made the comeback of our jobs, our economy, and our health possible. It lays out a vision for a nation that invests in its most vulnerable, fosters innovation, and protects every American's access to the care that she needs. This budget doesn't just strengthen Medicare, it strengthens it beyond our lifetime.

This budget continues our shift from a health system that treats illness to one that sustains wellness. All told, the fiscal year 2025 budget proposes $130.7 billion in discretionary and $1.7 trillion in mandatory funding to advance our mission and invest in key priorities. Let me share a few of the highlights.

The budget provides Medicaid-like coverage to low-income individuals in the outlier states that have not expanded Medicaid under the Affordable Care Act. When that happens, another 1.5 million Americans will have health insurance coverage and the peace of mind that comes with it. This budget builds on the largest investment in behavioral health in a generation. It bolsters the 988 suicide and crisis lifeline. It gives young people support at home

and at school. That means boosting our behavioral health workforce with 12,000 new psychiatrists, psychologists, clinical social workers, marriage and family therapists, counselors, and peer support specialists.

Across HHS the budget tackles the maternal health crisis by improving access to pre and postnatal care, supporting emergency care services, and expanding maternal care in rural and underserved communities. We are making childcare more affordable for working families and more available where families actually live and work. This budget would provide increased wages for early childhood education workers, and it would fund more than 750,000 slots for children in Head Start, and it funds universal preschool for our nation's 4 million 4-year-old children. And eventually it would include our three-year-olds, as well.

Our budget grows and strengthens our cybersecurity initiatives to ensure patient safety and privacy, and to keep our hospitals and providers, especially our smaller ones, and those in rural communities, running and secure.

Finally, this Administration has made tremendous strides in preparedness capabilities since the pandemic, and we keep building. This budget invests in countermeasures to combat antimicrobial resistant drugs, expands our monitoring of supply chains, and integrates 200 data sources across Federal, state, and local governments to improve information sharing.

We can't reduce the health and well-being of Americans to align on a budget spreadsheet, but we can transform the number on the balance sheet into investments and services that sustain health and promote wellness for all Americans. President Biden has presented a forward-leaning budget.

I look forward to taking your questions. Thank you.

[The statement of Secretary Becerra follows:]

TESTIMONY OF SECRETARY XAVIER BECERRA BEFORE THE HOUSE COMMITTEE ON WAYS AND MEANS MARCH 20, 2024

Chair Smith, Ranking Member Neal, and Members of the Committee, thank you for the opportunity to discuss the President's Fiscal Year (FY) 2025 Budget for the Department of Health and Human Services (HHS). I am pleased to appear before you today, and I look forward to continuing to work with you to serve the American people.

When President Biden took office, the number of Americans with health insurance was declining. We changed that. Over 300 million Americans now have health insurance – the most under any other Administration.

Until now, Americans paying far too much for prescription drugs haven't had any relief. We changed that. The Inflation Reduction Act, signed into law by President Biden in 2022, caps the price of insulin at $35 per month per insulin prescription for people with Medicare, and certain important vaccines, like the Shingles vaccine, are available for free. And now, for the first time, HHS is negotiating directly with drug companies to lower prescription drug costs for people with Medicare, and we're working to make health care markets more competitive across the board.

The Biden-Harris Administration has taken decisive action to protect access to reproductive health care, including abortion and contraception care. We are also fighting tooth and nail to stop the dismantling of the remaining rights and freedoms available to women across the country.

In three years, the Biden-Harris Administration has made the largest investment in behavioral health, which includes both substance use and mental health, in a generation. We are on the path to increasing the number of mental health counselors in schools, have improved support services for high-risk and underserved populations, and trained health care providers, families and school personnel on best practices for supporting young people with behavioral health needs, including those taking medications to treat opioid use disorder.

There are many, many more accomplishments that I could highlight – but, there is more work to be done. It is critical that we look forward to the challenges that lie ahead and take the actions that will ensure that we can continue to improve the health and wellbeing of all Americans.

This budget lays out a vision for a nation that fosters innovation, invests in health, and supports its most vulnerable.

HHS remains at the center of some of the most important issues for American families – including expanding access to care and lowering health care costs; protecting and strengthening Medicare, Medicaid, and the Marketplace; helping ensure access to reproductive health care; improving maternal health care; transforming the way we deliver behavioral health care, particularly for substance use disorders; improving care for older adults and people with disabilities; preparing for future public health threats; ending cancer as we know it; and ensuring access to high-quality education and support for children.

We also must continue to advance cutting-edge research, and meet the health needs of Tribal Nations and Native communities. And none of this would be possible without the resources to support our operations.

All told, the FY 2025 budget proposes $130.7 billion in discretionary and $1.7 trillion dollars in mandatory funding to advance our mission and invest in key priorities that will impact the lives of all Americans. We remain steadfast in our commitment to be good stewards of taxpayer dollars, and to continually improving the experience of the people whom our programs serve.

Expanding Coverage and Lowering Health Care Costs

Once again, a record-breaking number of Americans enrolled in the Health Insurance Marketplace in 2024—over 21.3 million people. That means more Americans are getting the health care coverage they need at an affordable cost. This is a testament to the success of the Affordable Care Act.

The FY 2025 budget continues to build on this success by making permanent the expanded premium tax credits that the Inflation Reduction Act extended and providing Medicaid-like coverage to low-income individuals in states that have not expanded Medicaid under the Affordable Care Act, along with financial incentives to ensure states maintain their existing expansions. For Medicaid and CHIP, the Budget allows states to extend the existing 12-month continuous eligibility for all children to 36 months, and allows states to provide continuous eligibility for children from birth until they turn age 6. Further, the budget prohibits enrollment fees and premiums in CHIP. It extends consumer surprise billing protections to ground ambulances, building on the No Surprises Act. The budget also advances the steps taken in the Inflation Reduction Act to improve access to affordable prescription drugs by further expanding Medicare's ability to negotiate prices directly with drug manufacturers, and expanding inflation rebates and the $2,000 out-of-pocket prescription drug cost cap beyond Medicare and into the commercial market.

Fundamental to our vision of affordable, accessible health care is ensuring Americans can rely on Medicare for generations to come. The FY 2025 budget proposes changes that indefinitely extends the solvency of the Medicare Hospital Insurance Trust Fund.

In addition, the budget continues on the path to doubling Health Center Program funding, which provides health care services to millions of Americans, particularly those in underserved communities. The budget provides $8.2 billion for Health Centers in 2025, allowing the program to serve approximately 3.9 million additional patients. This investment also supports the expansion of behavioral health services at Health Centers.

Transforming Behavioral Health

The FY 2025 budget proposes over $20.8 billion in investments to improve behavioral health across the Department. This includes $602 million, an additional $100 million, to the 988 Suicide and Crisis Lifeline for an expanded awareness campaign and increased technical assistance support and infrastructure. This investment in 988 also maintains specialized services for LGBTQI+ youth, Spanish speakers, and the Deaf and Hard of Hearing Community.

The budget seeks to expand access to high-quality mental health care, including through a $1 billion investment in the Community Mental Health Services Block Grant. The budget also improves behavioral health benefits for people with Medicare and Medicaid and in the private insurance market, with an emphasis on improving access, promoting equity, and fostering innovation. In addition, the budget

invests $1 billion in health information technology adoption for inpatient psychiatric facilities, as well as certain outpatient and residential behavioral health facilities. If we are serious about integrating behavioral health providers into the rest of the health care system, we must close the technology gap and advance better information exchange with other health care, public health, and community partners.

The budget also addresses the sobering impact of the behavioral health crisis on our nation's youth. National surveys of youth have shown significant increases in certain mental health symptoms, including depressive symptoms and suicidal ideation, compounded by the effects of the COVID-19 pandemic. The surveys underscore the urgency and importance of our commitment to equip our youth with the tools they desperately need to address these unique challenges. The budget expands mental health services in schools and bolsters youth mental health programs by investing an additional $50 million in Project AWARE (Advancing Wellness and Resiliency in Education) and an additional $50 million in Children's Mental Health Services. These programs provide services to states, tribes, and communities to support children with serious emotional challenges and their families. The budget also includes $30 million for the Centers for Disease Control and Prevention's (CDC) Essentials for Childhood: Preventing Adverse Childhood Experiences (ACEs) through Data to Action Program, which will increase the number of states, territories, localities, and tribes implementing ACEs prevention strategies and approaches in their communities.

In addition, the budget increases funding to states for overdose prevention and substance use disorders treatment. In January 2021, the overdose death rate was increasing 31% year-over-year. Today, the rate of increase has dropped to about 2% year-over-year. We're making great progress, but in the face of an increasingly dangerous drug supply, we need to do more. The budget provides an additional $20 million for the State Opioid Response program, which has provided treatment services to over 1.2 million people and has helped states to reverse more than 500,000 overdoses. It also includes a $5 million increase for the Tribal Opioid Response program to address the disproportionate impact of the overdose crisis on American Indian and Alaska Native people.

The FY 2025 budget also continues to invest in growing and diversifying the behavioral health workforce. The budget includes $254 million for the Health Resources and Services Administration (HRSA) for Behavioral Health Workforce Development Programs, including expanding the substance use disorder provider workforce. The budget also continues to expand key HRSA programs by providing $916 million for the National Health Service Corps and $320 million for Teaching Health Centers Graduate Medical Education programs in 2025 to ensure the continued growth of health care services and expand workforce capacity across the country, including for behavioral health. The budget also includes $20 million for the Substance Abuse and Mental Health Services Administration's (SAMHSA's) Minority Fellowship Programs to reduce health disparities and improve behavioral health care outcomes for underserved populations.

Improving the Well-being of Children, Families, and Older Adults

The FY 2025 budget invests in the future of our nation's children through high-quality early childhood education. The budget proposes to guarantee affordable child care to low- and middle-income working families from birth until kindergarten and offer preschool to all four-year-olds, making early care and education programs affordable and available where families live and work, and increasing wages for early childhood education workers. Under this proposal, preschool would be free and the average family would

pay no more than $10 per day for child care until their child starts kindergarten, saving them over $600 per child, per month. This proposal will go a long way to support our most vulnerable children and their families.

The budget continues to bolster Head Start for children from birth to age five and provides an additional $544 million for the Head Start workforce, allowing wages to keep pace with inflation and for us to maintain a high-quality child care workforce. As child care continues to be unaffordable or unavailable for millions of Americans, the budget provides funding to Americans that desperately need it to continue to work and support their families. It also provides an additional $500 million for the Child Care and Development Block Grant to continue our progress in stabilizing the child care sector and helping more Americans afford child care.

The budget also invests in child welfare, with a package totaling $11.4 billion over 10 years. This funding expands services and supports to families at risk of child maltreatment or involvement with the child welfare system, increases funding for prevention services and kinship placements and supports for older youth, and increases and streamlines funding to tribes.

Finally, we are also investing in supports for older adults and people with disabilities to ensure they can participate fully in our communities. The FY 2025 budget provides $2.7 billion for Administration for Community Living programs—a $70 million increase above the 2023 Enacted level. This includes additional funds for nutrition programs, as well as funding for suicide prevention for older adults.

Enhancing Long-term Care in All Settings

HHS programs support the health and well-being of people with disabilities and older adults. The FY 2025 budget includes a 10-year, $150 billion proposal to expand Medicaid home and community-based services to allow more older adults and people with disabilities to receive care at home and in their communities. Recognizing that a strong, well-trained workforce is essential to delivering high-quality services, the budget initiative is designed to enhance the quality of these jobs. When older adults' support needs become so great that they must enter nursing homes, they deserve safe, high-quality long-term care. At the 2024 CR level, state survey agencies would complete just 65% of statutorily required nursing home surveys in FY 2024, down from 100% in FY 2022 and 75% in FY 2023. To address the increasing workloads and align with the Administration's commitments to improve the safety and quality of nursing home care, the budget requests an increase in funding to allow CMS to conduct 85% of the mandatory surveys, as well as legislative proposals that strengthen quality and care in long term care facilities for FY 2025. In addition, the Administration's proposal to shift survey and certification funding for nursing home facilities from discretionary to mandatory and increase that funding to conduct 100% of mandatory surveys, effective in FY 2026, would allow for sustained and reliable oversight and enforcement in the nation's nursing homes and ensure that Americans receive high quality, safe services within these facilities.

Strengthening Maternal Health Outcomes and Reproductive Health care Access

The budget reflects the Administration's commitment to address the U.S. maternal mortality rate, which is higher than all other developed nations and on the rise. The majority of these deaths are preventable, and Black and American Indian and Alaska Native women are disproportionately affected. Across HHS,

the budget invests in tackling this maternal health crisis, including $376 million focused on addressing maternal mortality and maternal health equity. This includes targeted funding within the Indian Health Service (IHS) to provide culturally-relevant maternal health care in Indian Country, additional funding for CDC to expand maternal mortality prevention, and continued support for the Implementing a Maternal Health and Pregnancy Outcomes Vision for Everyone (IMPROVE) initiative in the National Institutes of Health (NIH). It also includes $215 million in HRSA specifically for reducing maternal mortality and morbidity. This funding will improve access to pre- and post-natal care, including for behavioral health, provide access to emergency care services, expand maternal care in rural and underserved communities, and more.

To help improve maternal health coverage and prioritize person-centered care, the budget also includes an optional Medicaid benefit that expands coverage of maternal health support services across the prenatal, labor and delivery, and postpartum periods, with enhanced federal funding available for the first five years in which states take up the State Medicaid option. This includes coverage for a range of maternal health support workers, including doulas. With this benefit, we aim to bolster maternal health supports throughout the entire continuum of care and to demonstrate our dedication to supporting women at every stage of pregnancy and beyond.

Access to reproductive health care, including contraception, is a more urgent issue now than it has been in decades. The budget provides $390 million, a 36 percent increase, to the Title X family planning program to meet the increased need for family planning services, which are essential to ensuring women have control over personal decisions about their own health, lives, and families. Title X remains the only federal grant program dedicated solely to providing individuals with comprehensive family planning services in communities across the United States.

Preparing for Future Public Health Threats

While this Administration has made tremendous strides in preparedness capabilities since the pandemic, there are many public health threats beyond COVID-19. The budget therefore includes over $28.9 billion in total resources across the Department to support preparedness, including efforts to prevent future pandemics, in addition to response capabilities, consistent with the President's plan to prepare for and respond to biological threats, as outlined in the 2022 National Biodefense Strategy and Implementation Plan.

This includes $8.9 billion in discretionary funding for preparedness across the Department. The budget invests an additional $38 million for CDC to manage the Response Ready Enterprise Data Integration platform, and an additional $20 million for the Biomedical Advanced Research and Development Authority to invest in medical countermeasures that combat drug-resistant microbes.
Our nation continues to face emerging public health threats and it is important that we are well positioned to adequately respond. The budget continues to strengthen our domestic supply chain by investing $95 million to accelerate development and domestic production of medical countermeasures, and onshore production of active pharmaceutical ingredients and essential medicines through the Administration for Strategic Preparedness and Response. It also includes $12 million to support the Food and Drug Administration (FDA) in addressing medical and food shortages and $10 million for a new supply chain coordination office within HHS.

As a continuation of our work to treat and prevent infectious diseases, the budget also includes a new HHS-wide proposal to eliminate hepatitis C infections in the United States. This five-year program focuses on high-risk populations and will increase access to curative medications, and expand implementation of complementary efforts such as screening, testing, and provider capacity.

Advancing Health in Indian Country

HHS remains committed to addressing the significant health disparities faced by Tribal Nations and Native communities, and the chronic underinvestment in the Indian Health Service. The budget proposes $8.2 billion for IHS, a $1.1 billion increase above the 2023 Enacted Level. This includes the proposed reauthorization of the Special Diabetes Program for Indians. This will maintain direct health care service levels, address targeted public health issues, and advance critical operational efforts like Health Information Technology modernization.

Beginning in FY 2026, the budget proposes full mandatory funding for all IHS accounts, and automatically grows funding each year to account for factors like inflation and pay. This approach will address chronic underinvestment by ensuring funding grows along with IHS's needs. The budget also includes a dedicated funding stream for public health capacity and infrastructure needs in Indian Country, a key lesson learned from the pandemic.

This budget also addresses health care workforce needs across the Indian Health Service by providing hiring authorities to improve the recruitment and retention of providers in our system. Workforce challenges– including significant staffing needs in behavioral health fields, such as substance use disorder care – are one of the top concerns raised by tribes to HHS. Addressing these challenges is critical to providing better-quality health care to the people IHS serves and to continuing to fight the concurrent substance use and suicide crises tribes are currently facing.

The Department will continue to partner with Tribes and Congress to realize mandatory funding, and to ensure we can continue to provide advance discretionary appropriations so IHS can maintain critical health care services if there is a lapse in appropriations.

Advancing Science to Improve Health

Cancer impacts Americans of all ages and from all walks of life. Decreasing the cancer death rate and the number of loved ones we lose to the disease remains a top priority for the Administration. The Biden Cancer Moonshot set ambitious goals to cut the cancer death rate by 50 percent over 25 years, preventing more than 4 million cancer deaths by 2047, and to improve the experience of people touched by cancer. The FY 2025 budget invests $2.9 billion across the Department to make that possible, including $716 million in discretionary resources at the NIH National Cancer Institute to continue their efforts to speed delivery of cancer drugs and vaccines and ensure access to current and new standards of cancer care. An additional $100 million increase for CDC will support cancer prevention activities, including tobacco prevention and cessation. The Advanced Research Projects Agency for Health (ARPA-H) will also support Cancer Moonshot goals by investing in the development of unprecedented breakthroughs to prevent, detect, and treat cancer.

Additionally, ARPA-H will maintain its role as a catalyst for transformation in the health ecosystem—including through its recently-announced Sprint for Women's Health. With its $1.5 billion budget, the

agency will continue finding real-world solutions for real-world problems, driving biomedical innovation in a variety of arenas.

The budget continues the Administration's commitment to support scientific innovation. It includes $50.1 billion in total resources for NIH, prioritizing in particular women's health research and firearms and gun violence research with additional funds. The budget also continues to support Brain Research Through Advancing Innovative Neurotechnologies, All of Us, and important research on opioids and pain management, HIV/AIDS, and health disparities to improve American health outcomes.

To keep our nation at the forefront of scientific innovation, we must seize the promise of artificial intelligence—while also managing its risks. NIH is committed to harnessing the power of artificial intelligence to advance research, and has already launched ambitious initiatives to propel the fusion of biomedicine and artificial intelligence and machine learning. In addition, the FY 2025 budget provides resources to oversee artificial intelligence within the Department to advance its responsible use in public health and health care.

The FY 2025 budget also invests in scientific research that has resulted in significant improvements to American lives. CDC's overall budget—increased by $499 million—prioritizes investments in areas such as improving public health data, preventing and mitigating the impact of infectious diseases, reducing injury and violence, and protecting against environmental health hazards. The budget also provides a total of $513 million to the Agency for Healthcare Research and Quality to further invest in their mission to produce scientific evidence that makes health care better, more accessible, and more affordable.

Supporting Program Operations and Mission-Critical Infrastructure

HHS needs sufficient operational funding to fulfill our mission. This includes resources to allow the Office of the Secretary to oversee the federal government's largest budget. The budget makes badly needed investments in Centers for Medicare & Medicaid Services (CMS) Program Management to ensure CMS can carry out its core operations, such as surveying hospitals and nursing homes to ensure quality care is being delivered to millions of Medicare and Medicaid enrollees. It also invests in FDA to support the agency's expert staff that ensures the safety of our food supply, guarantees the effectiveness of our medicines, , and that conduct rigorous and transparent scientific reviews.

The Nonrecurring Expenses Fund is a key source of funding for Departmental operations. The Fund permits HHS to transfer unobligated balances of expired discretionary funds into an account for necessary information technology and facilities infrastructure acquisitions. Since FY 2013, the fund has allocated over $6.5 billion in capital investment projects across the Department. HHS's proposed FY 2025 projects will address aging systems and facilities, including at IHS, NIH, and CDC. These improvements are integral in improving the health and well-being of the American people.

A fundamental component of HHS's infrastructure is its cybersecurity capabilities. We have seen a dramatic rise in large data breaches reported to HHS, and the health care information HHS protects is a prime target for cybercriminals. Our plan sets the direction for cybersecurity in health care, both from a policy and operational lens, and commits HHS to pursuing new priorities to both strengthen and support the sector at this critical time. The FY 2025 budget prioritizes investments to address cybersecurity threats and invests $141 million in cybersecurity initiatives in the Office of the Chief Information Officer to address cybersecurity mandates and allow deployment of cybersecurity initiatives and tools that will keep

the Department at the forefront in battling ever-evolving cyber threats. The investment in cybersecurity includes $11 million for the Department's Health Insurance Portability and Accountability Act modernization to increase compliance, enhance the privacy and security of health information, and to improve breach prevention and response efforts. The budget also includes an increase of $12 million above FY 2023 for ASPR as the agency designated to coordinate cybersecurity incident prevention and response in the health care and public health sector The budget also establishes a Medicare incentive program to encourage hospitals to adopt essential and enhanced cybersecurity practices.

The budget also invests in civil rights enforcement to ensure we do our part to protect the American people's fundamental rights of nondiscrimination and health information privacy. The budget provides the HHS Office for Civil Rights a $17 million increase, which includes a robust investment in enforcement staff to address and resolve major case increases that have led to a significant backlog.

HHS also invests in program integrity and promoting competition to support our commitment to good stewardship of taxpayer dollars. Our responsibility is to ensure that every dollar entrusted to us directly enhances the lives of the American people. The budget invests a total of $4 billion over 10 years in new mandatory Health Care Fraud and Abuse Control funding to provide oversight of nursing homes, managed care, and community-based settings. This mandatory investment will yield a net savings of $5 billion over 10 years. Additionally, the budget provides increased funding to the discretionary Health Care Fraud and Abuse Control program and the HHS Office of Inspector General to support its oversight.

Improving the Customer Experience for the American Public

Lastly, I wanted to talk about how we are making government and government programs easier for American people to access and use. HHS is improving customer experience throughout the Department, mostly using current administrative funds. In FY 2025, the budget includes an $11 million investment for the Department to improve data services for benefits delivery, as well as $3 million to support the Streamlining Medicare-Only Enrollment project, among other efforts. These investments are bolstered by the HHS-wide customer experience initiative launched in FY 2024, one of the largest such initiatives in the federal government to date. Our goal is to provide a customer experience that ensures the public can access and utilize the impactful resources within HHS. As part of the initiative, every agency within HHS will pursue substantial projects to improve services to the American people. This expands on the many customer experience initiatives HHS has already pursued. For example, HHS continues to partner with other departments and agencies through the Life Experiences initiative to streamline enrollment and eligibility across benefits programs such as Medicaid and the U.S. Department of Agriculture's Supplemental Nutrition Assistance Program, increase access to decision-making support for older adults, reduce burdensome and repetitive manual income verifications, and support states in innovating and improving federal-state benefits access and delivery.

Conclusion

I am honored to lead the Department of Health and Human Services, working alongside dedicated civil servants to enhance the health and well-being of the American people. Investments in this budget will allow us to continue fulfilling our mission, and we know you are all critical partners in achieving this goal. We are grateful for your support of the Department, and we are excited to work with you on funding for FY 2025.

I want to thank the Committee for inviting me to discuss the President's FY 2025 Budget for HHS. I look forward to working with you to fulfill that vision. Thank you for your partnership in advancing our shared goal to improve the health, safety, and well-being of our nation.

Chairman SMITH. Thank you. We will now proceed to the question-and-answer session.

On February 29, every Republican member of this committee sent you a letter asking what your department is doing to address the impact of the illegal immigrant crisis on our health care system. This influx of illegal immigrants has forced safety net hospitals like Denver Health in Colorado to turn away patients and reduce the number of beds reserved for Denver residents seeking substance use disorder and mental health treatments.

What is your department doing to address this growing crisis, given the real fear that other hospitals in sanctuary cities across the country may similarly be impacted, harming the nation's health care system safety net, and threatening health care access for vulnerable patients?

Mr. BECERRA. Mr. Chairman, thank you for the question. As you know, we have some of the most advanced and capable hospitals in the world. We count on them to be able to keep Americans healthy and safe. We continue to work with them day in, day out. When Change Healthcare had the cyber attack, we were there to support them, as well. We will do everything we can to make sure they continue to provide the services Americans count on, whether it was during COVID or whether it is now. We are prepared to work with every one of our hospital facilities to make sure that they continue to operate and provide the services that Americans count on.

Chairman SMITH. Has your department been working with Denver Health in Colorado with the issues that I just raised?

Mr. BECERRA. We have certainly been working with the State of Colorado. And if we were to get a particular request from a particular facility, we would certainly then try to work with them to resolve any issues they might have.

Chairman SMITH. Earlier this month the committee passed legislation introduced by Representative Fischbach to block the implementation of the unworkable, one-size-fits-all nursing home staffing mandate. Estimates show this rule will impose a $40.6 billion cost on nursing homes, 94 percent of which currently wouldn't be in compliance, jeopardizing access to care for 1.2 million Americans.

Can you commit to the Medicare beneficiaries watching this hearing that no nursing home will close, and patients won't lose access to care as a result of this rule?

Mr. BECERRA. Mr. Chairman, I could commit to you, and I commit to each and every one of the Medicare beneficiaries that is out there that, if they need a nursing home, they will find one that offers them quality care. We want to make sure that no nursing home becomes a death sentence for any American who has to use a facility, and we want to work with every nursing home to make sure that they are offering quality services.

And if you think about it, of the 1,200,000 or so Americans, 1,500,000 Americans who reside in nursing homes, that is a fraction, a little bit more than 1 percent, of—not even 1 percent of the population. But when you take a look at the death numbers that occurred during COVID, and you realize that one of every five

Americans who died from COVID died in a nursing home, something is going on, and we can't just close our eyes to it.

We have to make sure that if we are going to leave our loved one in a nursing home, there is a nurse that is available to provide care. And these standards simply say that: Make sure that, if you are going to claim that you are a nursing home, you have the professionals who can provide the services to our loved ones before we leave them there in your care.

Chairman SMITH. So, San Francisco recently enacted a law requiring residents who are suspected of using illegal drugs to undergo treatment as a condition to receive welfare benefits. Since 2011 my home state of Missouri has required certain TANF recipients to be screened for illegal drug use, a law that I helped advance at the time as a member of the state general assembly. And as it relates to the rise in opioid abuse, you yourself have said all options should be on the table when it comes to how communities across the country address the drug crisis.

Given that TANF has an outright ban on providing assistance to those with drug-related felony convictions, I appreciate your position, which many of us have believed for a long time, that states should be looking at how to utilize drug testing in their welfare programs. If San Francisco's actions are suitable, then surely other cities, counties, and states should be encouraged to make similar decisions.

And so, to that end, and consistent with your recent comments, is it fair to say you are open to Congress and states putting stronger protections in place to make sure recipients of welfare benefits are being screened or tested for drug use?

Mr. BECERRA. Chairman, thank you for the question. I want to make sure—please do not misinterpret what I said when I referenced the drug crisis, the overdose crisis that we face in this country. Certainly, we want to make sure we are exploring every opportunity to save a life when it comes to the overdose crisis that we face.

What decisions a local community decides to make for itself and how it will handle TANF dollars, which is different from specifically dealing with the overdose crisis, I won't pass judgment there. I don't represent that area. I don't have jurisdiction on those issues.

But what I will tell you is that any community, whether it is San Francisco or whether it is your district, Mr. Chairman, I will—we are ready at HHS to try to help address the overdose crisis because no American should die simply because of fentanyl and these other drugs that are now infecting our communities.

Chairman SMITH. Thank you, Secretary. I now recognize the ranking member for any questions he might have.

Mr. NEAL. Thank you, Chairman.

Before I get to cybersecurity, Mr. Secretary, I want to remind you of all that the success that we have had with open enrollment at the ACA has been stunning. I think that is a fair term. But also, the consequence of what happened in this very room 14 years ago, when you consider as we sit here today every child in Massachusetts has health insurance, 97 percent of the adults in Massachu-

setts have health insurance, and it polls in the high 60th percentile in terms of satisfaction.

So, I think that we should not forget the success that we had. Nationwide it is polling in the low to mid 60s.

Mr. BECERRA. Yes.

Mr. NEAL. And the enrollment process continues. And we are indeed grateful for the work that took place here.

Let me talk about cyber-attacks on the health care infrastructure that you are quite familiar with. Hospitals and health care providers are facing increasingly frequent and sophisticated threats, even when they are not directly targeted. The recent cyber-attack on Change Healthcare and the resulting fallout demonstrates the potential consequences we face if we do not take appropriate measures to protect and secure our data and the systems.

Talk about what HHS has done to support the health care system in light of what we have learned at Change Healthcare and the attack over the last few weeks.

Mr. BECERRA. Thank you, Congressman.

Since we first learned of the attack on February 21, we have been in near constant communication with not just UnitedHealth Group, but with most of the stakeholders, especially the insurers who are the payers for most of the bills that providers submit. We stood up our preparedness operations to try to be as available to providers as possible.

To date, we have, I believe, issued some $2.5 billion in payments in advance. And I want to make sure that is clear. We haven't received the bill, but we have provided $2.5 billion in payments because we know that these providers typically will bill us a certain amount every month or have certain number of patients that—where they will bill us for Medicare or Medicaid.

So, we have made an arrangement so they can bill us in advance, and we will reconcile the differences later. But we want to keep them afloat so they can make their payroll. That means that some nearly 6,000 providers today have already received, as a result of Medicare or Medicaid's actions, payments, even though the bills have not come through the door. And we are going to continue to do that.

And now we are insisting that the insurance companies that have, by the way, receive money from the Federal Government under Medicare and Medicaid, that they also do the same, and make it available to those providers.

Mr. NEAL. Thank you, and I am going to give you a chance to talk, Mr. Secretary, rather than just dominating the time. So, talk about the steps that CMS is taking to support the long-term care workforce and to increase oversight of those who operated outside the rules, which we painfully learned during the COVID crisis. And you have got a couple of minutes to talk about it.

Mr. BECERRA. Congressman, thank you for that.

One of the biggest depressions that we faced in America with COVID was the loss of a workforce that cares for Americans. Whether it is childcare, whether it is long-term care, whether it is nursing homes, so many of those workers never returned, many because they died, many because they just found something else, or they found that it was too dangerous to do the work.

We are now trying to make sure that we help the various sectors bring up the workforce, and so we have made several hundred billion dollars in investments to try to support the training and the development of a more broad workforce. And we are focusing quite a bit of that investment on the behavioral workforce side.

And so, we continue to try to make sure that, if you are going to go into the business of care, it pays you more than going to flip burgers at the local fast-food joint. And it is tough, but that is what we have to do if we want to professionalize the service of caregiving in America.

Mr. NEAL. Thank you.

Thanks, Mr. Chairman.

Chairman SMITH. Mr. Buchanan is recognized.

Mr. BUCHANAN. Thank you, Mr. Chairman.

Thank you, Mr. Secretary, and I appreciate the time you made available to me on a couple of different occasions working on different issues.

I do want to touch back on the cyber attack. They claim a billion a day. How much does that fall kind of—what created that scenario? Is it more industry, government, or—what happened that they were in that situation? Because we are talking about a lot of people being put in the street, a lot of industries, businesses that might have to close. It is a big issue, and we need to learn from this and make sure, ideally, it doesn't happen again.

Mr. BECERRA. Congressman, thanks for the question.

Consolidation, if it means efficiency, can be a good thing. But consolidation, if it means you rely too much on one big player, can be very dangerous. UnitedHealth, the owner of Optum, the organization, the company that essentially does billing for about a third or a half of the entire health care sector that provides medical data back and forth electronically, when it got attacked through this cyber attack, it went down. And when it went down, it took pretty much all those providers who depend on them to be able to pay their payroll, to do their billing. The result was essentially a bit of a—not a bit—a crash in the industry.

What we have to do is recognize that if one player is going to be so big, they have to have the fail safe option if something happens to them, very similar to what happened with the infant formula situation, where a big manufacturer of infant formula went down, all of a sudden the rest of the manufacturers weren't ready to cover for the loss of that manufacturer's supply. We can't allow the private sector to run its operations as if it is not going to face some of these cyber attacks.

Mr. BUCHANAN. Yes, let me ask you this. And when we were at your office, we talked about it. My big passion is trying to work in terms of preventative care. We are spending $4.4 trillion, but yet we spend less than 3 percent on preventative care. So, in other words, I don't want people to get cancer in the first place. I don't want people, ideally, to get a heart attack in the first place and might not see the next day. What more can we be doing?

And the other thought is type 2 diabetes, it is off the charts. So, I read the other day someone said you got to be the CEO of your own health. I realize not everybody is going to do that or want to

do it for whatever reason, but I think there are a lot of people that want to be more knowledgeable, more educated.

And a lot of the food, I hate to say it, not all of it, but a lot of it is junk food. So, it is not all on them, you know. They think they are eating food, but it is highly processed food, there is not much quality to it in terms of food value. But what are your thoughts on what we can do?

I think government has a role in trying to educate people where they—you know, a little better diet, a little exercise, today—two miles a day, five days a week, so they take some of the responsibility on themselves.

Mr. BECERRA. Congressman, we are with you on this. As I said in my remarks, opening remarks, we want to shift the system of health care from one that treats illness when you are already at that stage where you—whatever happened, it wasn't good, now you are having to treat it, to one where we sustain wellness, keep you healthy, as you said.

So, we are very much into moving towards what we call food as medicine. So, we treat food as medicine. It is better than popping a whole lot of pills. How about if you put fresh fruits and vegetables, nuts and berries in the diet of your kids?

We are also very much in favor of things that are very low cost, but highly effective. Cancer screening. During the COVID pandemic, about nine million people missed their cancer screenings. That means they probably found themselves, when they did go into the doctor, sicker with cancer than they could have been.

Mr. BUCHANAN. Let me just——

Mr. BECERRA. We want to go back to the screening——

Mr. BUCHANAN. I have only got a minute, so——

Mr. BECERRA. Yes.

Mr. BUCHANAN. That is what I mean by prevention, like, lung cancer and stuff, one of the highest killers, and people aren't getting screenings. If you got a physical once a year in January, it would make a big difference, head it off at the pass.

The other thing I just want to talk just quickly on is the whole thing on telehealth. I am in a senior, very senior area, fifth oldest district. It is really critical to them. There is some discussion. Obviously, the extenders expire at the end of the year.

Where are you at on that in terms—I think it is the future, you know, for—a lot of these seniors or 80, I see it, 85, a lot of them are in pretty good health, but they might have to drive an hour, two hours a day to get where they have got to go. And this would be a lot better for them, and maybe not on the initial visit but after a couple of visits. Your thoughts?

Mr. BECERRA. We are with you. We can't allow those flexibilities to expire, and we need to work closer with our state partners, because much of the flexibility that comes from telehealth means that—being able to go over state lines. And right now, because states decide who gets licensed to do care, we have to have the cooperation of the states so we can make sure that telehealth can go beyond its own state borders.

Mr. BUCHANAN. Thank you, Mr. Secretary.

Chairman SMITH. Mr. Thompson is recognized.

Mr. THOMPSON. Thank you, Mr. Chairman.

Mr. Secretary, thank you for being here. It is good to see you back at your old home.

Mr. BECERRA. I would be sitting right next to you, I think, if I were still here.

Mr. THOMPSON. Actually, I kind of like it where I am, closer to the middle. [Laughter.]

Mr. THOMPSON. I appreciate the points that you made in your testimony about mental and behavioral health, especially among young people. It is something that I am extremely concerned about, and I am glad the Department continues to take proactive steps in this regard.

But I am going to repeat something today that I said the same time last year: There is not enough money in the world to address the mental health crisis by treating symptoms. We invest far too little in understanding the brain itself and the underlying neurological roots of depression, bipolar disorder, and other common and challenging conditions. We have got to get ahead of that curve. And if we do, the benefits to our health and, frankly, to our economy are impossible to over-estimate. That is why Mr. Kelly, my friend on the tax committee, and I have been working on legislation to provide tax incentives for this sort of broad neurological research.

Mr. Secretary, we are kind of fine-tuning our legislation right now, and I would appreciate it if your team could take a look at and offer comments as we do this. Your support would be incredibly important and appreciated, and we can truly help people with mental illness challenges.

Mr. BECERRA. We look forward to working with you.

Mr. THOMPSON. Thank you. I would also like to ask about telehealth and telemedicine. As you know, Mr. Secretary, I have been working on this issue for a long time, since even before we were colleagues in this committee. And I wrote, along with Mr. Schweikert, the legislation that made telehealth available to seniors on Medicare during the pandemic that you referenced earlier in your testimony. That access provided invaluable—and it was—the telehealth flexibilities that we put in place are set to expire at the end of this year.

Mr. Secretary, how does your department view that upcoming deadline?

Have you been evaluating the data coming in from the past few years?

And can you tell us more about the need for this, the importance of this, and what you think we should be doing?

Mr. BECERRA. Congressman, I don't think there is any doubt that we need to maintain these telehealth flexibilities. In fact, even more so on the behavioral health side.

When we hit the pandemic and we started doing telehealth, a lot of folks thought it wouldn't work on the mental health side. But it is actually one of the areas where we have the greatest success. And so, the last thing we need to do is allow them to expire. We are prepared to work with you to make sure that you all are able to, on a bipartisan basis, reach some agreement on how to extend those flexibilities.

Mr. THOMPSON. Thank you very much. And the chairman stated when he made his opening comments how important it is to pro-

vide health care opportunities and access to people in rural areas, and that is all underserved areas. And telemedicine is a way that we can really expand our reach. So, thank you for your help, and I look forward to working with you.

And I yield back the balance of my time.

Chairman SMITH. Thank you. Mr. Smith.

Mr. SMITH of Nebraska. Thank you, Mr. Chairman.

Thank you, Secretary, for sharing your time here today. I would like to start off with an issue that I have worked on for quite a while now, and that is TANF reform. I think there is ample opportunity to get some things done here.

I, a while back, introduced Jobs for Success Act in a previous Congress and, you know, to really focus on helping folks who need the most help, who are very needy, that—in fact, the neediest among us. One of the most important provisions of that bill, I will say, is that it would prohibit the use of TANF funds for families with income greater than twice the poverty line, so 200 percent of Federal poverty.

I am pleased to see the priority was reflected as a key proposal in the Administration for Children and Families' recent proposed rulemaking on strengthening TANF as a safety net and work program. In fact, the very first proposal included in that proposed rule is to establish a ceiling on the term of "needy," so that it may not exceed a family income of 200 percent of the Federal poverty guidelines. So, I certainly appreciate that the ACF recognizes this issue.

So, setting aside other issues of TANF, I am wondering where we—I think there could be some other things that we would disagree on, but I am just wondering if, when it comes to establishing this ceiling of 200 percent of Federal poverty, could you support the legislation? I have introduced the legislation already. Could you support that as a standalone measure?

Mr. BECERRA. Congressman, first, thanks for the work you are doing on this, because it is not easy. It will take congressional action to get reforms to TANF that will get it to work better to do as you said, to concentrate the money on the most needy families.

We, as you mentioned, in our proposed rule looked to try to do that, as well, but we are absolutely prepared to work with you to see how we can do it. Because if it is in a statute versus a regulation, far more powerful.

Mr. SMITH of Nebraska. Okay. So, I will take that as a yes.

Mr. BECERRA. We will work with you because we are—our own proposed rule is right now undergoing a lot of comment, as well. So, we are trying to take in comment to figure out where best to go. But, without a doubt, you all will be indispensable in making sure we can get TANF moving in a better direction.

Mr. SMITH of Nebraska. Okay, thank you. Earlier this week I am glad our committee held a hearing in Texas to discuss problems that our constituents encounter in accessing emergency care. I am glad to say that a critical access hospital, formerly critical access hospital in my district, Friend Nebraska, previously having been a critical access, shifted into a rural emergency health facility, and that was rocky. That transition was rocky.

There are concerns that it didn't need to be that way, obviously, but wanting more information at the local level they tried to get

that information and it was not available. I think it took some four months to—for this institution, you know, that was facing budgetary problems to shift gears into this new category so that they could help their own patients.

And so, I am just wondering—you know, fortunately, they had local government to help back them up, but not every facility would have that. So, I know that this rural emergency health care designation is very new, but I am wondering what HHS can do to make the process faster and even more transparent. And, you know, could there be a dashboard to allow the local level to pursue the—you know, the status of where they stand at a given point in time so that they can get this done more quickly?

Mr. BECERRA. Yes, and Congressman, you bring up a very important point in that this new classification will be very important for a number of these facilities.

We want to make sure we do it right because, as you know, there is always an effort when there is money involved to game the system. And we have to make sure it is done right. So, we have reserved the category for those who truly qualify. I think, with time, we are going to start to really get a better sense of how to move this faster for those who wish to qualify.

But, you know, the best thing I could tell you is that we are going to do everything we can to sustain some of these hospitals and facilities in rural America, because if they go there is nothing to replace them.

Mr. SMITH of Nebraska. Okay, thank you. And just briefly here, I am concerned that, despite ongoing attention to the Office of Refugee Resettlement losing track of thousands of unaccompanied minors, I am just wondering, do you truly believe that ORR is doing everything possible, especially when it appears that we have lost contact with nearly 20 percent of children released through the unaccompanied children program?

Mr. BECERRA. Congressman, thank you for posing the question. And respectfully, I am going to correct what you have said. We haven't lost any child. Please remember that our jurisdiction that you all gave us, that Congress gave us, is for custody of children. Once we find a vetted sponsor, which we are obligated by law to do for these migrant kids, we lose all jurisdiction over them. We don't have the ability to follow up with them or require them to follow up with us. So, it is hard to lose anybody you don't have jurisdiction over.

Mr. SMITH of Nebraska. Okay.

Mr. BECERRA. What we do try to do is voluntarily keep tabs of them as we transfer them out to a sponsor. But while they are in our care, they are—they do not get lost.

Mr. SMITH of Nebraska. Everything is working fine. Is that your suggestion?

Mr. BECERRA. In our jurisdiction, the custody that we have the kids, I welcome you to come and take a look. We are taking care of these kids.

Now, what happens to a child once they are into the community and they get attracted to get a job at some, you know, meat packing plant, I can't—that—I wish I could tell you I could speak to

that. Until you all give us jurisdiction to oversee some of that, I can't go there.

Mr. SMITH of Nebraska. Well, last March, a year ago, I wrote a letter and got a response in July. I had to follow up in October, and still haven't heard. So, I am concerned that there are problems. So, I hope we can work together to establish a better system.

Thank you, I yield back.

Chairman SMITH. Thank you. Mr. Larson.

Mr. LARSON. Thank you, Mr. Chairman.

And Mr. Secretary, welcome back.

Mr. BECERRA. Mr. Chairman——

Mr. LARSON. It is good to see you.

Mr. BECERRA [continuing]. Good to see you.

Mr. LARSON. Listen, President Biden's budget is an incredible vision for supporting seniors in this country.

And his State of the Union message, I think, as Americans were listening in, were both bolstered by what he had to say about Social Security and expanding it——

Mr. BECERRA. Yes.

Mr. LARSON [continuing]. An issue I know that you care as deeply about as I do.

But his budget also builds on the success that Democrats on this committee have had in lowering prescription drug prices. And this is a big deal not only for seniors in my district, but across the nation.

Mr. BECERRA. Everywhere.

Mr. LARSON. And the amazing step that was taken forward in terms of reducing drug costs has been incredible in terms of what it has meant to seniors.

Now, as I indicated, and the President's budget calls on Congress to build on those successes by capping generic drugs for chronic conditions. How, having viewed this from the position of both having sat here and now being in the critical position as Secretary, how do you see that impacting and cutting costs for seniors?

Mr. BECERRA. Congressman, first, can I thank you for the dedication you have demonstrated on these issues for older Americans, and certainly your commitment to make sure we continue to improve Social Security?

If you think about it this way, when you go to any American and say, "What if I could tell you that you are not going to pay more than $2 out of pocket for a prescription medication," they would say, "Get out of here."

But now that we have said to them, "What if I tell you, you are only going to pay $35 for that insulin you used to pay $200 for," they are saying, "Hey, you know what? That is true, because now I am getting it for $35." Now we are getting their attention. Now I think they are willing to say, well, maybe you really got something there.

And I think the American public is beginning to see that we may finally get a grip on these drug prices and not let the pharmaceutical companies just dictate to Americans what we will pay, because typically it means we are paying two or three times more than everyone around the world is.

Mr. LARSON. What would you recommend that Congress do to build on our previous successes, and, as you point out, to be able to say to someone that $2 is the most you are going to be paying?

Mr. BECERRA. Well, the President put this prescription on your lap and in his budget when he said, rather than only allow us to negotiate, to bring down the prices of 10 of the most costly drugs for Medicare recipients, let us do 30, 40, 50 of those drugs. Why not save on all of them?

And then he also said, hey, why don't we also make sure that, if the drug companies are overcharging us beyond the rate of inflation, that we get to pull some of that money back for Medicare?

And then finally, what he said is, hey, $35-a-month insulin, pretty good. For 65 million people on Medicare that is very good. But how about the rest of the 330 million Americans? Extend the $35 cap for insulin to every American in this country. That is in his budget.

Mr. LARSON. Well, that is extraordinary. You went through the numbers there, et cetera. When we are talking about seniors specifically, you know, the 70 million Social Security recipients, what kind of costs are we talking about, and what kind of savings is that going to mean?

You talk about kitchen table issues and discussions. Imagine the discussion at a table anywhere in America about what that would mean to individuals in terms of prescription costs.

Mr. BECERRA. I had a woman who was from Dallas who told me the story that in January, when the price of insulin had gone down to $35, she didn't realize it. December, she had paid—I think she said she paid $117. She is on fixed income, relies on her Social Security check. She went into the pharmacist, purchased her insulin, walked out, looked at the receipt. She said, "I felt so guilty, so I went back, and I told the pharmacist, 'You undercharged me, I owe you some money,' and he said, No, no, that is the new price, $35." She said, "I was over the moon. I was over the moon," because she did not expect to be saving so much money. For a person on fixed income relying on Social Security, that is a big deal.

Mr. LARSON. Thank you, Mr. Secretary.

Mr. BECERRA. Thank you.

Mr. LARSON. I yield back.

Mr. BECERRA. Thank you. Mr. Schweikert.

Mr. SCHWEIKERT. Thank you, Mr. Chairman.

Mr. Secretary, a whole bunch of things, and so we will try to do machine gun. But you are good at this, you have done this before.

Since the data breach, one of the constituent's works we are getting in our Phoenix office is a number of more entrepreneurial doctors who are having real trouble getting payments. So, if you are doing some chasing of—you have been sending the money and it is not getting processed, particularly doctor's offices, when I have casework saying they are having to open up credit lines—thank you for chasing that down.

Mr. BECERRA. Congressman, if you want, we insisted that each of the payers, the insurance companies that make payments for the most part, that they give us a contact of who a provider can speak to who could actually make a decision on payment. So, if you want to have your staff——

Mr. SCHWEIKERT. I am going to have to reach out to you and get that——

Mr. BECERRA. Please reach out.

Mr. SCHWEIKERT [continuing]. Because——

Mr. BECERRA. Please reach out.

Mr. SCHWEIKERT [continuing]. I think we are writing letters to people.

Two, and this is less—because I am—this is more a tiny diatribe. If I remember Inflation Reduction Act, we buy down the price of insulin. Wasn't the cost 16 billion? So, we are functionally buying down the price to make it more affordable, right?

Mr. BECERRA. Actually, if you think about it, the fact that now insulin is being made available to people outside of Medicare for that price means we didn't pay a cent for that.

Mr. SCHWEIKERT. Well, actually, no, that is—but we did spend $16 billion.

Mr. BECERRA. Yes, I don't remember what the——

Mr. SCHWEIKERT. Yes.

Mr. BECERRA [continuing]. Cost was.

Mr. SCHWEIKERT. But my point is you have Civica Rx, what, 70 miles from here making three types of generic, and their market price is actually cheaper than the subsidized price, yet we are handing cash to the very pharma companies that we were saying were gouging.

And the reason I do that set-up is, conceptually, you and I have had side conversations now for years of there is an opportunity for a revolution around us if you want to crash the price of health care. A year ago, there was a company that came up with 3D printing for small molecule drugs. The fact of the matter that off-patent drugs in the United States are like 16 percent cheaper than the rest of the industrialized world, it is our ones that are on patent still. The fact that now you actually have some of the large pharma companies actually selling directly, you actually have some of the PBMs going into the manufacturing business.

You actually have—my hunger here is maybe more of a side conversation because we are heading towards the time of the quality life year measurements that are used in Western Europe and those things, which is a rationing model instead of a classic American model of let's make everyone compete with each other, let's open it up, encourage all sorts of different supply chains.

You also touched—and this is just in that same vein, when I am reading articles that are very hopeful of a fentanyl vaccine potentially coming and things like that, you are the 10,000-pound gorilla—in a nice way—in the marketplace. You are saying you want innovation, you want disruption, the technologies you and I have talked about.

Mr. BECERRA. Yes.

Mr. SCHWEIKERT. My frustration is we do talk about the financing of health care instead of what we—it actually costs. What technologies can you adopt either in the next breakthrough——

Mr. BECERRA. Yes.

Mr. SCHWEIKERT [continuing]. Technology, the thing you blow into that knows you have a flu, and do you allow the algorithm to write a prescription—I know that is very controversial—to when

the Joint Economic Committee wrote a chapter last March on what obesity—if HHS particularly went after obesity in America, morally what it would mean to the economy, to the debt. It is a few trillion dollars over the ten and would raise labor force participation, family formation, everything else.

What can I do, as one of the members up here, to help that fixation on let's make our brothers and sisters healthier?

Mr. BECERRA. Congressman, first I would say keep the inquiry going because we are heading there. As we discussed just before we started this hearing, we are going to be heading there whether we want to or not, and we have to be ready to meet that moment, especially when it comes to the financing, because we are—this—the structure we have is very obsolete. It is not geared for these new inventions.

And the other thing I would mention to you is you should really—we really should get you together with our folks at ARPA–H.

Mr. SCHWEIKERT. I would like to. I wasn't going to, but ARPA–H can be incredibly impactful on taking on U.S. sovereign debt and making America healthier and more productive, but I—but sometimes I have innovators that could not get a meeting or a return phone call if their life depended on it. We are going to have to find some way to make it more robust.

Mr. BECERRA. Maybe we will connect you with ARPA–H, because they do have lots of folks inquiring because they have real money, and they are putting it out there to those small innovators who are just aching to have somebody make an investment in them.

Mr. SCHWEIKERT. Well, look. I believe the morality in the solution is in some ways the disruption, not just spending more cash on the model we already have.

And with that, I yield back.

Chairman SMITH. Thank you. Mr. Blumenauer.

Mr. BLUMENAUER. Thank you, Mr. Chairman.

Mr. Secretary, thank you again for joining us. I appreciate you starting your comments reminding us of where we were four years ago. I mean, the sky was falling. People were running around lighting their hair on fire. We were deeply, deeply concerned about the economy, workforce. It is staggering, what has happened over the course of the last four years. And I appreciate you providing that context, because sometimes people forget how bad it was——

Mr. BECERRA. Yes.

Mr. BLUMENAUER [continuing]. The situation you inherited.

I appreciate the partnership with the Department. I am excited in my state, working to implement a waiver for Medicaid——

Mr. BECERRA. Yes.

Mr. BLUMENAUER [continuing]. To demonstrate the power of food as medicine, and innovation. And so far, it has been kind of encouraging on the ground, and I hope we can continue.

But you know where I am going, I think, on my next question, because one area that I could not be more disappointed is what this Administration has failed to do dealing with issues relating to cannabis. The President has made some minor adjustments. There have been a few people who have been pardoned. He commissioned an effort to reschedule cannabis. But Vice President Harris just

this week was extraordinarily frustrated with the policies of her own Administration, and she is right. I think it borders on political malpractice and beyond. This is an area that just breaks my heart.

I am frustrated that the legislation we passed in 2022, which should have been fully implemented months ago, we are still waiting. Mr. Secretary, this is an area that is profoundly affecting millions of people in the United States. We are denying opportunities for research that almost everybody agrees could be transformative. And we are not in the forefront of this research. We outsource it to Israel or Great Britain. There is no excuse for our not being in the forefront for something that is now legal for 97 percent of the American public. And where people have a chance to vote, they vote to change the policies.

I am hopeful that we can see some action following through on the legislation I passed, but more importantly on the things that the American people want. Treatments are being delayed, research is being denied, honest entrepreneurs are being caught up and, frankly, it is politically damaging to the Administration.

I would hope that you could work with us to be able to break the logjam, make the progress that the American people demand, and things that we could do in a matter of months. We have been dancing around this for as long as I have been in Congress. I have been talking to you throughout your tenure. I think it is time for the Administration to actually follow through on some good intentions.

Do you have any comment?

Mr. BECERRA. Congressman, I do, and I will take back much of your message.

I do want to make sure I recognize that the work that HHS has done was pretty far-reaching. And quite some time ago—we were asked by the President back in 2022 to take a close look at cannabis. We delivered. We finished our work last year, and we submitted, as we were required by law, our findings based on the science. We don't get to make the final call, that is left to the—to DEA to make. But when it comes to a cannabis, the President asked us to do something. We did it.

But I will take back the message to the Administration where you stand.

Mr. BLUMENAUER. We are missing an opportunity for the American people. And frankly, if I were the President and maybe interested in young people voting for me and being identified with change and reform, I think somebody ought to light a fire somewhere.

There are lots of things here that people, deal with formalities. I had watched this Administration jump into action four years ago when there was an imperative to do so. There is no excuse to continue dragging our feet on these formalities. The evidence is clear. The public wants it. There are millions of people who demand the products, and we are damaging a whole new sector of the economy. I think there ought to be a sense of urgency to fix this so the Vice President isn't confused.

Thank you, and I appreciate your consideration.

Mr. BECERRA. Thank you.

Chairman SMITH. Thank you. Mr. LaHood.

Mr. LAHOOD. Thank you, Mr. Chairman.

Welcome, Mr. Secretary, glad you are here. Mr. Secretary, as the chairman of the Work and Welfare Subcommittee, we have responsibility, as you know, over TANF, the Temporary Assistance for Needy Families, which, of course, helps families move from government dependance to realizing their full potential through work. And we have been heavily focused in a bipartisan way on the subcommittee.

Last year HHS issued proposed rulemaking with substantial changes to the TANF program. In a letter to you sent in November by Chairman Smith and me, we requested that HHS withdraw the proposed rule which goes well beyond the statutory authority granted to the Department, and we laid that out in the letter. Instead, our letter called on the Administration to work with the committee to develop, in a bipartisan way, a proposal with legislative changes to strengthen accountability in the TANF program, which we think is essential.

In your prior testimony before this committee, you indicated your intent—and we applaud you for that, for your willingness to work with Congress—to make the needed changes to the TANF program.

Further, in June of last year, in a response to the committee's letter expressing concerns about the welfare fraud scandal in Mississippi, former ACF Assistant Secretary Contreras indicated her willingness to work with us to improve TANF, as well. And again, we commend her for that.

Unfortunately, as we look at this year's budget, it did not include language regarding the reauthorization of TANF. And it appears the Administration's intent is to sidestep Congress through this rulemaking process.

And we share collectively with you the need that TANF needs to be focused on achieving its statutory purposes, and we have clearly demonstrated our intent to reform TANF through legislative action. The first of these reforms was included in the Fiscal Responsibility Act last year. Continuing our work on TANF, we have held two hearings, initiated a GAO investigation of non-assistance spending, and earlier this month members of this committee introduced several bills to put in place guardrails to ensure TANF dollars are intentionally focused on removing barriers to work.

I would also add, in fact, several of the reforms, Mr. Secretary, mirror the Administration's own proposals and what you have talked about with TANF.

And so, Mr. Secretary, I ask you again, will you work with the committee to develop a bipartisan proposal with our subcommittee with legislative changes to strengthen the accountability of TANF?

Mr. BECERRA. Congressman, we are absolutely ready to work with you. I think we have been in dialogue with not just your team, but many of the members on this committee's team when it comes to what we do on TANF.

As you have mentioned, our goals are increased accountability. We want to make sure that there is a focus on family well-being and work, and we also want to make sure that states have the flexibility they need to make use of their dollars as best possible.

But what we certainly want to make sure we do is avoid a court litigation on what we can and cannot do under TANF. That is where I think you all come in, and are very, very important, be-

cause to the degree that there are some questions about how far we can go with our regulations, you all have the statutory capability to make sure that we reform TANF in ways that bipartisanly get us moving, because I think all of us agree we don't want to see the kind of fraud or abuse of money for very needy families that we have seen.

Mr. LAHOOD. And I guess—is there a reason why the budget didn't include the language regarding reauthorization of TANF?

Mr. BECERRA. Well, remember, we did have a proposal out on rulemaking. It is still out; we are still taking comments. And certainly, this kind of discussion is good.

My suspicion—and again, I can't tell you that I wrote every aspect of the budget—is that we think that there is a proposal that we put forward. We know that you all are working on legislation, as well. And I hope what we can do is continue to work together.

Mr. LAHOOD. Thank you for that. Also, our subcommittee recently held a hearing on modernizing child welfare, where we heard from witnesses with experience administrating the Title IV–B child welfare program which expired in 2021 and needs to be reauthorized. Witnesses shared with us how complex and duplicative child welfare funding streams are.

The Biden Administration has acknowledged the need to overhaul Title IV–B. However, the fiscal year 2025 HHS budget proposes to increase funding without legislative changes, and I am particularly interested in how we can make sure that Title IV–B is complementing the investment that we made in the Family First Prevention Services Act to prevent children from coming into foster care in the first place.

Does HHS have a substantive legislative proposal for updating this program?

Mr. BECERRA. Congressman, I am trying to think as to where we stand right now. We are trying to make sure that we implement with our proposed actions at the administrative level so that we focus on what the law requires us, to make sure we are providing safe and proper care.

As you know, we are trying to make sure that every child has access to a loving home. And so, we are going to continue to push, at least at the regulatory level, to make sure that no child goes without access to a home that will be loving and safe and provide that child with the care that he or she needs.

Mr. LAHOOD. And the last question: Can we get a commitment with you on working on the reauthorization of Title IV–B?

Mr. BECERRA. Absolutely.

Mr. LAHOOD. Thank you.

Mrs. MILLER [presiding]. Mr. Pascrell, you are recognized.

Mr. PASCRELL. Thank you. Thank you, Madam Chair.

Welcome back, Mr. Secretary. Congratulations to you, your department, on a most successful ACA enrollment, as the ranking member referred to, over 21 million people. Who would have thought? Five years ago. Selected an ACA marketplace for 2024, 21 million people. And now states have expanded Medicaid. What do you know about that?

And of course, the enactment of the Historic Inflation Reduction Act, which capped insulin at $35 for seniors on Medicare. We got to expand that, Mr. Chairman.

So, you know my long interest in medical device safety. And I have looked back through the records over the last 20 years, and nothing has improved. Nothing. And I lost a friend because of a medical device, which piqued my interest 20 years ago.

Currently, when a device fails or is recalled, it is very difficult to identify which patients will be affected. This leads to complications. It also leads to high costs.

In 2017, the HHS inspector general found that recalls or premature failures of just 7 faulty cardiac devices resulted in $1.5 billion in Medicare payments to providers and 140 million in out-of-pocket costs to beneficiaries.

I have been demanding unique device identifiers to be included in Medicare claims for ages. The process is interminable. I have been working on this issue for a decade. I am a slow learner, but I am getting there. What is the status of your Department's implementation to include the medical devices Unique Device Identifier, the UDI, in Medicare claims?

I think all the parts of your agency need to be clear-eyed on pushing in the same direction to implement this. What is happening?

Mr. BECERRA. Congressman, thank you for the question and for your commitment to this issue over the years.

I know that the entity that reviews this, the National Committee on Vital and Health Statistics, did not recommend that HHS adopt the new claims form that would deal with the Unique Device Identifier.

Mr. PASCRELL. Why didn't they?

Mr. BECERRA. I could get back to you on that. This is a committee that reviews those items, and I could try to get back to you to make sure that you have the answers to those questions.

Mr. PASCRELL. Oh, wait a minute, wait a minute, wait a minute. I think I asked you an honest question. And we could be talking about health care. We could talk about transportation. We could be talking about a lot of things. Oversight is important. And that sounds like an industry answer to me through the Secretary. I don't like that. That is not how it is supposed to go.

This has been going on not just yesterday, this has been going on for 20 years. People have died because of the devices did not work, were not able to handle what was supposed to be handled medically. And we can't accept it. And it seems to me everything that comes out, everything that comes out, regardless of who the president is, regardless of who the secretary is, it all sounds like the same thing. Everybody is protecting everybody, and people are dying. I have not got a good answer.

Mr. Secretary, you are doing a hell of a job, but this area stinks. I have seen no difference between you and 20 years ago on this issue.

And before I leave today, I would like an answer, Mr. Chairman.

Mr. BECERRA. Congressman, I will give you the best answer that I, as Secretary—but more importantly, I as a long-time friend

of yours—can give you, and that is to say this is handled by that particular committee.

I don't sit on the committee. It is within HHS. And what I am willing to do, because you are entitled to it, is to sit down with you and figure out what it is you need to find out about the work that was done by this committee that led them to say not this time.

Mr. PASCRELL. My personal close friend, Joe Stefanik, had a hip operation. They found out the medical device that went in his leg and his hip had titanium. And it would seem to me that we just touched the surface because of Joe, and I followed his case very carefully and we lost him.

But the point of the matter is that is just one case—a very important case to me.

Thank you, Mr. Secretary.

Mr. Chairman, thank you.

Mrs. MILLER. Thank you, Mr. Pascrell.

Dr. Wenstrup, you are recognized.

Mr. WENSTRUP. Thank you, Madam Chair.

Mr. Secretary, good to see you today. Thank you for being here. I want to comment on a few things.

You know, I hear a lot today about how more people have health insurance and all that, and I think that is a wonderful thing. But it doesn't always relate to health. It doesn't always relate to great outcomes.

You know, as a physician, you know, often insurance companies, CMS, it doesn't matter who, they will deny coverage, they will deny or delay care. Sometimes they will limit what you can do in an effort to prevent things. And we have some bipartisan efforts to try and reduce that, and to make things better.

And I was also—appreciated your concern about the nursing homes. But what we failed to mention today is what happened in New York and some other states. You know, I treat a lot of infections. You quarantine people that are highly contagious, you don't take them and put them into a nursing home with the most vulnerable people that are going to die from that particular contagious infection. And that is exactly what happened. And it wasn't consistent with CMS guidelines. And we need HHS to be more outspoken on what happened here, so we don't let this happen again. So those numbers are astronomical, but they—many of them were very avoidable. So, I appreciate your concern there.

I don't know where you stood on vaccine mandates, but you want to talk about confusing and aggravating the American people? It is "You need to get this, or you lose your job," which is not real good bedside manner, I might add, but it took away the doctor-patient relationship. We can't let that happen. Patients deserve the opportunity to talk to their doctor about what the vaccine is about, and what the potential side effects are, what the benefits may be. I am vaccinated, and I got COVID, and I was out vaccinating people. You know, I understand the benefits. So, I am not anti-vax, I am just saying, you know, that that was a problem.

But at the same time, what America saw, people coming across the border by the thousands, by the hundreds of thousands, not being tested and not being vaccinated, yet other people in America, hard-working people, were put under that same pressure. It didn't

make sense. We got to be consistent with what we say and what we do, and we need HHS to lead on that in many ways. It created a lot of confusions.

Listen, I want to thank you for spending time with the Doctors Caucus. I think we need to do more. Either you or some of the senior leaders——

Mr. BECERRA. Yes.

Mr. WENSTRUP [continuing]. Because we have a lot of things we can do on a bipartisan basis to make things better. We need to be embracing the health of America, not just because you have an insurance plan. We need to embrace health, overall, education and health of our youth. Do they know what healthy foods are?

You know, these are all the things that we can be doing and doing things that—preventive actions that result in better health of Americans. I keep saying I want us to be the healthiest nation on the planet, and it is not just having an insurance plan that gets you there. There is so many things that we have to do.

And, you know, health and human services. Are our human services giving us a return on the investment? Are we creating healthier humans through the things that we are doing? That is the real question that we have to ask ourselves. We can talk about this plan, that plan.

You know, I saw with TANF written down that they said one of their missions is to prevent out-of-wedlock births. Prevent out-of-wedlock births. What are we, China? How come we aren't talking more in there about promoting healthy mothers and healthy children, which, by the way, we did through the MIECHV bill that we passed, bipartisan, and was signed into law by the President. Let's start recognizing the value of the healthy human life and go in that direction.

So yes, I am taking this opportunity for messaging. That is what I am doing. And I am sharing with you the things that have people scratching their heads out there, right?

But I will get to one other thing that you are probably expecting from me, one that has to do with the No Surprises Act. And, you know, with Federal court and 23 invalidated—some of the HHS regulations, and I will get right to the point.

In January, January 12, 2024, the Department decided to withdraw its appeal regarding several important parts of the court's ruling, which—one prohibited insurance—insurers from using any out of specialty rates, and two, using the rates of other self funded plans in calculating QPAs. You know what I am talking about. And it has been more than two months since that decision, yet we haven't really seen any guidance instructing on that. I haven't—maybe it has been out there, I haven't seen it, and we need to be instructing insurers and IDRs to follow the law.

And I just want to know. When will the Department be issuing that update?

Mr. BECERRA. Congressman, we are—as you know, we are undertaking some audits on how those QPAs are being applied, what is underlying them. And I am hoping that pretty soon, whether it is at the Doctors Caucus or at another hearing, we will have some information to provide you.

In fact, because there is so many of these audits that we are doing, we will probably start to post them as quickly as they start to come out online so people could start to see them. But we are hoping that this informs everyone on what is expected when we talk about these QPAs, because we want to make sure that we don't have the issuers, the insurers, using a wrong foundation for which to, you know, market—or excuse me, to price their—the service.

And so, these audits will be very important, and we will stay in touch with you on that.

Mr. WENSTRUP. Please do. That would be very helpful every step of the way. Thank you.

I yield back.

Chairman SMITH [presiding]. Mr. Davis.

Mr. DAVIS. Thank you, Mr. Chairman, for this very informative hearing.

Mr. Secretary, let me thank you for your many visits to Chicago to meet with the provider community, meet with consumer groups. We feel like you are almost a part—or we will just make you an honorary part—of our city. And thank you very much.

As you know, I have worked closely with our friend, John Lewis, on a Ways and Means Committee investigation of discrimination against potential foster and adoptive parents based on religion and LGBTQ status during the Trump Administration. The results were alarming, particularly given that LGBTQ youth are over-represented among older foster youth, and more likely to suffer additional trauma while in our care.

John hated discrimination in every form, and championed legislation to address it. I am honored and pleased to carry on his work, and I know that he would be proud that you and President Biden are carrying on his work with your budget proposal. I hope to work with you to ensure that our most valuable, vulnerable foster youth are affirmed and loved.

I also want to raise a serious problem that children with sickle cell disease are having accessing Supplemental Security Income benefits. I have had the opportunity to speak with SSA Commissioner O'Malley, who has begun an expedited process to address the problem. The commissioners told us that they are consulting with sickle cell experts at HHS to make sure they get it right, and I appreciate anything you can do to facilitate this. A lot of families are counting on us.

I also want to associate myself with the discussion generated by Representative Larson. I, too, have a large senior population, and everything that we can do as it relates to their well-being I appreciate.

But I wanted to ask you a question relative to the whole business of violence prevention, and how the Department is handling it as a part of health and medicine and a part of the public health spectrum that we find ourselves in.

Mr. BECERRA. Congressman, as you know, we at HHS have declared gun violence as a public health crisis. We have also, in this budget, made commitments of resources to be able to do further research to find out what drives the violence, what can we do to try to most effectively prevent it, and we continue to make invest-

ments, especially in the mental health field, to try to address not just the consequences of violence that occurs and the trauma that many face, including young people, but also what we can do to try to prevent that type of violence from ever occurring.

We look forward to your support in that effort, because we are so far behind in the work that can be done. But there is no doubt that the more that we invest in this area, we are going to find out that we can reach families before they have a crisis and suffer the consequences of violence, especially gun violence.

Mr. DAVIS. It was my pleasure to see you with the Federally Qualified Health Centers. And of course, we go way, way back with them, as you do. For the future, in terms of the roles they play, would you just comment?

Mr. BECERRA. Without the Federally Qualified Health Centers, probably hundreds of thousands of Americans, more Americans, would have died from COVID. Without the Federally Qualified Health Centers, so many children wouldn't have access to dental services, preventative health services that they need. Without the Federally Qualified Health Centers, many of our schools could not afford to have a nurse or other caregiver available at the schools.

And so, President Biden has doubled down on the Federally Qualified Health Centers because, not only did they deliver during COVID, but they have delivered for, principally, families that are low-income and don't have other access to care than those community health centers. And we are going to continue to make investments in them. We look forward to working with you to make sure that that happens.

Mr. DAVIS. Thank you very much, Mr. Chairman, I yield back.

Chairman SMITH. Mr. Arrington.

Mr. ARRINGTON. Thank you, Mr. Chairman.

Mr. Secretary, thank you for your service to our country. I am going to run through some things that I want to note for you and your consideration, and observations that I want the American people to make.

I don't think there is a clearer or starker contrast between the President of the United States, Mr. Joe Biden, you, and the Democrat Party in terms of your view of the role of government, your policies and plans for the future of this country, and the policies and plans of the—of Republicans. I am generally speaking here, but there is a significant philosophical divide, and so I recognize that. I don't expect you to come up here promoting policies that I think would be better for the country.

But as budget chairman, one of the things we all have to do is find a way to rein in deficit spending that is now $2 trillion, and a debt that is 34, and an interest on the debt that is going to be $1 trillion, which is more than what we spend on all of national defense.

President Biden's budget—I am sure you are aware of this—is the highest level of sustained spending in the history of the United States. Of any budget ever submitted in this building, in this institution, the highest ever. And because of its high sustained spending and borrowing, even with $5 trillion in taxes, Mr. Secretary, we leave our children and our grandchildren, generations of Ameri-

cans, with 16 to $17 trillion more in debt, even after trillions of tax hikes on families, small businesses, et cetera, et cetera.

Our plan is different; we balance in 10. That is the plan. It has got to be followed. But that is the blueprint. We rein in spending; we root out waste. The $2.3 trillion in improper payments, $50 billion in Medicaid last year, but that is not picking on Medicaid, it is in every entitlement program. We re-ignite growth. We get 1 percent, which is $3 trillion. We don't raise taxes. We bring down the debt to GDP by 40 points. Now, we can debate the details of it, but those are the different views of the future and our children's future in this great country.

When I look at the health care side, let me make some observations. For example, you all suggest that you are going to somehow shore up Medicare and the Medicare trust fund. Hey, great. We should work together to do it, quite frankly, because that is the only way it is actually going to get done. But I want to make sure that we have a little bit of, you know, sort of an honesty test here on this.

When you all—you propose in the budget saving $200 billion in—for—with your price controls, you double down on. It saves $200 billion, as opposed to $100 billion in the IRA. And then you raise taxes, payroll taxes, about $750 billion. Combined is the money used to put to, presumably, to health care—I am sorry to the Hospital Insurance Trust Fund, or Medicare Trust Fund.

But my question to you is, why should we believe you are going to do that? Because when the Democrats had total control, and this Administration was in charge, the $100 billion that was saved from the IRA out of Medicare was used to subsidize green energy tax subsidies. So now you are telling me you are going to use $200 billion when you double down on that out of the savings of Medicare to save Medicare? It doesn't add up. Okay? So that is one.

Secondly, Medicaid. There are studies that say that people without insurance do better in terms of outcomes than people with—on Medicaid. So, we got to work to make that program work for our most vulnerable.

Here is the deal, and this is a question I would have for you, but I don't have time to ask it. Maybe you will respond somewhere in this session. But did you all fix the inequity? Because I hear a lot about inequities from this Administration. How about the inequity in terms of the match that you all give to the single adult population, the Medicare—I am sorry, the Obamacare expansion of Medicaid, versus the sickest, poorest, most vulnerable among us. There is a much higher match on the single adults. There is a great place that we can equalize the payments, save some money, and help the most vulnerable.

Site neutral, site neutral payments. We pay—we should be paying hospitals the same thing, same amount that we pay independent physicians for the same outpatient procedures. If we did that, we would save $120 billion. Now, where did that idea come from? Over 10 years. That idea came from President Obama. We used President Obama's good idea, put it in our budget. Why isn't it that in you all's budget? Maybe there is a good reason, but you already have a bipartisan, significant saver there.

And, you know, the last piece I will mention that drives me crazy is the Obamacare subsidies to people making—half of whom will make over 400 percent of the poverty level, some of whom make $500,000 or more. The only answer to that is that you are trying to drive everybody into a public health system, into a single payer system, into a government-run system.

I mean, I know that is the philosophy. I respect it. Look, we can be honest, we can debate it as which one works best. But that is what you are doing. Why would the taxpayer subsidize people making $500,000, $600,000 to go into a government-run health care, many of whom already have private insurance?

These are my concerns. I put them before you for your serious and sober considerations. I appreciate your service to our country.

Chairman SMITH. Thank you. Ms. Sánchez.

Ms. SANCHEZ. Thank you, Mr. Chairman, and thank you, Secretary Becerra, for being with us as we work to continue building on the numerous accomplishments of the Inflation Reduction Act.

The IRA is why more Americans have health coverage today than ever before. The IRA is the reason why 4 out of 5 people have access to high quality care for less than $10 a month. The IRA is why seniors only pay $35 per month for insulin and will pay no more than $2,000 a year of out-of-pocket costs for their prescription drugs.

And in September of last year the Administration built on those protections for older Americans when it proposed minimum staffing standards in nursing homes. And these were indeed long overdue and necessary protections. During the pandemic, understaffed facilities were twice as likely to have COVID–19 outbreaks, as comparable facilities with higher staffing levels. And unfortunately, a recent OIG report still found inadequacies in infection control practices.

Yet just two weeks ago this committee marked up legislation effectively rescinding this nursing home staffing rule that the Biden Administration recently proposed. Many of my colleagues and nursing home operators have claimed that this rule would devastate the industry, forcing closures across the country and impeding access to care.

Mr. Secretary, does the Biden Administration's nursing home staffing rule include an exemption process for nursing homes in this rule?

And can you walk us through that process for facilities that are not able to staff accordingly?

Mr. BECERRA. Congresswoman, thank you for the question, and great to see you again.

Yes, we do. We have exemptions, there are hardship exemptions. We look at rural facilities differently, as well. We try to make sure that those that always have a harder time competing and staying afloat because of where they are, for example, in rural settings or among a disadvantaged community, that we try to make sure that we take into account some of those hardships so that they don't have to move as quickly as others that are more prepared and equipped.

Ms. SANCHEZ. So, unlike what was said numerous times, it is not a one-size-fits-all rule.

Mr. BECERRA. That is correct.

Ms. SANCHEZ. Thank you. Private equity investors have also continued to flood the nursing home sector as a particularly lucrative investment. For-profit and private equity-owned nursing homes are less likely to have quality care or adequate staffing, and they often use complex ownership arrangements to hide their massive profits.

How is HHS addressing transparency in nursing home facilities and their ownership agreements to ensure that our Medicare dollars are actually being invested in patient care, and not lining the pockets of those who already have?

Mr. BECERRA. Congresswoman, as you are aware, we are now requiring the disclosure of ownership. And while there are many layers often times behind who is the actual owner, we are trying to make sure that we open the curtain so that everyone gets to see who truly owns that nursing home facility.

Ms. SANCHEZ. Great. I think transparency in anything is always a good rule of thumb.

Lastly, Secretary Becerra, I want to mention an issue that is personal to me because both of my parents suffered with Alzheimer's disease. I have a bill called the CHANGE Act, which I have introduced for the last five years. And what this bill would do is improve early detection of Alzheimer's and other dementia and cognitive decline by authorizing clinicians to use a qualified tool to detect cognitive impairment during the annual medical wellness exam, which is a preventive measure. So, if once a year folks are going in for a complete physical, they are also being tested for a baseline of their cognitive ability, and year over year they are testing to see if that cognitive ability is declining.

And it is important for many reasons, not the least of which is many times, particularly in communities of color, Alzheimer's goes under-detected, and it is often not diagnosed until medium to late stage, when some interventions are no longer necessary.

Both my staff and Mr. LaHood's staff have consistently engaged with CMS to implement this administratively, most recently meeting with CMS on the technical updates that we made to the bill on CMS's suggestion. I just want to urge you to work with me in making this small but very meaningful change that I think would help many of our nation's seniors and the family that give them care when they are diagnosed with dementia. It is relatively low cost to implement. And with the, you know, innovation in potential treatments for Alzheimer's and dementia early on, I think it could be a real valuable tool.

Mr. BECERRA. Congresswoman, we can follow up with you. I can commit to you that my team and I will be ready to work with you and Mr. LaHood.

Ms. SANCHEZ. I appreciate that very much, and I yield back.

Chairman SMITH. Dr. Ferguson.

Mr. FERGUSON. Thank you, Mr. Chairman.

Mr. Secretary, thank you so much for being with us today. I know you and I have spoken in the past about the challenge that the health care system and Americans are facing on antimicrobial resistance. This is something that costs our system tens of thousands of lives and over $4.5 billion a year. We have talked about

some of the challenges with the innovation, the research and development.

And, you know, we have got a bill out there called the PASTEUR Act that creates a unique pull system to pull these drugs into the market. Do you believe that congressional action is needed to address this issue?

Mr. BECERRA. I absolutely agree with that and thank you for the effort. It has not been an easy road, but we absolutely need something because we are not going to get the medicines and the attention that we need unless we have congressional action.

Mr. FERGUSON. And look, we appreciate the commitment through things like BARDA. And, you know, there has been a longstanding commitment to doing the basic research. But pulling those—but when these small, innovative companies, they almost go bankrupt getting the product developed, we have to develop that pull. So, I appreciate your answer on that.

You know, I want to go back. When the question was asked about, you know, the hospital in Denver, the safety net hospital, and you said you would work with them, we have got about 10 million people, conservatively, that have come across the border in the last three years.

With 10 million people, you are going to have a lot of those folks that are going to get sick, they are going to break a bone, they are going to have a baby. There is—stuff is going to happen. Where does the money come from? What pot of money comes out to help a hospital in Denver with that? Where does that fund—you said you will work with them. It is going to take money. Where does that money come from?

Mr. BECERRA. Congressman, thank you for the question. Now let me speak to you from the perspective——

Mr. FERGUSON. Well, no, no, no, no, no. If I could interrupt.

Mr. BECERRA. Okay.

Mr. FERGUSON. Who is paying for that right now?

Mr. BECERRA. Okay, so you are asking me to put myself in the shoes of that facility, and it is—without being actually the person in the shoes, it is hard for me to give you a precise answer.

Mr. FERGUSON. Somebody is paying for it. I would—I think, if you could get back to us with a summary of who is paying for the care of the folks that are in the country illegally, I think that would be helpful. That is probably a longer answer, and if you could submit that to us in writing at a later date, we greatly appreciate that. I just want to understand where it is coming from, because if it is coming from the local level, that puts a tremendous burden on that local hospital. If it is coming from the Federal level, that is an expense and a burden on our budget that, you know, we got—we have to figure that component out. So, if you will, come back to us on that.

You know, you have heard about, again, the one-size-fits-all policies with the nursing homes. Again, I just want to emphasize—I am not going to beat on this point, but it is not working, and that will not work in rural America. It does not matter how many—how much you pay folks. We simply don't have enough health care workers there to meet what the proposed rule is. And I know that you all have been investing in health care workforce, but that is

not happening fast enough to keep up with, you know, with the proposed changes. And——

Mr. BECERRA. Congressman, if I could——

Mr. FERGUSON. Yes.

Mr. BECERRA. Because it is not a one-size-fits-all proposal, and for rural communities the standards are different than they are for large, densely populated urban areas. So just to be sure it is clear, how it would work and apply to a facility in a rural setting is different from how it would work in an urban setting.

Mr. FERGUSON. And again, let's—I am going to fold in another component of this. When you are in a rural area—and I am in a rural district just south of metro Atlanta—we have got a problem with the wages down there, potentially, coming if we look at the—if we don't extend the low wage index hospital policy. It is too easy for nurses, physicians, other providers to drive 40 minutes to metro Atlanta to get 3 times the wages. So that is something that has got to be fixed. And I would just ask that you would commit or find a way to do an extension of the low wage index hospital policy.

Mr. BECERRA. We are committed to work with you and others who have an interest in making sure we have a good policy.

Mr. FERGUSON. Thank you. One final thing. Fourteen years ago, with the implementation of the ACA, it was supposed to be a panacea of things that worked well. I will ask three questions.

Number one, is health care less expensive today than it was 14 years ago?

Are Americans, as a whole, healthier today than they were 14 years ago?

And while you may have access, is utilization amongst our most vulnerable better today than it was 14 years ago?

By every metrics that I can find, health care costs more, America as a nation is not healthier, and we still have an immense problem with utilization by the folks that are the most vulnerable. So, with that, I just—I make that comment that we can't view it as the system is perfect right now. We have got—before we go dump a couple of hundred more billion dollars into raising the subsidies for wealthy Americans, we have got to fix what is broken in the system.

With that, Mr. Chairman, I yield back.

Chairman SMITH. Thank you. Mr. Estes.

Mr. ESTES. Thank you, Mr. Chairman.

Secretary Becerra, I am glad you are here for this important hearing, as your agency's budget request is somewhat troubling in what it includes and what it—what is absent from being included.

I mean, as several of my colleagues have noted, there is hardly a mention of the greatest health crisis that our country is facing, the fentanyl epidemic that spiraled out of control thanks to the open border policies that President Biden has been promoting.

However, my concerns aren't with the budget, but also with the policies HHS has elected to pursue, even over opposition from this committee and community health leaders across the country. Mr. Secretary, I am immensely concerned about the nursing home staffing mandate that the agency proposed last year. I know several other members have talked about that.

I mean, the rule that is currently under final review at OMB suggests that you are pushing ahead to finalize it, despite the fact that thousands of non-profit nursing homes and organizations, particularly representing rural providers, oppose the mandate as it is written, including nearly 1,000 that signed a letter to this committee in support of the bill to prevent the rule from being finalized.

And I know there were comments earlier about the number of people that died during COVID in a nursing home. That is really not apples and oranges in terms of comparing that. I mean, the problem with people dying in a nursing home was because governors in states like New York and New Jersey and Michigan ordered sick individuals to be put into the nursing homes, thereby to infect so many other residents. So, I don't know that we want to use that as a standard for moving forward during a non-pandemic time.

Mr. Secretary, can you remember the amount of money that your agency estimated compliance would cost nursing homes in Kansas?

Mr. BECERRA. Congressman, can you repeat the question?

Mr. ESTES. Do you remember the amount of money that you have assigned or that you had estimated would be compliance costs for the mandate in Kansas?

Mr. BECERRA. I would have to get back to you for Kansas in particular.

Mr. ESTES. That was a little bit of a—I understand, I didn't expect you to really to know, I know, with all the states you have to deal with. But I will jog your memory. It was $25 million for the State of Kansas. But along with the mandate for—across the country, it also provided $75 million to improvise and support nursing workforce nationwide.

I wanted to point out that $75 million is the same amount that my home state of Kansas will have to expend over 3 years, so it is less than 1 year, even, of implementation in your home state of California, where the agency estimates that it costs $222 million annually. We have heard nothing from the agency about how you are going to spend that $75 million.

Can you tell me, can you talk in details of how you are going to spend that money?

What do you expect it to cover?

How do you expect it to move the needle to enhance our staffing shortages?

Mr. BECERRA. Absolutely, Congressman. And if you recognize that we don't run nursing homes, we don't run most health care facilities, we support them and we—the way we do that is through the states. And so, when the President wanted to put out the $75 million to help boost the workforce to help make conditions better, it was in partnership with the states.

So, the states and the local health entities that would apply to get the money are the ones that would determine how it would be spent. What we did was we put guardrails to make sure how it could be spent, but then we leave it to the state and locals to determine who gets it.

Mr. ESTES. Right, but, I mean, $75 million won't cover $222 million in your home state of Kansas for one year, or your home state of California.

I guess I really have concern about the mandate wasn't really thought out, and that the support for nursing home workforce really wasn't necessarily good leadership, or good—that there was prethought in terms of how to make that happen.

I do have a bill. Like most of us up here, in terms of talking about how do we move forward, we have got a bipartisan bill called Ensuring Seniors' Access to Quality Care Act, which would allow nursing homes that have been forced to suspend their in-house CNA education programs due to restrictions from violations to resume those programs once the quality standards are met. It is a common-sense bill that actually accounts for some of the current workforce challenges that nursing homes face, and without compromising the commitment to quality care for residents. And it doesn't—it is not something where we are throwing money at problems. We want HHS to help commit to advancing creative solutions that will help address some of these problems health care providers and patients across the country face.

And we know, as mentioned earlier, in rural areas it is harder to staff, these challenges are even more acute and add to the burden and worry of patients in rural areas. A recent survey showed that 58 percent of rural hospitals are at risk of closing, with 82 percent losing money on patient care. And currently in Kansas, my home state of Kansas, there are 29 hospitals in Kansas with immediate risk of closure, which accounts for about 28 percent of the rural hospitals in the state.

So obviously, there are some health care concerns we have got to address. Unfortunately, I am out of time, and I don't have time to ask you any more questions about these issues.

Mr. Chairman, I yield back.

Chairman SMITH. Thank you. Ms. DelBene.

Ms. DELBENE. Thank you, Mr. Chairman, and thank you, Mr. Secretary, for being with us today.

As you know, every day 17 Americans die waiting for an organ transplant. A transplant provides a new lease on life. But our current system is woefully inadequate to meet the needs of the more than 100,000 people on the wait list. A big part of the problem is that one out of every four recovered kidneys go unused due to mismanagement, outdated technology, and other inefficiencies. And so, we have to do better.

Last year Congress passed legislation that gives HHS the authority to update our broken system, but this opportunity will be lost if Congress fails to fund these reforms. And so, I appreciate the President's budget request of 67 million to reform our nation's organ transplant system. I wondered if you could highlight for our committee why this funding is so critical, and some of the reforms the funding would go towards.

Mr. BECERRA. Congresswoman, thank you, and I very much appreciate your role in trying to move this, because there are Americans who are dying because they can't get their transplant.

We need to get rid of the monopoly. We had a monopoly that was running the organ transplant system, and it wasn't working well.

And the reforms—and thank you very much for the work on the reforms—that are now in place are going to let us remove that monopoly, put in place a board that will oversee the operations of the organ transplant system that is not biased, not based on profit, but is there to do the best for patients.

And then we are going to go out and competitively bid a lot of the operational work that has to happen so we can make sure we connect the dots right away. But we can't do that without the resources, and that is where Congress is indispensable. If we are going to implement your reforms, we need Congress to come up with the resources.

Ms. DELBENE. Thank you. Also, the rate of living donations has largely flatlined over the past two decades. This is in part because living donors face thousands of dollars in out-of-pocket costs when they are donating, including things like travel expenses, lost wages from taking time off of work, and childcare. And no one should have to pay to donate a lifesaving organ.

The Living Organ Donation Reimbursement Program helps low-income donors defray these costs by reimbursing up to $6,000, but current restrictions severely limit this program's impact. So, for example, 1 in 5 donors hit the $6,000 cap, and income rules disqualify individuals making more than $53,000 a year.

So, my office has been working with your agency on draft legislation intended to provide greater support for living donors. Do you agree that we should prioritize this effort so that we can save more lives?

Mr. BECERRA. Absolutely. It is not just good for the folks in need of a transplant, it is good for the economy and our taxpayers because it will cost us less at the end of the day.

Ms. DELBENE. Thank you. And then, for the past five years I have helped deliver funding for the Kidney X Program, which has invested $50 million so far in public and private dollars to develop the world's first artificial kidney and other breakthrough innovations. I am very concerned that the President's budget appears to eliminate this critical program.

I wanted, really, to know if you can ensure that HHS will continue the mission of Kidney X. The expense for kidney care is great, the opportunity is incredible, and continuing Kidney X means funding cutting-edge research to prevent and treat kidney diseases, including through the ARPA–H initiative. Can you support that?

Mr. BECERRA. Congresswoman, again, your efforts here are notable. And what I would say to you is that the initiative, which began as an effort to really jumpstart what we do with regard to those in need of kidney support, is one that—while it has value, it also costs money. And at this stage what I can tell you is that we will work with you and others in Congress to see where we can land.

But given that the Department of Health and Human Services is taking the largest cuts of any Department in the Federal Government when it comes to these—this latest budget, we are having to make decisions. But we look forward to working with you to see where we can go.

Ms. DELBENE. And, you know, Kidney X has been funded in incredibly small amounts. We are talking just a few million, single-digit million, dollars that can have an incredible impact. In fact, we should be doing more because private dollars come in to help, and the amount that we spend to treat kidney disease across this country, new innovations could be hugely lifesaving and make incredible difference in the amount of money that CMS spends here.

So, I hope you will continue to look at that and thank you so much for being here.

I yield back, Mr. Chairman.

Mr. BECERRA. Thank you.

Chairman SMITH. Mr. Smucker.

Mr. SMUCKER. Thank you, Mr. Chairman.

Good afternoon, Mr. Secretary. I would like to just weigh in, as well, on the nursing home staffing mandate, based on experience we had in Pennsylvania, where we see less access to care.

Pennsylvania just recently went through the phase one of implementation of a statewide staffing mandate, and we found that 80 percent of nursing homes in Pennsylvania have resorted to using temporary workers for NPA, LPN, and RN shifts, and 58 percent of those nursing homes have had shifts go unfilled, even when they were using temporary, because the temporary staffing agencies couldn't find people, as well.

And so, we have literally had homes reducing beds, reducing their census because they didn't have the help to meet those standards. They estimate if these new Federal standards are implemented, 62 percent of Pennsylvania's nursing homes are expected to further reduce their census, there will be an estimated cost of 463 million for our facilities in Pennsylvania to comply.

Are you concerned about that? Like, I am just not sure—I understand the need to ensure that seniors are well cared for, but I am really concerned that this is the wrong formula to do that. Are you concerned about nursing homes not having the staff, and so being able—reducing the number of beds they have available?

Mr. BECERRA. Congressman, thank you for the question, and I look forward to any information you would like to provide us.

We have heard a number of things from a number of different sources about where the nursing home industry is. I will tell you it is somewhat confusing to hear on one end that private equity firms and Wall Street are looking at nursing homes to make investments because they see that there is money to be made, and on the same—on the other end, people saying there is no money, and therefore we cannot staff up to levels that will provide quality care.

So, I will tell you that I will take a look at any information you have. I will look at it very closely, because what we do know is that right now too many Americans send their loved ones to nursing homes, and they don't get the kind of care that they would expect. And no one should be forced to send their loved one to a place that doesn't provide quality care. We all should live by certain standards.

Mr. SMUCKER. Yes, I——

Mr. BECERRA. And we think that having minimum standards—if you are going to call yourself a nursing home, you should have a nurse. That is pretty basic.

Mr. SMUCKER. I could see minimum care standards, which I think we already have. And it is not money, it is they simply do not have bodies, do not have the nurses to fill the spots. And I will be glad to share some of the information that I have received in regard to the situation in Pennsylvania.

I do want to bring up another situation, the Coverage with Evidence Development program, or CED, of course, is—you know, we all again agree that beneficiaries deserve access, Medicare beneficiaries deserve access to new medical devices, drugs, and technologies. And of course, with this program, with the delay in getting drugs out of the program, it again—it has been a hindrance to individuals, to seniors' access to treatments, I believe. There are currently 22 products under CED, 6 of which have been with the program for 15 years, which I think is unacceptable. And a 2023 MedPAC report even recommended recently that there be a clear process for timely completion of the CED studies.

I am working on legislation in response to that, the recommendation, that would establish a straightforward process for ending CED. And my staff has received technical assistance from CMS on that proposal. So, I am wondering whether you would work with me on that. Do you agree that the current timeline is unacceptable, and would you be willing to work with me on the issue?

Mr. BECERRA. Congressman, I know that my team has had an opportunity to work with your staff, and we look forward to working with you on this particular issue.

Mr. SMUCKER. Thank you. I look forward to that, as well.

I want to mention just one additional thing, again, relative to the situation in my district. Last February the Biden Administration issued a proposed rule that would eliminate more exceptions to the Affordable Care Act that protect individuals, small business, nonprofits, and other entities who object to providing health insurance coverage for contraceptives.

And whether you believe that they should provide that or not, in my district Conestoga Wood brought a case to the Supreme Court, where it was decided that businesses like theirs, who objected due to their religious beliefs to provide to providing access to contraceptives, that should be protected. This is what the Supreme Court decided. So, I think you are going against the decision of the highest court in the land in mandating coverage of contraceptives. It directly violates that ruling, and I would like to hear your explanation for that.

Mr. BECERRA. And thank you for the question, because it does get a little technical.

The law requires—the Affordable Care Act provides that every person is entitled to receive preventative health care services. Contraception care is considered preventative health care services. Where there are religious or conscientious objections, those objections should be respected, but that doesn't absolve the provider or the payer from providing that individual who needs the care with access to the care——

Mr. SMUCKER. But I think you have just—now calling it a moral objection, you are somehow trying to sidestep that ruling. So——

Mr. BECERRA. No, no, no——

Mr. SMUCKER. I would like to talk with you further about that, because I think——

Mr. BECERRA. Sure. No, we respect—we do respect the conscientious objection, but that doesn't—that should not prevent the individual, the patient who is supposed to get care, from receiving the care through some fashion that doesn't violate the religious objections that someone would have.

Mr. SMUCKER. Well, I am well out of time. I will be glad to talk about that later. Thank you.

Chairman SMITH. Thank you. Mr. Hern.

Mr. HERN. Thank you, Mr. Chairman.

Mr. Secretary, it is always good to see you. Thanks for being here.

The Federal Tax Refund Offset Program is a vital piece of the child support enforcement program. This offset program, when—is when a non-custodial parent is due a refund, but owes past child support, Treasury can withhold the tax refund and send it to the state child support agency to get it to the families, so these children are properly supported.

Sixty tribes across the country provide and manage their own child support services, ten alone in my home state of Oklahoma. Sadly, under current law, none of these tribes have direct access to the offset program. This means tribes are either forced to contract with states to get access to the program or forgo this vital program altogether for their families. This is devastating for thousands of tribal families across the U.S., and we must work together to grant tribal child support programs with direct access to the offset program.

Mr. Secretary, the President's 2025 budget includes a proposed fix to this issue and provides tribes with access to the Federal Tax Refund Offset Program. Do you have an estimation of how many tribes are currently forced to contract with states to get access to the offset program, and how many don't currently have access at all for their families?

Mr. BECERRA. Congressman, I don't have that with me, and I have a pile of papers, but I don't have that with me. But we could get back to you because you have touched on a very important issue.

Mr. HERN. Yes, I thank you, and I appreciate it. You know, there is a lot of people who depend on this. And having seen this early in my childhood, I think it is important that we have responsible parents, and being able to have that offset is really important. And so, I look forward to working with you on that.

And Mr. Secretary, health care treatments are rapidly changing and advancing at times, and Federal health care programs failed to keep pace. I don't have to say this as a criticism, it is just a fact.

An area that is proving worthy of further exploration and expansion is prescription digital therapeutics, which offer unique and promising ways to help cancer patients and those with behavioral health issues, key priorities of this Administration and this Congress. Will you work with us to create a reimbursement mechanism so that we can ensure that Medicare beneficiaries have access to these treatments?

Mr. BECERRA. Congressman, we look forward to working with you.

Mr. HERN. Well, I would appreciate that, because I think we all know that it is very important as we go forward in offering these services and being able to get it to our Medicare patients.

Finally, one that is probably a little more touchy that is on the hearts and minds of many people across America, not just in Congress, but certainly in the political world today, but it is because it is so important to the American people, and that is what is happening in our southern border. Public schools have been shut down to house the illegal immigrants, hospitals have been financially ravaged, and the influx of fentanyl has killed hundreds of thousands of Americans and is not slowing down.

This Administration continues to either willfully ignore or hide from the public the true extent of how the crisis at the southern border is harming our country.

Within the past year I have been to Asia, Europe, and South America, and I have talked to every leader in those particular areas, including presidents and people from our own State Department, and there is not a fentanyl problem east and west of Mexico or south of Mexico. The fentanyl problem flows north out of Mexico into the United States across our southern border.

And this problem is getting worse. The DEA has reported that a sharp increase in fentanyl mixed with xylene is being trafficked into our country. This mixture is even deadlier than fentanyl alone, and even Narcan doesn't work to reverse the mixture's effects. It is now blatantly obvious that this drug is being weaponized against the American people. There is no other thought when you look at the cost per pill of roughly $1 to $2.

Secretary Becerra, your department sees the damage that fentanyl has done to so many individuals, yet the word "fentanyl" is mentioned in President Biden's 2025 HHS budget a whopping one time. One time, even though this is clearly a public health emergency. Can you tell us how you expect to curb these fentanyl deaths and help with struggling addiction when the southern border continues to stay wide open and allow the free flow of fentanyl to our country?

And I will give you the balance of the time.

Mr. BECERRA. Congressman, thank you very much. I can tell you where—what we are doing, what the President has asked us to do, and the resources he has given us at HHS on the health care side to deal with fentanyl.

We are moving forward to try to make naloxone and other treatments that can counteract the effects of fentanyl overdose to keep a person alive more available. And today there are thousands more Americans who have access to the drugs they need to counteract a fentanyl overdose.

We are continuing to make the types of services that work to keep people from dying available. So, something as basic as a fentanyl strip, which lets someone know if they are addicted and they are about to shoot up, if—find out if that drug that they are about to ingest, to put in their body is laced with fentanyl that can save lots of lives.

Mr. HERN. Mr. Secretary, I have to take the last nine seconds, I apologize.

Mr. BECERRA. Okay.

Mr. HERN. But wouldn't it be better if we just stopped the flow across the southern border, instead of trying to find all these Band-Aids to fix the problem?—That is all I am saying.

Mr. BECERRA. Clearly——

Mr. HERN. It is flowing from Mexico, clearly, to the United States.

Mr. BECERRA. And the——

Mr. HERN. I yield back, Mr. Chairman.

Mr. BECERRA. And the President has been doing quite a bit on that. Again, I spoke to you from the perspective of HHS.

Mr. HERN. Thank you. I appreciate it.

Chairman SMITH. Thank you. Ms. Chu.

Ms. CHU. Secretary Becerra, it is so wonderful to see you, since your first elected office was representing me in the California legislature nearly 40 years ago. So, to see you in this position is just wonderful.

Mr. BECERRA. Thank you.

Ms. CHU. I wanted to talk about the Administration's commitment to reproductive health, including the Title IX family planning program. And I would like to bring up the issue of contraceptive access, which is more urgent than ever, considering the ongoing attacks on reproductive rights around this country.

As you just said, the ACA requires health insurance plans to cover preventative services, including birth control, at no cost to the patient. But for years, there have been extensive reports of plans failing to comply by illegally denying coverage, delaying claims, requiring cost sharing, forcing step therapy, or failing to maintain a transparent exceptions process.

Now, I appreciate that HHS recently released new guidance for insurers recommending they cover all forms of contraception, including a therapeutic equivalent, otherwise known as generics. But many of us members are very concerned about compliance with this, and that is why 143 House members and 13 Senators signed a letter to the health insurance plans asking whether they are going to comply with this therapeutic equivalent standard.

So, my question is, how will the Department enforce this new guidance to ensure that everyone has access to the birth control that works best for them?

Mr. BECERRA. Congresswoman, thank you for the question, and actually for your just intense dedication to trying to address this.

We have met with the plans and their—the plans' representatives. We have met with pharmacies and the pharmacy representatives to make it clear that, under the law, they must make contraceptive medications and services available at no out-of-pocket cost.

We have also told them that we have enforcement authority under section 1557 of the Affordable Care Act, and we are prepared to use that.

We also understand—we have explained to some of these entities that because they rely on services and reimbursement for services based on Medicare and Medicaid, that they must abide by Federal laws in order to continue to receive those dollars.

So, we are going to use every lever we can to make it clear that there are laws in place that protect patients' access to care, and we will do everything we can to enforce those requirements and protections.

Ms. CHU. Thank you. That is so reassuring to hear.

And then, on a different topic, I would like to bring up the role of artificial intelligence in Medicare Advantage coverage determinations. I am concerned that the increasing use of AI in coverage decisions has resulted in wrongful denials of medical care for an alarming number of seniors enrolled in Medicare Advantage plans. In fact, there is a class action lawsuit going on right now against one major insurer's use of AI to deny medical claims where AI systems allegedly played a role in the denial of over 300,000 payment requests within a 2-month period. The average time spent, supposedly, reviewing each of these claims was a mere 1.2 seconds.

So, in response to these care denials, I sent a letter to CMS last November with 30 other House Democrats expressing the need to increase oversight of the use of AI in Medicare Advantage payment denials. I appreciate that the Administration recently issued guidance that aims to increase oversight of AI tools.

Can you talk about how the Department plans to enforce the requirements that MA plans comply with Medicare rules, and do not inappropriately create barriers to care?

Mr. BECERRA. Congresswoman, thank you for the question.

And as you know, we are moving to try to remove some of the layers of obscurity that have made it very difficult for us to have clear sight on how the MA plans are operating, and to have the data that shows how they are administering some of their programs. And so, we are trying to make sure that we monitor the way the MA organizations use their utilization of utilization management tools that ensure—will assure us that they are complying with the new requirements that we put in place in regulations.

We are going to continue to make sure that, if prior authorization is used for making decisions on payment of bills, that we have better sight, and we understand what data they relied on. And certainly, because of the preoccupation with AI, we want to make sure that algorithms aren't being used that discriminate against communities and populations because they don't take into account the full breadth and scope of circumstances and the data that is necessary to make sure that decisions are being made based on coverage.

Ms. CHU. And that is exactly what our worry is. Thank you.

And I yield back.

Chairman SMITH. Thank you. Two-hundred and nine folks have not voted yet, but we will go to Mrs. Miller. I think we have time for that.

Mrs. MILLER. Thank you, Chairman Smith, and thank you, Mr. Secretary, for being here today.

West Virginia has the highest mortality rate in the country for patients with kidney disease. I have focused much of my energy in the health care space on advocating with patients who have chronic kidney disease, ESRD, and I am glad to be able to discuss these issues with you in the past.

Last year I led a letter with Congressman Blumenauer about the need for a pediatric ESRD modifier within the ESRD payment bundle, and I was very pleased when your agency took our advice and created one. I am excited to see how this improves childcare, or children's care with ESRD.

I also led a letter with Congresswoman DelBene about the need for Medicare coverage of home dialysis for patients with acute kidney injury. Many patients with AKI are at the beginning of their kidney disease journey, and studies show that almost 50 percent of the patients with AKI never regain kidney function. Ensuring that these patients have access to home dialysis from the start is critical to helping them remain on home dialysis down the road if they do develop ESRD. Just last week this committee heard a powerful testimony from a home dialysis patient about the absolute life-changing potential of home dialysis.

For these reasons I am concerned by CMS's decision not to allow home dialysis for patients with AKI, which does not seem aligned with HHS's overall goal of increasing home dialysis uptake. All patients, including those with AKI, deserve the opportunity to decide, along with their clinical team, what dialysis modality is right for them.

How are you working to ensure that CMS policies around AKI patients are aligned with HHS's overall goal of increasing home dialysis?

Mr. BECERRA. Congresswoman, thank you for the question. And by the way, thank you for your deep work on this issue, because for many folks—and it is not a large community—this is life and death.

Mrs. MILLER. It is.

Mr. BECERRA. And so, thank you for the work that you are doing.

We are talking about—we have to make sure that when we are extending access to some of these services through the Medicare or Medicaid programs, that we do it right because taxpayer dollars are involved. We have to make sure that we are focusing correctly.

On this particular issue we have been taking comment from the AKI community, and we will continue to do so. I will take back your comments today to our folks at CMS so we can follow up with your team, if you would like.

We are not done. And this is an issue I know you are not going to stop working on. And we will try to get there, because what I think we all understand is that, at the end of the day, the quicker and better we get services to these families, the less it is going to cost taxpayers.

Mrs. MILLER. And I do appreciate your commitment to kidney disease patients, and I thank you for working for me—with me.

In West Virginia, about half of Medicare beneficiaries receive coverage through Medicare Advantage. Your department recently cleared a CMS rule that is waiting for White House approval that would overhaul the Medicare Advantage enrollment process. This committee has been engaged on this issue. Fourteen members, including myself, sent you a letter on January twelfth on the proposed rule. Like you, we are concerned about bad actors and aggressive marketing practices that cause headaches for seniors.

We also believe seniors need resources to decide which plan to enroll in. But your proposal would limit resources in the enrollment market for everyone, not just bad actors.

Would you commit to me that CMS will not reduce enrollment resources nor limit the ability of agents and brokers to help beneficiaries find Medicare Advantage plans that do fit their needs the best?

Mr. BECERRA. Congresswoman, let me commit to you to work with you on that issue.

Now, one of the concerns we have is that we want to make sure that people are steered to the plans and services they need, and we want to make sure that, at the end, it is in the benefit of a patient that they end up in a particular type of plan or service. So I am more than willing to work with you to address that, because I think you and I both have the patients' interests most in mind.

Mrs. MILLER. Thank you.

Mr. Chairman, I yield back my time.

Chairman SMITH. Thank you. We are needing to recess, Secretary. The committee will recess now and reconvene immediately following this vote series.

[Recess.]

Chairman SMITH. Dr. Murphy, you are recognized.

Mr. MURPHY. Well, thank God. [Laughter.]

Thank you, Mr. Secretary, for coming back. Sorry for the pause.

I just have to say one thing. I think some folks are tone deaf around here. You know, I am not a big fan of private equity in health care. I think it is horrible in health care, personally. I think they are driving things out. But that is not the reason why we can't put nurses in nursing homes. We don't have the nurses.

You know, we have closed beds at my institution, at my medical center because, guess what? We don't have the nurses. I am fine if we work on some program to get nursing homes up to par, I believe it is absolutely necessary. But you can't make them out of thin air. You can't make them out of thin air. And I would urge you to postpone this until we actually can physically—we can reasonably do this.

Mr. BECERRA. Congressman, would you like me to comment?

Mr. MURPHY. Sure, I am happy to.

Mr. BECERRA. Yes, I don't think families can wait until a facility says they can find a particular——

Mr. MURPHY. Mr. Secretary, how are you—again, I will go back. It is tone deafness. If you don't have the nurses, how are we going to put—I agree, I agree with the problem. You and I agree on that.

Mr. BECERRA. But Congressman, are you saying that they don't need nurses in a nursing home?

Mr. MURPHY. No, I am not saying that at all. Please don't try to change my words. I am not saying——

Mr. BECERRA. No, no, I am not. I am just saying——

Mr. MURPHY. There are not enough nurses in this country.

Mr. BECERRA. But how can you then say that you have enough beds, you have enough people to provide quality care to someone if you don't have the personnel that really can provide the quality care?

Mr. MURPHY. Well, then, I mean, again——

Mr. BECERRA. Is it inferior care that people are supposed to accept?

Mr. MURPHY. No. But again, I am going to go back to the fact that there are not nurses. We can't pull them out of the air.

Mr. BECERRA. But then how do you call yourself a nursing home?

Mr. MURPHY. Because that is what is done. You don't have a nurse at every bedside.

Mr. BECERRA. No, but you——

Mr. MURPHY. You are rewriting the—all right, let's move on to more issues. You and I are not going to agree with that. I can't go poof with a magic wand and turn these things out.

Let's turn now to another debacle, and that is surprise billing implementation. I am so glad, after four lawsuits—four—we actually got the day. Now, here is the problem: things have been adjudicated, but insurance companies aren't paying people.

Mr. Chairman, I would like to submit to the record three examples: one from a NICU, one from an emergency department, and one from anesthesia for spinal services. These people have been adjudicated, were supposed to be paid, but our insurance companies still don't pay it—one up out to two years they have been adjudicated and not receiving their payment.

Chairman SMITH. Without objection.

[The information follows:]

[redacted]

4W-229*14*000028-PM-22147-101*E01EPSUHCTOPS

STD - PRA

UnitedHealthcare

PROVIDER REMITTANCE ADVICE

PAYMENT DATE:
TIN:
NPI:
PAYEE NAME:
PAYMENT NUMBER:
PAYMENT AMOUNT:
GROUP NUMBER:
GROUP NAME:

CPT 99480: "Subsequent intensive care, per day, for the evaluation and management of the recovering low or very low birth weight infant"

PATIENT:

SUBSCRIBER ID:
CLAIM DATE:
REND PROV ID:
SUBSCRIBER NAME:
DATE RECEIVED:
REND PROV:
CLAIM NUMBER:
PRODUCT:

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
					$904.00				$0.00	$904.00

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
01	03/29/22 - 03/29/22		99480			1	1	$904.00		$904.00	PR	242	$0.00	N
CLAIM#							SUBTOTAL	$904.00		$904.00			$0.00	M6

PAYMENT OF BENEFITS HAS BEEN MADE IN ACCORDANCE WITH THE TERMS OF THE MANAGED CARE SYSTEM.

NOTES

OA23	OTHER ADJUSTMENTS - THE IMPACT OF PRIOR PAYER(S) ADJUDICATION INCLUDING PAYMENTS AND/OR ADJUSTMENTS.
PI242	PAYER INITIATED REDUCTIONS - SERVICES NOT PROVIDED BY NETWORK/PRIMARY CARE PROVIDERS .
PR1	PATIENT RESPONSIBILITY - DEDUCTIBLE AMOUNT
PR2	PATIENT RESPONSIBILITY - COINSURANCE AMOUNT
PR242	PATIENT RESPONSIBILITY - SERVICES NOT PROVIDED BY NETWORK/PRIMARY CARE PROVIDERS .
05	BENEFITS ARE DENIED BECAUSE A CLAIM FOR THIS SERVICE HAS ALREADY BEEN PROCESSED. PROVIDER: IF THIS IS MEANT TO BE A REPLACEMENT CLAIM OR REPEAT MODIFIER, PLEASE RESUBMIT A NEW CLAIM FORM. IF IT IS A REPLACEMENT CLAIM, THE CORRECTIONS SHOULD REPRESENT A COMPLETE REPLACEMENT OF THE PREVIOUS CLAIM. USED THE FREQUENCY CODE OR BILL TYPE TO INDICATE IT IS A REPLACEMENT CLAIM OR CLEARLY MARK IT WITH THE WORD "CORRECTED". IF IT IS MEANT TO BE AN ADDITIONAL CLAIM WITH A REPEAT MODIFIER, YOU MUST SUBMIT INFORMATION THAT SUPPORTS THIS.
0T	MEMBER: THIS SERVICE WAS PROVIDED BY AN OUT-OF-NETWORK PROVIDER. WE PAID THE PROVIDER ACCORDING TO YOUR BENEFITS AND DATA PROVIDED BY DATA ISIGHT. IF YOU'RE ASKED TO PAY MORE THAN THE DEDUCTIBLE, COPAY AND COINSURANCE, PLEASE CALL DATA ISIGHT AT 800-355-7962 OR VISIT DATAISIGHT.COM. THEY WILL WORK WITH THE PROVIDER ON YOUR BEHALF. IF THE PROVIDER DISAGREES WITH DATA ISIGHT, THE PROVIDER MIGHT BILL YOU FOR THE DIFFERENCE BETWEEN THE AMOUNT BILLED AND THE AMOUNT ALLOWED. WE'VE ASKED THEM NOT TO. PLEASE CONTACT US IF THEY DO. PROVIDER: PLEASE DON'T BILL THE PATIENT ABOVE THE AMOUNT OF DEDUCTIBLE, COPAY AND COINSURANCE.
M6	THIS IS A RECONSIDERATION OF A PREVIOUSLY PROCESSED CLAIM.

[redacted]

[redacted]

UnitedHealthcare Insurance Company of New York
GREENSBORO SMALL GROUP
PO BOX 740800
ATLANTA GA 30374-0800
PHONE: 1-877-842-3210

STD - PRA

UnitedHealthcare

PROVIDER REMITTANCE ADVICE

[redacted]

[redacted]

CPT 99468: Evaluation and management of initial care of a newborn in neonatal critical care

United applied code "29" denoting out-of-network cost-sharing and benefits, in violation of the NSA

PATIENT: [redacted]

SUBSCRIBER ID: [redacted] **SUBSCRIBER NAME:** [redacted] **CLAIM NUMBER:** [redacted]
CLAIM DATE: 11/09/22-11/09/22 **DATE RECEIVED:** [redacted] **PRODUCT:**
REND PROV ID: [redacted] **REND PROV:** [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]					$6,721.00				$1,950.50	$4,770.50

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
[redacted]	11/09/22 - 11/09/22		99466			1	1	$6,721.00	$3,901.00	$2,620.00	PR	45	$1,950.50	29
										$1,950.50	PR	2		
CLAIM# [redacted]							SUBTOTAL	$6,721.00	$3,901.00	$4,770.50			$1,950.50	KL

PAYMENT OF BENEFITS HAS BEEN MADE IN ACCORDANCE WITH THE TERMS OF THE MANAGED CARE SYSTEM.

SUBSCRIBER ID: [redacted] **SUBSCRIBER NAME:** [redacted] **CLAIM NUMBER:** [redacted]
CLAIM DATE: 11/10/22-11/10/22 **DATE RECEIVED:** [redacted] **PRODUCT:**
REND PROV ID: [redacted] **REND PROV:** [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]					$2,691.00				$238.98	$1,080.77

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
3255416	11/10/22 - 11/10/22		99469			1	1	$2,691.00	$1,319.75	$978.35	PR	1	$238.98	1J
										$102.42	PR	2		
										$1,571.25	PI	242		
CLAIM# [redacted]							SUBTOTAL	$2,691.00	$1,319.75	$2,652.02			$238.98	KL

PAYMENT OF BENEFITS HAS BEEN MADE IN ACCORDANCE WITH THE TERMS OF THE MANAGED CARE SYSTEM.

[redacted] [redacted]

[redacted]

4W-229*14*000028-FM-22147-101*E01EPSUHCTOPS

STD - PRA

UnitedHealthcare

PROVIDER REMITTANCE ADVICE

PAYMENT DATE:
TIN:
NPI:
PAYEE NAME:

PAYMENT NUMBER:
PAYMENT AMOUNT:
GROUP NUMBER:
GROUP NAME:

CPT 99480: "Subsequent intensive care, per day, for the evaluation and management of the recovering low or very low birth weight infant"

PATIENT: [redacted]

SUBSCRIBER ID:
CLAIM DATE:
REND PROV ID:

SUBSCRIBER NAME:
DATE RECEIVED:
REND PROV:

CLAIM NUMBER:
PRODUCT:

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]					$904.00				$0.00	$904.00

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
01	03/29/22 - 03/29/22		99480			1	1	$904.00		$904.00	PR	242	$0.00	N1
CLAIM# [redacted]							SUBTOTAL	$904.00		$904.00			$0.00	M6

PAYMENT OF BENEFITS HAS BEEN MADE IN ACCORDANCE WITH THE TERMS OF THE MANAGED CARE SYSTEM.

NOTES

OA23	OTHER ADJUSTMENTS - THE IMPACT OF PRIOR PAYER(S) ADJUDICATION INCLUDING PAYMENTS AND/OR ADJUSTMENTS.
PI242	PAYER INITIATED REDUCTIONS - SERVICES NOT PROVIDED BY NETWORK/PRIMARY CARE PROVIDERS .
PR1	PATIENT RESPONSIBILITY - DEDUCTIBLE AMOUNT
PR2	PATIENT RESPONSIBILITY - COINSURANCE AMOUNT
PR242	PATIENT RESPONSIBILITY - SERVICES NOT PROVIDED BY NETWORK/PRIMARY CARE PROVIDERS .
05	BENEFITS ARE DENIED BECAUSE A CLAIM FOR THIS SERVICE HAS ALREADY BEEN PROCESSED. PROVIDER: IF THIS IS MEANT TO BE A REPLACEMENT CLAIM OR REPEAT MODIFIER, PLEASE RESUBMIT A NEW CLAIM FORM. IF IT IS A REPLACEMENT CLAIM, THE CORRECTIONS SHOULD REPRESENT A COMPLETE REPLACEMENT OF THE PREVIOUS CLAIM. USED THE FREQUENCY CODE OR BILL TYPE TO INDICATE IT IS A REPLACEMENT CLAIM OR CLEARLY MARK IT WITH THE WORD "CORRECTED". IF IT IS MEANT TO BE AN ADDITIONAL CLAIM WITH A REPEAT MODIFIER, YOU MUST SUBMIT INFORMATION THAT SUPPORTS THIS.
0T	MEMBER: THIS SERVICE WAS PROVIDED BY AN OUT-OF-NETWORK PROVIDER. WE PAID THE PROVIDER ACCORDING TO YOUR BENEFITS AND DATA PROVIDED BY DATA ISIGHT. IF YOU'RE ASKED TO PAY MORE THAN THE DEDUCTIBLE, COPAY AND COINSURANCE, PLEASE CALL DATA ISIGHT AT 800-355-7962 OR VISIT DATAISIGHT.COM. THEY WILL WORK WITH THE PROVIDER ON YOUR BEHALF. IF THE PROVIDER DISAGREES WITH DATA ISIGHT, THE PROVIDER MIGHT BILL YOU FOR THE DIFFERENCE BETWEEN THE AMOUNT BILLED AND THE AMOUNT ALLOWED. WE'VE ASKED THEM NOT TO. PLEASE CONTACT US IF THEY DO. PROVIDER: PLEASE DON'T BILL THE PATIENT ABOVE THE AMOUNT OF DEDUCTIBLE, COPAY AND COINSURANCE.
M6	THIS IS A RECONSIDERATION OF A PREVIOUSLY PROCESSED CLAIM.

[redacted]

[redacted]

UnitedHealthcare Insurance Company of New York
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PO BOX 740800
ATLANTA GA 30374-0800
PHONE: 1-877-842-3210

STD - PRA

UnitedHealthcare

PROVIDER REMITTANCE ADVICE

[redacted]

[redacted]

CPT 99468: Evaluation and management of initial care of a newborn in neonatal critical care

United applied code "29" denoting out-of-network cost-sharing and benefits, in violation of the NSA

PATIENT: [redacted]

SUBSCRIBER ID: [redacted] **SUBSCRIBER NAME:** [redacted] **CLAIM NUMBER:** [redacted]
CLAIM DATE: 11/09/22-11/09/22 **DATE RECEIVED:** [redacted] **PRODUCT:**
REND PROV ID: [redacted] **REND PROV:** [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]					$6,721.00				$1,950.50	$4,770.50

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
[redacted]	11/09/22 - 11/09/22		99468			1	1	$6,721.00	$3,901.00	$2,820.00	PR	45	$1,950.50	29
										$1,950.50	PR	2		
CLAIM# [redacted]							SUBTOTAL	$6,721.00	$3,901.00	$4,770.50			$1,950.50	KL

PAYMENT OF BENEFITS HAS BEEN MADE IN ACCORDANCE WITH THE TERMS OF THE MANAGED CARE SYSTEM.

SUBSCRIBER ID: [redacted] **SUBSCRIBER NAME:** [redacted] **CLAIM NUMBER:** [redacted]
CLAIM DATE: 11/10/22-11/10/22 **DATE RECEIVED:** [redacted] **PRODUCT:**
REND PROV ID: [redacted] **REND PROV:** [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]					$2,691.00				$236.98	$1,080.77

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
3255418	11/10/22 - 11/10/22		99469			1	1	$2,691.00	$1,319.75	$978.35	PR	1	$236.98	1J
										$102.42	PR	2		
										$1,571.25	PI	242		
CLAIM# [redacted]							SUBTOTAL	$2,691.00	$1,319.75	$2,652.02			$236.98	KL

PAYMENT OF BENEFITS HAS BEEN MADE IN ACCORDANCE WITH THE TERMS OF THE MANAGED CARE SYSTEM.

[redacted] [redacted]

[redacted]

STD - PRA

UnitedHealthcare

PROVIDER REMITTANCE ADVICE

CPT 99469: Evaluation and management of ongoing care of a newborn in neonatal critical care.

United applied code "NJ" denoting out-of-network cost-sharing and benefits, in violation of the NSA

[redacted]

PATIENT: [redacted]

SUBSCRIBER ID: [redacted] **SUBSCRIBER NAME:** [redacted] **CLAIM NUMBER:** [redacted]
CLAIM DATE: 11/11/22-11/11/22 **DATE RECEIVED:** [redacted] **PRODUCT:** [redacted]
REND PROV ID: [redacted] **REND PROV:** [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]					$2,891.00				$1,445.50	$1,445.50

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
[redacted]	11/11/22 - 11/11/22		99469			1	1	$2,891.00	$2,891.00	$1,445.50	PR	2	$1,445.50	NJ
CLAIM# [redacted]							SUBTOTAL	$2,891.00	$2,891.00	$1,445.50			$1,445.50	KL

PAYMENT OF BENEFITS HAS BEEN MADE IN ACCORDANCE WITH THE TERMS OF THE MANAGED CARE SYSTEM.

SUBSCRIBER ID: [redacted] **SUBSCRIBER NAME:** [redacted] **CLAIM NUMBER:** [redacted]
CLAIM DATE: 11/13/22-11/13/22 **DATE RECEIVED:** [redacted] **PRODUCT:** [redacted]
REND PROV ID: [redacted] **REND PROV:** [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]					$1,014.00				$0.00	$1,014.00

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
[redacted]	11/13/22 - 11/13/22		99478			1	1	$1,014.00	$1,014.00	$1,014.00	PR	1	$0.00	CK
CLAIM# [redacted]							SUBTOTAL	$1,014.00	$1,014.00	$1,014.00			$0.00	KL

PAYMENT OF BENEFITS HAS BEEN MADE IN ACCORDANCE WITH THE TERMS OF THE MANAGED CARE SYSTEM.

NOTES

PI242 PAYER INITIATED REDUCTIONS - SERVICES NOT PROVIDED BY NETWORK/PRIMARY CARE PROVIDERS .

PR1 PATIENT RESPONSIBILITY - DEDUCTIBLE AMOUNT

PR2 PATIENT RESPONSIBILITY - COINSURANCE AMOUNT

SP 03 364UTOPPD2013002-01736-03 3L-1736*03*000005-PM-22364-101*E01EPSUHCTOPS

STD - PRA UnitedHealthcare

PROVIDER REMITTANCE ADVICE

[redacted]

NOTES

PR45	PATIENT RESPONSIBILITY - CHARGE EXCEEDS FEE SCHEDULE/MAXIMUM ALLOWABLE OR CONTRACTED/LEGISLATED FEE ARRANGEMENT.
1J	MEMBER: THIS SERVICE WAS RENDERED BY AN OUT-OF-NETWORK PROVIDER AND PROCESSED USING YOUR NETWORK BENEFITS. IF YOU'RE ASKED TO PAY MORE THAN THE DEDUCTIBLE, COPAY AND COINSURANCE AMOUNTS SHOWN, PLEASE CALL DATA ISIGHT 800-355-7962 OR VISIT DATAISIGHT.COM. THEY WILL WORK WITH THE PROVIDER ON YOUR BEHALF. PROVIDER: THIS CLAIM HAS BEEN REIMBURSED AT A PERCENTAGE OF THE MEDICARE ALLOWED AMOUNT WHERE AVAILABLE. PLEASE DO NOT BILL THE PATIENT ABOVE THE AMOUNT OF DEDUCTIBLE, COPAY AND COINSURANCE APPLIED TO THIS SERVICE. IF YOU HAVE QUESTIONS ABOUT THE REIMBURSEMENT CONTACT DATA ISIGHT.
29	YOUR PLAN COVERS THE ELIGIBLE EXPENSE AMOUNT REIMBURSABLE UNDER YOUR PLAN FOR COVERED OUT-OF-NETWORK HEALTH SERVICES. THE ELIGIBLE AMOUNT IS BASED ON A DATABASE OF COMPETITIVE FEES FOR SIMILAR SERVICES OR SUPPLIES IN YOUR AREA. BENEFITS ARE NOT AVAILABLE FOR THAT PORTION OF THE CHARGE THAT EXCEEDS THE ELIGIBLE AMOUNT DETERMINED FOR THIS SERVICE.
CK	AN OUT-OF-NETWORK PROVIDER OR FACILITY PROVIDED THESE SERVICES. THE AMOUNT PAID FOR THIS SERVICE WAS DETERMINED USING MEDICARE RATES (OR OTHER SOURCES IF NO MEDICARE RATE WAS AVAILABLE), EVEN IF THE PATIENT DOES NOT HAVE MEDICARE. YOU MAY BE RESPONSIBLE FOR PAYING THE DIFFERENCE BETWEEN WHAT THE FACILITY OR PROVIDER BILLED AND WHAT WAS PAID. THE NOT COVERED AMOUNT MAY NOT APPLY TO YOUR ANNUAL OUT- OF-POCKET MAXIMUM.
KL	IN ACCORDANCE WITH YOUR EMPLOYERS' ENROLLMENT REQUIREMENTS, YOU MUST ENROLL YOUR NEWBORN CHILD(REN) WITHIN THE NUMBER OF DAYS SPECIFIED IN YOUR BENEFIT PLAN. FAILURE TO ENROLL YOUR BABY WILL AFFECT FUTURE CLAIM PROCESSING. PLEASE CONTACT YOUR EMPLOYER'S BENEFITS REPRESENTATIVE TO HAVE YOUR NEWBORN CHILD ADDED TO YOUR FILE AS AN ELIGIBLE DEPENDENT.
NJ	THIS CLAIM WAS PROCESSED USING YOUR PLAN'S OUT-OF-NETWORK BENEFITS. NETWORK BENEFITS ARE ONLY AVAILABLE WHEN YOU RECEIVE SERVICES FROM A PROVIDER IN YOUR PLAN'S NETWORK.

THE MEMBER, PROVIDER, OR AN AUTHORIZED REPRESENTATIVE MAY REQUEST RECONSIDERATION OR APPEAL THE DECISION BY SUBMITTING COMMENTS, DOCUMENTS OR OTHER INFORMATION TO UNITEDHEALTHCARE. NETWORK PROVIDERS SHOULD REFER TO THE ADMINISTRATIVE GUIDE FOR CLAIM RECONSIDERATION OR APPEAL INFORMATION. IF YOU ARE A NETWORK PROVIDER APPEALING A CLINICAL OR COVERAGE DETERMINATION ON BEHALF OF A MEMBER, OR A NON-NETWORK PROVIDER APPEALING A DECISION ON BEHALF OF A MEMBER, FOLLOW THE PROCESS FOR APPEALS IN THE MEMBER'S BENEFIT PLAN DOCUMENT. DECISIONS ON APPEALS MADE ON BEHALF OF MEMBERS WILL BE COMPLETED IN 30 DAYS OF SUBMISSION OR WITHIN THE TIMEFRAME REQUIRED BY LAW.

[redacted] [redacted]

[redacted]

United HealthCare Services, Inc.
BUFFALO SERVICE CENTER
PO BOX 740800
ATLANTA GA 30374-0800
PHONE: 1-877-842-3210

STD - PRA

UnitedHealthcare

PROVIDER REMITTANCE ADVICE

[redacted]

CPT 99480: Subsequent subsequent to the day of admission provided by a physician directing the continuing intensive care of the very low birth weight infant who no longer meets the definition of being critically ill

CPT 99468: Evaluation and management of initial care of a newborn in neonatal critical care

United applied code "1Q" denoting out-of-network cost-sharing and benefits, in violation of the NSA

United applied code "1Q" denoting out-of-network cost-sharing and benefits, in violation of the NSA

PATIENT: [redacted]

SUBSCRIBER ID: [redacted]
CLAIM DATE: 11/11/22-11/11/22
REND PROV ID: [redacted]
SUBSCRIBER NAME: [redacted]
DATE RECEIVED: [redacted]
REND PROV: [redacted]
CLAIM NUMBER: [redacted]
PRODUCT: [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]		[redacted]			$6,721.00				$1,557.70	$5,163.30

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
[redacted]	11/11/22 - 11/11/22		99468			1	1	$6,721.00	$1,947.12	$389.42	PR	2	$1,557.70	1Q
										$4,773.88	PR	242		
CLAIM# [redacted]							SUBTOTAL	$6,721.00	$1,947.12	$5,163.30			$1,557.70	

PAYMENT OF BENEFITS HAS BEEN MADE IN ACCORDANCE WITH THE TERMS OF THE MANAGED CARE SYSTEM.

SUBSCRIBER ID: [redacted]
CLAIM DATE: 11/20/22-11/20/22
REND PROV ID: [redacted]
SUBSCRIBER NAME: [redacted]
DATE RECEIVED: [redacted]
REND PROV: [redacted]
CLAIM NUMBER: [redacted]
PRODUCT: [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]		[redacted]			$904.00				$203.10	$700.90

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
[redacted]	11/20/22 - 11/20/22		99460			1	1	$904.00	$253.88	$650.12	PR	242	$203.10	1Q
										$50.78	PR	2		
CLAIM# [redacted]							SUBTOTAL	$904.00	$253.88	$700.90			$203.10	JP

WE RECEIVED THE REQUESTED INFORMATION ON 12/15/22 AND HAVE PROCESSED CLAIM NUMBER [redacted]

PAYMENT OF BENEFITS HAS BEEN MADE IN ACCORDANCE WITH THE TERMS OF THE MANAGED CARE SYSTEM.

[redacted]

[redacted]

STD - PRA UnitedHealthcare

PROVIDER
REMITTANCE ADVICE

[redacted]

NOTES	
PR2	PATIENT RESPONSIBILITY - COINSURANCE AMOUNT
PR242	PATIENT RESPONSIBILITY - SERVICES NOT PROVIDED BY NETWORK/PRIMARY CARE PROVIDERS .
1Q	THIS CLAIM PROCESSED USING THE MEMBER'S OUT-OF-NETWORK BENEFITS. MEMBER: THE AMOUNT YOU OWE IS YOUR COST SHARE (COPAY, COINSURANCE OR DEDUCTIBLE). IF THE PROVIDER BILLS YOU THE DIFFERENCE BETWEEN THE BILLED CHARGE AND THE ALLOWED AMOUNT (THE BALANCE BILL), CONTACT DATA ISIGHT AT 800-355-7962 OR VISIT DATA ISIGHT.COM BEFORE YOUR PAY. DATA ISIGHT WILL ATTEMPT TO WORK WITH THE PROVIDER. IF UNSUCCESSFUL, YOU MAY ALSO OWE THE BALANCE BILL. PROVIDER: THIS CLAIM HAS BEEN REIMBURSED USING DATA ISIGHT. PLEASE DO NOT BILL THE MEMBER MORE THAN THEIR COST SHARE. IF YOU HAVE QUESTIONS ABOUT THE REIMBURSEMENT, CONTACT DATA ISIGHT.
JP	IT IS IMPORTANT FOR US TO KNOW WHETHER OR NOT YOU OR YOUR COVERED FAMILY MEMBER(S) HAVE OTHER HEALTH INSURANCE. THIS WILL HELP US PAY YOUR CLAIMS QUICKLY AND ACCURATELY. WE ASK FOR THIS INFORMATION EVERY YEAR BECAUSE COVERAGE CAN CHANGE. TO UPDATE THIS INFORMATION, GO TO THE COORDINATION OF BENEFITS SECTION ON YOUR MEMBER WEBSITE OR CALL US AT 1-888-262-4001.

THE MEMBER, PROVIDER, OR AN AUTHORIZED REPRESENTATIVE MAY REQUEST RECONSIDERATION OR APPEAL THE DECISION BY SUBMITTING COMMENTS, DOCUMENTS OR OTHER INFORMATION TO UNITEDHEALTHCARE. NETWORK PROVIDERS SHOULD REFER TO THE ADMINISTRATIVE GUIDE FOR CLAIM RECONSIDERATION OR APPEAL INFORMATION. IF YOU ARE A NETWORK PROVIDER APPEALING A CLINICAL OR COVERAGE DETERMINATION ON BEHALF OF A MEMBER, OR A NON-NETWORK PROVIDER APPEALING A DECISION ON BEHALF OF A MEMBER, FOLLOW THE PROCESS FOR APPEALS IN THE MEMBER'S BENEFIT PLAN DOCUMENT. DECISIONS ON APPEALS MADE ON BEHALF OF MEMBERS WILL BE COMPLETED IN 30 DAYS OF SUBMISSION OR WITHIN THE TIMEFRAME REQUIRED BY LAW.

[redacted]

[redacted]

United HealthCare Services, Inc.
CHICO SERVICE CENTER
P.O. BOX 740800
ATLANTA GA 30374-0800
PHONE: 1-877-842-3210

STD - PRA

UnitedHealthcare

PROVIDER REMITTANCE ADVICE

[redacted]

CPT 99469: Evaluation and management of ongoingcare of a newborn in neonatal critical care.

United denied this claim because the provider was out-of-network, in violation of the NSA

CPT 99466: The provider accompanies and cares for a critically ill or injured child, in person, who is two years of age or younger, during transportation between facilities.

United denied this claim because the provider was out-of-network, in violation of the NSA

PATIENT: [redacted]

SUBSCRIBER ID: [redacted] SUBSCRIBER NAME: [redacted] CLAIM NUMBER: [redacted]
CLAIM DATE: 11/12/22-11/12/22 DATE RECEIVED: [redacted] PRODUCT: [redacted]
REND PROV ID: [redacted] REND PROV: [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]					$6,721.00				$0.00	$6,721.00

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
[redacted]	11/12/22 - 11/12/22		99466			1	1	$6,721.00		$6,721.00	PR	242	$0.00	NI
CLAIM# [redacted]							SUBTOTAL	$6,721.00		$6,721.00			$0.00	JP

SUBSCRIBER ID: [redacted] SUBSCRIBER NAME: [redacted] CLAIM NUMBER: [redacted]
CLAIM DATE: 11/13/22-11/13/22 DATE RECEIVED: [redacted] PRODUCT: [redacted]
REND PROV ID: [redacted] REND PROV: [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]					$2,691.00				$0.00	$2,691.00

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
[redacted]	11/13/22 - 11/13/22		99469			1	1	$2,691.00		$2,691.00	PR	242	$0.00	NI
CLAIM# [redacted]							SUBTOTAL	$2,691.00		$2,691.00			$0.00	JP

SUBSCRIBER ID: [redacted] SUBSCRIBER NAME: [redacted] CLAIM NUMBER: [redacted]
CLAIM DATE: 11/14/22-11/14/22 DATE RECEIVED: [redacted] PRODUCT: [redacted]
REND PROV ID: [redacted] REND PROV: [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
ZA830CI					$2,691.00				$0.00	$2,691.00

[redacted]

[redacted] [redacted]

STD - PRA UnitedHealthcare

PROVIDER REMITTANCE ADVICE

CPT 99469: Evaluation and management of ongoingcare of a newborn in neonatal critical care.

United denied this claim because the provider was out-of-network, in violation of the NSA

[redacted]

PATIENT: [redacted]

SUBSCRIBER ID: [redacted] **SUBSCRIBER NAME:** [redacted] **CLAIM NUMBER:** [redacted]
CLAIM DATE: 11/14/22-11/14/22 **DATE RECEIVED:** [redacted] **PRODUCT:** [redacted]
REND PROV ID: [redacted] **REND PROV:** [redacted]

CONTINUED

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
[redacted]	11/14/22 - 11/14/22		99469			1	1	$2,691.00		$2,691.00	PR	242	$0.00	NI
CLAIM# [redacted]							SUBTOTAL	$2,691.00		$2,691.00			$0.00	JP

SUBSCRIBER ID: [redacted] **SUBSCRIBER NAME:** [redacted] **CLAIM NUMBER:** [redacted]
CLAIM DATE: 11/15/22-11/15/22 **DATE RECEIVED:** [redacted] **PRODUCT:** [redacted]
REND PROV ID: [redacted] **REND PROV:** [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]					$2,691.00				$0.00	$2,691.00

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
[redacted]	11/15/22 - 11/15/22		99469			1	1	$2,691.00		$2,691.00	PR	242	$0.00	NI
CLAIM# [redacted]							SUBTOTAL	$2,691.00		$2,691.00			$0.00	JP

SUBSCRIBER ID: [redacted] **SUBSCRIBER NAME:** [redacted] **CLAIM NUMBER:** [redacted]
CLAIM DATE: 11/16/22-11/16/22 **DATE RECEIVED:** [redacted] **PRODUCT:** [redacted]
REND PROV ID: [redacted] **REND PROV:** [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]					$2,691.00				$0.00	$2,691.00

[redacted] [redacted]

[redacted]

STD - PRA UnitedHealthcare

PROVIDER REMITTANCE ADVICE

CPT 99469: Evaluation and management of ongoingcare of a newborn in neonatal critical care.

United denied this claim because the provider was out-of-network, in violation of the NSA

[redacted]

PATIENT: [redacted]

SUBSCRIBER ID: [redacted] SUBSCRIBER NAME: [redacted] CLAIM NUMBER: [redacted]
CLAIM DATE: 11/16/22-11/16/22 DATE RECEIVED: [redacted] PRODUCT: [redacted]
REND PROV ID: [redacted] REND PROV: [redacted]

CONTINUED

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
[redacted]	11/16/22 - 11/16/22		99469			1	1	$2,691.00		$2,691.00	PR	242	$0.00	NI
CLAIM# [redacted]							SUBTOTAL	$2,691.00		$2,691.00			$0.00	JP

SUBSCRIBER ID: [redacted] SUBSCRIBER NAME: [redacted] CLAIM NUMBER: [redacted]
CLAIM DATE: 11/17/22-11/17/22 DATE RECEIVED: [redacted] PRODUCT: [redacted]
REND PROV ID: [redacted] REND PROV: [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]					$904.00				$0.00	$904.00

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
[redacted]	11/17/22 - 11/17/22		99460			1	1	$904.00		$904.00	PR	242	$0.00	NI
CLAIM# [redacted]							SUBTOTAL	$904.00		$904.00			$0.00	JP

SUBSCRIBER ID: [redacted] SUBSCRIBER NAME: [redacted] CLAIM NUMBER: [redacted]
CLAIM DATE: 11/18/22-11/18/22 DATE RECEIVED: [redacted] PRODUCT: [redacted]
REND PROV ID: [redacted] REND PROV: [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]					$904.00				$0.00	$904.00

[redacted]

[redacted] [redacted]

STD - PRA UnitedHealthcare

PROVIDER REMITTANCE ADVICE

[redacted]

PATIENT: [redacted]

[redacted]

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
[redacted]	11/19/22 - 11/19/22		99460			1	1	$904.00		$904.00	PR	242	$0.00	NI
CLAIM# [redacted]							SUBTOTAL	$904.00		$904.00			$0.00	JP

SUBSCRIBER ID: [redacted] **SUBSCRIBER NAME:** [redacted] **CLAIM NUMBER:** [redacted]

CLAIM DATE: 11/20/22-11/20/22 **DATE RECEIVED:** [redacted] **PRODUCT:** [redacted]

REND PROV ID: [redacted] **REND PROV:** [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]					$904.00				$0.00	$904.00

[redacted] [redacted]

[redacted]

STD - PRA

UnitedHealthcare

CPT 99480: Subsequent subsequent to the day of admission provided by a physician directing the continuing intensive care of the very low birth weight infant who no longer meets the definition of being critically ill

United denied this claim because the provider was out-of-network, in violation of the NSA.

PROVIDER REMITTANCE ADVICE

[redacted]

PATIENT: [redacted]

SUBSCRIBER ID: [redacted] **SUBSCRIBER NAME:** [redacted] **CLAIM NUMBER:** [redacted]
CLAIM DATE: 11/20/22-11/20/22 **DATE RECEIVED:** [redacted] **PRODUCT:** [redacted]
REND PROV ID: [redacted] **REND PROV:** [redacted]

CONTINUED

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
[redacted]	11/20/22 - 11/20/22		99480			1	1	$904.00		$904.00	PR	242	$0.00	NI
CLAIM# [redacted]							SUBTOTAL	$904.00		$904.00			$0.00	JP

SUBSCRIBER ID: [redacted] **SUBSCRIBER NAME:** [redacted] **CLAIM NUMBER:** [redacted]
CLAIM DATE: 11/21/22-11/21/22 **DATE RECEIVED:** [redacted] **PRODUCT:** [redacted]
REND PROV ID: [redacted] **REND PROV:** [redacted]

PATIENT CONTROL NUMBER	PATIENT ID	AUTH/REF NUMBER	DRG	DRG WEIGHT	CLAIM CHARGE AMOUNT	CLM ADJ AMT	GRP CD	CLM ADJ RSN CD	CLAIM PAYMENT AMOUNT	PATIENT RESPONSIBILITY
[redacted]					$904.00				$0.00	$904.00

SERVICE LINE DETAIL(S)

LINE CTRL#	DATES OF SERVICE	SUB PROD/ SVC/ MOD	ADJ PROD/ SVC	MOD	REV	UNITS	SUB UNITS	CHARGE	AMOUNT ALLOWED	ADJ AMOUNT	GRP CD	CLM ADJ RSN CD	PAYMENT AMOUNT	REMARK/ NOTES
[redacted]	11/21/22 - 11/21/22		99480			1	1	$904.00		$904.00	PR	242	$0.00	NI
CLAIM# [redacted]							SUBTOTAL	$904.00		$904.00			$0.00	JP

NOTES

PR242	PATIENT RESPONSIBILITY - SERVICES NOT PROVIDED BY NETWORK/PRIMARY CARE PROVIDERS .
PR288	PATIENT RESPONSIBILITY - REFERRAL ABSENT.
FN	PAYMENT FOR SERVICES IS DENIED. BENEFITS ARE ONLY AVAILABLE WHEN YOU RECEIVE A VALID REFERRAL FROM YOUR PRIMARY CARE PHYSICIAN (PCP) BEFORE RECEIVING THE SERVICE.
JP	IT IS IMPORTANT FOR US TO KNOW WHETHER OR NOT YOU OR YOUR COVERED FAMILY MEMBER(S) HAVE OTHER HEALTH INSURANCE. THIS WILL HELP US PAY YOUR CLAIMS QUICKLY AND ACCURATELY. WE ASK FOR THIS INFORMATION EVERY YEAR BECAUSE COVERAGE CAN CHANGE. TO UPDATE THIS INFORMATION, GO TO THE COORDINATION OF BENEFITS SECTION ON YOUR MEMBER WEBSITE OR CALL US AT 1-888-262-4001.
NI	PAYMENT FOR THIS SERVICE IS DENIED. BENEFITS ARE ONLY AVAILABLE WHEN YOU RECEIVE MEDICAL SERVICES FROM A PROVIDER IN YOUR PLAN'S NETWORK.

[redacted]

ERA 5010 EOB DETAIL REPORT

OSCAR INSURANCE COMPANY OF FLORIDA
P.O. BOX 52146
PHOENIX AZ 65072

[redacted]

ELECTRONIC REMITTANCE NOTICE

NPI#:
Check/EFT#:
Check Date: [redacted]

Name: [redacted] HIC: [redacted] Acct: [redacted]
ICN: ASG:

Rend Prov	Serv Date	Pos	Nos	Proc	Mods	Billed	Allowed	Deducted	Co-Ins	Grp/RC	Amount	Prov Pd
[redacted] Rem: M115	10/21/22	1		99285		2064.00	2064.00	0.00	0.00	PR-242	2064.00	0.00
				Claim Totals		2064.00	2064.00	0.00	0.00		2064.00	0.00

Patient Responsibility: 2064.00

Adjustment to Totals: (Previously Paid) Interest: 0.00 Late Filing Charges: 0.00 Net: 0.00

Claim Status: 4 - Denied

HIPAA Code	Description
M115	THIS ITEM IS DENIED WHEN PROVIDED TO THIS PATIENT BY A NON-DEMONSTRATION SUPPLIER.
PR242	SERVICES NOT PROVIDED BY DESIGNATEDNETWORK/PRIMARY CARE PROVIDERS

CPT 99285: High Acuity Emergency Department Care

The No Surprises Act requries plans to cover emergency care under the in-network benefit regardless of facility's or provider's network status.

Denial reason codes M115 and PR242 both signify the claim was denied because the clinician was OON.

oscar

Oscar Insurance Company of Florida
PO Box 52146
Phoenix, AZ 85072

1-855-OSCAR-55
hioscar.com/providers

[redacted]

[redacted]
Attn: Billing
Fax: None

Re:
Member Name: [redacted]
Member ID: [redacted]
Member DOB: [redacted]
Oscar Claim ID: [redacted]
Date of Service: 2022-10-21-2022-10-21

To Whom it May Concern,

We received your request to review the above-referenced claim for services rendered to this member. We have reviewed your request. Our records indicate that your company is not a Participating Provider in our exclusive provider network (EPO). While we understand that the services may be medically necessary, our plan does not allow payment of network benefits to out-of-network providers except in urgent or emergent circumstances. Please see below for exact language from our Certificate of Coverage (CoC) "Provider Organization (PO) - Except in the case of Urgent Care or a medical Emergency, a Covered Person must obtain covered services and supplies from Network PO Providers to receive benefits under this Policy. Services and supplies obtained from Providers that are not Network PO Providers will generally not be covered." As this was related to services that do not qualify for urgent or emergent circumstances, nor is there an out-of-network agreement on file, the out-of-network denial stands.

If you have any questions, you can contact us at:

855-OSCAR-55

[redacted] | Oscar

Provider

Authorizations Payments Claims Menu

[redacted]

Care for [redacted]

See payment details

Overview

Updated Apr. 17, 2023

Not covered

Plan pays **$0**

Patient
[redacted]

Provider
[redacted]

Date of service
Start: Feb. 28, 2023
End: Feb. 28, 2023
Received: Apr. 17, 2023

TIN
[redacted]

Billed amount	$10,736.00
Negotiated rate	$0.00 ($10,736.00 overbilled)
Member owes	$10,736.00
Not covered	$10,736.00
Plan pays	**$0.00**

See a problem? Dispute this claim.

Documents

Date uploaded	File name	File type	Status
05/09/2023	[redacted]	Provider Dispute	Received
05/09/2023	[redacted]	Provider Dispute	Received

Claim details

[redacted]

[redacted] Claim [redacted] | Oscar

Service	Dates of Service	Billed	Negotiated rate	Member owes	Plan pays	Codes	Notes
00670	02/28/2023 - 02/28/2023	$10,736.00	$0.00	$10,736.00	$0.00		
Totals:		**$10,736.00**	**$0.00**	**$10,736.00**	**$0.00**		

Full claim codes:
242 Services not provided by network/primary care providers.
M115 This item is denied when provided to this patient by a non-contract or non-demonstration supplier.

Full claim notes: Services provided by an out of network provider are not covered under the plan.

CPT 00670: Anesthesia for procedures on the spine or spinal cord

This care was provided by an out-of-network clincian at an in-network facility. The No Surprises Act requires plans to apply the in-network benefit design under these circumstances.

Codes PR 242 and M115 have been applied to this claim by Oscar, both of which denote the claim has been denied because services were provided by an out-of-network clinician. Oscar has identified the full charge amount of $10,736 as the patient's responsibility.

[redacted]

Cigna Health and Life Insurance Company
SCRANTON CLAIM OFFICE
P.O. BOX 182223
CHATTANOOGA TN 37422-7223

[redacted]

Cigna.

[redacted]

[redacted]

[redacted]

How to Contact Us
Mail to the return address in upper left corner of this page
http://www.cigna.com
Phone: [redacted]

Provider Explanation of Medical Benefits

Understanding this Benefits Statement

This page provides a summary of the payments made this period.
The accompanying pages give more detail on the claims we processed for this period.
Please review both the front and back of each page to see how the benefit amounts shown in the Explanation of Medical Benefits Report were determined.

In the event a claim is denied.....

***Rights of Review and Appeal* - For Physician or Health Care Provider**

If you have questions or disagree with the payment identified on the Explanation of Medical Payment Report, you may ask to have it reviewed.
If you have a contractual agreement with Cigna HealthCare, please refer to the procedural guidelines associated with your Cigna HealthCare contract, or call our office for assistance.

***Federal Rights of Review and Appeal* - For Employee**

- Call Member Services at the toll free number on this Explanation of Benefits (EOB) or your ID card if you have questions regarding this EOB.
- If you are not satisfied with this coverage decision, you can start the Appeal process by submitting a written request to the address listed in your plan materials within 180 days of receipt of this EOB (unless a longer time is permitted by state law or your plan).
- Send a copy of this EOB along with any relevant additional information (e.g. benefit documents, clinical records) which helps to demonstrate that your claim is covered under the plan. Contact Member Services if you need further instructions on how and where to send you request for review.
- Be sure to include your 1) Name, 2) Operation Location/Group Number, 3) Employee/Patient ID number, 4) Name of the patient and relationship, and 5) "Attention: Appeals Unit" on all supporting documents.
- You are entitled to receive free upon request access to, and copies of, all documents, records and other information relevant to your claim for benefits.
- You will be notified of the final decision in a timely manner, as described in your plan materials. If your plan is governed by ERISA, you also have the right to bring legal action under section 502(a) of ERISA following our review.

Provider Summary

No Payment was made with this statement

The charges submitted were negated or offset by the deductibles, coinsurance, etc., or the patient(s) may be incurring liability for payment. See the following provider detail page for an explanation of how the benefits were determined.

[redacted]

[redacted]

Definition of terms used on the Provider Explanation of Medical Benefits Report section of this statement

Line:	Line item number.
Procedure Date:	Date you provided the service.
Procedure Code:	Code describing the service provided.
Adjusted Procedure Code:	Re assigned procedure code (See Note).
Billed Amount:	Dollar amount you charged for service.
Adjusted Procedure Code Amount:	Dollar amount due to adjusted procedure code.
Allowed Amount:	Dollar amount covered by benefit plan.
Not Covered / Discount:	Part of "Billed Amount" Not Covered under benefit plan or a Provider Discount.
Deduct / Copay Amount:	Portion of billed amount applied toward patient's deductible or copay (if any).
Coinsurance Amount:	The amount of the patient's coinsurance liability.
DRG / Per Diem / APC Type:	DRG (Diagnosis Related Group) / Per Diem / APC (Ambulatory Payment Classification) Category.
DRG / Per Diem / APC Number:	DRG (Diagnosis Related Group) / Per Diem / APC (Ambulatory Payment Classification) Code describing the service provided.
DRG / Per Diem Amount:	Dollar amount for DRG (Diagnosis Related Group) / Per Diem service provided.
DRG / Per Diem Benefit Amount:	Dollar amount payable by the benefit plan for DRG (Diagnosis Related Group) / Per Diem services.
Plan Benefit:	Dollar amount payable for services provided.
See Note:	If a portion or all of the charge is Not Covered, this is the written explanation of why it is Not Covered.
Other Insurance Paid:	The amount of another insurance carrier's payment.

Provider Explanation of Medical Benefits Report

Cigna.

Provider Number [redacted]

Provider Name [redacted]

Date through which claims where processed [redacted], 2023

THIS IS NOT A BILL
Retain for your Records

Page 1

Line	Procedure Date	Procedure Code	Adjusted Procedure Code	Billed Amount	Adjusted Procedure Code Amount	Allowed Amount	Not Covered/ Discount	Deduct/Copay Amount	Coinsurance Amount	DRG/ Per Diem / APC Type	DRG/ Per Diem / APC Number	DRG/ Per Diem / Amount	DRG/ Per Diem / Benefit Amount	Plan Benefit	Notes
[redacted]		99464		890.00			$890.00				00000	0	0	0.00	A0
Total				890.00		$0.00	890.00	$0.00							

Reminder: A coverage determination, prior authorization, or certification that is made prior to a service being performed is not a promise to pay for the service at any particular rate or amount. The patient's summary plan description governs amount payable, as every claim submitted is subject to all plan provisions, including, but not limited to, eligibility requirements, exclusions, limitations, and applicable state mandates.

PATIENT NAME: [redacted]

PATIENT #: [redacted] OPERATION LOCATION/GROUP#: [redacted] RECEIVE DATE: [redacted]/2023

PATIENT'S RELATIONSHIP TO SUBSCRIBER:DEPENDENT
SUBSCRIBER NAME [redacted]

PROVIDER NETWORK STATUS: OUT OF NETWORK
SUBSCRIBER#: [redacted]

REF#: [redacted]

BALANCE..... $890.00

** NOTES ON BENEFIT DETERMINATION:

IF YOU HAVE ANY QUESTIONS REGARDING THIS CLAIM, PLEASE INCLUDE THE REFERENCE NUMBER ON INQUIRIES.

SYS-BS1

FINAL PAYMENT DETERMINATION WILL FOLLOW THE REVIEW OF AVAILABLE FUNDS IN A CIGNA CHOICE FUND HEALTH REIMBURSEMENT ACCOUNT OR FLEXIBLE SPENDING ACCOUNT.

VIEW ELIGIBILITY, BENEFITS, AND CLAIM DETAILS AND GET PRECERTIFICATION ANSWERS FAST AT THE CIGNA FOR HEALTH CARE PROFESSIONALS WEBSITE (WWW.CIGNAFORHCP.COM)

CPT 99464: The provider is present during the delivery, at the request of the delivering provider, and during the basic stabilization of the newborn immediately after birth, typically when fetal distress or other complications are anticipated.

[redacted]

[redacted]

Provider Explanation of Medical Benefits Report

Cigna.

Provider Number	Provider Name	Date through which claims where processed		Page
[redacted]	[redacted]	[redacted] 2023	THIS IS NOT A BILL Retain for your Records	1

A0 CUSTOMER: YOUR PLAN WON'T PAY FOR THIS SERVICE UNLESS YOU GO TO A HEALTH CARE PROFESSIONAL IN CIGNA'S NETWORK.

[redacted]

[redacted]

[redacted]

Texas

Claim Fax

CPT 99469: inpatient care of a critically ill neonate or infant 28 days or younger

UMR

Please refer to the disclaimer on the first page for important information.
If you need additional information, please call 877-303-2414. When prompted for the employee's member ID, enter the following passcode: [redacted] You will then be connected with a customer service representative. This passcode is only valid one time and expires two weeks after the date of this fax.

Employee name:	[redacted]	Group number:	[redacted]
Employee ID:		Employer:	
Patient name:		Effective date:	
Patient birth date:		Termination date:	
Patient account number:		Date of service requested:	02/19/2023
Provider network:	[redacted]		

Claim Summary

Claim number:	[redacted]	Service dates:	02/19/2023 - 02/19/2023	Amount billed:	$2,891.00
Claim type:	Medical	Processed date:	05/15/2023	Amount paid:	$0.00
Claim status:	Completed	Provider name:	[redacted]	Patient responsibility:	$2,891.00
Status detail:		Provider tax ID:	[redacted]	Other insurance paid:	$0.00
Network status:	Your Claim Was Processed At The Out-Of-Network Level Of Benefits				

Claim Detail

Servicing provider name:	[redacted]			Amount billed:	$2,891.00
Service dates:	02/19/2023 - 02/19/2023			Provider discount:	$0.00
Procedure code:	99469			Amount not payable:	$2,891.00
Occurrence:	0			Allowable amount:	$0.00
Clinical remark:				Amount paid:	$0.00
Processed date:	05/15/2023			Patient responsibility:	$2,891.00
Type of service:	Medical examination			Deductible:	$0.00
ANSI:	242			Coinsurance:	$0.00
				Copay:	$0.00
Payment type:	Number:		Paid to:	Other insurance:	$0.00
Check	[redacted]		Provider	Withhold:	$0.00
Other amounts not paid:	Description:				
$2,891.00	Charge Denied. Provider Out Of Network. Service Must Be Performed In-Network. See Schedule Of Benefits In Your Benefit Booklet.				

Claim Summary

[redacted]

[redacted] | Oscar

Provider

Authorizations Payments Claims 9 Menu

[redacted]

Care for [redacted]

See payment details

Overview

Updated Apr. 17, 2023

Not covered

Plan pays **$0**

Patient
[redacted]

Provider
[redacted]

Date of service
Start: Feb. 28, 2023
End: Feb. 28, 2023
Received: Apr. 17, 2023

TIN
[redacted]

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[redacted]

Mr. MURPHY. All right, Mr. Becerra, can you tell me how many times does HHS level this $10,000 monetary fine against insurers who are violating the coverage protections?

Mr. BECERRA. Congressman, I don't think I have that particular information with me, but I can get you that information.

Mr. MURPHY. Can you take a guess?

Mr. BECERRA. It wouldn't be worth it for me to take a guess.

Mr. MURPHY. My question is, are we doing this at all?

Mr. BECERRA. We are——

Mr. MURPHY. I just—I think, you know, going on—I am going to go on a Medicare Advantage rant here in a second—I think we are really protecting our insurance companies way too much. I would like to know that information, hopefully by the end of next week, how many times the Department has levied that fine.

Mr. BECERRA. Let me try to get back to you as quickly as we can.

Mr. MURPHY. All right, thank you. I think we have shared interests, bipartisan interest in what I think the debacle has become in Medicare Advantage plans. I think it was incepted with a very, very good idea to try to deliver more personable, more expedient care in a more efficient system. But just like our pharmacy benefit managers, they have gone awry.

We now—it is my understanding we have MA plans that have received tens of billion dollars of overpayments. Is that your understanding?

Mr. BECERRA. There are clearly signs of overpayment. I won't categorize the dollar amount.

Mr. MURPHY. You know, this is critical because, you know, when you pop up Joe Namath on the television, everybody feels good about it. And I want our seniors to have care. But when we are adding 10,000 seniors to the Medicare rolls every day, and we are not providing them with care—my system, which—we have 74 percent government payer. Our margin is razor thin; razor thin in delivering care. We have decided to stop taking Medicare Advantage.

We have to fix this system. We have to reform the system, and I am very disappointed that we are not being presented now with a plan, even an offer of a plan to fix the disaster that is going to happen with Medicare.

Mr. BECERRA. Congressman, we have just published rules to try to provide reforms. I will tell you that we are prepared to continue those reforms. We continue to receive letters from your colleagues saying we are going too far.

Mr. MURPHY. I am happy to work with you. I know there are many things that may not be as conservative as people want, but when we are having the pyramid flipped upside down on who is paying into the system, the age right now—we are seeing that it is at 70—or, excuse me, 65 before, and now we are having 4 percent of our individuals live into their early 90s, the numbers just don't work. We have to fix that system.

Mr. BECERRA. Yes, and I know you are—I know you know what you speak of because you are in this field. I very much would look forward to working with you on that.

Mr. MURPHY. Excellent.

Thank you, Mr. Chairman, I yield back.

Chairman SMITH. Ms. Sewell.

Ms. SEWELL. Thank you, Mr. Chairman, and welcome, Secretary Becerra. Today I would like to spend my time talking about two topics that are really important to my constituency: expanding Advance Premium Tax Credits and continued support for rural health providers.

I am proud of the Biden-Harris Administration for taking the necessary steps to close the coverage gap in this country. As a representative of Alabama's 7th congressional district, a district with high rates of chronic diseases yet in a state that has not expanded Medicaid, closing the coverage gap remains a top priority for me. The Advanced Premium Tax Credits were established by the Affordable Care Act. And thanks to the American Rescue Plan, more Alabamians can benefit from this tax credit.

Prior to ARPA, the consumers with household incomes above, 400 percent of the Federal poverty line were excluded from qualifying for these tax credits. But in 2023 almost 240,000 Alabamians enrolled in the marketplace health plans received the tax credit. This means that more citizens in my home state, which did not expand Medicaid, can afford health care. This is really unprecedented and necessary in states that did not expand Medicaid.

So, my question to you, Mr. Secretary, is with the Advance Premium Tax Credits being vital to reducing the coverage gap, is your agency committed to working with Congress to expand and extend this subsidy expansion beyond the 2025 timeframe?

Mr. BECERRA. Congresswoman, that is a priority of the President's, yes.

Ms. SEWELL. Absolutely. I also remain committed to supporting the hospitals in my district. I applaud the Biden-Harris Administration for the new option available to support rural hospitals through rural emergency hospital conversions.

Just Monday I spoke about the challenges of access to emergency medical care in my district, issues from hospital closures to low-ground ambulance reimbursement rates have really caused a problem all across this nation, and it was just exacerbated during the COVID–19 crisis.

So, Dr. [sic] Becerra, can you share how the new rule emergency hospital designation has been helping rural hospitals provide emergency care?

And beyond the $5 million in technical assistance, how is your agency helping to expand this designation in communities across this country?

Mr. BECERRA. Congresswoman, the new designation, it becomes very important for rural emergency hospitals because it gives them enhanced support.

We know that if some of these facilities are going to survive, we are going to have to do something differently because they provide that critical care. And it is often times very expensive care. And it is not something that a facility can rely upon having at all times. So it is a very difficult financial proposition for a lot of these facilities.

We are hoping that this new designation of rural emergency hospital will help them survive in a place where, if they were to go, then families would really be in a hurt.

Ms. SEWELL. Not just families, whole communities really depend upon these hospitals. So, I wanted to say hats off on this designation, and do everything you can to try to expand that. Thank you.

I yield back the balance of my time.

Chairman SMITH. Mr. Kustoff.

Mr. KUSTOFF. Thank you, Mr. Chairman. Thank you, Mr. Secretary, for appearing today.

Mr. Secretary, if I can, last year in the hearing to discuss the President's fiscal 2024 budget request you were asked about the FDA's decision to change the REMs for mifepristone to no longer require an in-person visit to a medical professional. Now, I wrote down the part—in your answer you said, "You don't just get access to it because you want it. You still have to have it prescribed," and you were referring to chemical abortion drugs like mifepristone.

My question is, there are websites where users can purchase chemical abortion drugs delivered to their doorsteps, in many cases without a prescription. There is a website called PlanCpills.org. It runs a page, and it is called, "Where people get abortion pills in Tennessee." I represent the 8th congressional district of Tennessee. When you go to that page, there are 26 external websites "for people who want abortion pills by mail without consulting a clinician."

Now, some of these sites, Lifeeasyonpills.org, Bestabortionpill.com, Abortionease.com, drugs99.com, HomeabortionRx.com, and it goes on. So I have got two questions for you Mr. Secretary.

One, is the FDA and HHS keeping track of websites that mail these untested pills to Americans?

And my second question, is will you commit the FDA resources to warn the American public of the grave risks posed by the use of chemical abortion drugs acquired through unauthorized websites?

Mr. BECERRA. Congressman, thank you for the question.

I won't presume to speak specifically for the FDA in how they are conducting some of the work that they are doing. They are very—we consider them a very independent agency. But what I will tell you is that any time drugs are put up for public consumption that do not abide by the standards set by the FDA, we have to make sure every American understands that they are taking major risks. And the FDA has the authorities to do enforcement activity, and I know they are trying to keep pace with a lot of this fraudulent activity that is occurring.

And what I can do is get back to you on specifically what FDA is doing in this regard. But no doubt we have to make sure people understand you are putting yourself in peril if you go after—if you try to purchase some of these medicines that are not officially available.

Mr. KUSTOFF. And without a prescription, right?

Mr. BECERRA. And without a prescription.

Mr. KUSTOFF. And just so everybody knows the chain of command, anybody who is maybe watching this hearing, the FDA is an agency under HHS, correct?

Mr. BECERRA. Yes, it is.

Mr. KUSTOFF. You have got ultimate authority under—over FDA.

Mr. BECERRA. Ultimate authority in most cases. But because they are a regulatory body, we give them a great deal of deference so they can make regulatory decisions without interference from other sources.

Mr. KUSTOFF. Fair enough. What these websites are doing, at least the way I described it, it is not lawful, right?

Mr. BECERRA. The way you have described it does not appear to be lawful.

Mr. KUSTOFF. Okay. And I realize you have got to accept what I am saying. If I am right, shouldn't that require from you a referral to law enforcement to investigate these things, and maybe shut them down so that they don't distribute these drugs which may or may not be tested, and certainly that are being dispensed without a prescription from a clinician?

Mr. BECERRA. And Congressman, as I said, I know that FDA tries to get on some of these cases as quickly as it can. You could probably imagine how many vaping manufacturers are out there trying to sell products without the right—actually, in most cases, vaping should not be available out there. And it is difficult to keep pace with all that is coming out, especially on the Internet.

But I could try to get back to you to let you know precisely what FDA might be doing.

Mr. KUSTOFF. Well, doesn't it seem ripe, r-i-p-e, for the Secretary of HHS to refer these types of activities to Federal law enforcement?

Mr. BECERRA. I will make sure that—because—and again, remember, FDA's enforcement powers will differ from what local law enforcement powers——

Mr. KUSTOFF. I got it, I am a former Federal prosecutor.

Shouldn't you be referring these websites and the other dispensers to Federal law enforcement?

Mr. BECERRA. If you wish to give us that information that you have already tracked, we would more than be willing to make sure we provide that to the appropriate authorities.

Mr. KUSTOFF. I have just given it to you, but we will send something else to you, and——

Mr. BECERRA. It would help to have something in writing.

Mr. KUSTOFF [continuing]. We would appreciate a response.

Mr. BECERRA. Thank you.

Mr. KUSTOFF. Thank you, Mr. Secretary.

I yield back.

Mr. BECERRA. Thank you very much.

Chairman SMITH. Thank you. Mr. Steube.

Mr. STEUBE. Thank you, Mr. Chairman.

Mr. Secretary, your department has cleared a CMS rule that is waiting for White House approval. It would overhaul the Medicare Advantage enrollment process, undermining the integrity of the program, and pushes us closer to Medicare for all.

In my district I represent a constituent with nearly 20 years of Medicare experience who has served over a quarter million people who said of your agency's push—and I quote—"The proposed rule will harm the most vulnerable beneficiaries because they are dependent on support to access the ongoing health services they require for their own well-being."

In the contract year 2025 Medicare Advantage and Part D proposed rule, 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, or 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.

The HHS proposal would limit fees in the enrollment market for everyone, not just the bad actors who are aggressively pressuring seniors to sign up for a plan.

This committee has been engaged on this issue. I led a letter with a majority of 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.

Mr. Secretary, are you familiar with the letter that we sent to CMS?

Mr. BECERRA. I believe I am.

Mr. STEUBE. So, you have read it?

Mr. BECERRA. I believe I am familiar with what it says. I couldn't tell you that I had a chance to read it in the recent past.

Mr. STEUBE. It is signed by me and Mr. Buchanan, Mr. Adrian Smith, Mr. Kelly, Mr. LaHood, Mr. Wenstrup, Mr. Ferguson, Mr. Estes, Mr. Hern, Mrs. Miller, Ms. Tenney, Ms. Malliotakis, Ms. Van Duyne, and Mr. Carey.

Are you familiar with the response letter that we received from CMS?

Mr. BECERRA. I believe you just received it not long ago, right?

Mr. STEUBE. It is dated March 1, 2024. Have you reviewed this?

Mr. BECERRA. Again, it would have been a while ago.

Mr. STEUBE. Well, it is only, like, 20 days ago. So you don't remember reviewing the response from CMS?

Mr. BECERRA. Congressman, a lot of things happen in 20 days.

Mr. STEUBE. Well, I mean, you were coming to this hearing, and you had a letter to CMS, which—it is the agency underneath you, right?

Mr. BECERRA. Congressman, I am going through a whole lot of stuff. What I will tell you is I do recall the issue. Can I tell you that I read it in the last day or so? I could tell you for a fact not in the last day. I know I have been briefed on these issues.

Mr. STEUBE. Okay, Mr. Chairman, I would like to add to the record both our letter, which is the majority of the Republicans on this committee, and I would also like to add to the record the response from CMS.

Chairman SMITH. Without objection.

[The information follows:]

Congress of the United States
House of Representatives
Washington, DC 20515

January 12, 2023

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Dear Administrator Brooks-LaSure,

We write to request more information regarding the Centers for Medicare and Medicaid Service's (CMS) Contract Year (CY) 2025 Policy and Technical Changes to the Medicare Advantage Plan Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Programs of All-Inclusive Care for the Elderly and Health Information Technology Standards proposed rule (or the "proposed rule").

Medicare Advantage (MA) serves as a key option for seniors and patients who want to receive higher quality, more coordinated care than fee-for-service beneficiaries. The Congressional Budget Office projects that MA will grow to 62 percent of Medicare beneficiaries by 2034. As MA continues to grow it is imperative that we ensure the program remains viable and that seniors and individuals with disabilities eligible for Medicare can make informed decisions on their health care coverage.

Field marketing organizations (FMOs) provide vital support to these independent agents, offering services such as contracting, credentialing, compliance assistance, and technology support. The proposed rule will have significant implications for Medicare beneficiaries, FMOs, and the numerous agents and brokers who play a pivotal role in aiding millions of seniors in navigating the complexities of Medicare plan options.

We recognize the concerns that prompted these regulations but urge you to ensure efforts to address the integrity and accessibility of the Medicare program do not result in unintended consequences that jeopardize patient access to quality care. We therefore request that you respond to the following questions:

1. CMS is proposing to redefine compensation for agents and brokers who help seniors choose MA and MA prescription drug (MA-PD) plans to include administrative payments, which cover marketing, recruitment, customer service, new technology, and training among other services.
    a. How did CMS arrive at a $31 increase to cover these services?
    b. What data did CMS review to inform the decision to provide a $31 increase to cover these services? Please share this data with us.
    c. How did CMS calculate that $31 would be sufficient to compensate the services covered by administrative payments?

d. How many Medicare Advantage enrollees does CMS estimate rely on a licensed agent/broker?

2. How might the removal of administrative fees – which support the operations of local, independent agents – potentially hinder beneficiaries' access to and utilization of services they currently receive?
3. What impact does CMS project this rule will have on agents and brokers ability to assist beneficiaries with Special Needs Plans (SNPs)?

As the Medicare community considers these proposed changes, we urge CMS to closely examine the potential impacts on all stakeholders, especially our Medicare eligible senior citizens and individuals with disabilities accessing care.

We appreciate the opportunity to provide input on this critical matter and look forward to your prompt response.

Sincerely,

W. Gregory Steube
Member of Congress

Vern Buchanan
Member of Congress

Adrian Smith
Member of Congress

Mike Kelly
Member of Congress

Darin LaHood
Member of Congress

Brad R. Wenstrup, D.P.M.
Member of Congress

A. Drew Ferguson, IV
Member of Congress

Ron Estes
Member of Congress

Kevin Hern
Member of Congress

Carol Miller
Member of Congress

Claudia Tenney
Member of Congress

Beth Van Duyne
Member of Congress

Nicole Malliotakis
Member of Congress

Mike Carey
Member of Congress

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

March 1, 2024

The Honorable W. Gregory Steube
U.S. House of Representatives
Washington, DC 20515

Dear Representative Steube:

Thank you for your letter requesting information from the Centers for Medicare & Medicaid Services (CMS) on the Contract Year (CY) 2025 Policy and Technical Changes to the Medicare Advantage (MA) Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Programs of All-Inclusive Care for the Elderly and Health Information Technology Standards proposed rule (CY 2025 MA and Part D proposed rule).[1]

We agree that it is critical to ensure that as the MA Program continues 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.

[1] Available at https://www.federalregister.gov/documents/2023/11/15/2023-24118/medicare-program-contract-year-2025-policy-and-technical-changes-to-the-medicare-advantage-program.

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.

The proposed single compensation rate is based on calculations that we described in detail in the proposed rule. As part of this proposal, CMS proposed to increase the compensation rate to add certain appropriate administrative costs. Specifically, we proposed that beginning in 2025, the compensation rate for agents and brokers for new MA enrollments will be increased to account for licensing and training and testing requirements specified in 42 CFR 422.2274(b), as well as recording requirements specified at 42 CFR 422.2274(g)(2)(ii), and that the total value would be updated annually. As discussed in the proposed rule, the proposed increase reflects certain assumptions including the number of agent and brokers selling Medicare, the number of new enrollees per year for non-employer MA plans and stand-alone PDPs, and the percentage of new enrollments effected by agent brokers.

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. Thank you for your letter and for your commitment to improving the MA program. If you have additional questions or concerns, please have your staff contact the CMS Office of Legislation at (202) 690-8220. We will share this response with the co-signers of your letter.

Sincerely,

Chiquita Brooks-LaSure

Mr. STEUBE. Do you know why CMS didn't respond to us, the committee of jurisdiction, before sending the rule to final review?

Mr. BECERRA. Congressman, the process that CMS undertakes takes quite a while. You would have known the process was underway.

Mr. STEUBE. Right. We sent the letter January 12.

Mr. BECERRA. Our process would have begun way before then.

Mr. STEUBE. So, your answer is you don't know.

Mr. BECERRA. No, I am telling you that we began a process that—we engage with Members of Congress as they reach out to us.

Mr. STEUBE. All right. This is the committee of jurisdiction, correct?

And you had the majority of the majority on this committee send a letter to CMS. And I am simply saying, why is it that you guys sent the rule to finalization before responding to the committee of jurisdiction's majority?

Mr. BECERRA. Congressman, remember that the fact that we send the proposal to another interagency within the Federal Government doesn't mean it is done, that there won't be any changes that are made.

Mr. STEUBE. You sent it to the White House at this point.

Okay, well, the response letter we received from the CMS administrator says—and I am quoting—"The proposed single compensation rate is based on calculations that we described in detail in the proposed rule." I just reviewed the letter again. It is not detailed in the proposed rule. There is barely anything there, and CMS is proposing a $31 cap for these services.

Do you believe that $31 is a fair amount for these services?

Mr. BECERRA. Congressman, what I can tell you, what I recall is that we are trying to avoid having incentives that would have a broker or dealer direct patients to a particular type of plan over another, which may not be the best—in the best interest of a patient.

Mr. STEUBE. But as I just described, there is a ton of other very good businesses out there that are providing services to my constituents and everybody else on this committee to put them in the right plan.

Mr. BECERRA. Well,——

Mr. STEUBE. What I am asking you is, do you believe that the $31 that is in this rule promulgated by CMS that you approved is a fair amount?

Mr. BECERRA. I believe the rule tries to attack a problem of having patients being referred to particular plans not because——

Mr. STEUBE. But you can't use a sledgehammer for a needle. That can't be the approach.

Mr. BECERRA. No, I——

Mr. STEUBE. I am just simply asking if you think $31 for what these people do is a fair amount.

Mr. BECERRA. Again, what we are trying to do is prevent the steering of patients into plans that may not be in——

Mr. STEUBE. Do you know any of the services that are provided by some of these organizations?

Mr. BECERRA. I am sorry.

Mr. STEUBE. Do you know any of these services that are provided by the FMOs?

Mr. BECERRA. Do I know——

Mr. STEUBE. That you are now putting $31 as the amount that they do.

Mr. BECERRA. Are you talking about the——

Mr. STEUBE. I have five seconds left, so I will give you examples: IT infrastructure, logistics, human resources, marketing, partnership, broker training support, beneficiary enrollment support, compliance, retention, leadership and management, which—a number of these individuals rated about $615, and the rule is saying $31.

I just think that this needed to be addressed. You had members of this committee that were concerned about it, and we were basically ignored for two months, and they promulgated the rule anyways. And I would expect that the committee of jurisdiction would get a little bit more respect, especially from a former member of this committee.

I yield back.

Chairman SMITH. Ms. Moore.

Ms. MOORE of Wisconsin. Thank you, Mr. Chairman, and welcome, Secretary Becerra.

I think before I start asking you some questions, I want to clear the air on a couple of topics that have come up from Mr. Smith and Mr. Buchanan regarding no TANF for people above 200 percent of the poverty level. You said you were taking comment on that, so I am going to give you comment.

I do think that the framework for TANF was to respect flexibility. And although the quarterback, Brett Favre—and folks, you misused it in Mississippi—I do think that retaliating against the fund and people who need it is the wrong move, so that, you know, taking $5 million a year from the contingency fund, I think, is wrongheaded. I think it is wrongheaded to say that you won't serve anybody above 200 percent of the poverty level.

You know, when you start thinking about the kinds of things that you say you want to do under TANF, you know, some TANF monies is used to supplement the EITC, the state child tax credit. And so, before you fall into the trap of my colleagues on the other side by nodding your head to that, I would want you to think that through.

I was really pleased to see that the budget was addressing mental health and substance abuse problems. Once again, I have a bill that would provide perinatal mental health and substance abuse problems for pregnant women from the earliest stages of pregnancy until one year afterwards. And I think that you don't want to upend that with some sort of agreement about 200 percent of the poverty level. So that is my comment on that.

And with regard to drug testing TANF recipients, I say that, you know, I am not a lawyer, so I don't know much about the 14th and 15th Amendment, and due process, and equal protection, and stuff. But I know that if you are going to just pick out people who receive TANF, there are a lot of people who receive entitlements in our country, and you are not drug testing them. So maybe we should

expand the list of people who receive monies up to and including some very wealthy people who receive tax credits and tax benefits.

That being said, let me ask you some questions I intended to ask you before their testimony. I was really interested in understanding how HRSA, the HRSA opt-in modernization program, whether or not that can fill the gap in access for people of color to be included on the deceased donor transplant list. Will this help to decrease the disparity?

Mr. BECERRA. Congresswoman, I apologize. You are going to have to repeat the question.

Ms. MOORE of Wisconsin. All right, I will ask another question. How about the Medicaid unwinding? There are 12 million people out there who do not receive Medicaid because of procedural reasons. And so, is there anything that your department is doing to help with the states to do outreach to these 12 million people that lost Medicaid?

Mr. BECERRA. Congresswoman, since before last year we started working with governors and states about the Medicaid unwinding process, and making sure that as they go through the redetermination process, that they are making sure that for bureaucratic reasons people aren't kicked off of indispensable——

Ms. MOORE of Wisconsin. Well, they are being kicked off. So, is there any effort to make sure we contact or reach those people to get them back on?

Mr. BECERRA. Yes, we have engaged in a number of—the one where we were able to get 500,000 to 600,000 kids back onto the rolls because we found that the states were not applying the procedures properly——

Ms. MOORE of Wisconsin. Okay.

Mr. BECERRA [continuing]. One of the methods.

Ms. MOORE of Wisconsin. Good, thank you. I don't have much time.

I have legislation to reduce the tax disparity affecting the health professionals who receive the Indian Health Service's scholarships. So does your budget, which does a lot for Native Americans, address the tax gap between Indian Health Service scholarship recipients and others?

Mr. BECERRA. Gosh, I will have to get back to you on that one.

Ms. MOORE of Wisconsin. Okay, thank you. Let me ask the question that you didn't hear before.

There is a big disparity in organ transplantation for people of color and other people. The HRSA opt-in modernization, is that going to help people of color access the donor list?

Mr. BECERRA. The whole purpose behind the reform and the legislation that recently passed is to change the dynamic, so a monopoly doesn't run the system, and it is done on a more competitive basis. And the system that is in place to make sure who gets transplants is done fairly throughout the country is now going to be done without profit or other motive involved.

Ms. MOORE of Wisconsin. Okay, just one final question.

The Principal Illness Navigation, the PIN, for cancer and stuff, do you think that the kidney transplantation would benefit from this PIN navigation system?

Mr. BECERRA. Congresswoman——

Ms. MOORE of Wisconsin. Is that a possibility?

Mr. BECERRA [continuing]. You are going to win the prize for giving me the hardest questions to answer that I wasn't prepared to give you a direct answer to. So let me get back to you on that one, as well.

Ms. MOORE of Wisconsin. Thank you so much. And thank you, Mr. Secretary.

And thank you, Mr. Chairman.

Chairman SMITH. Thank you. Ms. Tenney.

Ms. TENNEY. Thank you, Mr. Chairman. Thank you, Ranking Member——

Ms. MOORE of Wisconsin. [Inaudible.]

Chairman SMITH. Ms. Tenney is right after you, Ms. Moore.

Ms. MOORE of Wisconsin. I adore Ms. Tenney——

Chairman SMITH. Yes, I didn't call you Ms. Tenney, but thank you. [Laughter.]

Ms. TENNEY. Are we ready?

Thank you, Ms. Moore. I always love hearing your testimony. Thank you for the great questions, for really putting the Secretary on the hook. I appreciate that. You always do a great job.

Thank you, Mr. Secretary, for being here. Obviously, it is very important to have you here.

And I know many of us are, at least on our side of the aisle, are concerned about the Department of Health and Human Services' fiscal year 2025 budget request and some of the political priorities that seem to be permeating this budget over the needs of the American people. And I want to just kind of jump into some of the questions.

My first one is the co-chair of the Election Integrity Caucus says in response to President Biden's executive order—it is 14019, I am not sure if you are familiar with it—your department has announced that it plans to turn more than 1,400 community health centers into voter registration hubs. Implementing this policy will require these essential safety net providers to take their focus off rural, disadvantaged communities they serve on and to get involved in political activity.

And you just cited to Dr. Murphy that we really have to be focused on our core mission, which is the mission of providing health care, and good health, care to our communities. Do you think it is appropriate for the Federal Government under this executive order to be engaging in electioneering or these vote-harvesting types of drop boxes and political activity while they are doing their official jobs as members of the Health and Human Services——

Mr. BECERRA. Congresswoman——

Ms. TENNEY [continuing]. Government payroll?

Mr. BECERRA. Thank you for the question.

Those community health centers cannot engage in electioneering. That would be a violation of Federal law. And simply by providing people with access to information so they could register to vote is not a violation of Federal law.

Ms. TENNEY. How about providing—having staff have to monitor drop boxes and other political entities over there, is that something that the people from Health and Human Services would be doing at this election coming up?

Mr. BECERRA. What you have just described does not sound anywhere near what the job would be——

Ms. TENNEY. But the executive order specifically asks Federal agencies to engage in this type of political activity. Is that something you are going to prohibit, as the Secretary?

Mr. BECERRA. I think you have inaccurately described it. But if you have the executive order and read me that, I could tell you what it means. But I know——

Ms. TENNEY. It is 14019. We have talked about—I mean, it is on my—you can go to my website, Tenney.house.gov. I explain my votes there, too.

But let me move on because I think it is really dangerous for our federal employees, who are on our government payroll, to be engaging in electioneering to the extent——

Mr. BECERRA. They can't do that. It would be a violation of law.

Ms. TENNEY. But somebody has got to monitor and make sure we have election integrity there. So I assume that—you know, who is going to be monitoring this, other than maybe our—some of our—I just want to be sure that you, as Secretary, are making sure there is a wall between the people who are serving the public for health care reasons and those who are engaging in political activities.

Mr. BECERRA. We make it clear to all of our employees that——

Ms. TENNEY. Will you be doing that to make sure that happens?

Mr. BECERRA. We always make it clear to them that they cannot engage in activities that cross the line.

Ms. TENNEY. Including what would be under executive order 14019?

Mr. BECERRA. That is where I disagree with you. I don't believe there is any electioneering that would be done by Federal Government personnel.

Ms. TENNEY. You think a drop box is something that—who monitors a drop box at a federal agency?

Mr. BECERRA. As I said, if you show me what you are referring to in the executive order——

Ms. TENNEY. We would be happy to provide that. I want to get to the next question.

So, I know that the Administration's—I want to just ask you quickly a question. It could be your personal view, or it could be the view of the Administration that you serve. Do you consider yourself, when it comes to the issue of abortion, as pro-choice?

Mr. BECERRA. I am here testifying as the Secretary of Health and Human Services. I have a pretty long record about where I am personally, but I am here today as the Secretary of Health and Human Services. So, I would answer the question, if you would like, as the Secretary of Health and Human Services.

Ms. TENNEY. That would be great, yes.

Mr. BECERRA. And so, I would answer you by saying that we provide every type of health care service available to the American public. We will protect every American's right to access the health care that they are entitled to under the law.

Ms. TENNEY. So, if a woman wants to choose to have a baby, that service is protected, as well.

Mr. BECERRA. Every service that is entitled to—that a person is entitled to under the law, if we have a role in providing that service, we will make sure that that right is protected.

Ms. TENNEY. Thank you. I greatly appreciate it, because under your leadership HHS is expected to finalize a rule that will block crisis pregnancy centers from receiving Temporary Assistance for Needy Families, otherwise known as TANF funding. These pregnancy centers are dotted throughout the country that do provide pregnancy testing, testing for sexually transmitted diseases, prenatal pregnancy education, ultrasounds, adoption referrals, and all—a number of items for needy families. And TANF is about keeping families together, I assume.

So, I want to make sure that you are going to make sure—well, why isn't this rule covering pregnancy crisis pregnancy centers, if indeed you are looking for access for all families and all choices they make, whether they choose to have the child or choose the abortion route?

Mr. BECERRA. Congresswoman, I think you have mischaracterized what the rule would do.

So long as people—entities qualify to receive the money will be providing the services that are required by the statute and regulations, they will receive their monies.

Ms. TENNEY. But it specifically prohibits crisis pregnancy centers from receiving money.

Mr. BECERRA. No, it doesn't. No, it doesn't. It prohibits anyone that is not providing the services that are—they are obligated to provide if they want to receive the money.

Ms. TENNEY. Thank you. I appreciate it.

Chairman SMITH. Mr. Fitzpatrick.

Mr. FITZPATRICK. Thank you, Mr. Chairman, for holding this hearing.

Mr. Secretary, thank you for being here today. During the 118th Congress my office has submitted approximately 160 individual cases on behalf of my constituents to HHS, specifically regarding their Medicare coverage. And this is a period of just over one year now in this Congress.

Just yesterday a constituent of mine who has diabetes contacted me regarding Medicare's inability to address payment processing. Her insulin pump is covered under Part B, yet she was presented, essentially, with only two options: number one, wait until the end of the week, and hopefully the payment processing issue would be resolved; or she could pay $300 for traditional insulin, which her Part D plan clearly does not fully cover.

As you know, Mr. Secretary, insulin is a—it is a lifesaving drug for diabetics, and expedited back-end payment processing is essential for those that rely on receiving insulin in a timely manner. So, my first question, sir, if you could, just share with us what HHS is doing to speed up this payment processing because this does have a real impact on people's lives, and it can become a very frightening experience for them.

Mr. BECERRA. Absolutely. And Congressman, let me begin by first saying, if you would like, we can be in touch with your staff because, if your constituent is still having issues, we have had conversations directly with the payers, the various insurance compa-

nies, and we have had—we have a contact for them so that, if there is an issue for that provider being able to provide a service, that we can get that provider connected with the payer so that there is no delay.

Mr. FITZPATRICK. That is great. Thank you.

Mr. BECERRA. So, we will work on that with you. But just to give you a sense of what we have done, immediately we started working with UnitedHealth Group to try to understand what they were going to do to make sure payments did not stop, even though the billings were not coming across the threshold.

We are also trying to make sure that every other payer—because many of these payers, as you know, receive Medicare and Medicaid dollars, so we have already paid them, the Federal Government has already given them money for the services they are going to provide, and yet they are not paying for the services that these patients need. And so, we are trying to make sure that they show us what they are doing to make sure payments will occur, even if in advance, and then you reconcile the differences later.

So far, as far as Medicare and Medicaid, we have made sure that some 6,000—nearly 6,000 doctors, hospitals, and other providers are able to receive from Medicare advance payment. So far, the total that we have put out to these providers, doctors, hospitals, and other providers so far is over $2.5 billion.

Mr. FITZPATRICK. Okay. Thank you, sir. I also want to use the remainder of my time to talk about the recent cybersecurity attack.

Obviously, numerous medical practices in our community have reached out to us. These cyber attacks, as you know, sir, have the potential to impact billing and cash flow, Medicare submissions, eligibility checks for patients, and impact transmission for electronic prescriptions, many of which are heavily relied on by people across the country, particularly our seniors.

Given the already existing constraints on local practices that they are facing like cuts to Medicare reimbursement, high inflation, labor shortages, and the like, including overall payment delays, can you share with us, you know, HHS's plan to address those pressing concerns that our constituents are facing?

Mr. BECERRA. So, if the question is on cybersecurity and how we move forward——

Mr. FITZPATRICK. Yes.

Mr. BECERRA [continuing]. We have put out a plan, and it is open for comment. It was subject to comment and further discussion.

What we believe is that everyone in the sector has no choice but to, you know, get with it, understand that you can't leave your security doors unlocked. You got to close those doors from cyber attack. And so, what we are suggesting is that we are willing to put in—I believe the President's budget has about a—over $1 billion, $1 billion, $200 million to help providers begin to transition to greater cybersecurity.

But after a point in time of providing support, essentially carrots to get providers to, you know, amp up their security. At some point we are all going to be in danger if somebody doesn't, so we want to make sure everyone has done something.

So first we are providing support and incentives. But after a while, if you haven't done what it takes to protect not just yourself but everybody who depends on you, then you are going to have to start paying a bit of a price for not having joined the rest of the team.

Mr. FITZPATRICK. Got it. Thank you, sir.

I yield back, Mr. Chairman.

Chairman SMITH. Mr. Beyer.

Mr. BEYER. Mr. Chairman, thank you very much. And, Mr. Secretary——

Mr. BECERRA. Good to see you.

Mr. BEYER. It is good to have you here. I want to just add my voice to the concern about the new TANF rule, specifically about high school dropout prevention programs. Some of the most important ones around the country, Jobs for America's Graduates and others, rely on TANF funds to pay for it. And the argument, of course, is better for the people that don't need to go on TANF in the first place. And I hope that you and your folks will pay attention to that. What we would like to do is ultimately reduce the overall TANF burden. And that is the old pay me now or pay me later piece.

I also want to thank you and applaud your dedication to suicide prevention and mental health. You know, it is really important that we adequately fund the 988 number, the CDC's suicide prevention effort. I believe there were 507,000 calls alone in the month of January. It is making an enormous difference.

And I also want to applaud you for your work on long COVID. You know, we have done a lot. Last week we had Long COVID Awareness Day, but we still don't really understand post-illness-acquired conditions, and now is the time to ramp up for the lessons learned.

You know, President Biden is leading on the AI revolution, and I know you have testified its consideration in your budget. You have been using artificial intelligence in health care—the FDA, specifically—for years. But can you talk about what gaps you see in your existing regulatory authorities and funding when it comes to supporting AI innovation in health care?

Mr. BECERRA. Congressman, great question, and thank you for the work that you have done on this subject.

We don't have enough authority to really go in and see behind the curtain of what is going on with a lot of these entities that are using AI. We would like to make sure, for example, that the algorithms that they are using won't end up discriminating against people because the data they are using to input into these algorithms don't take into account the needs of particular communities.

We would also like to make sure we have a better sense of how they are going to deploy some of this AI technology, because it could be done in a way that, once again, it leaves out certain communities if they don't happen to fit the criteria or the perspective of that particular algorithm.

AI can be a tremendous asset. It can help produce efficiency, accelerate access. At the same time, if we are not careful, it will do it only for some, but not all Americans. And so, our interest is being able to look behind the curtain to make sure that the plat-

forms that are being used have equity in them from the very beginning.

Mr. BEYER. Yes, very good. Thank you very much.

There is a lot we can also learn from the electronic health records conversation with respect to AI. And one of the ideas has been an assurance lab, which I know the FDA Device Center chief has been considering. Can you talk about if this is something HHS is seriously pursuing, the whole notion of assurance labs?

Mr. BECERRA. I am going to tell you I am not as deep on that as I should be. And what I could do is get back to you and make sure the team responds well from HHS.

Mr. BEYER. Okay. I also want to say, on the negative side, we are still disappointed at the continued under-funding of A-H-R-Q, AHRQ. It is a really important part of your HHS piece to get the quality right to begin with.

Mr. BECERRA. I have got to give you a hug, Congressman, for saying that, because you are absolutely right, they do some tremendous work.

Mr. BEYER. Thank you. And finally, on CMS data concerns, the research community has talked to us about CMS has announced changes to its research identifiable file data and the continued delivery of physical data extracts. We are hearing that they could be incredibly damaging to public health system research and health research at large.

The Virtual Research Data Center—all caps—has significant coding limitations. It is slow, has regular system errors, interoperability limitations, among other things. And apparently there are significant new fees to access that can run tens of thousands of dollars per researcher, per year, per project, with no option even for having screen-sharing among researchers in the same project.

Can you talk about how HHS and you can address the access and affordability?

What makes VRDC usable in the first place?

Mr. BECERRA. Congressman, you have touched on something that I think will become a very important subject to resolve, and that is that data is so valuable. And for researchers, it is gold. And we want to make sure that researchers have that information that they need so they can continue to come up with innovations and therapies that will keep people alive.

At the same time that—we know, as we saw with Change Healthcare, that there are bad actors who are constantly trying to get access to that same data and use it for the wrong reasons. We have to make sure that everyone who accesses data—and we provide a lot of data—that it is not misused.

And so, we are just doing what everyone is now having to do, is moving toward platforms that provide more security because you don't want your personal data, I don't want my personal data to get—to go into the wrong hands. If it is a researcher doing the right thing with it, great, but we don't know. And we have to live in this new world. That is why we are migrating to something that provides more protection.

But we will continue to take comment, because we have heard these concerns, and we want to make sure at no point do we stifle research.

Mr. BEYER. Great, thank you very much, Mr. Secretary.

I yield back, Mr. Chair.

Chairman SMITH. Thank you. Mrs. Steel.

Mrs. STEEL. Thank you, Mr. Chairman.

And it is so nice seeing you, Secretary Becerra, for long hours, thank you, you are staying, testifying.

Last year I asked you about hospice fraud—you know California so well—and why CMS was still certifying new hospices in California. You said during the last hearing, "You will not be abreast of what the State of California is doing [sic]."

I have a few articles here that I am going to submit on the record that new hospices cropping up, and fraud hotbeds are made ongoing program integrity push hospice fraud back in the spotlight, with new data also raising questions about the home health care. California Hospice Network falls short in curbing potential malfeasance. Medicare certifies hospices in California, despite state ban on new licenses.

These are all the articles. We can find more. But you know what? I have four here.

So, my question is, I want to ask you again, why is CMS certifying hospices, despite California's moratorium due to rampant fraud?

Mr. BECERRA. Congresswoman, I can make sure that we give you a more complete answer than what I can give you right now. But what I will tell you is that there are programs in place where, if the applicants go through the process and certify to CMS that they have a program that will service the needs of a community when it comes to hospice care, and they are able to meet the standards, that we will certify them to be able to provide hospice care.

That then some of them go out and do things that are against the law or do things fraudulently, there is no doubt. That is one of the reasons why, under Medicare or Medicaid, we are constantly trying to go root out that fraud, and we would like to crack down on it.

And so, we know that hospice care is growing, and it is going to continue to grow, but we have to have more accountability. I look forward to working with you to make sure we can address that.

Mrs. STEEL. But Los Angeles only CMS certified an additional 98 hospices. You know, we really have to crack down on these hospices care, and then we really have to look at it.

Last summer CMS embarked on a nationwide hospice site visit project, and you claim to have made unannounced site visits to every hospice, over 7,000 total, in an effort to catch fraudulent providers. And there are a lot of bad actors in southern California, more than anyone else in the country. So how many hospices have been terminated?

And as a result, how many of the hospices in LA County or Orange County—those are where I am representing—is CMS saying aren't fraudulent? My constituents need to know if they visit a CMS-certified hospice, they will take care of them.

Mr. BECERRA. Congresswoman, you are asking for very granular information about Los Angeles County or southern California. I don't have that before me. I could make sure our teams respond to those questions in particular.

But what I can tell you is that we are—and if you look at our budget that the President has proposed—we increase the funding for program integrity to go after that fraud. And we will look forward to your support, because we know that there is always someone trying to game the system, and we know that there are people, like my father before he passed, who needed hospice services.

And so, I very much would look forward to working with you to try to make sure we root out that fraud.

Mrs. STEEL. And I want to know about those 7,000 hospice care that——

Mr. BECERRA. Yes, we——

Mrs. STEEL [continuing]. Visited, unannounced site visits, and just took care of it or not.

So Medicare beneficiary ability to make informed decisions about their care is one of my top priorities. HHS has a tool for the public to review Medicare survey and certification data. The website, Qualified Certification and Oversight Report, has been unable to provide the information for home health agencies since early 2021, due to a system migration issue.

So, my question here is, the public has a right to know what providers are enrolled in the Medicare program, and it is completely unacceptable that a public-facing website has not been operational since 2021. Can you explain why this has occurred, and why the agency proceeds with enrolling over 800 new home health agencies in California?

Mr. BECERRA. Okay, Congresswoman, what you are presenting to me is something that I have not heard, so I will have to get back to you on that.

But I will tell you, just as we talked in our discussion about hospice care or nursing home care, home health care, which is a growing industry as well, is something that we are trying to monitor more closely. We are constantly doing program integrity work in this field, as well. And we could try to respond more specifically to any questions you have, but what you have just mentioned does not sound familiar to me.

Mrs. STEEL. Thank you. I hope that you will have more conversations.

My time is up, and I yield back.

Chairman SMITH. Thank you. Mrs. Fischbach.

Mrs. FISCHBACH. Thank you, Mr. Chair.

And first I want to correct the record. The staffing requirements proposed in the rule are the same for urban and rural nursing homes. There is a difference in implementation timelines, but the requirements are the same. Thank you very much for letting me just correct that.

But I know that we have talked a lot about the staff, the nursing home staffing ratio issue, and various questions have been asked. But I guess I am really wondering; do you plan to finalize the rule?

And if so, will the final rule be responsive to the thousands of comments that you have received, you know, thousands from nonprofit nursing homes that oppose it?

And have you reached out to any of those stakeholders to try to improve this and make it work?

So, will it be responsive?

Mr. BECERRA. Congresswoman, we absolutely have reached out. We have had many listening sessions with any number of the stakeholders we received, as you are aware, thousands of comments. We are taking—the reason we are taking some time to finalize the rule is because we are trying to respond to all those comments, as well. So absolutely, we will take them into consideration.

And I must disagree with you. There is a distinction in the treatment between rural facilities and urban facilities. Whether it is only because of time or the hardship exemptions, smaller facilities, facilities that have—are in very difficult circumstances have hardship exemptions that they can apply for, as well.

Mrs. FISCHBACH. Well, and—but I want to know—I mean, okay, so you said you have had stakeholder meetings. Have you changed the rule?

I mean, so you can have meetings, I mean, I can have meetings.

Mr. BECERRA. Yes.

Mrs. FISCHBACH. But that doesn't mean that it will—anything, you know, the rule and the issue that we are dealing with, is going to reflect the concerns that they have brought forward because they are serious concerns.

Mr. BECERRA. I hear you, and now you are asking me to tell you what we are going to do. I can't do that until the final rule were to come out. It would be a violation of our laws to disclose what we are doing.

But I will tell you this. We have had several sit-down meetings with the nursing home facilities, the representatives of nursing home facilities, to discuss this with them, along with other stakeholders. And we are absolutely taking into consideration their and others' comments.

Mrs. FISCHBACH. Well, I am concerned when you say, "taking into consideration," you know. The original thoughts on it with the nursing staffing ratios were not good. And so, I don't know necessarily if you are saying that you are taking it into consideration gives me any comfort that it will be sufficient.

I mean, because we are—and I don't think——

Mr. BECERRA. I appreciate what you are saying.

Mrs. FISCHBACH. And I don't think you—from some of the comments that I have heard, and from some of the responses to things, I don't think you understand the seriousness that it will—what it will do to rural nursing homes. And we can't find enough staff now.

And you can come back and say—you know, you can make comments, snide comments to people, but it doesn't solve the issue.

Mr. BECERRA. Congresswoman, I hope they don't sound like snide comments. I am simply saying there are problems, there are real challenges in the nursing home industry, and it is not something that we can just ignore. Because if we do, chances are one of our loved ones is going to pay the price.

Mrs. FISCHBACH. Have you looked at—so you—the only answer you have is to increase nursing staffing.

Mr. BECERRA. No, no, there is much more.

Mrs. FISCHBACH [continuing]. When they can't—okay, well——

Mr. BECERRA. There is much more.

Mrs. FISCHBACH. Then there better—there should be.

Mr. BECERRA. Yes, there is much more.

Mrs. FISCHBACH. Because you can't just say that that is the one answer, because that will shut them down. I mean, it will in rural areas when they can't get enough staff.

Mr. BECERRA. But Congresswoman, can I ask you a question?

If a nursing home is saying, "We cannot find the staff to do the work," does that give you a comfort level that the services that are being provided to the loved ones who are there is sufficient?

Mrs. FISCHBACH. There are already nursing staffing ratios.

Mr. BECERRA. And you are saying that those are sufficient?

Mrs. FISCHBACH. They are already there.

Mr. BECERRA. And you are saying that those are sufficient.

Mrs. FISCHBACH. I can't say that in every case. And that is the kind of comment where you are not looking for the kind of creativity or things that we can do to help solve that. You are just going to add more regulation to an already—to an industry that is already over-regulated, and adding something that is impossible for some rural areas to meet.

Mr. BECERRA. I hear your concern.

Mrs. FISCHBACH. So please, help us instead of answering with the kinds of questions that you asked me.

I mean——

Mr. BECERRA. My obligation is to protect people that use services at nursing home facilities. I have to make sure that they——

Mrs. FISCHBACH. And if those nursing——

Mr. BECERRA [continuing]. Are safe and effective.

Mrs. FISCHBACH [continuing]. Facilities shut down in rural areas, those people have nowhere to go.

Mr. BECERRA. Well, what——

Mrs. FISCHBACH. So that is the option in a lot of these places.

Mr. BECERRA. Congresswoman——

Mrs. FISCHBACH. So, if there were other, more creative ways that could be answered—and my time is up. So, thank you.

Mr. BECERRA. But there are many facilities that are providing care——

Mrs. FISCHBACH. My time is up.

Mr. BECERRA [continuing]. In rural communities——

Mrs. FISCHBACH. My time is up.

Mr. BECERRA [continuing]. That are not——

Mrs. FISCHBACH. I——

Mr. BECERRA [continuing]. They cannot provide those services.

Mrs. FISCHBACH. All right.

Chairman SMITH. Mr. Evans.

Mr. EVANS. Thank you, Mr. Chairman.

Thank you, Mr. Secretary, for your time before this committee today, and for the work over the past several years of fighting to expand access to health care for Americans and to increase equity for our nation's social service.

Earlier this year the Ways and Means Worker and Family Support Subcommittee held a hearing on the importance of supporting young Americans aging out of foster care. I am encouraged that the President's budget appears to have requested for this purpose specifically. I look forward to working with you in improving our nation's foster care adoption.

So, the question I want to ask, how else is the Administration and the President working to end discrimination and ensure that every child can find a welcome family?

Mr. BECERRA. Congressman, thank you for the question. And as you know, often times the foster care situation for some of our kids is intolerable. And it is often times because of who they are or—that there are people who are not accepting of who these kids are. And we are making it very clear that the obligation of any foster care program is to, first and foremost, focus on the child.

The safety and care of that child is paramount, and the interests of that child. So, if that child happens to be someone, for example, who is transgender, that child's interests come before any other interest that the foster care entity might have, because it is our obligation to make sure that that child is getting the best care available to that child.

And so our rules now will reflect that, that the interest, the focus is on the child, not the person who wants to become or the entity that wants to provide the foster care. It is on the child.

Mr. EVANS. I yield back, Mr. Chairman.

Chairman SMITH. Thank you.

Ms. Beth Van Duyne.

Ms. VAN DUYNE. Thank you very much, Mr. Chairman. [Slide]

Ms. VAN DUYNE. Secretary Becerra, do you recognize this building? It is in the Van Nuys neighborhood in Los Angeles.

Mr. BECERRA. I couldn't tell you——

Ms. VAN DUYNE. So, CMS is a sole authority in certifying hospice facilities, yet there are over 100 unique hospice providers registered at this location alone. It is frightening that that has been allowed to happen.

And Mr. Secretary, as you are aware, I raised this issue with you a year ago at our last budget hearing, and somehow here we are again, dealing with the same problems. My staff was looking forward to a long-planned meeting with CMS last week on this issue to find out how this continues to have more enrollment, and how we are continuing to enroll other facilities here. And yet, at the last minute, we had a cancellation of the meeting with nothing—no other explanation than a scheduling conflict.

So, I am here to ask you directly. Do you commit to seniors watching this hearing that your agency will prevent them from becoming embroiled in fraudulent hospital schemes that deprive them of needed medical care?

Mr. BECERRA. We certainly can commit to every senior who is in need of hospice——

Ms. VAN DUYNE. Well, I appreciate you saying that.

Mr. BECERRA. And we will do everything we can to ensure that——

Ms. VAN DUYNE. So now I would like to——

Mr. BECERRA [continuing]. They are not the victims of fraud.

Ms. VAN DUYNE [continuing]. Turn to the ongoing crisis at the southern border and the response from your agency. I want to follow up with some of the questions that have been already asked.

Since President Biden took office, Border Patrol has encountered over 473,000 unaccompanied alien children. Not only has the Office of Refugee Resettlement reportedly lost contact with more than

85,000 of those children, but now we are also hearing concerns that ORR is diverting already scarce foster care resources to respond to the surge at the border, in addition to reports that ORR has failed to properly vet and place these children.

Due to this Administration's crisis at the border, has HHS assessed the burden that you are placing on state welfare agencies, particularly in states like mine and Texas, that already have high numbers of migrant children?

Mr. BECERRA. Congresswoman, let me first begin by saying that you have inaccurately depicted the work that we do, so it is hard to answer——

Ms. VAN DUYNE. Well, I am simply asking. Have you assessed the burden that you are putting on these agencies that are already stressed for services?

Mr. BECERRA. We provide the service to these children under the—under law that you all passed——

Ms. VAN DUYNE. Correct. So there are a number of children, even before we had this migrant count, that were not getting the services that were necessary. And now we are putting on hundreds of thousands of additional burdens on them. Have you assessed what this is doing to those states?

Mr. BECERRA. We continue to perform the work that we are required under law——

Ms. VAN DUYNE. Have you—are you assessing the burden that you are putting on them?

Mr. BECERRA. We make assessments of the needs of these kids, and make sure that when we do provide——

Ms. VAN DUYNE. I want to highly recommend that you actually talk to your employees, because when I went to the Kay Bailey Hutchison facility in Dallas when they were there, your employees were so upset with what is going on. They are looking at the border, and they are saying, "We are sending these kids to places we have no idea what their future is going to be." We know that they have been sexually assaulted. A high number of them have been raped on the way here. And the immense amount of mental stability that they are going to need in the future, those services are outside of our range. Talk to your people. And I would really hope that you would talk to this Administration about what they are doing at the border and how this is burdening not only an already-stressed system, but what this is looking to the future of our youth.

I want to change now to a pregnancy center, because I know we have also had some questions on that. In your statement on the budget you went out of your way to say that you have taken action with what—President Biden to expand access to reproductive health care to, quote, "The Biden-Harris Administration has taken action to protect and expand access to reproductive health care in every way possible, and HHS is committed to promoting access to reproduction health care."

But we have talked about the CPCs, and yet I am confused. If it is specifically a service that the pregnancy centers are not providing, can you tell me what that service is?

Mr. BECERRA. I am sorry, what service are we talking about?

Ms. VAN DUYNE. For crisis pregnancy centers. They have been targeted within the excerpt from the proposed rules that states

that provide funding for these types of programs, including through entities sometimes known as crisis pregnancy centers, basically have a burden to prove that they meet TANF's purpose. You have called them out.

Mr. BECERRA. Yes, and are you speaking about the TANF program, or what program are you speaking about?

Ms. VAN DUYNE. I am speaking about the funding for TANF and your restrictions on crisis pregnancy centers.

By the way, it specifically states that they have to——

Mr. BECERRA. There aren't restrictions for these centers.

Ms. VAN DUYNE [continuing]. Prevent or reduce out-of-wedlock pregnancies, but you have already identified TANF as being fine for Planned Parenthood, which 94, 95 percent of their services are abortion, which obviously, to have an abortion, you are not preventing a pregnancy, you are preventing a birth.

So why are TANF's—why are you limiting TANF dollars from going to crisis pregnancy centers when you claim that you actually want to have all this freedom of services available for women who find themselves in this position?

Mr. BECERRA. And I know time has expired, so I will try to respond quickly to the question.

We restrict services only based on the qualifications of the entity to provide the services that are required by law. If the entity is going to provide——

Ms. VAN DUYNE. What does that mean? What——

Mr. BECERRA. If I could finish my answer, that would be very—really helpful.

Ms. VAN DUYNE. But you are talking in generalities, and I would like you to be more specific.

Mr. BECERRA. So Congresswoman——

Ms. VAN DUYNE. Because all day we have heard you talk in generalities. I am asking you to be more specific.

What specific services are not offered by the crisis pregnancy centers that you have targeted them in your proposed rule?

Mr. BECERRA. May I answer your question?

Ms. VAN DUYNE. I would hope that you would answer the question, not just give me generalities, please.

Mr. BECERRA. So, we have an obligation to make sure that when we send out a taxpayer dollar, it is being used for the purposes required by the law.

Ms. VAN DUYNE. So again, you are not answering the question.

Mr. BECERRA. I am getting to the answer.

Ms. VAN DUYNE. Okay.

Mr. BECERRA. And what I am saying is, if an entity is not—is restricted from accessing those dollars, it is because they are not providing the services that are required by law. We don't identify any particular entity as not eligible——

Ms. VAN DUYNE. You identify—in the excerpt from your proposed rule you are identifying it.

Mr. BECERRA. If they do not provide the services that are required by the program——

Ms. VAN DUYNE. What services are they not? That is the question I have asked you now four times.

Mr. BECERRA. The services under TANF, and TANF is to help prevent pregnancy.

Ms. VAN DUYNE. Thank you very much, Mr. Chairman, I yield back.

Chairman SMITH. Thank you. Mr. Schneider.

Mr. SCHNEIDER. Thank you, Mr. Chairman.

And thank you, Mr.—Secretary Becerra, for being with us. It is always good to see you, and I appreciate you staying until the very, very end.

Several people before me have touched on the pandemic crisis that started four years ago this month. And it is important that we remember our journey through the depths of the crisis to what is really, I think—no other way to describe it—the extraordinary recovery our nation has enjoyed since, much of it because of the policies passed in the last Congress, the 117th Congress, but also the work of the Biden Administration.

I do want to touch on one lingering matter affecting one of my constituents and many like her across the country. Janine Morabito stepped up to provide free COVID testing through HRSA's uninsured program, relying on assurances that they would be reimbursed later by HRSA, only to be told last year that the program ran out of money. These people acted in good faith, and yet today they are left holding the bag. Many owed millions of dollars.

What I would like to ask is a commitment that you and HRSA will continue to work with me to help these people get the reimbursements that they were promised.

Mr. BECERRA. Congressman, I certainly commit that we will work with you. The difficulty is, as you know, we—Congress swept away the monies we had for these programs. It is hard for us to give money that we don't have.

Mr. SCHNEIDER. I understand. I know we are trying to claw back the money that others took that they didn't deserve. And hopefully, some of that will come in. So I understand the challenges, but I would like to continue to work together. So thank you.

Let me shift gears. As you know, pharmacists across our country are safely and effectively providing testing, vaccination, and treatment services for respiratory viruses like COVID–19, influenza, and RSV. During the pandemic, as our health care system was stretched to its limit, these pharmacists stepped up and played a vital role in providing the critically needed testing and vaccination services. While most private insurers pay pharmacists for these services, Medicare does not.

I joined my colleague, Adrian Smith, to introduce the Equitable Community Access to Pharmacist Services Act—it is a mouthful—to fix this disparity. Our bill would allow Medicare Part B reimbursement to pharmacists for these services within the state's scope of practice laws.

The cost of a hospitalization is far greater than prevention or early treatment, and we should be able to enable pharmacists to deliver these treatments to seniors to help make sure that we are keeping them healthy.

My question, Mr. Secretary, is, considering our seniors are among the most vulnerable populations susceptible to respiratory viruses, do you think it makes sense for Congress to consider poli-

cies that improve seniors' access to the services like the proposal Mr. Smith and I have introduced?

Mr. BECERRA. Congressman, we are absolutely prepared to work with you to provide technical assistance as you try to move forward legislation. We do believe that seniors need to have access to the care that they need as quickly as possible and at an affordable rate. So we would be willing to work with you to see if there is a chance for your legislation to move forward.

Mr. SCHNEIDER. Great, thank you, and let me shift gears again.

Ranking Member Neal, in his opening remarks, rightly touted the Affordable Care Act. Like his state, I am proud that in Illinois we have record ACA enrollment, with approximately 380,000 individuals covered. Ninety-seven percent of Illinois children have health insurance, and enhanced ACA premium tax credits are saving a family of 4 approximately $7,500 a year.

As we work to improve health care access and affordability, I am proud the Democrats worked to extend key health care benefits like the Affordable Care Act premium subsidies, as we did as part of the Inflation Reduction Act. Many important aspects of the IRA, such as the $35 insulin cap and inflation rebates, are lowering health care costs for all Americans. Also in the IRA is a policy I helped champion to expand Medicare Part D premium subsidies for low-income seniors. All told, the IRA is saving taxpayers and seniors billions of dollars.

That said, I want to focus on another contributor to the high cost of medications, specifically pharmacy benefit managers, or PBMs. I suspect you would agree that market incentives for PBMs have become misaligned. I helped introduce the Bipartisan Drug Act to delink the fee PBMs receive from the price of the drugs that patients pay, thereby removing the incentive PBMs have to push higher-cost drugs when cheaper alternatives are available. The Drug Act would also prohibit PBMs from spread pricing, which also needlessly contributes to the high cost of these medications.

I am thankful that HHS is also considering action to address PBMs' role in the drug value chain. Mr. Secretary, can I get your commitment that we can work together to address this issue and ensure patients are getting the best medicines for their needs at the best or lowest prices?

Mr. BECERRA. Absolutely.

Mr. SCHNEIDER. Great, thank you. And with that, I want to say one last thank you. I want to thank HHS for working with EPA to better regulate ethylene oxide, or ETO, emissions for medical device sterilizers. We had to get to a balanced solution, one that addressed the health concerns of these emissions, but also the health needs of sterilized medical products. It has been a top priority for my community, and I am grateful that EPA established sensible, strict requirements on ETO emissions to protect the public health but did so in a way that continues to provide the supply chain for sterilized medical devices.

And with that, I yield back.

Chairman SMITH. Mr. Moore.

Mr. MOORE of Utah. Thank you, Chairman, Ranking Member, Mr. Panetta, for holding this hearing.

Secretary, it is great to see you again. Now that you have been through a whole bunch of questions back and forth, we are finally going to get to the brass tacks. We are going to solve the problems here.

Mr. BECERRA. Looking forward to it.

Mr. MOORE of Utah. And as we wrap up your day, you know, that is not just—it is said in jest, but I do appreciate your willingness to show up and dialogue with us.

Before I get to my questions, I just want to urge the Department to closely—monitoring the Change Healthcare cyber attack and its impact on patients and providers and health systems back in Utah. It is a big concern for them, and this issue matters. So thank you in advance for continuing to focus heavily on that.

Last year I was proud to co-lead my friend, Dr. Wenstrup's bill, 1691, bipartisan legislation to establish a robust and meaningful transitional pathway for Medicare coverage of innovative technologies and devices approved by the FDA. Multi-year delays in receiving Medicare coverage impedes patient access to breakthrough products and disincentivizes the already risky investment being made in these therapeutic areas.

In June of last year, CMS published its Transitional Coverage for Emerging Technologies, TCET, the notice for that. The comment period for the notice closed last August. When do you expect CMS to finalize the TCET notice, and will you commit to providing an update soon on the agency's work?

Mr. BECERRA. Congressman, thank you for the question. And I know that this was an important one, and I appreciate the work that you have done.

I wish I could give you a specific timeframe. You know, this year there is a mad rush in trying to complete a lot of the work that we have. And why don't I do this? Why don't I get back to you to give you a better sense? But I couldn't right here today give you a sense of when that rule might come out.

Mr. MOORE of Utah. Do you think—I mean, is this within the calendar year? Do you have a sense for even just an estimate?

Mr. BECERRA. Yes——

Mr. MOORE of Utah. And I won't even hold you to the estimate, I am just——

Mr. BECERRA. Yes, my—I want to say that we are—you know, it is not just us. There are a lot of agencies that are involved.

Mr. MOORE of Utah. Yes.

Mr. BECERRA. And OIRA, the OMB are working through this, as well. Probably the best thing is for me to try to get back to you.

Mr. MOORE of Utah. So, I mean, these are—there are many—what Utah is trying to do in the health care space—and we are even going to try to highlight it. In this committee I try to use it as every opportunity, having folks in. Like, we are all about medical innovation. And you can look at the advancements we have made from particularly device—you know, medical devices and finding, you know, better ways, more—less invasive ways to do this. And I am just—I am very bullish on the industry to continue to be able to do this and come up with solutions here.

This bill—again, very bipartisan—needs to be prioritized. And so, I urge you and your colleagues to take a really serious look at it. So thank you, and we will follow up.

Mr. BECERRA. Okay.

Mr. MOORE of Utah. So shifting gears, last month I introduced legislation to enhance work supports for Americans receiving TANF, work supports for TANF. The bill is called the Restoring Temporary to TANF Act, and it would require that the states set aside 25 percent of Federal TANF dollars to spend on core work activities, including work supports, education and training, apprenticeships, non-recurrent short-term benefits, work activities, and case management for TANF individuals' responsibility plans. We want a quarter of TANF dollars to be spent in every state for work-related, work development, educational opportunities.

Like, I know I am learning, you know, a lot more about this place. Been here just over three years. And I think, if you put this down, it is like everybody would agree with it. And things get tied into one thing versus another, and there is a political—like, on the merits of that, 25 percent, do you think that the Administration or the—or your branch could be supportive of that effort?

Mr. BECERRA. So you know we have a rule that has been proposed, and we are taking comments on it. I will consider what you have just said as the comments that we will take into consideration as we look at what we have been proposing, at least through the administrative route.

Certainly, through the legislative route, you could do far more than we can. What I can do is try to follow up with you in response to some of your questions, but we are on—we are in comment period, so I have to be careful how—what I say and how I say it, because I have to make sure that I don't violate the terms of the comment period, where we are not supposed to give any indications about where we will go.

Mr. MOORE of Utah. And with that, in my last eight seconds, I will just highlight this is a sincere effort to make sure we are going to help lift people out of poverty, and we want states to engage.

I am from a state, luckily, that does this type of stuff very well. I would put us up against anywhere. And I want to take those best practices and try to permeate it through the rest of our programs. A quarter of the funds to go towards work development programs to get people back on their feet is a primary motivation.

And with that, sir, I yield back.

Mr. BECERRA. And Congressman, I could just really comment and say I appreciate that, because I think there—I heard a number of good faith efforts on what we should do on TANF, and all of those are going to be considered. We are—we have got our rule. You all may do legislation. Either way, I think we all agree we can reform TANF to make it better.

Mr. MOORE of Utah. Thank you, Secretary.

Mr. BECERRA. Thank you.

Chairman SMITH. Mr. Panetta.

Mr. PANETTA. Thank you, Mr. Chairman.

Secretary Becerra, good to see you. Not just because it is always good to see a California boy in your position, but it is good to have

this opportunity to talk to you about an issue that I consistently bring up with you, and will continue to do it, especially today.

Mr. BECERRA. I think I know where you are going to go.

Mr. PANETTA. Look, we have discussed in this committee before, in your time as well as in other areas, that California patients and providers are facing serious challenges when it comes to Medicare reimbursement rates and their failure to keep up with the cost of care, especially—especially—in districts like mine in the 19th congressional there in California.

I have asked you a number of times about this issue, with the goal of trying to figure out how we can work together to fix it, how this committee, which you were on, can work with HHS that you are now the Secretary of, to bring some relief to the many Americans in Californians that are dealing with this challenge.

Now, I recently wrote to the Centers for Medicare and Medicaid Services about the lack of geographic adjustments and the area deprivation index for my district to keep up with the cost of care. I am pleased that CMS did provide a response, which I appreciated, and they also expressed a willingness to work with my community to address future payments. However, as you know well, Mr. Secretary, they mentioned that geographic adjustments are not up for review until 2026.

So, my question to you, Mr. Secretary, is, in the meantime, how can CMS help alleviate physician payments?

And can you give us an idea, or at least describe some of the tools that HHS has in its current statutory authority, if there are, that can help payments match the cost of providing care in my district?

Mr. BECERRA. And Congressman, you always raise this, and you raise it for good reason. And again, being—both of us being California boys, we recognize that we have got very high-cost areas and we have got areas that are rural, where the costs are nowhere near what they are in some of these other areas.

And I believe you probably have Carmel, Monterey, and those areas in or near your district. And just outside of there you get to Salinas, and it is a far different place.

Mr. PANETTA. Exactly.

Mr. BECERRA. But as you know, as I have said, and as I suspect our team has told you, that—you know, the way the rules are written by statute, it really constrains what we can do. And if we try to push a button here, another button comes out over here. And it is difficult, because we have to live by this linear formulation of how you do it.

We are absolutely prepared to provide the technical assistance it might take to make the changes to the statutes that address the needs of some of the communities that are impacted by the way we do these formulations for reimbursement. But I don't think I have a good answer for you right now, given the state of the statutes.

Mr. PANETTA. One option I have heard, Mr. Secretary, is reforming administrative costs for the merit-based incentive payment system. Are there other administrative costs that HHS can reduce so doctors don't have to spend the resources and the time on paperwork and resources serving patients?

Mr. BECERRA. Yes, we—I have heard this, as well. And certainly, if more physicians and physician practices and providers had access to the best technology so they wouldn't have to do things with old fashioned paper, it would probably speed things up for them.

But having that infrastructure costs money, as well. And so, chances are these particular providers, small and rural areas, probably don't have the money to buy the latest technology easily. So it is no easy fix, but certainly the efficiencies that could be extracted by being able to move towards electronic record keeping and so forth would be helpful.

Maybe there is some way we could just support the efforts of some of those providers to get themselves boosted up. But again, that is where we are probably going to have to come to you to see if we can find the support.

Mr. PANETTA. Understood. And I guess going forward and you have shown this, and I appreciate this, but just to be frank, have you on the record, will HHS commit to working with me and my office and my constituents on solutions to fix Medicare reimbursement rates?

Mr. BECERRA. Absolutely, because my daughter and her husband live in Salinas. So you got my word that either you are going to tell me about it, or she and her husband are going to tell me about it.

And by the way, he is a physician.

Mr. PANETTA. Oh, you got it. You understand well. Well, thank you, Mr. Secretary, I appreciate that.

I yield back, and thanks for your time today.

Mr. BECERRA. Thank you.

Chairman SMITH. Thank you, Secretary Becerra, for appearing before us today and going through the entire committee, even though we had to break for votes. We appreciate that.

Please be advised that members have two weeks to submit written questions to be answered later in writing. Those questions and your answers will be made part of the formal hearing record.

And with that, the committee stands adjourned.

[Whereupon, at 6:25 p.m., the committee was adjourned.]

MEMBER QUESTIONS FOR THE RECORD

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 AI/ML medical devices, the majority of which are medical imaging devices. At the same time, fewer than 10 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 AI/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 AI/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 1822(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.

PUBLIC SUBMISSIONS FOR THE RECORD

Comments for the Record
United States House of Representatives
Committee on Ways and Means
The President's FY 2025 HHS Budget
Wednesday, March 20, 2024 - 2:00 pm

By Michael G. Bindner
The Center for Fiscal Equity

Chairman Smith and Ranking Member Neal, thank you for the opportunity to submit these comments for the record on the HHS FY 2025 Budget Request.

General Approach

For obvious reasons, this year will be more hectic than the last. The budget and appropriations process needs to be simple. To do this, pass a consensus caretaker budget with two draft partisan supplemental bills, one of which can be enacted during the Lame Duck Session or at the beginning of the next Congress for the President-Elect to sign upon taking office, depending on who wins.

If such a budget is enacted, use it as the basis for spending caps for a new Budget Control Act. Make the targets realistic and self-enforcing for purposes of Appropriations Committee allocations.

Contingencies

In the event the majority in the House shifts due to early retirements or insurrection indictments, the Senate majority and the House minority should have legislation ready to enact a Public Option, including reconciliation instructions for the FY24 budget year. Please see the attachment for details.

As any such change in control will only last through the special election cycle, this should be the second priority. The first must be amending the Electoral Count Act and the jurisdiction of the Ethics Committees to provide for the enforcement of the Fourteenth and Twentieth Amendments, including provisions for removing and related disability for members and the president-elect.

The **President's Budget** addresses the following two top line points:

Lowers Health Care Costs, making permanent the expanded premium tax credits that the Inflation Reduction Act extended, providing Medicaid-like coverage to individuals in States that have not adopted Medicaid expansion, paired with financial incentives to ensure States maintain their existing expansions.

Protects and Strengthens Medicare, extending the solvency of the Medicare Hospital Insurance (HI) trust fund indefinitely by modestly increasing the Medicare tax rate on incomes above $400,000, closing loopholes in existing Medicare taxes, and directing revenue from the Net Investment Income Tax into the HI trust fund as was originally intended.

Regarding lowering healthcare costs, the President is forgetting his promise to create a Public Option.

We disagree with the president on how to shore up the HI trust fund and expand the *Affordable Care Act.* ACA subsidies are too low and are funded by taxing the wrong people (investors). Families in the Silver Plan still have problems meeting copays and paying premiums. The funding

is also unfortunate. Rather than expanding Medicaid, replace it for the non-elderly with the Public Option proposed in 2009.

The public option should be extended to individuals who are denied coverage under pre-existing condition rules. Such rules must be revoked as the price of passing the bill. Such a trade-off is necessary for enactment of such a proposal on a bipartisan basis.

Developing the Public Option needs to be funded in this budget. Particularly, it should explore the impacts on coverage and cost of automatically enrolling individuals who are denied coverage under pre-existing condition rules.

The way to fully fund healthcare is through an employer-paid subtraction value added tax.

Taxes to support Medicare should be broad based, funded either by an employer paid subtraction VAT or a border adjustable goods and services tax (credit invoice VAT). **This would allow for the repeal of the ACA-SM surtax on higher income individuals enacted as part of the Affordable Care Act.** Tax increases on higher income individuals should be dedicated toward fully funding net interest, eventually reducing the national debt, funding veterans healthcare and overseas military and ocean deployments.

The President's Budget cites PhARMA profits as a rationale for increasing business income tax rates. He proposes **raising Tax Rates for Large Corporations**

Instead, we suggest eliminating Corporate Profits taxes and taxation of business income on Form 1040 with a Subtraction VAT (with offsets for employee and retiree healthcare) and a credit invoice tax on both labor and profit. The combined rates of these taxes will burden both profits and labor costs, raising much more money.

This tax will be levied for all income earned in the country of production (for subtraction VAT) and of sale (Credit Invoice VAT). A new agreement on rate uniformity for our proposed Asset VAT will prevent rate shopping for stock trading (see the second attachment).

From Tax Reform Attachment: Subtraction Value Added Taxes

Subtraction Value-Added Tax (S-VAT). Corporate income taxes and collection of business and farm income taxes will be replaced by this tax, which is an employer paid Net Business Receipts Tax. S-VAT is a vehicle for tax benefits, including

- Health insurance or direct care, including veterans' health care for non-battlefield injuries and long term care.
- Employer paid educational costs in lieu of taxes are provided as either employee-directed contributions to the public or private unionized school of their choice or direct tuition payments for employee children or for workers (including ESL and remedial skills). Wages will be paid to students to meet opportunity costs.
- Most importantly, a refundable child tax credit at median income levels (with inflation adjustments) distributed with pay.

Subsistence level benefits force the poor into servile labor. Wages and benefits must be high enough to provide justice and human dignity. This allows the ending of state administered subsidy programs and discourages abortions, and as such enactment must be scored as a must pass in voting rankings by pro-life organizations (and feminist organizations as well). To assure child subsidies are distributed, S-VAT will not be border adjustable.

As above, S-VAT surtaxes are collected on all income distributed over $75,000, with a beginning rate of 6.25%. replace income tax levies collected on the first surtaxes in the same range. Some will use corporations to avoid these taxes, but that corporation would then pay all invoice and subtraction VAT payments (which would distribute tax benefits). Distributions from such corporations will be considered salary, not dividends.

Funding Orphan Drugs and the issue of PhARMA profits

PhARMA justifies its profits because it is burdened with high development costs for new and orphan drugs. We renew our call for a more "corporate approach" for government research and testing of new drugs.

Part of ARPA-H is the funding for research on orphan drugs and the lingering problem of their cost once research leads to product development. In comments to Senate Finance on March 16th of this year, we repeated our proposal in this area for NIH to retain ownership in any such drug and contract out its further development and manufacture. Keeping ownership in public hands ends the need for drug companies to charge extreme prices or increase prices for its existing formulary to fund development.

PhARMA would still make reasonable profit, but the government would eat the risk and sometimes reap the rewards. NIH/FDA might even break even in the long term, especially if large volume drugs which were developed with government grants must pay back a share of basic research costs and the attached profits, as well as regulatory cost.

Closing

We have serious concerns with the way President Biden is paying for the future of Medicare and extending Obamacare. Please share these with the Secretary and request a response.

Thank you for the opportunity to address the committee. We are, of course, available for direct testimony or to answer questions by members and staff.

Attachment: HHS Budget FY 2022

Single Payer

We address the funding of the Affordable Care Act, the need for an immediate COLA for retirees,funding the Social Security Administration's non-fund costs and the idea of cost savings for Social Security.

So far, the Administration has not yet addressed changes to the **Affordable Care Act,** at least not publicly. We suggest that the Committee ask the Secretary about any such plans.

At minimum, the individual and employer mandates, with associated penalties, that were repealed must be restored. The President campaigned on restoring and perfecting the Act, adding a public option. We agree, although the public option need not be self supporting. It must be subsidized through a broad based consumption tax. Such a tax burdens both capital and wage income.

The current funding stream seems to have been designed to draw opposition from wealthier taxpayers. It is an open secret that the Minority does not oppose most of the Affordable Care Act (which was designed by their own Heritage Foundation as an alternative to Mrs. Clinton's proposals). Broaden the tax base to fund the program and the nonsense on repeal will end.

The current funding stream from student loan initiation and interest, which was included in the baseline, should also be ended. Graduates (and non-graduates) with student loan debt cannot afford both their loan payments and insurance payments under the Affordable Care Act. When they apply for lower loan payments, which are always granted, they face either a balloon interest payment or capitalized interest, which makes their funding situation worse. No one should have to retire with student load debt, yet quite a few soon will (or already have).

Forgive capitalized interest and apply any overpayments to principal. There should not be a one-size-fits-all subsidy. Also, when payments are deferred, return to the practice of deferring interest (or allow debts to be discharged, at least partially, in bankruptcy).

To deal with these issues, whatever is budgeted for analytical support in the Department should likely be doubled.

The following analysis comes from the Single Payer attachment that has previously been provided. Because of the President's preference for establishing the public option, we will repeat those analyses here. Aside from a broader base of funding, other compromises are necessary to enact a public option.

To set up a **public option** end protections for pre-existing conditions and mandates. The public option would then cover all families who are rejected for either pre-existing conditions or the inability to pay. In essence, this is an expansion of Medicaid to everyone with a pre-existing condition. As such, it would be funded through increased taxation, which will be addressed below. A variation is the expansion of the Uniformed Public Health Service to treat such individuals and their families.

The public option is inherently unstable over the long term. The profit motive will ultimately make the exclusion pool grow until private insurance would no longer be justified, leading-again to Single Payer if the race to cut customers leads to no one left in private insurance who is actually sick. This eventually becomes Medicare for All, but with easier passage and sudden adoption as private health plans are either banned or become bankrupt. Single-payer would then be what occurs when insurance companies are bailed out in bankruptcy, the public option covers everyone

and insurance companies are limited to administering the government program on a state by state basis.

The financing of the Affordable Care Act should be broadened. It should neither be funded by the wealthy or by loan sharking student loan debtors. Instead, it should be funded by an employer-paid consumption tax, with partial offsets to tax payments for employer provided insurance and taxes actually collected funding a Public Option (which should also replace Medicaid for non-retirees). Medicaid for retirees and Medicare should be funded by a border adjustable goods and services tax, which should be broad based.

Why the difference? The goal is to not need a public option as employers do the right thing and cover every worker or potential worker. Using an employer based tax is an incentive to maximize employee coverage. Medicare, however, is an obligation on society as a whole.

Medicare Part E

State governments (were) under financial pressure as a result of the pandemic, especially in the area of healthcare costs, most especially for seniors in nursing homes who are “dual eligibles.” The heart of President Reagan’s New Federalism proposal was the transfer of state Medicaid expenses to the federal government, largely to fund baby boomers who would become dual eligible with time. Time is now up, or will be shortly.

Welfare has been reformed, allowing state and federal governments to save money - which was part of the New Federalism bargain that was not accepted at the time. We will address this part shortly, but the irony is that federal money was reduced without the second part of the trade-off.

Finish the process and create Medicare Part E for low income disabled and retirees. This will put investigation of nursing home conditions into the federal sector. States have done a poor job in enforcement of health and safety standards. It is time to make this a national responsibility.

One way to increase benefits generally is to increase the minimum wage, the higher the better, and rebase current benefits to consider such an increase to be wage inflation. Such a change will fund itself, because wages funding benefits will be increased across the board.

Asset VAT - The President's Fiscal Year 2023 Budget, June 7, 2022

There are two debates in tax policy: how we tax salaries and how we tax assets (returns, gains and inheritances). Shoving too much into the Personal Income Tax mainly benefits the wealthy because it subsidizes losses by allowing investors to not pay tax on higher salaries with malice aforethought.

Asset Value-Added Tax (A-VAT) is a replacement for capital gains taxes and the estate tax. It will apply to asset sales, exercised options, inherited and gifted assets and the profits from short sales. Tax payments for option exercises, IPOs, inherited, gifted and donated assets will be marked to market, with prior tax payments for that asset eliminated so that the seller gets no benefit from them. In this perspective, it is the owner's increase in value that is taxed.

As with any sale of liquid or real assets, sales to a qualified broad-based Employee Stock Ownership Plan will be tax free. This change would be counted as a tax cut, giving investors in public stock who make such sales the same tax benefit as those who sell private stock.

The repeal of corporate profits taxes as part of the creation of a subtraction value added taxes and repeal of capital gains taxes in the United States will lead to their repeal worldwide. If Asset Value Added Taxes are adopted, the rate should be negotiated so that investors who are able do not market shop for the lowest rate. The recent OECD compact on minimum rates is an example of how tax cooperation on capital can work for other types of asset taxation.This tax will end Tax Gap issues owed by high income individuals. The base 20% capital gains tax has been in place for decades. The current 23.8% rate includes the ACA-SM surtax), while the Biden proposal accepted by Senator Sinema is 28.8%. Our proposed Subtraction VAT would eliminate the 3.8% surtax. This would leave a 25% rate in place.

Settling on a bipartisan 22.5% rate (give or take 0.5%) should be bipartisan and carried over from the capital gains tax to the asset VAT.A single rate also stops gaming forms of ownership. Lower rates are not as regressive as they seem. Only the wealthy have capital gains in any significant amount. The de facto rate for everyone else is zero.

With tax subsidies for families shifted to an employer-based subtraction VAT, and creation of an asset VAT, taxes on salaries could be filed by employers without most employees having to file an individual return. It is time to TAX TRANSACTIONS, NOT PEOPLE!

The tax rate on capital gains is seen as unfair because it is lower than the rate for labor. This is technically true, however it is only the richest taxpayers who face a marginal rate problem. For most households, the marginal rate for wages is less than that for capital gains. Higher income workers are, as the saying goes, crying all the way to the bank.

In late 2017, tax rates for corporations and pass-through income were reduced, generally, to capital gains and capital income levels. This is only fair and may or may not be just. The field of battle has narrowed between the parties. The current marginal and capital rates are seeking a center point. It is almost as if the recent tax law was based on negotiations, even as arguments flared publicly. Of course, that would never happen in Washington. Never, ever.

Compromise on rates makes compromise on form possible. If the Affordable Care Act non-wage tax provisions are repealed, a rate of 26% is a good stopping point for pass-through, corporate, capital gains and capital income.

A single rate also makes conversion from self-reporting to automatic collection through an asset value added tax levied at point of sale or distribution possible. This would be both just and fair,

although absolute fairness is absolute unfairness to tax lawyers because there would be little room to argue about what is due and when.

Ending the machinery of self-reporting also puts an end to the Quixotic campaign to enact a wealth tax. To replace revenue loss due to the ending of the personal income tax (for all but the wealthiest workers and celebrities), enact a Goods and Services Tax. A GST is inescapable. Those escapees who are of most concern are not waiters or those who receive refundable tax subsidies. It is those who use tax loopholes and borrowing against their paper wealth to avoid paying taxes.

For example, if an unnamed billionaire or billionaires borrow against their wealth to go into space, creating such assets would be taxable under a GST or an asset VAT. When the Masters of the Universe on Wall Street borrow against their assets to avoid taxation, having to pay a consumption tax on their spending ends the tax advantage of gaming the system.

This also applies to inheritors. No "Death Tax" is necessary beyond marking the sale of inherited assets to market value (with sales to qualified ESOPs tax free). Those who inherit large cash fortunes will pay the GST when they spend the money or Asset VAT when they invest it. No special estate tax is required and no life insurance policy or retirement account inheritance rules will be of any use in tax avoidance.

Tax avoidance is a myth sold by insurance and investment brokers. In reality, explicit and implicit value added taxes are already in force. Individuals and firms that collect retail sales taxes receive a rebate for taxes paid in their federal income taxes. This is an intergovernmental VAT. Tax withheld by employers for the income and payroll taxes of their labor force is an implicit VAT. A goods and services tax simply makes these taxes visible.

Should the tax reform proposed here pass, there is no need for an IRS to exist, save to do data matching integrity. States and the Customs Service would collect credit invoice taxes, states would collect subtraction VAT, the SEC would collect the asset VAT and the Bureau of the Public Debt would collect income taxes or sell tax-prepayment bonds.

Contact Sheet

Michael Bindner
The Center for Fiscal Equity
14448 Parkvale Road, Suite 6
Rockville, MD 20853
240-810-9268
fiscalequitycenter@yahoo.com
mbindner@umd.edu

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All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears:

This testimony is not submitted on behalf of any client, person or organization other than the Center itself, or the University of Maryland.