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THE PRESIDENT'S FISCAL YEAR 2024 HEALTH AND HUMAN SERVICES BUDGET

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

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THE PRESIDENT'S FISCAL YEAR 2024 HEALTH AND HUMAN SERVICES BUDGET

WEDNESDAY, MARCH 22, 2023

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:01 a.m., in Room SD–215, Dirksen Senate Office Building, Hon. Ron Wyden (chairman of the committee) presiding.

Present: Senators Stabenow, Menendez, Carper, Cardin, Brown, Bennet, Casey, Warner, Whitehouse, Hassan, Cortez Masto, Warren, Crapo, Grassley, Cornyn, Cassidy, Lankford, Daines, Young, Barrasso, Johnson, Tillis, and Blackburn.

Also present: Democratic staff: Shawn Bishop, Chief Health Advisor; Eva DuGoff, Senior Health Advisor; Joshua Sheinkman, Staff Director; Tiffany Smith, Deputy Staff Director and Chief Counsel; Kripa Sreepada, Senior Health Counsel; and Polly Webster, Senior Health Counsel. Republican staff: Kellie McConnell, Health Policy Director; Gregg Richard, Staff Director; and Conor Sheehey, Senior Health Policy Advisor.

OPENING STATEMENT OF HON. RON WYDEN, A U.S. SENATOR FROM OREGON, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The Senate Finance Committee will come to order.

We are meeting today to discuss with Secretary Becerra the budget for the Department of Health and Human Services. The President's budget comes down to a simple proposition: helping working families and the middle class get ahead and reducing the Federal deficit are not mutually exclusive. So today, we are committed to doing both.

When it comes to health care, that means protecting Medicare for the next generation by making sure that the wealthy pay their fair share in taxes; strengthening Medicare's negotiating power for the cost of prescription medicine; and investing in priorities like mental health care, home-based care, and the health-care workforce. That is a sharp contrast to the Republican approach to the Federal budget.

Since the beginning of the year, there has basically been a demand for secret negotiations on unspecified cuts to Federal programs, while holding hostage the full faith and credit of the United States Government. Budget Committee Chair Whitehouse and I asked the nonpartisan Congressional Budget Office to run the numbers, and it is clear that Republican promises to spare certain

parts of the budget like Social Security simply do not add up. Sparing essential lifelines for seniors in addition to Republican priorities means essentially zeroing out everything else in the Federal budget.

I would like to take a moment to address press reports that some House members are considering proposals that cut earned benefits in Medicare or Social Security for those who are not yet at retirement age. I want to be clear. As long as I am chair of this committee, I will fight any effort to engage in intergenerational warfare. There are plenty of ideas to improve the financial health of these programs that do not include forfeiting the earned benefits of current workers.

Now I am going to take a minute to talk about what that means in practical terms, starting with Medicaid. Contrary to popular belief, Medicaid acts as our country's backstop for nursing home care, not Medicare, and since my days as director of the Gray Panthers, I have been stunned at how many people still believe Medicare leads in the effort to fund nursing home care. That is just not accurate. It is Medicaid.

That means when your parents are in their 80s and 90s and require nursing home care, Medicaid is there to help cover the costs once they have essentially gone through all the hard-earned retirement savings and everything they did to try to plan for retirement while they were working. If Republicans go after Medicaid the way they did in 2017 by cutting Federal support to State Medicaid programs and giving States free reign to pare back benefits, that guaranteed backstop of nursing home care for seniors is ripped away.

That means a return to times from distant memory before the social safety net was created, when older Americans who ran out of savings and could not count on a family member were essentially consigned to a poor farm. Nobody wants America to return to that time. So let us look for ways to work together to take on the big challenges of our time, rather than pursuing reckless cuts that imperil the country's older people.

Now, a couple of important priorities in the President's budget—first on prescription drugs. The President's budget has several bold proposals to build on the Inflation Reduction Act that hold pharma accountable for years of high prices while lowering costs for seniors. That includes speeding up Medicare negotiations and increasing the number of drugs subject to negotiation. I strongly support this approach, especially as the Centers for Medicare and Medicaid Services continue to steadily implement the laws that are already on the books.

For example, last week the Biden administration announced that the anti-price-gouging law that was written in this committee, in this room on a bipartisan basis in 2019, will lower coinsurance payment for 27 drugs in Medicare Part B. Part B pays for prescription drugs to treat diseases like cancer and rheumatoid arthritis administered in a physician's office. That includes Humira and, folks, Humira is Exhibit A for why drug pricing reforms were needed in the first place.

Important steps like these coinsurance reductions, free vaccines, and the insulin cost cap in Medicare are just the beginning of the big league impact this law will have on Americans' health-care

costs. I have said from the beginning that when the Federal Government leads on flagship health reforms in Medicare and in its key programs, we know as sure as the night follows the day that the private sector is going to follow, and that is exactly what is happening.

Next, mental health care—very fitting, since my seatmate here has been the leader of that cause here in the Senate, Senator Stabenow. Last Congress, the committee wrote black letter law to move the country towards a reality where all Americans can get quality mental health care when and where they need it. I especially want to thank my partner here on the Finance Committee, Senator Crapo. At the beginning of 2021, we said on mental health care we were going to be ready on every single bill, every single one, to make sure that we advance the cause of mental health needs. And we were able to do that—on the gun safety law; with improved mental health care in schools; funding for community behavioral health centers led, as I mentioned, by Senator Stabenow; coverage for therapists in Medicare; and new GME slots for psychiatrists. Senator Crapo and I talk often about this, and we intend to continue our mental health work in this Congress, again in a bipartisan way.

Now one final point with respect to mental health care, to clear up a little confusion. When it comes to mental health parity, the Congress passed a landmark law in 2008 based on the proposition that physical and mental health would be treated equally. That, unfortunately, does not happen today. Fifteen years after the law was written, the insurance companies, the big insurance companies, are still finding ways to drag their feet on carrying out the parity law with respect to mental health.

So the challenge for the committee is to stop the foot-dragging that is taking place under current law, colleagues—a 2008 law—and develop fresh approaches to give Americans what they thought they were getting in 2008. The President's budget takes important steps in that direction, and I am pleased that Senator Bennet also is leading the way to put mental health care on a better footing.

We are also pleased that the President's budget takes a big step when it comes to postpartum coverage for new mothers in Medicaid. At the end of last year, Congress came together on a bipartisan basis to create an option for every State to cover postpartum care for new mothers for 12 months. The President's budget, to its credit, takes the next step to make that coverage available for the country.

Finally, I want to say I think all of us had a chance over the last few days to read a stunning report about cracks in the health-care system for disabled folks. It was reported on in *The Washington Post*. We are going to need to develop smarter policies that provide long-term care options for families to get the care that is best for them. One option is offered by our colleague from Pennsylvania, Senator Casey, for home and community-based services, and we are going to continue to promote that.

So this is all about making some smart investments in better health for the people of this country, consistent with showing that you can do that while reducing the Federal budget deficit.

After Senator Crapo has a chance to make his opening remarks, we will introduce Senator Becerra and we will get underway.

Senator Crapo?

[The prepared statement of Chairman Wyden appears in the appendix.]

OPENING STATEMENT OF HON. MIKE CRAPO, A U.S. SENATOR FROM IDAHO

Senator CRAPO. Thank you very much Mr. Chairman, and I thank you, Secretary Becerra, for being here today.

Before we begin, let me let you know. I have to at this very time be introducing a judicial nominee for an Idaho district judge position. So, when I finish my remarks and I step out, I am not walking out on you. I will be back, and before I get to my prepared remarks, I do want to respond a little bit on the question about the debt ceiling negotiations.

I want to make it very clear. The Republicans are asking for negotiations on the debt ceiling process, to add some fiscal restraint into the debt ceiling extension. I ask you, Secretary Becerra, to take back to the President my plea that he engage with us in negotiations. I want to make it clear. We are not talking about trying to reduce benefits in Medicare or Social Security for our seniors. What we are talking about is reasonable reforms that can help us get to some kind of fiscal restraint on our spiraling debt. I would just encourage all of my colleagues in the Senate, but particularly the President, to engage with us in those kinds of negotiations.

I want to start my formal remarks on the positive. You have testified before and talked to me privately about the fact that although we have our differences on a lot of different policy areas, we want to find those areas where we can work together, and we found some last year. Last year, as Senator Wyden has already indicated, we came together on a package of bipartisan reforms to produce common-sense solutions, ranging from mental health improvements to comprehensive telehealth coverage for seniors and working families.

Moreover, we accomplished all of this by reducing the deficits by billions of dollars, and the administration and you, Secretary Becerra, worked with us on this, and we have made good progress. I look forward to partnering with HHS, as well as with my colleagues on both sides of the aisle, to advance further reforms like this in this Congress, to improve health-care access, affordability, and choice for all Americans.

That being said, I do have concerns with the budget that the President has put forward. Unfortunately, many of the proposals in the President's budget run directly counter to these types of initiatives that I have discussed. I have serious concerns with the focus on partisan policies that risk harming health-care access and affordability for both current and future patients. We talked about some of this yesterday.

The budget's central proposal, for instance, would dramatically expand the size and scope of the bureaucratic government-run drug-pricing program enacted last year in the IRA. Prior to that law's passage, my Republican colleagues and I warned repeatedly that imposing sweeping price controls would prove disastrous for

patients, biomedical research and development, and domestic manufacturing jobs, and many of our fears have already come to pass.

We pointed to the risk of higher launch prices and distorted pricing practices based on projections validated by the nonpartisan Congressional Budget Office. And sure enough, *The Wall Street Journal* reported in January "the impact in 2023 may actually be higher drug prices." We also expressed concerns around lifesaving R&D, as a University of Chicago study estimated the IRA would result in 135 fewer new drug approvals in the next 2 decades.

That figure would inevitably skyrocket under the budget's proposed expansion. Already, numerous manufacturers have signaled plans to table certain projects in light of the uncertainty created by the IRA. In recent months, we have also seen a rash of drug shortages, which even leading U.S. Food and Drug Administration officials have attributed to pricing dynamics. Doubling down on the IRA's price controls would exacerbate the law's most harmful consequences.

Americans deserve better and more affordable access to prescription drugs, and we can find bipartisan results-oriented solutions to advance that goal. Government price mandates, however, are a step in the wrong direction. I also have profound concerns with the budget's bold claims of averting the Medicare hospital insurance trust fund's looming insolvency, largely through massive tax hikes and budget gimmicks.

This unbalanced approach does nothing to address Medicare's cost drivers. It would also punish the small business job creators and entrepreneurs who drive our economy. Unfortunately, the budget takes a similarly shortsighted approach to Medicaid, reviving a number of rejected policies from past proposals, including hundreds of billions in new spending tied to burdensome conditions and efforts to circumvent State leaders.

The Federal Government should focus on supporting States as they work to return Medicaid to post-pandemic normalcy, rather than imposing new top-down mandates. Instead of turning to a one-size-fits-all solution, we should look to proven models for Federal programs, such as Medicare Advantage. With sky-high patient satisfaction rates, Medicare Advantage shows that consumer choice and market forces can produce more benefits and better outcomes.

As we move forward, I encourage your Department, Mr. Secretary, to focus on our shared goals, from cost-cutting competition to sustainable telehealth access and other similar issues, rather than on these partisan priorities.

I thank you again for being here today, and I thank you, Mr. Chairman.

[The prepared statement of Senator Crapo appears in the appendix.]

The CHAIRMAN. I thank my colleague, and my colleague and I are not going to go back and forth about who said what, when. I am just going to put into the record, by unanimous consent at this point, the House Republican Study Committee proposals* to cut

*RSC Blueprint to Save America, Fiscal Year 2023 Budget, *https://hern.house.gov/uploadedfiles/fy23_budget_final_copy.pdf*.

Medicaid and Medicare. So specifically, that is what we are talking about.

So, Secretary Becerra, we welcome you, the 25th Secretary of the Department of Health and Human Services, the first Latino to hold the office in the history of the United States. You have dedicated your career to public service, most recently serving as the Attorney General of California from 2017 to 2021. Prior to that post, you served 12 terms in the Congress as a member of the House of Representatives.

While serving in Congress, Secretary Becerra was the first Latino member of the Committee on Ways and Means. He served as ranking member of the Ways and Means Subcommittee on Social Security and ranking member of the Subcommittee on Health.

Mr. Secretary, we welcome you. I have appreciated the chance to work with you often over the years and appreciate your commitment to advocating for the people served by the Department of Health and Human Services. Go ahead with your remarks.

STATEMENT OF HON. XAVIER BECERRA, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Secretary BECERRA. Chairman Wyden and Ranking Member Crapo, and to all the members, thank you for the invitation.

A lot has happened in the year since I last spoke to you about budgets. More than 16 million Americans have secured health insurance through the Affordable Care Act marketplaces. That is an all-time high. Altogether, more than 300 million Americans now carry insurance to cover their health-care needs, a historic high as well.

The President's new lower-cost prescription drug law has capped insulin at $35 per month and made preventative vaccines like the flu, COVID, and shingles vaccines available for free under Medicare. Moving forward, this new law gives us the right to finally negotiate lower prescription drug prices for Americans. And to cap it all off, the Biden-Harris administration has safely and effectively executed the largest adult vaccine program in U.S. history, achieving nearly 700 million shots in arms during the COVID pandemic without charge.

The Fiscal Year 2024 budget proposes $144 billion in discretionary funding and $1.7 trillion in mandatory funding for HHS. It positions us to tackle the urgent challenges we face, including a growing behavioral health crisis and future public health threats. It also funds operations in mission-critical infrastructure needed to build a healthier America, moving the Nation from an illness care system to a wellness care system.

An illness care system leaves our most vulnerable families behind. A wellness care system invests in providing the full spectrum of health care to all Americans. Illness care allows the price of prescription drugs to skyrocket. Wellness care starts by prescribing fruits, vegetables, and exercise; it treats food as medicine. Illness care requires you to get a referral by your family physician to see a specialist for mental health services. Wellness care—well, it lets you get mental health care the moment you walk through the door of your family physician's office.

Illness care forces hardworking Americans to deplete their life savings to get the long-term care they need. Wellness care, it invests early in long-term care, like in-home care, so our older American adults and our Americans with disabilities can thrive at home and in their communities.

Our budget invests in wellness care. We invest more than $30 billion to prepare us for the next COVID or public health crisis, including the billion dollars to replenish our Nation's strategic national stockpile.

On behavioral health, too many of our loved ones are dying from suicide or overdose, so we increase access to crisis care. We grow the behavioral health workforce, and we beef up substance use services. We are also gearing up to handle more than 6 million additional contacts from people who are experiencing a mental health crisis, through 988, the 3-digit suicide prevention lifeline we stood up last year.

This budget covers 2 million adults left out by Medicaid by their home States and extends tax credits that make health care more affordable for millions of Americans. It would also ensure that expanded postpartum Medicaid coverage for a new mom and her baby is here to stay. The President's budget not only strengthens Medicare for today's seniors but protects and strengthens it for the next generation.

We also take care of our family members in this budget, investing $600 billion in child care and preschool programs, and $150 billion to strengthen Medicaid home and community-based services. This budget funds the Cancer Moonshot and ARPA–H. It invests in the title X family planning program essential to so many of our families, and it delivers on our commitments made as part of the National Strategy for Hunger, Nutrition, and Health. It opens more community health centers and—important to me as a former Attorney General—it bolsters our health-care fraud and abuse detection and enforcement work.

And the President's budget honors our responsibilities to Indian country, with more than $2 billion in new resources in 2024. Last year for the first time, you gave the Indian Health Service advanced appropriations, providing the same protection against budget uncertainty that other health services receive. We hope to build on that progress this year.

This budget reflects the President's and our values and commitments. It helps to begin the move from a Nation focused on illness care to one about wellness care. And importantly, it ensures health and wellness are within the reach for all Americans.

On behalf of the women and men of the Department of Health and Human Services, we look forward to working with you, and I thank you for having me today.

[The prepared statement of Secretary Becerra appears in the appendix.]

The CHAIRMAN. Mr. Secretary, thank you. I will start it off with respect to the trust fund. Now, the President and Democrats are committed to protecting what we have always called Medicare's guarantee. Medicare is not some kind of voucher. It is a guarantee of high-quality health care, and Americans have earned this benefit with each paycheck.

So, with this budget, the President is focused on making sure billionaires and the very wealthy pay their fair share. It would strengthen Medicare's negotiating authority and lower the price of more prescription drugs and extend Medicare's solvency for 25 years. Now what we are hearing from the other side is giving a free pass to billionaires. All these budgets work it out so that billionaires basically are left untouched. And now we are seeing the full faith and credit of the United States being threatened.

So, what I would like to do is make sure that you have a chance to make it clear what the differences are with respect to these issues. The President's budget, in my view, does not cut Medicare benefits by taking steps like raising the eligibility age, reducing access to care, or basically just handing everything over to a bunch of big insurance companies. Is that factually, correct?

Secretary BECERRA. Senator, the President made it very clear he will not propose any budget that cuts benefits under Medicare for the 67 million people who today count on Medicare, and to the millions more who are added every year. He would in fact increase benefits at the same time that he is strengthening the program for the future generations to come.

So, it is a proposal that was due because so many Presidents have come before President Biden and never offered a proposal. I, for 24 years in Congress, never saw Congress try to tackle this in a serious way. Finally, we have a President who says, "Here is how we do it, and we can not only strengthen Medicare, but we can do it without cutting one benefit for any senior in America."

The CHAIRMAN. All right.

Let us move on to prescription drugs and the implementation of the Inflation Reduction Act. And I think you heard me mention right here in this room with Senator Grassley—Senator Stabenow was here, Senator Crapo was here. That is where we locked in the first-ever set of financial penalties for pricing gouging in Medicare. We saw the benefits of this this week, with the reduction in coinsurance that is going to be of help to millions of people. That was done in 2019 in this room, in a bipartisan way. So we want to keep building on that.

CMS is working on a tight timeline with respect to the drug pricing reforms, and there is a lot to do in advance of the September 1st announcement of which 10 drugs will be the first to go forward on the negotiation process. Last week, as I indicated, was an important milestone with the release of the proposed Medicare price negotiation guidance. This is in addition to the implementation of the penalties for price gouging, and you and I have talked about that.

It is so important that the Inflation Reduction Act guidelines are met, and we ensure that the people who are participating in this program are ready and that the law delivers for seniors and the public. So my first question to you—and you and I have talked about this—is, is it possible for you today to commit to a timely release of the final negotiation guidance which would come about this summer?

Secretary BECERRA. Senator, that is our goal. We have never done this before. We thank you for the resources to try to do it right. We understand that September is a magical date when we

announce the 10 drugs that would be part of the first negotiation. We will continue to work with you. I am committed to make sure that each and every member in the Senate and the House has the information they need to see where we are going, and because you were gracious in giving us the resources to staff up, we hope to not only meet the deadlines, but hopefully beat them.

The CHAIRMAN. We look forward to working with you, really month by month, to meet this September deadline. You and I have talked about this before. This was an extraordinary victory for the millions of seniors who would stand in those pharmacy lines and feel like they were getting mugged by the prices. Pharma, you know, protected this ban on negotiation like they were protecting the holy grail. Senator Stabenow and so many others kept making the case.

Of course you ought to negotiate. There are more than 50 million seniors on Medicare. Who in the world does not negotiate? So last week's announcements were very good with respect to price gouging, with respect to the list for negotiation. We are moving ahead to make sure this gets implemented. Tell me a little bit about what the American people can expect to be told as this goes forward and how it impacts them, and I will yield to my colleagues.

Secretary BECERRA. Mr. Chairman, I believe we are going to not only be transparent with you and your colleagues, but with the American public, about how we are going about selecting those drugs, the process in which we are going to engage the manufacturers in this. We want them to be able to participate as much as possible in a public setting, so people can see how they behave in this process of negotiation and let the American people see. Sunshine is the best disinfectant, as they say, and we have no problem with that.

The CHAIRMAN. Very good; thank you.

Senator Stabenow will be next.

Senator STABENOW. Thank you very much, and welcome, Mr. Secretary. There are so many different things we can talk about that are so important and are making a difference in people's lives. And thank you, and thank the President for doing what you are doing.

First, I do want to recognize, I have a lot of friends in purple shirts here from the Alzheimer's Association, and we want to celebrate, I think over the years now, something like a 700-percent increase in research, which is so critical, and efforts we have done to support caregivers. And the next step is making sure that patients have the critical and urgent treatments that they need.

And so, I will be following up with you more on that, but this is the moment to really delve into that, and so I appreciate that they are all here with us this week.

Let me start also by saying that Medicare and Social Security are great American success stories that lifted a generation of seniors and people with disabilities out of poverty. We certainly are not going to go backwards; at least certainly the majority in the United States Senate is not going to go backwards.

When the chairman talks about the House Republican study group budget, which has been lifted up as a major foundation for what the House is talking about, it raises the age of Medicare to

70, raises the age of Social Security to 70. I cannot imagine doing that or privatizing the systems, turning them over to Wall Street or private insurance companies. So I congratulate you, and I congratulate the President for going in a different direction, which is to strengthen Medicare and to focus on the costs of prescription drugs and so on as we move things in the right direction for people.

You know I have to talk about mental health. I have to talk about Certified Community Behavioral Health Clinics. I am so excited that this is something that we have done on a bipartisan basis. I see Senator Cornyn here. We worked really hard together on the Safer Communities Act, and really have the most, the strongest investment in mental health and addiction services literally in 50 years, and that is not an exaggeration. So, thank you for working on that, as well as our chairman and ranking member, who have been so pivotal in all of it.

We have had a demonstration project with 10 States fully funded—like health care, with clinics, quality clinics, 24-hour emergency services. We are now working on the next piece. You announced SAMHSA has the process for identifying the next 10 States. We want to get that all the way to 50. But I would like you to elaborate a little more on your plans for this really transformative system. We are moving from grants; grants are good, but it's much better to have this be an integral part of our health-care system with ongoing funding and support, support for staff through work that this committee did in expanding Medicare access for therapists, and so on. And GME slots for psychiatrists at the end of the year—really important work that we have done.

But could you expand a little bit on this program and the vision around community behavioral health?

Secretary BECERRA. Yes. And I have to begin, Senator, by thanking you, Senator Cornyn, and others who really championed this. Your fingerprints are all over this expansion of Certified Community Behavioral Health Clinics, and thank God, because we know that mental illness does not end at 5 o'clock. It goes forward at midnight, 3:00 in the morning. You need to have someone you can turn to, and that is where these Certified Community Behavioral Health Clinics will be indispensable.

The fact is that we are going to try to give them a permanent stream of funding so they are not open just 9:00 to 5:00, or they are not open just the first 5 months of the year and then they run out of money. This has a consistency, and we know that, for folks who are going through a mental health crisis, they are looking for some stability. And so this helps add that at all hours, all days in the year, and we are going to build on this.

You started with a project, a pilot, and now you see what is happening. And it is great that we are also going to be able to help those States that start off in those projects to expand as well, because what a shame if the States that first took the lead and showed its success would be deprived of the chance to expand. So, thank you very much to you and your colleagues for what you have done.

Senator STABENOW. Well, I am really thrilled that in the President's budget, he makes the Certified Community Behavioral Health Clinics permanent, which is so critical. And I have to say

this was a major bipartisan accomplishment. And while he is no longer in the Senate, my partner, Senator Roy Blunt, was integral to this. And so, a shout-out to Senator Blunt as well.

So, thank you, Mr. Chairman.

The CHAIRMAN. I thank my colleague.

Next will be Senator Crapo. The next three—it is a very hectic day up here, Mr. Secretary, as you know on Wednesdays. At this point, the next three in order of appearance would be Grassley, Menendez, and Cornyn.

So next is Senator Crapo.

Senator CRAPO. Thank you very much, Mr. Chairman.

And I think I will start out with Alzheimer's. As Senator Stabenow mentioned, we have a number of our Alzheimer's friends here with us today. The FDA's accelerated approval pathway has provided a lifeline for countless Americans, advancing access to safe and effective medicines for cancers, rare diseases, HIV, and other conditions like Alzheimer's, years before these treatments could otherwise come to the market.

Unfortunately, this administration has taken unprecedented steps to erode this pathway, deterring lifesaving innovation and delaying access to care. This troubling trend began with CMS's coverage restrictions for an entire class of Alzheimer's therapies, and it seems set to continue with the recently announced Accelerating Clinical Evidence Model, which would slash payments for treatments that rely on accelerated approval.

Secretary Becerra, I recently led a letter urging the administration to abandon this misguided model, given the potential for slower and slimmer pipelines of new medicines for seniors, among other serious conditions. I also wrote to you last year about the grave implications of the Alzheimer's coverage decision. How does your department plan to ensure that accelerated approval pathways remain a robust and viable option for innovators, and most importantly for patients?

Secretary BECERRA. Senator Crapo, you have touched on something very important for me, having my father, my father-in-law and mother-in-law with dementia in the last years, last months of life. Very tough. We were there. My father died in my home. We cared for him. Same with my mother-in-law and father-in-law. My wife and her siblings cared for them. This is tough. Dementia—it is all of us, not just the patient, and we want to be there.

We are fortunate that in America we are coming up with new, innovative treatments, and we are doing everything we can to accelerate them. I give you the evidence of the COVID vaccine. No one expected that the COVID vaccine would come out so quickly. Whether it is Alzheimer's, COVID, hepatitis C, we are moving and we want to be there, and we will look for every innovative approach, every pathway possible to make sure that, one, we can put a safe and effective drug in front of the American people, and then also determine whether it will be covered by Medicare.

Senator CRAPO. Well, I understand that commitment. But the accelerated model that you have adopted or are looking to adopt and pursue is going in exactly the opposite direction. I encourage you to revisit this model.

Let me move on to Medicare Advantage. CMS recently released their annual advance notice, which included some significant changes to the Medicare Advantage risk model for the upcoming bid process. We have heard concerns from providers, patients, and plans that these changes will disproportionately impact the most vulnerable MA beneficiaries, including those with low incomes or chronic conditions. Mr. Secretary, does the administration plan to address these concerns in its final MA rule?

Secretary BECERRA. Senator, thanks for the question. Half of all seniors who have Medicare use the Medicare managed care model. This is critically important. We are absolutely going to make sure that when the final gavel falls on this, it will not only move us in the right direction with more efficiency, but it also will protect every Medicare beneficiary, seniors, and disabled Americans who use the Medicare program.

Senator CRAPO. Well, thank you. And I encourage you to look at this carefully, and if you have not already done it, to conduct an impact analysis, to determine how the model you are currently considering changes to would affect different groups of beneficiaries. I think you will find that, once again, these proposals are going in the wrong direction.

Let me move on to one where we can agree. That is on telehealth. As the budget request mentions, my colleagues and I came together late last year to advance a crucial 2-year extension of wide-ranging telehealth flexibilities, including for Medicare beneficiaries. Without further action, however, these policies will expire at the end of 2024, creating a coverage cliff for tens of millions of seniors across the country.

Secretary Becerra, I realize this requires Congress to get engaged and involved. But from the administration's perspective, how should Medicare telehealth coverage look in the longer term, and can you commit to working with Congress to develop meaningful solutions that will protect access well beyond the end of next year?

Secretary BECERRA. Yes, Senator, this one is crucial. We absolutely will work with you, because we do not want those statutory flexibilities to expire. We are going to need your help. Thank you for the leadership you have demonstrated over the past on this one. We, for example, want to make sure that everyone has the broadband that will make telehealth work. We want to make sure that everyone can use a doctor wherever that doctor is located. This requires the States to work with us to make sure we can cross State borders.

We want to make sure that if you are in rural America or inner-city America, you do not have to worry that you do not have a way to get to the doctor. You will have access through telehealth.

Senator CRAPO. Well, thank you. And encourage us as strongly as you can to get that legislatively done. I know Senator Wyden and I are working very closely together on this, and I just want some strong support from the administration.

The CHAIRMAN. Thank you, Senator Crapo. And you are right: we are working together on a number of these issues. I just want very quickly, before we go to Senator Grassley, to say we very much appreciate having Alzheimer's advocates in the house today.

My mother was at Channing House in Palo Alto for years and years on end with Alzheimer's, and they were one of the country's—and continue to be one of the country's leading institutions in terms of dementia care and Alzheimer's. So you are hearing from all of us up here that we are committed to working with you.

The other point I wanted to mention involves the medicines, the drugs. That is, I am a very strong supporter of accelerated approval for these very exciting new drugs for Alzheimer's. My colleague and seat mate, Senator Stabenow—I am still trying to persuade her to not retire—is leading the cause in terms of these new medicines.

It is just very important to remember what was agreed to originally, and that was, when you have accelerated approval so we can make sure we are keeping our commitments to these patients, it would be followed up by the drug companies presenting evidence of the progress with respect to how the drugs are working on patients and working with patients.

That was part of the accelerated pathway in 1992. So I want all the folks who are doing this wonderful work advocating for patients to know, we are going to support you. We are going to look for research, we are going to look for new medicines. The accelerated approval is part of it, and the pharmaceutical companies have agreed, after the drug is approved, to continue to furnish evidence of its progress. That is very important. Mr. Secretary, you remember that was what Dr. Califf agreed to with me when we were considering his nomination.

Senator Grassley?

Senator GRASSLEY. Thank you very much and—two thank yous. First of all, you very quickly instituted the over-the-counter hearing aid, the hearing aid law that Senator Warren and I sponsored. I also want to thank you for enabling the transition health plans to continue, because 65,000 Iowans are benefiting from that action, and many of these people are farmers and small business owners. Letting them continue has been a bipartisan priority under Presidents Obama, Trump, and now Biden. So I hope HHS allows them to continue in the future beyond 2024.

Now let me go to my first question. Members of this committee, including this Senator, are investigating the deadly failures of our Nation's organ donation system, the Organ Procurement and Transplantation Network. I have been looking into this network a long, long period of time. The problems have gotten worse. Thousands of patients are dying every year, and billions of taxpayer dollars are wasted because of gross mismanagement. The system is rife with fraud, waste and abuse, corruption, and even criminality. This committee has received credible allegations regarding the United Network for Organ Sharing, relating to that organization threatening whistleblowers, including even patients and caregivers.

Simply put, this is beyond unacceptable. These efforts appear to be part of an attempt to cover up failures and prevent competition for its government contract. So, a question to you: I hope that you can commit to fully investigating all instances of whistleblower retaliation and harassment. Would the HHS commit to removing anyone involved in that improper conduct from any involvement in the Organ Procurement and Transplantation Network leadership and committees? If you do not agree with me, why not?

Secretary BECERRA. Senator Grassley, first, thank you for the work that you have done. As you mentioned, this has taken a long time, and thank God that you have committed to it. On the whistleblower question, we are absolutely committed to working with you to make sure that if there is a claim made about a particular operation, we dive right into it to find out what is going on.

Let me give you the more important news. Today we are announcing at HHS that we are going to put forward a modernization initiative, which will do a number of things that I think you are going to like. One, we are going to call for competition in who becomes the contractor for these organ procurements and the transplant services, and so it will no longer be just one company the way it has been for what, 40 years? So that is one big change that will occur.

Secondly, we are going to require transparency. They have got to start sharing their data. They cannot hide, as you just said, behind this confidentiality and say, "We cannot show you what is going on because it is confidential." We are going to require far more data transparency. Again, this follows all the work that you have done.

Then finally, we are going to try to upgrade the IT system which, as you can imagine with these contractors never having changed—everything gets stale; so does the IT.

We are going to try to update the IT so we can be efficient with those organs that we receive, so we can get them to someone, instead of have them ultimately be discarded because they did not get used in time. Those are things we are announcing today, and in the President's budget, he calls for resources so we can implement this. So we are absolutely going to call on you for your help to try to move this forward, get your input. But again, much of what we are announcing today is a result of the work that you have done over the years.

Senator GRASSLEY. Thank you for your initiative.

I want to turn to rural health care. I want to thank the administration for implementing the new and voluntary Rural Emergency Hospital program that I have worked for 3 or 4 years to get passed. Another rural hospital program that you may not know so much about is called the Rural Community Hospital Demonstration. It extends the financial viability of 26 small rural hospitals in 11 different States, five in Iowa.

The program has taken up to 30 hospitals. But CMS is currently underutilizing the program. Congress has authorized the program for several more years. While there is interest in rural hospital participation, CMS has told me that they have no interest in filling the four additional slots. I realize that you may not know much about this program. Do you think that we should be underutilizing cost-effective rural hospital programs like the Rural Community Hospital Demonstration?

Secretary BECERRA. Senator, I am familiar with the program, and we are making a concerted effort in rural America to inject some life into some of these facilities, because as you know very well, too many of them are closing, and they are not being replaced. When they are being replaced, they are first being gutted of some of the essential services that they used to provide. So we have dedicated services into rural community hospitals.

But we are going to try to do more, and we certainly will take your lead on some of these initiatives, because we know that those of you who go back home every day and have to deal with those providers know exactly what they need and where they need to go. So we will look forward to working with you.

Senator GRASSLEY. Thank you, Mr. Secretary, and thank you, Mr. Chairman.

The CHAIRMAN. While he is in the room, let me thank Senator Grassley for working in such a bipartisan way over the years to improve the system with respect to organs and organ procurement. Yesterday, there was, in my view, a big victory for families across the country who have been fighting for more effective organ procurement and transportation system. The administration indicated they would work with us to have more competition in this UNOS contract.

This committee has felt, on a bipartisan basis, that there has not been enough competition for the contract and meeting the expectations of Americans waiting for transplants. So I want to thank my colleagues on both sides of the aisle. Senator Grassley in particular has been at this for years, and I look forward to working closely with him.

Senator Menendez is next.

Senator MENENDEZ. Thank you, Mr. Chairman. Mr. Chairman, before I go to my questions, I just simply want to say, I want to echo your comments as someone whose mother had a 10-year-long goodbye with Alzheimer's. We have a moral, as well as an economic imperative to end Alzheimer's in our time, and so I hope the budget will reflect that as well.

Mr. Secretary, for years communities across the country have struggled to fill major provider workforce gaps, a growing crisis exacerbated by the pandemic. I have long championed legislation to address the physician shortage by increasing the number of Medicare-funded graduate medical education slots, and based on my legislation, the Resident Physician Shortage Reduction Act, Congress authorized the creation of 1,000 new Medicare-funded GME slots in the Consolidated Appropriations Act of 2021.

It outlines specific eligibility criteria for distributing these slots. However, the kingdom of CMS, in its final rule for 2022 and again in 2023, included additional criteria not specified in the law. This additional location-specific prioritization unfairly disadvantages States that have few geographic or population HPSAs. As a result, in New Jersey and other States, we are completely, completely shut out from obtaining these critical residency positions.

The CAA of 2021 clearly specifies that "the Secretary shall," not may, "shall distribute up to 200 residency positions each year and shall distribute not less than 10 percent of the residency positions to each of four specified categories of providers." That is the law. That is what Congress's intent was. Now, I raised this with CMS last year. They failed to address this issue.

Can I have your commitment to work with me to revise the methodology used to distribute future residency positions so that we follow Congress's intent and the law, and that States are not totally shut out of this program?

Secretary BECERRA. Senator, first, thank you very much for the work you have done on graduate medical education, and absolutely, you have my commitment to work with you on this.

Senator MENENDEZ. Thank you. Now, I am concerned that the proposed advance notice Medicare Advantage rate announcement will create further health disparities for the 640,000 Medicare Advantage beneficiaries in Puerto Rico. As you know, Puerto Rico seniors overwhelmingly depend on the MA program, with an MA penetration rate of 94 percent among beneficiaries eligible for Medicare Parts A and B.

The proposed changes could impose the largest year-to-year reduction in Federal health funding to Puerto Rico, a change that is harmful not only to the most vulnerable beneficiaries, but to the island's health-care system and economy, one that we have been working towards improving. This is going to set them back. Further, the MA program in Puerto Rico supports health access and equity by filling gaps in care resulting from the island's exclusion from many of the Federal health benefits.

I am concerned these changes could undermine progress we have made to date to address disparities on the island, including recent funding gains achieved for the Medicaid program, which I fought for. What is the administration's plan to ensure any proposed changes are not magnifying disparities and reducing services provided to beneficiaries on the island who are United States citizens?

Secretary BECERRA. Senator, thank you for the question, and as we mentioned earlier, when 67 million people count on Medicare, about half of them count on it within the managed care program of Medicare. We have to make sure we get it right. We are in the process of reviewing all the comments that we received based on that advance notice, and what the President said is, we will guarantee that there will be no cuts to the benefits under Medicare in this proposal, that the providers will see in most cases an increase—a substantial increase in some cases—to the reimbursement monies they are receiving——

Senator MENENDEZ. Yes, and this is—with all due respect, this is in the broader context. But you've got to look at Puerto Rico specifically in the disproportionate way it gets affected. So I am worried that while we are talking broadly, the effect in Puerto Rico for the 3.5 million United States citizens is disproportionate. So I am going to follow up with a letter regarding Medicare Advantage in Puerto Rico, urging you to address anomalies in the rate formula to mitigate funding disparities for the island.

Secretary BECERRA. I look forward to that.

Senator MENENDEZ. Finally, last month *The New York Times* published a disturbing report on the illegal use of migrant child labor by several major companies. Some as young as 13-year-olds are unaccompanied minors who came to the United States and were placed with sponsors by the Office of Refugee Resettlement. They are often made to work long hours in hazardous conditions. What are we doing to make sure that that does not happen again?

Secretary BECERRA. And, Senator, like you, I have three daughters. Children are children. We should treat every child in America the way we would expect to have our children treated. It is a serious issue when someone claims that a child is being forced to work,

especially in dangerous conditions. We take very seriously our role at HHS to make sure that while we have custody of a child—and remember, we receive custody of these unaccompanied migrant kids from the Department of Homeland Security.

When we do, we are obligated to provide them with the care that you would expect for a child, while we are in the process of trying to find them a suitable setting to live in, because a large congregant care setting is not the most ideal for any child. And so we go through the process of trying to look for a sponsor. We go through a vetting process where we vet all potential sponsors. And by the way, almost all—about 90 percent of those sponsors—end up being a family member, an immediate family member.

And so what we try to do is make sure that when we do finally place that child in the hands of a sponsor, that they will receive the care that they are supposed to. What we are finding is that, oftentimes, a lot of these children are now being employed, and I hope that we go aggressively—you, we—all go aggressively at any employer that would think that it is right to allow a 12- or 13-year-old to work in conditions that are not even safe for adults.

That is where we have to go and make sure that we are not failing children, and that is why we announced that in a joint effort, the Department of Labor and the Department of Health and Human Services will work to try to make sure that we can do what we can within our jurisdiction to avoid that happening. At HHS, that means trying to get sight from DOL if they know of a particular individual who is seeking to be a sponsor, who may be engaged in the practice of using or employing, or allowing kids to be employed, in ways that are detrimental to them.

We are going to try to do the best we can to make sure we have that fight early, so that no sponsor like that would ever pass our vetting process.

Senator MENENDEZ. Thank you, Mr. Chairman.

The CHAIRMAN. I thank my colleague, and I want my colleague to know I appreciate his leadership, and I especially want to help with that last point that you made. This is outrageous, that companies are exploiting 12-year-olds. In order to make a quick buck, they are taking advantage of these kids. It is outrageous, and I look forward to working with you and following your lead.

Senator Cornyn?

Senator CORNYN. Thank you.

Mr. Secretary, last year, approximately 108,000 Americans died of drug overdoses, including 71,000 roughly from synthetic opioids like fentanyl. Do you believe we have a public health crisis when it comes to these overdose deaths?

Secretary BECERRA. Absolutely; absolutely.

Senator CORNYN. And one reason why we have this public health crisis—which you and I both recognize as such—is because we have lost control of our southern border. We have seen millions of people show up, some claiming asylum, some being placed—like unaccompanied children—through your offices with sponsors in the interior. And of course the asylum system now essentially is a free pass into the interior of the United States, and due to the backlog in the immigration court system, many of these cases will never be reached,

assuming people actually show up for their immigration court hearing in the future, with very little consequences for failing to do so.

As you know, title 42, which is the public health title that was implemented because of COVID, will expire in May. I would like for you to tell us what the administration's plan is to deal with this public health crisis and this humanitarian crisis caused by the lack of any controls at our border?

Secretary BECERRA. And, Senator, I will try to concentrate my comments on the work that we are doing at HHS, and I will let my colleagues speak to the work that they are doing, for example, at the Department of Homeland Security and others, on other aspects of this.

Senator CORNYN. Well, I would like to know what the plan is. I assume you have been consulted and collaborate on that plan. But so far, we have not seen anything that is credible in terms of dealing with this, and as bad as it is now, which has never been worse when it comes to the flow of drugs and people across our border, it will get worse if title 42 expires and there is not an adequate plan put in its place to deal with both the flow of drugs and people.

Secretary BECERRA. Yes, and to your point, because we are having to work under a very broken immigration system, as you mentioned, these are the things that happen. I know that, for example, the Department of Homeland Security has tried to move the asylum process in a way that lets us get to these cases quicker and adjudicate them, so that way we can move through that process.

But in terms of HHS, we continue to try to be prepared, because we do not know who will cross that border as a child who is unaccompanied and when we will have to be ready to secure them from DHS within 72 hours, so they can be in an appropriate setting. So what we are doing is preparing for whatever the eventual outcome is, to make sure that we respect the rights of any child to receive care that is essential, and we are going to continue to do that at HHS.

Senator CORNYN. Well, Mr. Secretary, I will just give you one person's opinion. I think the Biden administration has completely dropped the ball when it comes to the border, and unfortunately, we have seen all of these deaths. I went recently to a high school right outside of Austin, where I live, and talked to the parents who have lost young people who thought they were taking something relatively innocuous, but it was laced with fentanyl. And as you know, the cartels use industrial-type pill presses to make what looks like a normal pharmaceutical product, but in fact it is tainted with fentanyl, which, as you know, is extraordinarily powerful, and small amounts will kill.

I want to just say the one thing I would congratulate the Biden administration on is their commitment to implement the bipartisan Safer Communities Act. Senator Stabenow acknowledged one of the most important parts of that bill that Senator Tillis and Senator Sinema and Senator Murphy and I were involved in, and actually all of our colleagues were involved in, in one way or the other.

But we made the single largest investment in community-based mental health care in American history, and I think that is something we are all going to be very proud of and will address a huge unmet need.

But the last thing I want to say in the few seconds I have is just to ask for your help. Senator Menendez talked about the workforce shortages. Nowhere is that more apparent than in the mental health and physical health delivery systems.

We tend to focus, like through a soda straw, on reimbursement rates, because the Federal Government is trying to figure out how can we cut health-care costs, make it more affordable. But we have a confluence of problems when it comes to recruiting and retaining health-care professionals. We have erosion of the standards for providing those professional services through scope-of-practice issues.

I would like to ask if you will be willing to work with us—particularly the chairman, the ranking member, who obviously will set the agenda—in working on all of these issues as part of the same problem, as opposed to dealing just with the reimbursement issues in isolation.

Secretary BECERRA. Senator, we will look forward to hearing from your staff so we can follow up with you. This is absolutely something the President has asked us to follow up and work on. The President does dedicate monies to workforce expansion and development and also resilience. So we will look forward to working with you on this.

Senator CORNYN. Thank you.

The CHAIRMAN. Senator Cornyn, thank you again for your leadership, your ongoing leadership on these mental health issues, and I think there are some more opportunities, particularly for public-private partnerships. In our part of the world Connie and Steve Ballmer have funded behavioral health studies at the University of Oregon. I think it is going to be a model for the country to get more workers.

Senator CORNYN. Mr. Chairman, as you know, it was the product mainly of this committee, the Finance Committee, that made that possible as part of the bipartisan Safer Communities Act. So, thank you for your leadership, as well as that of Senator Crapo. I think that is a big deal.

The CHAIRMAN. To be continued. You are absolutely right.

Next will be Senator Cardin.

Senator CARDIN. Thank you, Mr. Chairman. Secretary Becerra, welcome. It is good to see you.

I want to underscore the point of Senator Grassley in regards to the organ transplant issues. The reform of the OPTN process will save lives. We lose 17 Americans every day awaiting an organ transplant. So this is an urgent issue, and I just thank you for your response and the actions that you are taking.

I want to turn to the issue of drug shortages. We are the wealthiest Nation in the world that spends the most of any nation on drugs, and yet we have important drugs that are in short supply here. According to the American Society of Health-System Pharmacists, 160 drugs were added in 2022 to the drug shortage list. Forty-eight percent were in sterile injections, making a total of 295 active drug shortages here in the United States. These are drugs that are critically important to your health care. Some are in cancer treatments and other areas. So the President's budget deals with extending expiration dates, which I think is important.

Senator Collins and I have introduced legislation on that to deal with disclosure. How do you intend to mitigate this challenge that we have in this country?

Secretary BECERRA. You know, Senator, I am glad you raised this because, whether it was the issue of infant formula or whether it was the winter flu, we are seeing that in so many cases, the industries that we count on to provide us effective medications are not ready for disruptions, for a broadside. That is because we have gotten into a system where these industries, to save money—and they are entitled to try to save money—have gone towards a supply chain methodology that essentially says we are going to keep in inventory only the stock that we need immediately.

If all of a sudden you have a major increase in demand, you cannot meet it. Or if something happens with a manufacturer that has to go down because there is an issue of safety or cleanliness, then all of a sudden the supply goes down, and they are not ready to meet the need. So what we have done is, we have begun to do more surveillance over how these private-sector industries are handling their supply.

We do not regulate that supply, but we want to have more eyes on it so we can make sure they are preparing for that broadside that might come. We are also trying to make sure we help to mitigate any supply chain interruption. So, if they get some of their material for their product from overseas, some country, we want to make sure there is not going to be a disruption—whether politically based or supply-based—that keeps them from being able to produce. So we will work with you, because this is a big issue.

Senator CARDIN. Well, as we saw for the pharmaceutical industry, how they manipulated the market for profits for insulin, the same thing is happening on less-expensive drugs, where they are changing their production capacities in order to maximize their profits, which we understand. But since we are the largest payer for these services, it seems to me we can have a stronger impact on their decision-making.

Secretary BECERRA. We will look forward to working with you on that.

Senator CARDIN. As you know, oral health is closely tied to physical health. The final Calendar Year 2023 Medicare physician fee schedule rule expanded dental services tied to medically necessary conditions, which means that these services will now be covered for Medicare beneficiaries. That is a step in the right direction.

But as you and I know, we have major gaps in both the Medicaid and Medicare programs in regards to coverage for oral health and dental services, particularly in the underserved communities. They are particularly vulnerable. So what steps do you intend to take in order to deal with access to oral health care in America, particularly in underserved communities?

Secretary BECERRA. Well, as you said, one of the first steps we took is to try to make sure that where we had the authority, we expanded access to dental care services to folks on Medicaid. And we have made the effort—with your support—to try to expand coverage within Medicaid for dental health services more directly.

We count, in many respects, on our community health centers, which are able to use some of the funding they get to expand serv-

ices, including in dental health. We are going to try to do everything we can within the authorities we have to expand access, because we know an infection that is related to your dental situation could ultimately impact your overall health.

You know the story of Deamonte Driver, a young man from your State of Maryland, who died because, at the end, a toothache which his parents did not have the money to have him go see a dentist for, became an abscess and it became an infection, and before you knew it, Deamonte was dead.

Senator CARDIN. It is one of the best investments we can make—oral health. We get great returns.

Let me just say in concluding that, in hepatitis C, I thank you for your efforts there. We need to identify those who have hepatitis C. The treatments are there. It saves lives, and it saves cost. So I appreciate the initiative in your budget, and I would hope Congress would work on budget rules which would encourage that type of service to deal with diseases.

Secretary BECERRA. We are backing up your hope.

The CHAIRMAN. Senator Bennet is next.

Senator BENNET. Thank you, Mr. Chair.

Mr. Secretary, thank you for coming back, and thank you for your service.

As you know, Congress acted in a bipartisan way to address surprise medical bills through the No Surprises Act in 2020. I worked with Senators Cassidy and Hassan on that legislation. We built a big, broad bipartisan coalition, and we hoped to ensure a level playing field between providers and insurers as they resolve payment disputes.

Through the dispute process that we set up, both parties were supposed to be able to provide information specified in statute—specified in statute—and the arbitration entities were required to take this information and weigh it equally. But we have heard a lot about how the implementation has been challenged, and to be completely plain and simple about it, Mr. Secretary, we believe the administration is not implementing the legislation as intended. We are seeing lawsuit after lawsuit from providers. Insurants are not responding in a timely manner, sometimes not at all.

And even when the payment determinations are won by providers, payers still do not pay providers after the statutory deadline. It is a big mess, and CMS has frozen and unfrozen the process over the last few months, which has led to a significant reduction in cash flows, leaving providers on the hook for tens of thousands of disputes. While patients are still technically protected, these implementation challenges harm every single patient because they do not know whether providers are actually going to be there to provide the services that they need.

So, we've got to get this back on track, and I just want you to know that I am willing to work with you and others to get this in the right place. In the budget, HHS requested another $500 million to implement this bill, but I do not see evidence that it has gone well or right by congressional intent. Can you give me your assessment of what has gone wrong and how you intend to reduce the backlog and legally implement this bill?

Secretary BECERRA. First, thank you, Senator, for your work in helping us have this critical law passed. But secondly, I do not think you or I knew what was going to come. So let me ask for your help. I am going to plead for your help. We are receiving more than ten times the number of claims that anyone ever expected, and these arbitrators that are supposed to go through these claims are swamped.

Remember, they do not get paid unless they adjudicate the claims. What we are finding is that way too many—I don't want to say the vast majority—but way, way too many are frivolous, because there is no cost to file a claim. So, everyone is just filing all sorts of claims, and these arbitrators are trying to figure out what cases to handle. That is what is bogging down the system. But I will tell you this: we are staying true to the law. We are not letting patients get caught in this food fight between the provider of the care and the insurance company that has to pay for the care.

We are making sure patients are not getting the bills in the mail saying "you owe this money." It is going to be between the provider and the insurer, and what we are trying to do is have a system that works. So I plead with you and your colleagues: help us make sure that we get to the legitimate cases, so a provider who is looking for a real payment or an insurer who is saying, "Hey, you are asking for too much," we could adjudicate that——

Senator BENNET. Okay. Well, let's—I have another question I want to ask, but I think we have—I do not know whose fault it is, but we have a system that does not work, I think. So I certainly will help, and I volunteer Senator Hassan and Senator Cassidy too, to figure out how we can all work together to do it. [Laughter.]

Secretary BECERRA. I am writing names down.

Senator BENNET. Well, you should only write my name down three times, but I will try to get the other folks. And I want to say again, thanks for your leadership. Just a few months ago, as the chairman knows, the CDC put out their latest youth mental health report. It confirmed what I have heard across Colorado over just the past few years: we have a youth mental health epidemic in America, a mental health crisis in America.

According to the CDC report, 40 percent of high school students felt so sad or hopeless last year that they could not engage in their regular activities for at least 2 weeks. I was saying to my staff the other day that, when I get a call from Colorado that somebody the age of my daughter has died, I no longer ask if it was a car accident or was it leukemia. The question is, was it suicide, or was it fentanyl, or was it a gun?

By the way, when I was the Superintendent of the Denver Public Schools, we never asked that question just 15 years ago. It is also true for seniors, you know. One in five Medicare beneficiaries have mental health conditions and, among Latino seniors, that goes up to nearly one in three. I know we have done a lot in this committee on mental health, but we have to do more, and I am glad the HHS budget calls for parity in Medicare Advantage and invests in integrated mental health in the primary care.

This is why I introduced with Senator Wyden, Chairman Wyden, the Better Mental Health Care for Americans Act. Our bill would require parity for Medicare Advantage plans, Part D, and Med-

icaid, and increase reimbursement across programs for integrated care. I am extremely grateful—I am coming to the end of my questioning; I know I am out of time. I am extremely grateful to your staff for working with us to draft that bill, and I just want to ask you if, as we continue to work on it, whether you would be willing to work with us on it, because I am sure you're detecting the same trends in mental health that we are. Maybe with just 5 seconds you could——

Secretary BECERRA. One second: yes.

Senator BENNET. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Bennet, and thank you for your leadership on this. It takes your breath away what some of these gaps are. You know, we know in Eugene, OR, for example, if a young person has a problem in school, in effect has a major breakdown, there is literally no treatment bed for them at that time. So you are doing incredibly important work.

Senator BENNET. Thank you.

The CHAIRMAN. Senator Lankford is next.

Senator LANKFORD. Mr. Chairman, thank you. Mr. Secretary, good to see you again.

I had a parent who was in my office today. As you can imagine, the parents who come here to DC do a lot of research and a lot of background, and when they bring questions, they bring very different types of questions. Their particular child had a health-care issue, and they were asking about the cost of drugs. They went through several different proposals that are out there, but then they asked a very specific, pointed, well-educated question about pharmacy benefit managers.

They asked what is being done, because that seems to be a black hole, and all I am reading and seeing seems to be a lot of information on that. Now that's interesting. I said they were very perceptive to be able to go through the different aspects on that. You talk a lot about drug policy, but there is nothing about PBMs in some of the proposals in your budget piece.

Now CMS—we work with them directly on it. I want to talk to you about some of that as well. But for the PBMs in particular, they are not even mentioned once. What is the plan at this point on dealing with drug pricing and the PBMs?

Secretary BECERRA. And, Senator, thank you. And they may not be as directly included within the budget, but the administration is working on PBMs, because we know more and more, there is a growing concern that the middlemen in the process of getting drugs from manufacturer to patient are skimming off a good deal of the money that is being generated. What we want is for consumers to get the drug at the lowest price possible.

I will tell you that most of these issues will likely end up in court, as you can expect, but we are going to try to move to make sure that if there is a middleman that is going through the process of making sure a drug is getting from the manufacturer to the patient, that it is done efficiently. So we could use your help to make sure——

Senator LANKFORD. Well, we would be glad to work with the administration. You will find bipartisan support to be able to deal

with this. Some basic elements of transparency—obviously, PBMs are very opaque about where the pricing is, where the money actually goes, or even the standards for evaluation. Different pharmacies are evaluated different ways, different months even, where they don't even know the evaluation of the price on it. So getting some standardization—we have made those recommendations to your team. We would love to be able to work on that, and if we need legislation, be able to fix it. Let us continue to work on that.

If I can continue on that same theme, this issue of tiering is becoming more and more important—where the drug will be released out. There can be a generic drug that is released out later in competition, but according to the PBMs and the original manufacturer, it is put on a branded tier, meaning that the patient at the pharmacy counter is paying the more expensive rate, rather than the generic rate for their pharmaceutical, and it also becomes an issue for Medicare as well.

That is not an issue that you brought up on this, but it is a really big issue that we need to be able to address: this whole issue of tiering, of where a new generic drug comes out, whether it is on a branded tier or generic tier. Can you help us try to settle this issue to lower prices?

Secretary BECERRA. We will follow up with you, Senator.

Senator LANKFORD. Thank you for that.

Let me talk a little bit about something Senator Menendez brought up as well, and it is this issue of the children in ORR custody who have come across the border. These are the unaccompanied minors. *The New York Times* published this report that was pretty horrific about labor, but this is not new. It is something Senator Portman and I and several others have worked on for several years, trying to be able to figure out how we can actually manage this.

The Times actually identified that there is a stat that there are 85,000 children that HHS lost immediate contact with once they were placed in sponsorship. So that is my first question: is that number accurate, because once HHS does the vetting, places them with sponsors, the next question is, do you know where they are, even for those first 30 days? And then when you get to Day 31, do you know where they are?

And if I can push this a little farther, if they do not show up for their first hearing, is someone from HHS checking on them, because at that point they are lost.

Secretary BECERRA. And, Senator, every week I get briefed by my team, sometimes two or three times a week, on this situation with the unaccompanied migrant kids and where we stand. I have never heard that number of 85,000. I do not know where it comes from, so I cannot attest. I would say, it does not sound at all to be realistic, and what we do is, we try to follow up as best we can with these kids. Congress has given us certain authorities. Our authorities essentially end the moment we have found a suitable sponsor to place that child with.

We try to do some follow-up, but neither the child nor the sponsors are actually obligated to follow up with us. We make every effort to follow up with them as best we can.

Senator LANKFORD. But that is the first 30 days; there is the follow-up that is actually happening there. But if they do not show up for the first hearing, there is no follow-up at that point; is that correct?

Secretary BECERRA. The follow-up for purposes of the immigration proceeding would be, I believe, through the Department of Homeland Security.

Senator LANKFORD. Okay. Well, at this point, no one's following up. There are some assumptions that are made there that if an unaccompanied minor has been placed in the home and then they do not show up for hearings, no one seems to be checking on them to be able to figure out are they still at the same address they were dropped off at, what are they doing, and why are they not showing up at hearings?

I also understand that you have called for an audit, a 4-week audit in February, on that. My understanding is, that audit concludes next week. Is that something that we could get a copy of—that audit report as well—to be able to see next week when it is finished?

Secretary BECERRA. Let me make sure, Senator, when we have that audit finished, if we are able to share publicly the results of that. I believe we can probably share most of the information, because most of the process that we use is public.

Senator LANKFORD. Right.

Secretary BECERRA. And what we are trying to do is make sure that our checks on vetting are catching anyone who should not be considered a suitable sponsor. And so our audit is for the purpose of making sure that our background checks are fulfilling that mission.

Senator LANKFORD. Right. I do not know why there would be a good reason you could not share with this committee. And even if we were seeing it just locked in with this committee to be able to see it and it was not publicly released, I do not know of a reason that audit could not be released.

Secretary BECERRA. There are issues of privacy for the children and so forth, but we will——

Senator LANKFORD. I get that, but there are probably not kids' names in the report; but thank you.

The CHAIRMAN. Senator Lankford, thank you for bringing up the pharmacy benefit managers, what we all know as PBMs. We are going to be having a hearing next Thursday in this committee specifically on them. It is a result of Senator Crapo and I having had a number of conversations about it, and I want to let my colleagues have a chance to ask their questions. But this conversation will continue, and I hope, colleagues, every member can come next Thursday.

Senator Cassidy?

Senator CASSIDY. Thank you. Mr. Secretary, thank you, sir.

We had kind of let you—thank you for, you know, the dialogue before the meeting. We told you we were concerned about, how do we know the people at HHS are working? So let me put this picture up. This is a picture taken at 10:40 a.m. last Monday at HHS headquarters. It's like empty, and then we could have pictures of other parking lots that are similarly empty.

So you know, wow! The building's empty. If there's no cars, the building's empty. So we just appropriated $3 billion—well, first, tell me this, please. Can you give a breakdown of how many full-time employees are at their desk in one of these buildings every day?

Secretary BECERRA. Senator, when you take a look at the workforce at HHS, we are close to 90,000 throughout the country, and working in various parts of the country, some here at headquarters. By the way, at headquarters, we have an underground parking lot——

Senator CASSIDY. I have limited time, so this may be misleading. So tell me what percent of the employees are at their desk, full-time employees are at their desk on any given day. And I do not mean to be rude. There is just such limited time.

Secretary BECERRA. No, and I appreciate that. Our folks are working full-time.

Senator CASSIDY. No, but how many are at their desk as opposed to being at home or someplace else, the coffee shop or whatever?

Secretary BECERRA. What we make sure we care about is that they are performing, and they are delivering, and that is why——

Senator CASSIDY. Well, that is not really answering my question, because I know the best practice now in many industries is to bring people back in. So, is it 5 percent, is it 10 percent, is it 1 percent? How many folks are actually sitting at their desk in a government building when they are working full-time every day?

Secretary BECERRA. And we have folks who, as they are working full time——

Senator CASSIDY. So that is kind of not an answer. Clearly, sir, you do not want to answer that question, and I do not mean to be rude, but you do not. But that kind of begs that the answer may not be flattering.

When CMS put out a request for employees, as regards to the complex drug negotiation that was in a recent bill, the posting offered "generous telework policy." What does "generous telework policy" mean? If somebody hired into that program, how many days a month would they be expected to actually be in a government building, as opposed to wherever they wish to be?

Secretary BECERRA. And, Senator, that would depend on the worker. Some people have never left their job even during the height of the pandemic.

Senator CASSIDY. I am not speaking about leaving their job. I am speaking about being at their desk. I am not speaking of some, but of a percent, if I may, because anecdotes are not data.

Secretary BECERRA. You are limiting the scope of what we do. We have investigators who never sit at desks.

Senator CASSIDY. No, but say, take somebody who traditionally would have been at their desk before the pandemic, please.

Secretary BECERRA. And depending on the work that has to be performed, they will be in the office at times; sometimes they may be in the field. But what is important——

Senator CASSIDY. Can I ask just for the record—because, obviously, it does not seem, Mr. Secretary, you are prepared to answer that question—but for the record, can you give us a percent of the actual workers who are full-time who would be expected to be at

their desk, not an inspector in Louisiana, but someone else? If you can give us that for the record.

Secretary BECERRA. We can follow up, Senator.

Senator CASSIDY. Can the agency provide us VPN data, or some other measure of accountability, that shows that the people truly are working from home?

Secretary BECERRA. We can certainly show you that they are performing. The fact that 700 million shots have gone into the arms of Americans——

Senator CASSIDY. But do you have that VPN data, because initially when the pandemic started, we saw VPN data that showed a double-digit number of employees were not turning on their VPN every day, and so it suggested they were not accessing emails, for example. So is that data still being collected? If so, can you share those results?

Secretary BECERRA. I could try to get back to you on that.

Senator CASSIDY. Now, if you live in the DC area, you get a work differential. So you get a little bit more. Your cost of living is more. So if someone who is in this building with an empty parking lot, if someone in that building, not knowing where they are currently working, are they still getting a cost-of-living adjustment as if they are working in Washington, DC?

Secretary BECERRA. Yes. First, I have to tell you, Senator, that is not the headquarters of the HHS, of the Department of HHS.

Senator CASSIDY. It is CMS headquarters.

Secretary BECERRA. Oh, okay, okay. So we can get back to you on it. If someone is working—as I said, we have been coming in day-in/day-out. We have been performing day-in/day-out.

Senator CASSIDY. But let us assume that because—I have heard from people within the agency that, in reality, people are only required to come in 1 day out of a month, and this has been something we have heard from CDC along those lines, but I have also heard from somebody who is working at CMS. Now, I assume that you have a global policy, because you have the same union negotiating for all of HHS. So it seems to me as if it is going to be the same policy wherever you are.

So my question is, if you are working from home consistently, and originally you were based in DC, are you still getting a cost-of-living adjustment, even though we frankly do not know what, where—you might be flying in 1 day a month, but living in West Virginia.

Secretary BECERRA. Again, Senator, I am not familiar with this statistic that you are throwing out that says——

Senator CASSIDY. But is there a cost-of-living adjustment for people who are taking advantage of "generous telework"?

Secretary BECERRA. There is certainly a cost-of-living adjustment for folks who work in high-cost areas.

Senator CASSIDY. Even if they are teleworking?

Secretary BECERRA. If they are performing their work, they are entitled to receive a cost-of-living adjustment if they work in a high-cost living area.

Senator CASSIDY. And when you define "work in a high-cost living area," do you mean telework? I mean they could be—their VPN could show them in DC, but they could be in West Virginia. So are

they getting paid as if they are living physically and showing up every day and parking in that parking lot every day in the DC area?

Secretary BECERRA. So, you would have to take a look at the particular job description to find out what type of work is done and where they are located to be able to make that determination.

Senator CASSIDY. I yield.

The CHAIRMAN. I thank my colleague.

Next is Senator Hassan.

Senator HASSAN. Well, thank you, Mr. Chairman and Ranking Member Crapo, for having this hearing, and thank you, Mr. Secretary, for being here.

I want to start with a discussion of State opioid response grants. I was really pleased that the Department's proposed budget includes $2 billion for State opioid response grants. These grants, which I have worked since 2017 to secure and expand, have really helped my State significantly improve our response to the fentanyl crisis.

Last year, you and I discussed this program's impact in New Hampshire. New Hampshire's been really hard hit by the fentanyl crisis in particular. We discussed the importance of continuity of funding, because it helps States plan and avoid drastic cuts. Just before the hearing, we were talking about a program in Rochester, NH called Hope on Haven Hill, which focuses on treatment, recovery, and transition for pregnant moms and parenting moms who have substance use disorder. The continuity of funding has been really critical for them to be able to develop that program and really help these women turn their lives around and get better.

So, in last December's appropriations bill, Congress acted on a bipartisan basis to require HHS to, and this is a quote, "prevent unusually large funding changes from year to year in these grants." I know from our past conversations that you understand and share this really important goal. How does HHS plan to implement this statutory requirement to prevent year-to-year funding cliffs in State opioid response grants for States like New Hampshire?

Secretary BECERRA. Senator, first I have to say "thank you," because in many ways these are your babies, these SOR grants. You have championed them, and you have made it possible for us to actually get money into communities that need to deal with opioids. And you are saving lives, so thank you for that.

The President has followed your lead. He is calling for some $2 billion in investment. That should help a lot of these agencies that are administering the funds to get services to folks who are trying to get off of opioids, a way to know that they are going to have a consistent and hopefully permanent stream of support, because the last thing you need is to be there one day, but not the next.

The work that you all are doing is helping us not only make sure that we institutionalize these programs under the SOR grant program, but that we also make sure that it stays consistent, so that we do not have one day you have the resources to do it, and the next day you have to close down all these shops. But we will work with you on that.

Senator HASSAN. Well, I appreciate that. I really just wanted to make sure that your staff and mine will continue to work on this.

It is everything from certainty and predictability for patients, as well as being able to recruit people into the workforce to do this work, right? So I look forward to working with you and your staff on that.

Secretary BECERRA. Thank you.

Senator HASSAN. Now I want to turn to discuss title X family planning funding. I want to thank you for including robust funding for maternal and reproductive health in the Department's budget, including doubling funding for title X family planning to $512 million. Along with Senator Warren, I am leading a letter to appropriators echoing that request.

Title X is the only Federal program dedicated to providing family planning, and it has historically been a program that has been underfunded. But we all know that in light of the Supreme Court's decision last year to restrict women's reproductive freedom, this is a program that is more essential than ever. So can you speak to the importance of Congress appropriating this essential title X family planning funding, and then I want to ask you one more question, so if you can, be a little bit brief.

Secretary BECERRA. Family planning has not received a boost in funding in 8 years. It is time. We know how essential it is. It is not just funding for one type of care; it is funding for family planning services—indispensable. The President's budget recognizes it. We look forward to working with you to get that across the finish line so we can actually expand services and get them to communities that absolutely need them.

Senator HASSAN. Well, and it is absolutely essential to a woman's capacity for self-determination and dignity, so I appreciate it very, very much.

I want to turn to one other issue, which is the MAT Act implementation. At the end of last year, the Mainstreaming Addiction Treatment Act, MAT, which I led with Senator Murkowski, was signed into law. This bill eliminates needless outdated restrictions on health-care providers that prevented them from prescribing buprenorphine, a critical treatment option for people struggling with fentanyl and other opioids.

I know that you, and the administration more broadly, are strongly behind this new law, and I really want to thank you for your and your colleagues' work to support it. Can you please speak to the importance of these changes and what HHS is doing now in coordination with other agencies to expand access to buprenorphine by ensuring that health-care providers know about these changes?

Secretary BECERRA. Senator, gosh; where do I start? Medication-assisted treatment is critical, because it is one of the ways you save a life. If you give buprenorphine to an individual before they OD, you have just saved a life. If you can try to remove the barriers that kept a physician from participating in a program to be able to prescribe a lifesaving drug, you saved a life. When we were able to really remove the X waiver cap, we were able to make it more likely that a physician would want to participate in this program and not find themselves subjected to law enforcement oversight as if they were encouraging drug use.

What we did was, we liberated the system to actually treat drug addiction and take away the stigma. So we look forward to working with you on that.

Senator HASSAN. Well, I look forward to that too, and just—I am over time. But one of the critical things here could be making sure that we work with law enforcement, as well as health-care providers, to stock buprenorphine in pharmacies, and make sure that primary care physicians and other primary prescribers know that they can prescribe this lifesaving medication.

So, thank you. I look forward to continuing to work with you.

Secretary BECERRA. Thank you.

The CHAIRMAN. And thank you for your work, Senator Hassan, especially on title X, an enormously important program—and it has not come up yet today.

Senator Johnson, you are next.

Senator JOHNSON. Thank you, Mr. Chairman. Secretary Becerra, welcome.

Do you believe it is important that we understand how the coronavirus originated?

Secretary BECERRA. Absolutely.

Senator JOHNSON. Is there somebody in your agency, your department, who is spearheading the investigation to determine that?

Secretary BECERRA. We have done a number of—taken a number of initiatives to try to move forward there, including having OIG take a closer look.

Senator JOHNSON. So you are saying it is the OIG? I mean, is there somebody within the Department outside of the Inspector General that is spearheading this, somebody in charge?

Secretary BECERRA. CDC and NIH are also doing a scrub. We are all trying to get as much information—the difficulty is that we are not getting a lot of cooperation from some of the sources externally that could probably give us——

Senator JOHNSON. Well, let us talk about lack of cooperation, because I would say the same thing is true in terms of cooperation out of the agencies. Do you believe the public has a right to know how the agencies are spending their money and how they are operating?

Secretary BECERRA. The public does have a right to know, yes.

Senator JOHNSON. There are two primary methods for that. You have FOIA, Freedom of Information Act requests, and then you also have congressional oversight. Would you agree that FOIA is generally subjected to more redactions than congressional oversight would be?

Secretary BECERRA. I would not say that, but we do have to be careful what goes into the public domain with respect to confidentiality and privacy.

Senator JOHNSON. I understand. There are some exceptions that are very explicit out there, and a lot of them make sense. But I would argue, I think many people do, that congressional oversight really is not subject to those same redactions, particularly when we have security clearances, and we can take a look at classified information that is appropriately redacted under FOIA.

Let me give you a couple of examples. We requested these documents. [Holding up pages.] By the way, in June of 2021, under a

FOIA request—court-ordered—4,000 pages of different documents, primarily emails of Anthony Fauci, were produced under the FOIA. In September 2021 we—well, that month, we had five members of Homeland Security and Governmental Affairs ask for those same pages unredacted, and there is a law that says you shall turn that over to us.

In September 2021, we started working with HHS to produce those documents in an accommodated process. So we narrowed the 4,000 pages down to 400 to get those things unredacted. They were not handed over to us. What we did—we were allowed to read them 50 pages at a time in a reading room and take notes. Some productions we did get. For example, we got this document dated February 4th, between Anthony Fauci, Jeremy Ferrar of the Wellcome Company, and Francis Collins. You see the redactions here. This is the same document produced under FOIA without the redactions.

So now we know what was redacted, and this was redacted, by the way, under (b)(4), which is trade secrets. One thing that was redacted here is Anthony Fauci saying, question mark, "serial passage in ACE2 transgenic mice," in other words, humanized mice. They were talking about—Ferrar is writing to Francis Collins. "Remains a very real possibility of accidental lab passage in animals to give glycans."

He said that "Eddie thinks it's a 60–40 lab side." Ferrar said he thinks it's 50–50. Again, this is February 4th. There is nothing to do with trade secrets in that redaction.

Another example. This is February 2nd. Again, this is with their understanding that they funded this dangerous research, and now they are into cover-up mode. Here is what we got in our production, the heavy redactions. [Holding up document.] This is what was released under FOIA. [Holding up document].

Now this was released under the (b)(5) exception, which is privileged information within or between agencies. Again, this is with Jeremy Ferrar of the Wellcome Trust. So we have redactions with—you know, privileged information did not apply, and we still had it redacted. I do not have time to get into that. This is completely inappropriate, and by the way we are down—you have produced 350 pages to us in the reading room. For over a year, we have been asking for the last 50 pages. This is what the 50 pages looked like, okay? [Entire pages are blacked out.]

Now again, I would argue congressional oversight should not be subject to the same redactions that were applied under a FOIA request. I am asking you: will you commit today to provide for our oversight—now Senator Paul is on this. Again, we had five members of Homeland Security and Governmental Affairs, under a law that says you shall provide this. Will you commit to provide us the last 50 pages of communication between Anthony Fauci, Francis Collins, Jeremy Ferrar, as it relates to the origin of the coronavirus? Will you commit to that?

Secretary BECERRA. Senator, I absolutely will commit to make sure we follow up with you on your request to get some of that information. Again, this is in compliance with the law that you received the information. I do not know what particular statute with regard to disclosure was applied here, but you are absolutely enti-

tled to the information that by law a member of the Senate or the House could get to follow up——

Senator JOHNSON. Yes. But again, you are not complying with the law, because you are redacting things, for example under the deliberative process between and within agencies, and it is communication outside of the agencies with the Wellcome Trust. Again, these redactions are not complying with the law. So again, I will appreciate—we will follow up with you. I expect to see the unredacted 50 pages very soon.

Secretary BECERRA. We can comply with the law, Senator, but we absolutely will make sure we follow up with you.

The CHAIRMAN. Thank you, Senator Johnson.

Next is Senator Cortez Masto.

Senator CORTEZ MASTO. Thank you, Mr. Chairman. Mr. Secretary, it is always great to see you. Thank you.

Before I get to my questions, I do want to quickly touch on Medicare Advantage. Seniors in my State rely on Medicare Advantage to access affordable, high-quality health care. I often hear from Nevadans how vitally important this program is to supporting their health and the health of their loved ones. That is why I have long been a supporter of Medicare Advantage. This year, I am proud to have led the annual bipartisan letter, and I believe there were 57 Senators, my colleagues, who signed onto the letter urging the administration to preserve and strengthen the program. Last week, I spoke with CMS Administrator Brooks-LaSure about the proposed updates to the program for 2024 and what they mean for Nevadans.

And I will just reiterate today, Mr. Secretary, that any efforts to address overpayments in Medicare Advantage should support program integrity and preserve the sustainability of the entire Medicare program without disrupting access, without increasing cost or jeopardizing the quality of care. So, as you move to finalize 2024 policies, I urge you to prioritize the program improvements that benefit patients and deliver value to seniors and taxpayers. So, I just wanted to start with that.

Secondly, I too noticed all the purple here in the room. Thank you to the Alzheimer's Association, everybody who advocates. It is something that I dealt with within my family with my grandmother. I appreciate your advocacy over the years. Thank you. You always have a supporter with me.

Secretary Becerra, let me talk about the commercial prescription drug inflation rebates.

Last year, as you well know, we passed historic drug pricing policies in the Inflation Reduction Act. This law is already working to lower drug costs for our seniors with Medicare. Importantly, the Inflation Reduction Act penalizes drug companies for raising prices faster than inflation. However, as it stands today, these companies are only held accountable for hiking drug prices in the Medicare program.

That is why I am introducing a bill to extend the inflation rebate penalty to include drugs used by people with private commercial insurance. My bill will ensure that Nevada families, as well as our seniors, are no longer squeezed by drug companies' outrageous price hikes.

Secretary Becerra, I am glad to see the goals of my bill reflected in the President's budget proposal. How would the inflation rebate penalty for the commercial market impact drug prices for patients at the pharmacy counter, as well as health-care payers like employers and unions?

Secretary BECERRA. Senator, well first, thank you for that effort. We want to help any way we can, because we know what happens—take insulin. Insulin was only to apply to those who were on Medicare, 67 million Americans on Medicare. Today, the three leading manufacturers of insulin have said they are going to drop their price of insulin for those who are not on Medicare, so those in the private insurance market.

And so we see what happens when you introduce competition into this. The prices come down, because everybody now has to compete to get your business. Your bill, I suspect, would do the same thing. It would introduce that competition in the private insurance sector that would complement what we do in Medicare, and the end result is, you drop the price for a whole lot of Americans who are not on Medicare.

Senator CORTEZ MASTO. Thank you, I appreciate that. And let me just add that my commercial prescription drug inflation rebate bill has the potential to generate significant savings for the Federal Government. In fact, CBO projected that a similar provision would save $34 billion over 10 years. So, I thank you.

Let me jump to something very quickly here as well: mental health. I have heard my colleagues here talking about this. As you well know, this is such an important issue for me as well, and I support my colleagues on both sides of the aisle for working to address this. I appreciate the support for the crisis services in the budget proposal around mental health in the Fiscal Year 2023 funding bill, the significant expansion in funding for 988. The new suicide and crisis lifeline has helped communities manage increased demand in call volume since the line went live last summer.

I know; I talk to my folks in Nevada all the time about this. On this committee, we are very focused on what comes next, what happens when someone in crisis dials the line and needs somebody to come help or somewhere to go for that treatment. I was proud, with the chairman, to pass increased funding for 988 and crisis care through mobile units in the December omnibus bill, but we have more work to do.

My question for you is, in your view, what is the biggest challenge to improving crisis care coordination when we are talking about the mental health support that is needed across the country?

Secretary BECERRA. Senator, workforce. We need to hire up more folks, pay them decent wages so they will stay in the field, because right now we know that health care has a shortage of workers period, but mental health is even worse. So, if we really want to say to somebody "call 988 and you are going to get real help," we have to make sure that there really will be real help at the end of that call.

Senator CORTEZ MASTO. I look forward to working with you, because I am hearing the same thing. I see it in my State and across the country; so, thank you.

Secretary BECERRA. Thank you.

The CHAIRMAN. I thank my colleague for her questions, and especially the points about MA, Medicare Advantage. We have worked very closely on this committee with Chairman Casey, who has also put in a lot of effort on this at the Aging Committee.

Just a quick word. I believe Oregon, Nevada, and Minnesota have the highest percentage of senior citizens in MA in the country. And having spent a lot of time in these precincts since my days working with seniors, I have come to the conclusion that, unfortunately, not all Medicare Advantage is created equal.

There has been some very good MA, there has been some not so good, and we are going to work very closely with our colleague to make sure we get the former and have less of the latter, because her points are very well taken. We are going to work closely with the administration to make sure that we recognize that kind of distinction, and I appreciate her comments.

Next is Senator Tillis.

Senator TILLIS. Thank you, Mr. Chairman. Secretary Becerra, thank you for being here.

Before I make some comments or questions, I also want to recognize the Alzheimer's Association. You all were in my office, the North Carolina delegation was in my office yesterday, and my staff have been meeting with them. I looked at my staff and said, "Are there any priorities that they have discussed that we do not support?" They said the answer is "no." We support them all, including a "dear colleague" letter for funding for NIH. So you can count on my support. But the reason I did that is because I wanted to talk with them about something that should be on your agenda, and it relates to research, and it relates to prescription drug pricing, and I will get to that in a minute, because I want to use a few examples.

I know that we have had some members talk about the great advances, Secretary Becerra, in the Inflation Reduction Act. I think, based on patterns that I am seeing in the industry, you could call it the Investment Reduction Act. Mr. Chairman, I have three documents that, without objection, I would like to submit to the record.

The CHAIRMAN. Without objection, so ordered.

[The documents appear in the appendix beginning on p. 179.]

Senator TILLIS. Two are related to Eli Lilly, one to another player in the pharmaceutical space, that have said they are making business decisions to drop small molecule research and other things because the time that they would need to recover the investment they anticipate is not there. So you can expect reductions in small molecule research. You can expect reductions in an eye drug that they were trying to expand.

You can see the effects of not getting well-intended policy right, and Secretary Becerra, Congressman Becerra, I think the work that you did on a bipartisan basis, whether it was the 21st Century Cures bill, or even more importantly, the heat that you took from your side of the aisle to get Trade Promotion Authority—tells me you are a person who likes to get to a positive end, a productive end.

The only reason, the primary reason I did not support your confirmation—in full disclosure—is the position you have taken on

march-in rights. And so, I am not going to have enough time to get to many questions, but I think it needs to be said that I believe we are going about it the wrong way in terms of the haircut that needs to be done to get prescription prices lower, not at a point in time and not at the expense of other research and investment that is necessary.

I tell everybody in the industry I believe that there is a haircut coming, but I have not heard any member talk about who needs to be in the barber shop. I think it needs to be pharma; I think it needs to be the pharmacy benefit managers. It needs to be insurers—I just wrote this down as notes—the medical profession, the pharmacies, the FDA, and the legal community. If you are really going to fix the fundamental problems with drug pricing and look people in the eye and say you are doing something not just to claim victory, as it was done with the IRA, but something that is sustainable, every single one of them needs to be there.

They are all a part of the value chain, they all need to be at the table, and we need to get it right. Because you may be able to correct me if I am wrong, but I have not seen a single, successful, sustainable solution to this, or at least a part of the solution, except when Bayh-Dole passed something not too long ago. Now, Mr. Chairman, I would like to submit for the record an op-ed that was written by Senators Bayh and Dole in 2002 that said they never intended for their legislation to become weaponized.

The CHAIRMAN. Without objection, so ordered.

[The op-ed appears in the appendix on p. 179.]

Senator TILLIS. And in spite of the fact that the NIH has recently just rejected imposing price controls based on price, now we have a work group that is going to consider price as one of the ways that we go about getting down on this industry. If we do it, we are going to have a longer window for work, the very promising work that is being done for Alzheimer's.

I've got a vested interest in that. I was a part-time caregiver to my grandmother. I've got a vested interest in broader research. I've got two potentially deadly—one incurable and one curable—diseases in my body. One is prostate cancer, the other is Wegener's granulomatosis. Both of them are being managed. Prostate cancer has a lot of promise, provided that it is within that window. Wegener's is a rare disease. It is not going to be something that we are going to see a cure for, particularly if we do not get this right and incent the private sector to invest in things where they may have to walk away from it, like an Alzheimer's drug, after a billion dollars in investment.

And so I told the Alzheimer's Association to please study up on the attacks on intellectual property protections; take a look at what the administration's done with TRIPS waivers and other things, really threatening the return on investment that these companies have to make; and please make sure that that is a part of your pitch when you come to these members of Congress and expect them to produce a prescription drug pricing strategy that they can look you in the eye and say is going to produce year-over-year results.

Thank you for being here.

The CHAIRMAN. Senator Tillis, thank you for your point with respect to the nature of how pharmaceuticals, particularly as it relates to the regulatory system, have a breakdown at every step of the way. That is what Senator Grassley and I found in our mammoth research report. If anybody is having trouble sleeping tonight, you can go through the scores and scores of footnotes, and it starts with pharma, but it is the PBMs, it's the distributors; it is every step of the way.

Senator TILLIS. And, Mr. Chair, it is the FDA too. We learned so much from COVID, and we figured out how we could accelerate approvals under emergency use authorizations. The fact that we would have those snap back post-pandemic after they have been proven to work, to me is meaning that we are not learning some of the good things that came from that stress.

The CHAIRMAN. Your point is correct.

Senator Warren and then Senator Blackburn.

Senator WARREN. Thank you very much, Mr. Chairman. I also want to say "welcome" to the Alzheimer's Association. I wore my Alzheimer's purple today. We have a very active group in Massachusetts, and I just want to say a special "thank you" for all of the advocacy you do on behalf of so many people we have lost to a terrible disease. So, thank you.

I want to talk today also about Medicare Advantage. You know, every February, the Federal agency that runs the Medicare program releases a report outlining how Medicare Advantage or MA insurers are going to be paid for the following year. MA is a program that allows private insurance plans to offer Medicare benefits. Now taxpayers pay these insurance companies a set amount per beneficiary, and this amount can go up if the beneficiary is sicker.

The more diagnosis codes that a beneficiary has, the higher the payment, and whatever insurers do not spend on care they actually get to keep. These companies have built entire businesses around making beneficiaries look as sick as possible and, unsurprisingly, government watchdogs have discovered widespread abuse. This year, CMS made a few updates to ensure that the government's payments more accurately reflect what it actually costs to pay for the care for beneficiaries in this program. And in response, the insurance industry has kicked into overdrive, sending an army of lobbyists to claim that the changes will hurt Medicare.

So let us go through this. Let us start with the basics, Mr. Secretary. Under your proposal, will total payments to insurance plans that run Medicare Advantage go up or down?

Secretary BECERRA. Total payments will go up.

Senator WARREN. So they will go up. CMS is proposing to increase payments to MA plans next year. In other words, the insurance companies overall are going to get more taxpayer dollars, not fewer. But insurance companies want a lot more taxpayer dollars, not just a little more, so they are kicking and screaming, and they even shelled out millions of dollars for a prime time Super Bowl ad opposing the proposal. Now these Medicare Advantage companies are also peddling industry-funded studies that claim Medicare premiums would go up and benefits would be cut if your proposal is finalized. Mr. Secretary, are those claims accurate?

Secretary BECERRA. No, they are not. Benefits are not cut.

Senator WARREN. All right. So numerous experts agree with HHS's assessment. When Medicare Advantage was created, the insurance companies argued that they could provide better care than the Federal Government at a lower cost. But for years now, MA plans have been using a long list of tricks and games to take advantage of loopholes in the government's payment rules, to squeeze literally hundreds of billions of extra dollars out of the program.

Researchers at the Kaiser Family Foundation found that profit margins for MA plans are double those for other kinds of insurance. In other words, because of lax rules, running Medicare Advantage plans is a lot, lot more profitable than running any other type of insurance plan, and the insurance companies do not want the party to end.

Mr. Secretary, are the private insurance companies that run Medicare Advantage actually delivering health care for seniors at a lower cost than the traditional Medicare program run by the Federal Government?

Secretary BECERRA. The numbers show that it costs more to provide care to seniors in Medicare through the managed care Medicare Advantage program than through the traditional program called fee-for-service.

Senator WARREN. So the cheaper way to do this is actually just to run people through the Medicare program. That's not to say there are not some programs that work with Medicare Advantage, but overall, that is what the data show?

Secretary BECERRA. Yes. We are talking overall. So, if you lump everyone who is in the Medicare Advantage program, the managed care program within Medicare, and those who are in the traditional Medicare program called fee-for-service, the per-beneficiary cost is higher under managed care or what we call Medicare Advantage.

Senator WARREN. Exactly the reverse of what they promised they would deliver. They said, "Hand it over to us, and we will do this cheaper." You know in fact, according to the Medicare Payment Advisory Commission—which is the independent congressional agency that studies Medicare—the private insurance companies running MA have never delivered health care at a lower cost than traditional Medicare in the entire history of the program.

So I just want to say, I urge CMS to finalize this proposal. I cannot get an ad on the Super Bowl, but I hope that having you at this hearing will have some influence on this. It is important to take these steps to strengthen Medicare. I also want to say I do not think it is enough. CMS needs to double down on its efforts to crack down on industry abuses in the MA program. I stand ready to work with you and to help you do that, to ensure that Medicare beneficiaries get the care that they have rightly earned. Thank you, Mr. Secretary.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Warren.

Senator Blackburn?

Senator BLACKBURN. Thank you, Mr. Chairman. And, Mr. Secretary, thank you for being here. I am so grateful we have the Alzheimer's volunteers here. We have a great group in Tennessee, and so—there are some back there. Love seeing them.

But you know, Mr. Secretary, the budget that you brought to us, it is full of things that get in the way of research. It would prevent new drugs and therapies from coming to market. It would weaken those IP protections, and it would expand the government, and it is something that does cause us some concern.

I want to return to the issue of telework. I know that Senator Cassidy discussed this with you. Adding to the list of how many HHS employees are working through telework, I would like for you to identify the essential and non-essential components of that list of those who are teleworking. And also, looking at you and your team personally, when you look at telework, how many days have you spent in California during COVID–19?

Secretary BECERRA. Thank you, Senator, for the question. With regard to my status, I know that requests have been made for my schedule, and we will try to provide as much information as we can.

Senator BLACKBURN. Yes. I think it would be great if we were able to get the schedule for you, your security detail, and the records, expense reports, so that we could see how much—the reason this is important is because you are overseeing an agency that is the equivalent of a tenth of our Nation's GDP, and I think that it is vital that you be on site in overseeing that department. So, can you even ballpark how long you were in California and how often you were absent?

Secretary BECERRA. I do not get to California very often. When I do, it is usually because I am doing work, and I travel——

Senator BLACKBURN. During the pandemic, because I think it is important that during the pandemic that you were there. And I want to read this back to you. In 2019, talking about the border crisis, you said of President Trump, and I quote, "And to say that is an emergency and then within 24 hours of having said it, go off to Florida to your Mar-a-Lago resort, when you think there is a national emergency. I think all the evidence, including what Donald Trump says and does, proves this is no national emergency." So, by your own standard, you would equate COVID to not being a national emergency if you are spending those hours in California and being absent from the headquarters. It is time to get people back to work.

Faith-based organizations. We have 8,000 faith-based organizations across the country that are irreplaceable members of the Nation's child welfare system. Senator Ossoff and I are going to do some bipartisan work at the Judiciary Committee on these issues. Tennessee relies heavily on faith-based agencies for services like foster care, adoption, different child and family services, and the recruitment of those adoptive families.

Now, under your leadership, one of the first actions that HHS took was to rescind waivers issued by the previous administration, which allowed faith-based groups to place children with families in accordance with their sincerely held religious beliefs. The President's budget now proposes to combat sexual orientation and gender identity discrimination by penalizing foster care and adoption providers for operating in accordance with the tenets of their faith.

So, with nearly 400,000 children in the foster care system, would you not agree that placing those kids in loving homes is a greater priority than advancing an agenda?

Secretary BECERRA. Senator, thank you for the question. There is no doubt that being able to place any child who is in foster care in a loving home should be our top priority, and we want to make sure that that is always possible. We want to make sure laws are not violated that would prevent that child from going to a loving home.

Senator BLACKBURN. Then let us do this. Let us have you submit how many potential foster and adoptive homes would be forced out of the system if the President's budget were put into effect on that issue.

I want to go back—I know Senator Menendez talked to you about the Office of Refugee Resettlement, and this department is responsible for the care and placement of unaccompanied children who come across the U.S. border; correct?

And are you aware of the recent *New York Times* article that really reported on the large numbers of unaccompanied children who are being placed with exploitative sponsors and working long hours in dangerous conditions?

Secretary BECERRA. I am aware of the fact that a number of children have been reported to be working in ways that are violating our law, but I am not aware of the situation you mentioned about being placed in exploitative circumstances. So, if you could clarify that a bit more for us.

Senator BLACKBURN. I will be happy—Mr. Chairman, I would love to submit that article for the record.

The CHAIRMAN. Without objection, so ordered.

[The article appears in the appendix beginning on p. 165.]

Senator BLACKBURN. That is wonderful. Thank you for that.

Now the agency—*The Times* reported that under the Biden presidency, the agency cannot find 85,000 children, and that the agency lost contact with a third of the migrant children who are coming into the country. So I would like to know what you are doing to find the children and what you are doing to make certain that these children are not being trafficked?

Secretary BECERRA. Senator, first, those statistics that you have mentioned—as I said previously in regards to another question by one of your colleagues—is those are unfamiliar to me. I have no idea where those statistics come from, if they are based in reality or not, and we do everything we can to make sure any child, before we allow them to be released to a sponsor, that that sponsor has been vetted. The vast majority of these children end up with a family member, an immediate family member, as a placement. So some of those statistics that are being thrown out there that do not seem to be based in fact, really would go contrary to what actually we have done.

Senator BLACKBURN. Okay. My time is over, but let me tell you, we have to get this thing straightened out. At any time, you had 10,500 children under your care; the money works out to about $1,400 a day to take care of these children, and you cannot find these children. We have to get it straightened out.

Thank you, Mr. Chairman.

The CHAIRMAN. I thank my colleague. We are going to go to Senator Daines.

I am just going to put one document into the record. Reference was made of how the notion, according to some, of making sure Medicare can bargain to hold down the cost of medicine would somehow reduce innovation and damage future drug creation. The nonpartisan Congressional Budget Office looked at this issue specifically, and estimated, their words, "minimal impact of new medicines coming to market under Medicare drug price negotiation."

This was an issue very important to me, because clearly what we wanted was more competition without reducing innovation. That was the finding of the nonpartisan Congressional Budget Office.*

Senator Daines?

Senator DAINES. Mr. Chairman, thank you. Mr. Secretary, thanks for being here today.

There are several concerning proposals in this budget, including, yet again, the omission of the Hyde Amendment, to allow for taxpayer-funded abortions. It is clear the administration has no intention of protecting the precious lives of the unborn. In fact, since the *Dobbs* decision was first leaked in May of last year, over 80 pregnancy resource centers and pro-life groups have been attacked and vandalized, as have hundreds of churches that support the pro-life cause, some even in my home State of Montana.

Mr. Secretary, given the continued assaults against pregnancy centers and churches, would you publicly condemn this violence? If you want to do it right here, I would be happy to hear it.

Secretary BECERRA. Senator, I do not believe anyone here would condone violence against any American, whatever the sort, and certainly I would hope that we could all work together to prevent any American from being harmed simply because they are either trying to exercise their rights or receive services they might need. So I would love to join you in sending a message to all Americans: please, respect people's rights, and also make sure that we are not abridging people's rights.

Senator DAINES. Would you publicly condemn what has happened? Would you condemn this violence?

Secretary BECERRA. I condemn any sort of violence against——

Senator DAINES. Thank you, Mr. Secretary; thank you.

As you are aware, over 30 million seniors and people with disabilities in this country enrolled in the Medicare Advantage plans—including one quarter of Montana seniors—due to the added choice and control they offer beneficiaries. Rural States like Montana face unique challenges when it comes to recruiting and retaining physicians. Oftentimes, we are a long way away from larger communities, and the changes to the CMS HCC model in the proposed rate notice will further jeopardize Montanans access to care.

My question is this. What data can you provide that might show that the current rate notice will not impede access to care in rural and underserved areas?

Secretary BECERRA. Senator, thank you for the question, because it is very important. The rate notice actually provides a greater

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*Congressional Budget Office, Cost Estimate, September 7, 2022, *https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf*.

level of funding than last year, and what we do is, we try to make sure that it is funding that goes for a particular service, and not to line the pocket of a middle person in the process. What I will say to you—especially because of the rural communities that you represent—is, we need to make sure every dollar that the Medicare program puts out for a Medicare recipient gets to service a Medicare recipient.

What we are finding is that too often, programs are gaming the system. And for example, as you heard earlier, some of the plans are claiming that a Medicare beneficiary is sicker than what the person may be as a result of upcoding that person. You get more reimbursement, even though you may not provide the care that a sick person under those circumstances would need.

But what I will tell you is that, at the end of the day, whatever we have done with this rate notice, it does not cut any benefit provided by Medicare, and in fact it actually provides more resources to those who provide services under Medicare itself.

Senator DAINES. I want to shift gears and talk about Medicare taxes. Mr. Secretary, the President's proposed budget raises Medicare taxes, because the President claims to care about the solvency of the Medicare program, and that the wealthy should pay their fair share. However, there is mounting speculation—and this is as reported in *The Wall Street Journal*—that according to his own tax returns, the President improperly classified the money he made on book deals and speaking events, allowing him to dodge over $500,000 in Medicare taxes. This is again according to *The Wall Street Journal*.

How can the President propose tax increases on Americans and call for the wealthy to pay their fair share, when he potentially owes half a million dollars in taxes to the Medicare program?

Secretary BECERRA. Senator, let me respond on the Medicare program. The President's budget would make sure that, not just for today's seniors, that they would get the benefits they expected when they paid into the Medicare program for decades, but it actually now makes it clear that, moving forward to the next generation, they would receive the same level of benefits. There would be no cuts, and that's the beauty of the President's proposal. He has figured out a way to do that.

Senator DAINES. But the question is, do you not think this pledge to protect America's seniors might ring a bit hollow in light of the President's own hypocrisy of dodging $500,000 in Medicare taxes?

Secretary BECERRA. My suspicion, Senator, is that the President would challenge the way you have described his circumstance. But what you cannot challenge is the fact that his proposal actually increases benefits under Medicare, and it moves it forward in strengthening it for the next generation, something that no other President that I have seen when I was here in Congress for 24 years, had really done. And I have not yet seen anyone in Congress really produce a plan like the President's that would provide that guarantee for seniors of tomorrow, that they will have the protections they expect under Medicare.

Senator DAINES. Mr. Secretary, I am out of time. We lost our chairman.

Okay, it looks like Chairman Casey.

Senator WHITEHOUSE. Chairman Casey is recognized by himself.

Senator CASEY. Thank you very much. Senator Whitehouse is letting me go ahead of him, so he gets a lot of credit.

Mr. Secretary, great to be with you, and thank you for your testimony and your enduring commitment to public service. The members of the Alzheimer's Association are here. We are grateful for your presence and the determined advocacy that you bring to our offices year after year. We are grateful and will continue to work with you.

Mr. Secretary, I want to talk to you about long-term care in the context of two settings. I will mention one, but I really want to ask you about the second. The first is in this broader context of what can only be described as a caregiving crisis when it comes to seniors, people with disabilities, and I would include children in that as well.

We are in that crisis, and one of the paths forward I believe—not the only one—but one of the paths forwards is greater investment in home and community-based services, so-called HCBS, for seniors, people with disabilities, and the workers who do that heroic work. I have legislation to do that that I know you are aware of, the Better Care Better Jobs Act, and we have much to do on that.

But I want to set that aside for a moment and talk to you about the other setting, which is the institutional setting: long-term care, skilled care in a nursing home—by way of the leading example—and in particular the Special Focus Facility program that I have worked to oversee for a number of years, to make sure that we are investing in oversight that is particularly centered on those facilities that have had the greatest problems.

When you look at that number, about 90 percent of nursing homes are not on that list. That is the good news. The bad news is, the 3 percent that are have real problems in terms of care. I was pleased to see that there is a 39-percent increase in funding for survey and certification activities of nursing homes in the President's budget. I am grateful for that, but I also think that more funding is needed to expand the Special Focus Facility program. How would additional congressional appropriations toward nursing home quality and oversight be beneficial to better protect residents in these facilities?

Secretary BECERRA. And, Senator, thank you for focusing so much attention on this. While I think most Americans would say it's great that the majority of nursing homes do not fall within this program, there are some that do, and they are Americans who are in these facilities, and we have to make sure that we protect them. So the money that the President proposes would help us do more oversight.

It would help us do the surveillance to find out if these poor-performing nursing homes are increasing services and improving services, and it would let us take action quickly so we can prevent a mishap, an accident, or perhaps death to occur in one of these facilities.

Senator CASEY. And I will submit a question for the record with regard to the plans to revise the program, the Special Focus Facility program.

My second and final question is about countermeasure injury compensation. We know that 700 million COVID vaccines were administered in the country, but there are instances where there are injuries related to any vaccine. I know they are rare, but they do happen.

I was encouraged to see that the HHS budget requested significant increases in funding for administering two programs: the Countermeasures Injury Compensation Program and the Vaccine Injury Compensation Program. I have written to Administrator Johnson at HRSA earlier this year about the Countermeasures Injury Compensation Program, and I want to make sure that we reiterate the message from that letter: that individuals with these COVID–19 vaccine injury claims are waiting too long for adjudication.

So we want to make sure that people are not waiting for years for that kind of compensation. What additional resources or authorities do you need in order to speed up the process and respond to these claimants faster?

Secretary BECERRA. Senator, your help in getting that money across the finish line will be indispensable, because we do need to try to move through those backlogs. One of the things that we would do is, if we get additional resources, to try to make some process improvements in trying to get those claims through. So we would set up, for example, an injury table that lets us better target who is being harmed, what the issue is, and whether or not they qualify for some compensation.

But the biggest issue right now is just having the wherewithal, the resources to get through the number of cases, because all these Americans deserve to be compensated if they were injured.

Senator CASEY. Thank you, Mr. Secretary.

Senator CARPER. Mr. Secretary, your friends and admirers in the First State send their best. Thanks very much for joining us today.

Last year Congress passed, and President Biden signed into law, the Inflation Reduction Act, as you know. It was not just the most significant climate legislation in this country's history, but also included landmark provisions to lower the high cost of many prescription drugs. I was happy to join a number of my colleagues in authoring those provisions.

But our work to lower drug prices, as you know, is not done. We have a real opportunity to continue tackling the cost of prescription drugs through the reforms to the pharmacy benefit manager system. There is bipartisan interest on this committee—and outside of this committee—to do so.

My colleague—our colleague and friend Senator Lankford brought up, I believe, PBMs earlier while I was in another hearing, and I want to follow up on his question. What common-sense PBM reforms do you think should Congress—and in particular this committee, the Finance Committee—consider that will lower the cost of prescription drugs for American families further, and will you and your team at HHS work with us to move those reforms forward during this Congress?

Secretary BECERRA. Senator Carper, thank you for the question, and as you know, this is an area where whatever move or change

we make, we probably will find ourselves facing a complaint filed in court. There is money involved in this.

But what I will tell you is that transparency is so critical, to know how these middlemen are operating, so we understand where the money is going and how the drugs are getting to people who need them from the manufacturers. So I would say to you that we are going to try to do the work possible to try to increase oversight and transparency of the way PBMs operate.

Senator CARPER. Thank you, sir.

I want to talk a little bit with you about implementation of the youth mental health provisions. When I was privileged to serve as Governor of Delaware, we put a public-school nurse in every public school. We opened up wellness centers in just about every high school in our State. Now we are extending those, as you may recall, to our middle schools and to our elementary schools.

But throughout the 8 years I was privileged to serve as Governor, we focused on making sure that kids get the care that they need where they are at, in many cases in schools. Last Congress, I was co-chair, along with Senator Cassidy, of the Youth Mental Health Working Group, alongside our colleague from Louisiana. Several of our priorities were included in the bipartisan Safer Communities Act, as you may recall, including important provisions to make it easier for schools to provide mental health services to students, and to get reimbursed for those services under Medicaid, and I think maybe under the CHIP program as well.

I understand that HHS is now in the process of implementing those important provisions. I would like to say, "Find out what works and do more of that." In that spirit, could you just share with us some best practices from States that are doing a great job providing mental health services to students in school-based settings, so that other States can learn from their success?

Secretary BECERRA. And, Senator, you are right. You probably can identify a number of these programs that are really having success.

What I will tell you is that we are trying to partner with those that have really gone into the schools to provide kids with access, early access to preventative behavioral health and mental health services. One of the programs we have is Project Aware, which really works closely with students to ensure that we are reaching them when they are manifesting certain issues regarding behavioral mental health.

The other thing we are really going to try to push—and here is where we need the help of the States and Governors—is to see if we can get Medicaid into the schools far more deeply and quickly, because many of these kids would qualify for Medicaid services.

Why wait until a parent applies and finds out that the child is eligible to receive mental health services at a doctor's office or a hospital when, as you mentioned, the beauty of having a nurse at a school and maybe having a behavioral health specialist at a school where you get reimbursed through Medicaid funding for having those professionals there, helps us get to those children quickly?

Senator CARPER. Yes.

Last question is: Federally Qualified Community Health Centers are up, as you know, for reauthorization at the end of this fiscal year. As you noted in your testimony, the President's budget includes a pathway to double the program size over 5 years, and greatly expands its reach.

I was pleased to see the President prioritize community health centers in his budget, as co-chair of the Senate Community Health Center Caucus, with several beloved centers up and down my State that provide critical health-care services to my constituents. And my question, the last question, Mr. Secretary, is, can you share your thoughts on maybe the top three areas, the top three areas, where Congress should focus when it comes to reauthorizing the Federally Qualified Community Health Center program?

Secretary BECERRA. Well, the community health centers really delivered. They saved lives. Tens of millions of Americans got their COVID shots at community health centers. They are the centers that are oftentimes providing dental health services to Americans who otherwise don't have dental insurance.

And so, the two or three top priorities: expand them. There are parts of rural America that do not have good access to community health centers. Let them expand their services. Some do not provide OB/GYN services because they are expensive. And at the same time, please, please pass the President's budget on community health centers, because we expand the scope of community health centers and their funding so we can continue to have those great successes for so many Americans.

Senator CARPER. Good. Thank you so much.

Mr. Chairman, I am Tom Carper, and I approve that message.

The CHAIRMAN. Very, very, very good, and we are glad you are on the committee; so, thank you.

Senator Whitehouse?

Senator WHITEHOUSE. Thanks very much. Thank you, Mr. Secretary, for being here.

As usual, I want to bring up my graph, which we have updated to show that from the original CBO Federal health-care cost projections, this actually happened [pointing], with a spike obviously for COVID here, and that brings us up to today. In that backward-looking period in the past, that is an actual $2.2-trillion savings in health-care spending below what CBO forecast.

And, if you bring the forecast forward, in the next 10 years, the budget period, the projected savings are $6.9 trillion against the extended earlier CBO projections. So that tells me that something is going on out there, and I think that it has a lot to do with the improvements in the quality of care, the move to value-based care, the success of Accountable Care Organizations, and perhaps also some of the pharmaceuticals that have come our way.

But I do think that this is worth taking a good, hard look at, because, if we can get those kinds of savings out of the health-care system without taking away benefits, we should be all over that. I know for sure that the ACOs in Rhode Island—Integra and Coastal Medical—hit it out of the park and produced significant savings, wrote big checks back to Medicare, and their patients loved it because the patient experience got so much better. So, I

commend that point to you as I always do, and I hope we can make more progress there.

I also want to go back to something that I have referred to you before, which is my efforts to try to get an end-of-life care model set up in Rhode Island, using the CMMI pilot. I am not asking the rest of the world to come with us, just let us try it. We have been working for years.

This began under CMMI Director Boehler, and then when he left, it was Groundhog Day, and we started in with his successor. And then the administrations changed; it was Groundhog Day again, and now it is Liz Fowler. The thing that we have been asking for is a pool of waivers that really relate to things people near the end of their lives can use.

The 3-day rule—it is preposterous to take somebody who is within perhaps weeks or months of dying and the family thinks they need to be at a nursing home, and you insist on 2 nights and 3 days in a hospital on the way there? That is frightening; that is expensive; that is, you know, just unjustifiable. So we would like to see that waived for people who are in that category.

Curative and palliative ought to be able to proceed in parallel, and home health resources ought to be available. If you are towards the end of your life but you can still walk out into the garden, that should not bar you from getting home health services, because going elsewhere to get the services is more expensive and cruel to the family. So I really want to try to land this and try to get CMMI to say "yes."

The 3-day rule you have already agreed to under COVID. It was waived for COVID. The curative/palliative distinction you waived for the Medicare Choices rule. The home health services you waived for CMMI models. So it is not as if I am asking you to do things that are not sensible and eligible and ready to go. I just want a package so we can land this program in Rhode Island that I have been working on, I think, now for 8 years. Would you please help me with that?

Secretary BECERRA. Very persuasive, Senator. Very, very persuasive. And absolutely, let me work with you on that, because as you said, many of these items are already in place or have been used.

Senator WHITEHOUSE. Yes, yes.

Secretary BECERRA. And I think everyone——

Senator WHITEHOUSE. And CMMI says "No, you should do it our way." No. Just do it our way, right? We are going to be the pilot. We will put it all together. We will make it work. You can measure and model us. We will work with the ACOs, and we will do whatever they want, but I have had enough Groundhog Days.

Secretary BECERRA. Yes. Let us follow up, because I think CMS would like to get there as well. Again, we are heading in that direction, so let us see if we can get there with a good model.

Senator WHITEHOUSE. Thank you.

And just because I see all the terrific purple shirts in the back—my Rhode Island Alzheimer's folks were in yesterday, and they were eager to have Medicare approve lecanemab and aducanumab for early onset Alzheimer's, and if there is anything that you can do to help facilitate that, I think that would be particularly helpful and welcome.

Then, last question, we would like to try to make sure that medication-assisted treatment for people who have opioid disorders can be accomplished through telehealth. We did that through COVID. Can we please find ways to extend that, because it seems to have worked very well, at least according to everybody in my recovery and treatment community? That last part was a question. Should we do more of that? Can we keep doing that?

Secretary BECERRA. Yes, and there, Senator, we will work with you, because that goes beyond HHS. It goes into other of our departments as well. So it is a joint effort to work on that, and we can follow up.

Senator WHITEHOUSE. Thanks, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Whitehouse.

Senator Brown? All the chairmen are here.

Senator BROWN. Mr. Secretary, nice to see you again. And, Senator Whitehouse, thank you for your work, especially on Alzheimer's. We also appreciate that.

Secretary Becerra, as you know, the Norfolk Southern derailment in East Palestine—I was there again yesterday—has left many community members with questions. They want to know how the toxic exposure they and their loved ones experienced will affect their health.

It is important in the process of searching for and receiving answers about these effects that their concerns are taken into account. I know some of your agencies have been there since the very beginning, and you are aware of that, of course. Thank you. I know that, moving forward, HHS will be heavily involved. Yesterday, on one of my trips back to East Palestine, I visited the mobile health clinic, set up and partially funded by HRSA.

People are still coming in seeking help for symptoms relating to exposure, and of course they fear for the future. People are frustrated; they are scared. They feel like time is of the essence. They are afraid when the cameras leave that the help leaves. Can you assure me that HHS will continue to move with urgency in response to this disaster?

Secretary BECERRA. Senator, we were there from the beginning; we are not leaving. And we have been on the ground, and as you said, we have also provided resources, for example to that community health clinic.

Senator BROWN. Thank you, and I know that even though the President did not go right away, or you did not go right away, your people were there and made a real difference. Thank you.

I want to talk to you about drug pricing briefly. One of the victories of the Inflation Reduction Act was capping the Medicare copay for insulin at $35 a month. Walk through what that means for an average Ohio senior who needs this lifesaving drug.

Secretary BECERRA. For the average Ohio senior, it is probably about $500 they get to keep in their pocket; $500 just like that, because before they were paying $100 for that insulin a month, some paying up to $150, $200 a month. But on average—so some will save much more, some will save maybe a little less. But on average, every senior in Ohio who needs insulin, $500 extra in your pocket this year.

By the way, if we had done this last year, that would have been $500 last year you would have kept in your pocket, and the year before. There is no reason why a drug that we know costs no more than about $10 to manufacture should be costing seniors $100, $200.

Senator BROWN. Thank you. That was said so very well. Thank you.

Switching gears for a moment, my last question, Mr. Chair. I know there is a vote. Talk about Medicare Advantage, a great program that serves millions of beneficiaries well. I am concerned some seniors overpay and are not receiving the benefits they deserve. Some Medicare Advantage plans misrepresent how sick their patients are to CMS, in order to take more money from taxpayers.

MedPAC says without fixing this, taxpayers and seniors will be paying billions of dollars more than they should be. MedPAC estimates it cost us over $20 billion—$20 billion—in 2023 alone. Seniors are literally paying for this in the form of higher premiums. Fixing this sounds like a great way to save money, but I keep hearing that saving this money is bad, that it is going to hurt our seniors, put them in danger of having their benefits cut. Explain to me why that is just not true.

Secretary BECERRA. Well, Senator, it is not true because there is nothing that we are doing in this advance notice that would require any insurer to cut Medicare benefits. In fact, they remain the same. Those benefits must be provided by law. What we do is, we take out that extra charge, and we are going to try to get back some of the money that we were overcharged as a Medicare program that should have been used to provide more services to Medicare recipients.

So we think it is the right thing to do, to make sure that every dollar that someone paid in when they were working and saw their deduction from their paycheck, is used to provide Medicare once they are retired, not to help line the pockets of those who are overbilling. We are going to go after any overbilling where we can.

Senator BROWN. Good, and I know you will, and your record shows that.

So, thank you, Mr. Secretary, Mr. Chairman.

The CHAIRMAN. I thank my colleague. Before he leaves, I just want to say "thank you" to Senator Brown, and then we will go to Senator Young, because he remembers in 2019, when we were in this room, and we were not going to be able to get everything we wanted in that bill, we came up with an anti-price-gouging strategy to protect consumers.

Just this week, we saw the fruits of that, because the administration announced lower co-insurance payments for 27 drugs in Medicare Part B as a result of the penalties for price gouging, and you see it particularly with drugs like Humira, which is sort of a poster child for why you ought to have more bargaining power. So, in this room, Senator Brown was incredibly helpful with that, and I want to thank him.

Senator Young?

Senator YOUNG. Thank you, Mr. Chairman. Good to be with you, Mr. Secretary. Welcome to the committee.

The world is facing an antimicrobial resistance crisis. I know you know that super-bugs make us all more vulnerable. They undermine treatment of everything from common ear infections to cancer treatments and routine surgeries. We are seeing more resistance to infection right now than we ever have before, and blessedly there has been a lot of public attention that has been paid to this.

The antimicrobial market is failing. They are hard to develop, and they are almost impossible to sell for at least 5 years because of the need to hold new antimicrobials in reserve, to prevent resistance to those antimicrobials from developing. The administration has stated that drug resistance is a crisis, and the budget highlights a program to provide an incentive for novel antimicrobials, similar to the PASTEUR Act, which is bipartisan legislation that I have introduced with Senator Bennet.

Just days later after the budget was submitted, CMS rolled out a list of 27 medicines that the Inflation Reduction Act is going to penalize for price increases. Five of them are antimicrobials, with prices that are overall well below the total expenditures of other classes of drugs, and they are generally used for short durations for acute infections. These are infused medicines, the kind that you get if there is nothing else available to you.

So, Mr. Secretary, I am going to give you an opportunity to tell me how will penalties on these antimicrobial medicines help our super-bug crisis?

Secretary BECERRA. First, Senator, you are the only one who has asked a question about antimicrobial resistance, and I thank you for that, because we do not think about it, but we are losing the effectiveness of some of these drugs like penicillin, and we count on them. But because they are being overused or misused, we are losing the effectiveness of those drugs. So, thank you for posing the question.

Secondly, remember that the only drugs that will fall on this list to rebate back some of the money is drugs that were raised beyond the rate of inflation, and they can't be new drugs. So these are drugs that have been on the market, and that manufacturer would have to explain why they had to increase that drug beyond the rate of inflation, in some cases dramatically beyond the rate of inflation.

So we are trying to be careful here, and we are going after only those drugs where we see the prices being hiked dramatically.

Senator YOUNG. The price increases on these antimicrobials are based on relatively low overall cost, compared to many other disease treatments. I do not think that patients are going to see much benefit from the penalties that are imposed by the Inflation Reduction Act, if any at all.

It seems like a pretty arbitrary penalty to me that could impact development of new antimicrobials, and you just indicated we really need to develop them.

Secretary BECERRA. And I would love to follow up with you any way you would like on that, because you have touched on something that is really important. We have to figure out a way to have a consistent flow of new drugs that combat bacteria, and as you mentioned, it is a tough business. There is not as much money in it as you might think, and so definitely, I am interested in following up with you any way you would like.

Senator YOUNG. Well, I am interested in working together on this. I know the administration, through their budget proposal, has indicated they support something seemingly similar to the PASTEUR Act. Maybe you can just share with the committee how that proposal, you imagine, might strengthen the antimicrobial pipeline.

Secretary BECERRA. Part of what we think may be in the solution is, rather than have a manufacturer produce a good drug and now try to market it and depend on the market actually receiving the drug and buying it, is maybe have more of a subscription model, where what you do is, you say to the industry, "Come up with the drug," and like these subscription services, Netflix and all the rest, everybody pays in a little bit.

This way there is always money in the pot, and these manufacturers have an incentive to go forward with their production and creation of the drugs, because they know that there will be money in the pot. Most of these manufacturers are afraid that there will not be a market for their drug.

Senator YOUNG. Sounds very similar to the PASTEUR Act, and all the more reason we should work together on this moving forward.

Mr. Chairman, if I can just add a very quick question about organ procurement, something you have been such a leader on.

The CHAIRMAN. I was just going to commend you, because yesterday we got some good news, that the administration is going to be receptive to recommendations that you and others worked with all of us on, to have a more competitive system and not just give out the contracts. So I was just getting ready to praise you.

Senator YOUNG. Oh, well, thank you. Thank you for that, and I will just pointedly ask the Secretary on topic here.

The CHAIRMAN. Please, please.

Senator YOUNG. Getting OPO process data has been a real challenge. The chairman and I have both requested this data. We think it is consistent with our oversight responsibilities in ensuring that more organs are available to save more lives and extend lives. So will you commit to release OPO process data in line with the bipartisan calls from this committee?

Secretary BECERRA. Senator, we are working to change the way we handle organ procurement and transplantation. We are definitely interested in working with you on this subject, and I do not know if you heard, but we just announced that we are doing three specific things that are changing the dynamic in this space.

We are going to call for more data transparency from the contractors. We are actually going to open up competition for the contract, so that the same contractor that has had this for years and years does not just expect that they will get the contract. Then we are also trying to—and the President's budget calls for more resources to—actually modernize our IT, because we are not keeping up with technology. We are losing time, which could be letting an organ go to waste.

Senator YOUNG. Those seem like the right priorities. I would say that I hope the OPO process data is forthcoming, consistent with the data transparency focus.

Thank you so much.

The CHAIRMAN. I thank my colleague.

Senator Barrasso?

Senator BARRASSO. Thanks, Mr. Chairman. Mr. Secretary, welcome back to the committee. Thanks for taking the time to be here.

As you know, as a physician I know the importance of protecting Medicare for future generations. And stopping waste and fraud and abuse are critical for all of us, and it is a bipartisan priority.

Late last year, I was joined by my colleagues on the Comprehensive Care Caucus in sending a letter to CMS. The purpose was to point out the proliferation of new for-profit hospice providers. I think about the hospices in Wyoming, such as Central Wyoming Hospice that I am very involved with in Casper. We have some around the State of Wyoming—community involvement, people volunteer, go to events, raise money, help, and these are amazing centers that provide care and comfort and compassion.

Most troubling is that your own data shows the proliferation of these new for-profit hospices. They are actually sharing the exact same addresses, and we are trying to figure out what exactly is going on here, why this is happening. Do you share my concern regarding this pattern of this sudden growth of these Medicare-certified hospices in certain parts of the country?

Secretary BECERRA. Absolutely, and we have actually conducted some unannounced site visits at some of these hospices that were identified in that article.

Senator BARRASSO. Yes. What are you finding out in terms of—are there bad actors out there or are there things we can do to curb them, so that we can prevent some of this waste, fraud, and abuse?

Secretary BECERRA. We will absolutely share some of that information, but no doubt what we are looking for is to find out if they are taking advantage of people, if they are defrauding the American taxpayer, and if they are abusing the privileges that they have by being able to provide these services.

Senator BARRASSO. You know, I point out there is a bipartisan group on this committee—and in this body—that wants to assist you in that and help you and share the information that you come up with so we can put an end to this sort of thing.

Secretary BECERRA. As someone who cared for his dad, giving, offering hospice care as best my family and I could, we are absolutely with you on that.

Senator BARRASSO. Thank you.

The next is, you know rural health remains a top priority with me. We met today with the Wyoming Alzheimer's Association. There are a number of people here in the audience today listening to you testify, wearing the sashes representing family members and others with Alzheimer's. So I am encouraged that there is a new class of Alzheimer's treatments. It is giving families some hope that they may have more quality time with their loved ones before the disease takes hold.

It is not a cure, but there is hope there. And we just need to make sure that what is available in certain locations could also be made available to our Tribal communities and to our rural beneficiaries. You know, the Centers for Medicare and Medicaid Services, they have a policy for coverage that is with evidence development, and they are requiring additional clinical trials or registries that could create logistical challenges for people in rural areas, as

well as the providers who are trying to take care of them, because they are not all eligible, based on where they are.

So how does CMS plan to ensure that those with Alzheimer's in rural settings and Tribal communities gain access to therapies which are currently FDA-approved?

Secretary BECERRA. And, Senator, I think this is where we all would agree we have to do more work together. But COVID taught us that telehealth flexibilities let us reach people more directly, more efficiently. We would love to keep those telehealth flexibilities in place. We would like to make sure that an actual skilled, specialized provider is available in these rural communities, so we are trying to expand the number of people who actually go into the profession. But this is where we can all team up together to figure out how we better serve our communities, especially in rural America.

Senator BARRASSO. And specifically, with FDA-approved drugs, unless you are part of this kind of next-generation follow-through, it is harder to get those, you cannot actually get them in rural communities, Tribal communities, based on your location, even though they are FDA-approved.

Secretary BECERRA. Yes. We look forward to working with you on that subject.

Senator BARRASSO. Then I wanted to get to rural health clinics. There are about 5,200 Centers for Medicare and Medicaid Services certified rural health clinics. They provide outpatient services all across the country. The Census Bureau no longer defines urbanized areas—it was previously defined as urban areas of 50,000 or more. They have kind of changed that.

But the rural health clinic statute requires that the rural health clinics must be located in areas that are not in urbanized areas, as defined by the Census Bureau. So they do not define them anymore, so there is kind of a lack of policy. So what we are seeing is that rural health clinic applications are currently being either inappropriately rejected, based on assumptions of what the new policy is, or blocked by States waiting for some clarification from CMS. I know you are aware of this. Could you just hold forth on that for a bit?

Secretary BECERRA. Yes. Thanks for pointing that out. CMS is in the process of trying to provide some guidance to clarify that. But Senator, I will say this. If there is a particular facility, clinic that believes it was denied access to funding and so forth as a result of what the Census Bureau did, please have them contact us.

Senator BARRASSO. We will do that. Thank you, Mr. Secretary.

Thank you, Mr. Chairman.

The CHAIRMAN. Before he leaves, I just want to thank my neighbor. Those are important points with respect to rural care, and I am not aware of these for-profit hospice issues the way my colleague talked about them. So I would like to know more about those as well.

Senator BARRASSO. Well, thank you. Thanks so much, Mr. Chairman.

The CHAIRMAN. I thank my friend.

All right, let's see. I believe we have a couple of other Senators on their way. Senator Cantwell; no?

Mr. Secretary, you have been very patient. We really appreciate that. What we wanted to do when we set out 3 hours ago, before your infinite patience, is to show that working families and the middle class can get ahead in this hugely important area.

I have always felt, since my days when I was director of the Gray Panthers, if you and your loved ones do not have your health, everything else goes by the board. It is the most important issue—the most important issue. What we have set out to do here is to show that we can help working families and seniors and the middle class get ahead. And making sure we reduce the deficit—those two things are not mutually exclusive. We can do both, and we certainly showed that with respect to prescription drug cost containment.

I have one other question for you, and it is as much a statement as anything else. We have seen the great bipartisan interest in this committee over the last 3 hours for advocacy for Alzheimer's patients, and it is just so urgent.

I just want you to pass on to the Department—we work often with CMS Administrator Chiquita Brooks-LaSure, and if you will just convey that I will be calling her very shortly to talk about how—given what we have heard today about Alzheimer's—she can lead this effort to speed up access for Alzheimer's treatments and services. I think that that is——

[Applause.]

The CHAIRMAN. As a general rule, we are not supposed to advocate clapping, and so I probably have a conflict of interest here, so go figure. But I think, Mr. Secretary, seriously, we have seen how strongly the committee feels. We have seen how strongly the country feels. This is urgent, urgent business. Please, as I say, let the Administrator, Ms. Brooks-LaSure, who is juggling a lot of stuff and juggling it very well, know I will be calling her about speeding up access.

Thank you. We will be working with you often in the days ahead, and I thank you for your patience this morning and your professionalism.

And with that, the Committee on Finance is adjourned.

[Whereupon, at 12:48 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF HON. XAVIER BECERRA, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Chair Wyden, Ranking Member Crapo, and members of the committee, thank you for the opportunity to discuss the President's Fiscal Year (FY) 2024 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.

It is my great pleasure to serve as the head of the Department of Health and Human Services—a department full of dedicated civil servants who work tirelessly to meet our mission of enhancing the health and well-being of the American people. We know this goal is also shared by all of you, and we are excited about working with you to fund key initiatives that will enable us to continue to meet that mission.

The FY 2024 budget proposes $144 billion dollars in discretionary funding and $1.7 trillion dollars in mandatory funding to continue the work of the Department and make major investments in several critical areas. Our country faces numerous health-care challenges—and HHS is at the center of addressing many of these issues—including the need to transform behavioral health care; prepare for future public health threats; support unaccompanied children and refugees; protect the health of all Americans; meet the health needs of Indian Country; expand the health-care workforce; expand coverage and access to care, including high-quality early childhood education; improve the health and well-being of children, families, seniors, and people with disabilities; advance science to improve health; end cancer as we know it; and promote effective and efficient management and stewardship.

TRANSFORMING BEHAVIORAL HEALTH CARE

In response to the current behavioral health crisis, HHS makes substantial investments in services to provide more Americans with access to the care they need when they need it. The 988 National Suicide Prevention Lifeline operates 24/7 to provide access to trained counselors to people in crisis. In the FY 2024 budget, the Substance Abuse and Mental Health Services Administration (SAMHSA) will dedicate an additional $334 million to the 988 program to meet an expected volume of 9 million contacts. Investing in the crisis response continuum more broadly is critical to ensuring that the system is responsive at any time and in any place. The budget builds on previous investments to provide $100 million for mobile crisis response to expand partnerships with 988 local crisis centers, community providers, 911 centers, and first responders to promote health-first responses to mental health, suicidal, and substance use crisis events.

One in 4 adults in the United States had a mental illness and 46 million Americans had a substance use disorder in the past year.[1] To address these challenges, the budget continues to invest in the Nation's mental health infrastructure and to further integrate behavioral health care into health care, social services, and early childhood systems. The FY 2024 budget proposes to increase the Community Mental Health Services Block Grant by $645 million and proposes to increase the Substance Use Prevention, Treatment, and Recovery Services Block Grant by $700 million. The budget converts the Certified Community Behavioral Health Clinics demonstration

[1] "Facts about Suicide," Centers for Disease Control and Prevention, *https://www.cdc.gov/suicide/facts/index.html.*

to a permanent program to further ensure access to comprehensive behavioral health care for all who need it.

Additionally, to help build the behavioral health workforce needed to provide such care and services, the FY 2024 budget expands Medicare coverage of, and payment for, additional behavioral health professional services including those furnished by clinical social workers, peer support workers, and certified addiction counselors.

To develop new approaches to addressing mental health and substance use disorders, the FY 2024 budget includes an additional $200 million for the National Institutes of Health (NIH) to prioritize innovative mental health research and treatment, with the agency allocating a portion of these resources to launch a new precision psychiatric initiative. NIH will also continue to invest over $1.8 billion in research on opioid misuse, addiction, and pain disorders, including the Helping to End Addiction Long-term (HEAL) initiative. HEAL aims to develop innovative treatments for opioid addiction and chronic pain and associated health disparities. The budget also includes proposals to modernize and expand Medicare's mental health benefits and improve behavioral health for the private insurance market, with an emphasis on improving access, promoting equity, and fostering innovation.

PREPARING FOR FUTURE PUBLIC HEALTH THREATS

On February 11th, HHS renewed the COVID–19 Public Health Emergency (PHE) for what we expect will be the final time. The Nation has made tremendous progress: the administration effectively implemented the largest adult vaccination program in U.S. history, with nearly 270 million Americans receiving at least one shot of the COVID–19 vaccine. Second, we made available to the American public 1.16 billion COVID tests at no cost. And we were able to provide over 23 million therapeutic courses of treatment to Americans. According to the Commonwealth Fund, 2 years of COVID vaccinations saved over 3 million lives, in addition to preventing more than 18.5 million hospitalizations.

The FY 2024 budget prioritizes preparedness for the next health crisis. The budget includes $20 billion in mandatory funding, available over 5 years, across the Administration for Strategic Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and NIH to support the President's plan to transform the Nation's capabilities to prepare for, and respond rapidly and effectively to, future pandemics and other biological threats. This includes investments in enhancing early detection and warning systems, advancing, and securing safe and effective supplies and medical countermeasures, and strengthening public health systems and core capabilities. For ASPR, the budget includes $1 billion in discretionary funding for the Biomedical Advanced Research and Development Authority (BARDA) to develop innovative medical countermeasures, $995 million for the Strategic National Stockpile, and $400 million to bolster the medical supply chain and create medical countermeasures that address key preparedness gaps. The FY 2024 budget includes $10.5 billion in discretionary funding for the CDC to protect health, safety, and security at home and abroad. Additional strategic investments, including at the FDA and NIH, are proposed to bolster our national preparedness posture as we ready ourselves for the next public health threat—no matter its origin. These funding proposals are paired with a suite of legislative proposals that would provide HHS with authorities to enable HHS to respond to future threats nimbly and effectively.

SUPPORTING UNACCOMPANIED CHILDREN AND REFUGEES

Children presenting at the border without a parent or guardian, and refugees arriving in our Nation, must be cared for in a safe and humanitarian manner. At HHS, we will continue to do our part to protect the safety and well-being of unaccompanied children by providing them appropriate child-centered care while they are in our custody; placing them in the custody of parents, relatives, and other appropriate sponsors after thorough vetting; and providing post-release services including safety and well-being calls. HHS already provides post-release services to more than 40 percent of children released from our care, nearly double the percentage receiving services when the Biden administration took office, and is on track to provide services to nearly 60 percent of children by the end of this fiscal year, and all children within the next 2 years.

The FY 2024 budget provides $5.5 billion for unaccompanied children and $1.7 billion for refugees and other new arrivals eligible for benefits. In addition, to address the inherent uncertainties in budgeting for these populations, the budget includes a discretionary contingency fund, which would provide additional resources if either

population exceeded certain levels and is estimated to provide $2.8 billion in FY 2024. The fund expands on the unaccompanied children contingency fund that Congress enacted in FY 2023. These services and resources are critical to our country, and I would like to thank Congress for your continued dedicated support.

PROTECTING THE HEALTH OF ALL AMERICANS

The administration aims to reduce maternal mortality and morbidity, through proposals such as the "Birthing-Friendly" hospital designation, which drives improvements in maternal health outcomes. The budget includes $1.9 billion for the Health Resources and Services Administration (HRSA) Maternal and Child Health programs, an increase of $205 million, directing $276 million toward reducing maternal mortality and morbidity and $185 million to the Healthy Start program to reduce racial disparities in maternal and infant health outcomes. The budget also provides $30 million for NIH to continue the Implementing a Maternal Health and Pregnancy Outcomes Vision for Everyone (IMPROVE) initiative to support research focused on interventions for preventable maternal mortality and morbidity and associated risk factors that contribute to health disparities in maternal care. The budget further includes $3 million for NIH's continued research on the effects of COVID–19 on individuals during pregnancy, lactation, and the postpartum period. The budget also requires states to provide 12 months of postpartum coverage through Medicaid and the Children's Health Insurance Program.

HHS is also committed to protecting and strengthening access to reproductive health care. The budget provides $512 million to the title X family planning program to address the increased need for family planning services for approximately 4.5 million individuals, with 90 percent having family incomes at or below 250 percent of the Federal poverty level. Title X is the only Federal grant program solely dedicated to providing individuals with comprehensive family planning and related preventive health services in communities across the United States.

In 2022, HHS released the Viral Hepatitis National Strategic Plan, which provides a framework to eliminate viral hepatitis as a public health threat in the United States by 2030. The Viral Hepatitis Plan focuses on hepatitis A, hepatitis B, and hepatitis C—the three most common hepatitis viruses that have the most impact on the health of the Nation. The Viral Hepatitis National Strategic Plan is the first to aim for elimination of viral hepatitis as a public health threat in the United States. Building on this work, the FY 2024 budget includes $11.3 billion for a new HHS-wide proposal to establish a 5-year national program to significantly expand screening, testing, treatment, prevention, and monitoring for hepatitis C infections. This program would increase access to tests and curative medicines and expand public health efforts, with a net cost of $5.1 billion over 10 years once accounting for health improvements and reduced health-care spending. Continuing this work is vital to protecting and improving the lives of Americans who are impacted by this serious disease.

Health Centers provide health-care services to underserved populations across the country, including low-income patients, ethnic minorities, rural communities, and persons experiencing homelessness. The budget proposes a pathway to doubling the program's funding with a critical 3-year down payment on this goal. The FY 2024 budget provides $7.1 billion for Health Centers, which includes $5.2 billion in proposed mandatory resources, an increase of $1.3 billion above FY 2023 enacted. At this funding level, the Health Center Program will provide care for approximately 33.5 million patients.

The FY 2024 budget also makes critical investments to establish Vaccines for Adults program within CDC, as a complement to the successful Vaccines for Children program. The Vaccines for Adults program will begin expanding access to routine and outbreak response vaccines recommended by the Advisory Committee on Immunization Practices for uninsured adults at no cost.

MEETING THE HEALTH NEEDS OF INDIAN COUNTRY

HHS is committed to upholding the United States' responsibility to Tribal nations by addressing the historic underfunding of the Indian Health Service (IHS). Building on the historic passage of advance appropriations for the IHS in FY 2023, the FY 2024 budget proposes $8.1 billion in discretionary funding for the IHS Services and Facilities accounts, an increase of $2.2 billion above FY 2023 enacted. This funding will expand access to healthcare services for 2.8 million American Indians and Alaska Natives, address key operational capacity needs, and modernize outdated facilities and information technology systems. The budget also includes $1.6

billion in proposed mandatory funding in FY 2024 for Contract Support Costs, payments for section 105(l) Tribal leases, and the Special Diabetes Program for Indians.

Beginning in FY 2025, the budget proposes all IHS resources as mandatory. The budget would automatically grow IHS funding each year to account for inflationary factors, population growth, key programmatic needs, and existing backlogs in both health-care services and infrastructure needs. The mandatory funding approach would ensure that the IHS budget grows sufficiently to both address historic underinvestment and expand capacity for increased service provision. It also includes new funding streams to address key gaps, including the lack of dedicated funding for public health infrastructure in Indian Country. HHS firmly believes that mandatory funding is the most appropriate long-term solution to address chronic underinvestment in IHS. The Department will continue consultation with Tribes and working in partnership with Congress to see this important goal realized. While this work is underway, it is critical that Congress continues to provide discretionary advance appropriations to ensure that the critical advancements achieved through enactment of advance appropriations in the FY 2023 Omnibus are not reversed.

EXPANDING AND RETAINING THE HEALTH WORKFORCE

The health workforce plays a vital role in responding to public health needs. As the demand for health-care workers increases, HHS remains committed to strengthening, expanding, and retaining the workforce. The FY 2024 budget provides $2.7 billion for HRSA workforce programs, including $947 million in mandatory resources, to expand workforce capacity across the country. The discretionary budget includes $28 million for a new program to support innovative approaches to address health-care workforce shortages and strengthen retention efforts. The budget also provides $25 million for a program to support the adoption of workplace wellness in health-care facilities including hospitals, rural health clinics, community health centers, and medical professional associations. The budget includes $106 million within CDC to support public health training and fellowship programs to strengthen the existing workforce as well as support a pipeline of personnel ready and able to address public health threats. In addition to these investments, HHS prioritizes the importance of diversifying the health-care workforce to better serve all communities and build a more equitable health-care system.

EXPANDING COVERAGE AND ACCESS TO CARE

It is ever more crucial to promote the health, safety, and dignity of older adults and people with disabilities, particularly as America's older population increases. The FY 2024 budget makes essential investments to strengthen our Nation's long-term care system and invests $150 billion over 10 years to improve Medicaid home and community-based services, to ensure that more people who are aging and those with disabilities can receive care in their home or community and to strengthen the home care workforce. President Biden also issued a call to action to improve the quality of America's nursing homes, and HHS continues to take action to ensure that older adult nursing home residents receive the highest quality care. The FY 2024 budget includes multiple provisions to strengthen nursing home oversight, transparency, and enforcement, including $566 million for surveying and inspections. The provisions protect older adult residents by identifying and penalizing nursing homes that commit fraud, endanger patient safety, and/or prescribe unnecessary drugs.

Since the passage and subsequent expansions of the Affordable Care Act, tens of millions of Americans have gained access to quality health insurance through the marketplace. To build on this success, the FY 2024 budget invests in making private insurance even more affordable. This includes new proposals to build on historic progress made in Congress, including a permanent extension of the enhanced premium tax credits in Pub. L. 117–169, commonly known as the Inflation Reduction Act. The budget proposes to extend protections from the No Surprises Act to ground ambulances. The FY 2024 budget also provides Medicaid-like coverage to low-income individuals in States that have not expanded Medicaid under the Affordable Care Act, paired with financial incentives to ensure states maintain their existing expansions.

IMPROVING THE WELL-BEING OF CHILDREN, FAMILIES, SENIORS, AND PEOPLE WITH DISABILITIES

Early childhood programs have a return of up to $9 for every $1 spent due to the positive long-term health, educational, and social impacts on vulnerable children. The budget includes $13 billion for Head Start, an increase of $1.1 billion, to provide

comprehensive early learning and development services to roughly 760,156 slots for eligible children and pregnant women. Within this total, $440 million is included for a cost-of-living adjustment for Head Start workers, and $575 million is included to further improve compensation. Collectively, these investments ensure that families have access to high-quality services by retaining and supporting the workforce. In addition, the budget includes a legislative proposal to expand tribal, migrant, and seasonal Head Start eligibility.

The budget likewise invests in child care, critical to both working parents, and particularly to mothers and children. For the discretionary Child Care and Development Block Grant, the budget provides for an investment of $9 billion, an increase of nearly $1 billion over the FY 2023 enacted funding level. In addition, the budget includes a mandatory proposal to invest $400 billion over 10 years in high-quality child care, and $200 billion over 10 years in universal preschool.

The $400 billion in mandatory funding over 10 years for high-quality child care includes funding for States to serve children ages zero to five for families earning up to $200,000. It provides higher Federal matching funds for child care providers serving low- and middle-income families and allows those families to pay the lowest copays—with a goal of ensuring that the lowest income families pay nothing and that most families pay no more than $10 a day per child, meaning that a median-income family with young children saves about $400 per month while accessing higher-quality care. The administration's proposal enables States to expand access to affordable, high-quality child care to more than 16 million children. This reflects an expectation that all States will choose to adopt the program but, if some States do not, the administration is committed to serving low-income children through a Federal alternative.

The $200 billion in mandatory funding over 10 years for universal preschool supports free preschool in the setting of a parent's choice—from public schools to child care providers to Head Start—to support healthy child development and ensure that children enter kindergarten ready to succeed. The proposal provides funding through a Federal-State partnership to expand high-quality preschool education to all 4-year-old children, with the flexibility for States to expand preschool to 3-year-olds once high-quality preschool is fully available to 4-year-old children. The proposal also includes funding to provide access to preschool to children in underserved communities in States that do not choose to participate in the new preschool program, so that families in every State have access to high-quality preschool.

To further protect and enhance child well-being, the budget also includes $4.9 billion in mandatory funding over 10 years for prevention services and kinship navigator programs, $1.3 billion in mandatory funding over 10 years to give States an incentive to place children with kin, and $1 billion in mandatory funding over 10 years for support for youth who experienced foster care in transitioning to adulthood.

The COVID–19 pandemic revealed that millions of children, families, seniors, and people with disabilities are living with food insecurity. The increased need for nutrition programs has not abated, and the FY 2024 budget supports the administration's National Strategy on Hunger, Nutrition, and Health by including $137 million across HHS to reduce hunger, food insecurity, and malnutrition. Within the $137 million, the budget includes $12 million at the Administration for Community Living (ACL) for nutrition services for older adults and people with disabilities and $72 million to expand CDC's State Physical Activity and Nutrition program, which implements evidence-based strategies to reduce chronic disease. In addition, the budget proposes to increase funding at NIH for nutrition research. The budget also expands Medicare coverage for nutrition and obesity counseling, and includes a new pilot project on medically tailored meals.

HHS is committed to ensuring that seniors and people with disabilities have the essential resources and services they need. The FY 2024 budget also makes key investments in the Elder Justice Adult Protective Services program. And, to help more older adults and those with disabilities receive care in their home or community. As noted above, the budget also includes a $150 billion mandatory investment over 10 years in improving and strengthening Medicaid home and community-based services and provisions to improve safety and quality in our Nation's nursing homes.

The budget extends the solvency of the Medicare hospital insurance trust fund by at least 25 years without cutting benefits. The budget builds on efforts in the Inflation Reduction Act to lower prescription drug prices. It also invests $8 billion to enhance Medicare benefits, such as preventing diabetes, expanding access to behav-

ioral health services and community health workers, improving the quality and safety of long-term care services, expanding coverage for nutrition and obesity counseling, eliminating hepatitis C, and advancing equity. Additionally, the budget aligns income and asset determination processes for Medicare low-income assistance programs, easing administrative burdens for States and removing enrollment barriers for individuals.

ADVANCING SCIENCE TO IMPROVE HEALTH

As President Biden has said, "cancer does not care if you're a Republican or a Democrat," which is why the President and First Lady reignited the Cancer Moonshot 1 year ago. HHS is committed to leading the public sector in pursuit of cutting the cancer death rate by 50 percent over the next 25 years and supporting families, their caregivers and family members, living with and surviving cancer.

NIH will continue to build on the Cancer Moonshot's momentum by supporting projects that will deliver important insights into preventing, detecting, and treating cancer. The FY 2024 budget includes $716 million in discretionary resources for dedicated Cancer Moonshot activities at NIH. In addition to the FY 2024 resources, the budget also proposes to reauthorize the 21st Century Cures Act Cancer Moonshot through 2026 and provide $2.9 billion in mandatory funding in 2025 and 2026, $1.45 billion each year. To support the goals of the Cancer Moonshot, the FY 2024 budget includes an additional $183 million for a total of $839 million to support cancer prevention and control programs across CDC, including screening programs, tobacco prevention, Human Papillomavirus (HPV) prevention and analysis of cancer clusters, and laboratory and environmental health activities. An additional investment of $20 million for HRSA is also provided, to expand partnerships between federally funded health centers and NCI-Designated Cancer Centers to facilitate access to lifesaving cancer screenings and early detection services for medically underserved populations. The budget also includes $108 million within IHS to address specialized cancer care needs in tribal communities. The budget also proposes to create a new Cancer Care Quality Reporting Program for all Medicare providers furnishing cancer care services. This unified program would enable the Centers for Medicare and Medicaid Services (CMS) to assess and compare cancer care delivered through multiple provider types, drive improvements in the quality of cancer care, and standardize data collection to identify and address potential inequities in care.

The FY 2024 budget includes several investments for FDA to support food programs including $20 million for the Emerging Chemicals and Toxicology Issues program to streamline regulatory frameworks for food products that may pose chronic risks to human health. Funds support post-market reassessment of previously approved food chemicals and develop approaches to inform and modernize safety assessments using science and risk-based approaches. An additional investment of $5 million is provided for the 21 Forward food supply chain continuity system, which enables the agency to develop accurate models for situational awareness and forecast the impact of a pandemic, product shortages, or other high-risk threats on the food supply chain. Within medical product safety, the budget dedicates a total of $59 million to continue efforts that strengthen public health supply chains and promote the availability of medical devices by proactively monitoring, assessing, and communicating risks and vulnerability.

The budget will prioritize innovative mental health research and treatment and the NIH climate change initiative. NIH will continue to invest funds to address the opioid crisis, end HIV, and advance other research areas, such as improving health disparities and inequities research, as well as continuing the agency's progress towards a universal influenza vaccine. NIH's budget also continues support for the All of Us and Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) initiatives, both started with the 21st Century Cures Act.

The budget also invests in high-impact research advances that drive innovation through the Advanced Research Projects Agency for Health (ARPA–H). As an independent research entity, ARPA–H will be able to accelerate health breakthroughs with the potential to transform important areas of health and medicine. The budget provides $2.5 billion for the agency's approach to prevent, detect, and treat cancer and other diseases such as diabetes and dementia. ARPA–H will advance high-potential, high-impact biomedical and health research that cannot be readily accomplished through and other existing research or commercial activity.

In keeping with the Agency for Healthcare Research and Quality's (AHRQ) mission to provide evidence-based research, data, and tools to improve health-care quality, the FY 2024 budget includes $564 million to support AHRQ's research on qual-

ity, health costs, and outcomes to make health care safer, more accessible, equitable, and affordable for all Americans. Included are additional resources to further Long COVID care, primary care, and diagnostic safety research.

PROMOTING EFFECTIVE AND EFFICIENT MANAGEMENT AND STEWARDSHIP

As Federal stewards, it is our duty to ensure that taxpayer dollars are spent appropriately through the delivery of high-quality services, through necessary security, and through strong action to prevent fraud and abuse. To protect against information technology threats, the budget provides an increase of $88 million above FY 2023 enacted for cybersecurity initiatives in the Office of the Chief Information Officer (OCIO). Due to the increasing frequency of cyber-attacks that impede the delivery of health care and leak private patient health information, the ASPR and OCIO budgets have been increased to understand, mitigate, and identify Health-care and Public Health (HPH) Sector cybersecurity risks, as well as, to prevent, detect, respond, and recover from HPH cyber-attacks.

The budget makes robust investments in the Health Care Fraud and Abuse Control funding to provide oversight of CMS health programs, strengthen the HHS Office of Inspector General investigations, and protect beneficiaries against health-care fraud. Our comprehensive program integrity legislative package and allocation adjustment yields $19.7 billion in net savings over 10 years. The Office of Civil Rights would receive significant additional funding to address a sharp rise in its caseload, from 45,000 cases in 2020 to a projected 80,000 in 2024. Finally, the budget includes much-needed investment in core infrastructure, oversight, and operations, including in the Nonrecurring Expenses Fund, General Departmental Management, CMS Program Management, and ACL.

CONCLUSION

I want to thank the committee for inviting me to discuss the President's FY 2024 budget for HHS. The budget represents the continued investment in the health, growth, protection, and vitality of the American people. With adequate funding in these critical areas, we can support the forward mobility of our country and continue to make stride towards a brighter future. Thank you for your dedication and partnership in our shared goal to improve the health, safety, and well-being of our Nation.

QUESTIONS SUBMITTED FOR THE RECORD TO HON. XAVIER BECERRA

QUESTIONS SUBMITTED BY HON. RON WYDEN

HOSPITAL PRICE TRANSPARENCY

Question. On January 1, 2021, Federal Hospital Price Transparency regulations went into effect. Federal hospital price transparency rules require each hospital to make public the standard charges for items and services they provide. Hospitals are required to make standard charges public through a consumer-friendly display consisting of at least 300 shoppable services and a comprehensive, machine readable file. During the second year of hospital price transparency rules, CMS reviewed 600 randomly selected hospitals, and 70 percent of hospitals met the requirements. As of January 2023, CMS sent nearly 500 warning notices and 230 requests for corrective action plans. Nearly 300 hospitals addressed noncompliance. CMS issued civil monetary penalties against only two hospitals for failure to come into compliance. It is critical for CMS to ensure compliance with hospital price transparency rules to help patients shop for information, to provide researchers information to analyze variation in charges, and to help employers negotiate more competitive rates.

Which metrics does CMS use to define compliance with Federal hospital price transparency requirements? Does this account for differences between CMS's assessment of compliance and studies conducted by third parties?

How does CMS define a shoppable service?

What are some of the challenges accessing data that are not publicly available to determine compliance?

What is CMS's timing for requiring compliance with a standardized hospital price transparency template?

Will CMS post publicly information about hospitals that are issued a written warning notice and have to complete a corrective action plan to come into compliance with hospital transparency rules?

Does CMS have plans to provide a more detailed compliance analysis to capture more hospitals? Would this require additional funding from Congress?

Answer. 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. After significant outreach and technical assistance to hospitals, hospitals have made substantial progress since January 2021.

Compliance Analyses

CMS's Hospital Price Transparency compliance analyses focus on aspects of the regulation that can be unambiguously determined by looking at the data posted by the hospital on its website. CMS's analysis aligns closely with many other external assessments. CMS evaluates according to the regulatory requirements. For example, the fact that there is no specific negotiated charge associated with a particular service—*e.g.,* deep brain stimulation, a commonly performed surgical treatment for Parkinson's disease—may mean that the hospital has not in fact established a negotiated rate for that procedure because it just does not offer that type of neurosurgery, or it may signal the omission of required information and indicate noncompliance. That type of information—whether or not the hospital is actually offering the service—is the type of information that is gleaned during the comprehensive compliance review in the back and forth between a hospital and CMS.

CMS's compliance assessments thus far were done primarily to understand and quantify the general state of hospital compliance, in support of our policy and enforcement activities. Beyond the initial proactive assessment (done in early January 2021), CMS has been systematically working through the high volume of complaints submitted by the public through the website. As of January, 2023, CMS has issued nearly 500 warning notices and over 230 requests for corrective action plans. 300 hospitals have addressed problems and have become compliant with the regulations, leading to closure of their cases, including the 2 hospitals which we have issued civil monetary penalties.

Shoppable Service

The Hospital Price Transparency regulations define a shoppable service as "a service that can be scheduled by a health-care consumer in advance."[1]

Standardized Data

CMS continues to work to improve the collection and display of standardized data, including by holding a listening session to discuss ways to display information for consumers, and by encouraging hospitals to format and validate their data sets. In an effort to assist hospitals in complying with the requirements under the Hospital Price Transparency regulations and also providing consistency in how those disclosures are viewed by consumers, CMS has made available several sample formats using a standardized set of data elements that hospitals may use to make public their standard charges. CMS also has finalized a requirement that the machine-readable file be accessible to automated searches and direct downloads. Further, CMS has clarified that the estimate from a price estimator tool, voluntarily used by the hospital in lieu of making public a consumer-friendly list of standard charges, must be tailored to individuals' circumstances and represent a real-time individualized out-of-pocket estimate of the amount they would have to pay the hospital that takes into account any applicable benefit information.

Enforcement

In CMS's enforcement of the hospital price transparency rules, the agency's goal is to increase access to useful, meaningful information for consumers and ensure hospitals are following through on their obligations to make information available. CMS is working closely with hospitals to bring them into compliance, and the agency in the process of examining further improvements to the program, including ways that CMS enforcement could be used to increase compliance.

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[1] 45 CFR part 180—Hospital Price Transparency, *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-E/part-180.*

DIGITAL THERAPEUTICS

Question. The President's FY 2024 budget includes a legislative proposal to establish Medicare coverage of evidence-based digital applications and platforms that facilitate the delivery of mental health services, especially for beneficiaries who live in rural or health professional shortage areas. As the Senate Committee on Finance continues to advance legislation to address barriers to mental health care and use innovative tools to address mental health workforce shortages, it will be important to gain additional detail on this proposal.

Is it possible for Medicare to establish coverage for these digital applications and platforms (hereinafter "apps") via existing national or local coverage determination processes?

Would this FY 2024 budget proposal require the creation of a new benefit category in Medicare, or could coverage for these digital apps and platforms be incorporated into an existing Medicare benefit?

Does HHS or CMS have any criteria that Congress should consider for determining the scope of digital apps and platforms that should be covered by Medicare? Would information sharing between the apps and a patient's physician or mental health provider be a required aspect of the operation of Medicare-covered digital apps and platforms?

Would Medicare payment for the digital apps and platforms be built into an existing Medicare payment system or would a new payment system need to be created?

If Medicare payment for digital apps and platforms were added within an existing Medicare payment system, which payment system would be used?

In CMS's view, how have innovations without defined benefit categories made their way into the standard reimbursement structure?

Answer. Thank you for your interest in expanding access to digital technologies in Medicare. As you noted, President Biden's Fiscal Year 2024 budget includes a proposal that would allow for Medicare coverage of evidence-based digital applications and platforms that facilitate greater access to behavioral health services, especially for beneficiaries who live in rural or health professional shortage areas.[2] If you are interested in drafting legislation to address Medicare's coverage of digital technologies, CMS would be happy to provide technical assistance.

ADOPTION AND FOSTER CARE ANALYSIS AND REPORTING SYSTEM (AFCARS)

Question. The President's budget does not include proposals to improve the Adoption and Foster Care Analysis and Reporting System (AFCARS) to address longstanding concerns about the over-representation and lack of equitable treatment of LGBTQ+ and Native American children and youth in the child welfare system. As you know, AFCARS requires reporting on key metrics with the goal of understanding trends in child welfare and improving outcomes for children and youth.

Will the Children's Bureau be promulgating a rule to address gaps in data collection concerning LGBTQ+ and Native American children and youth to capture existing disparities in the child welfare system and improve outcomes for children in foster care?

If so, when can we expect to see a Notice of Proposed Rulemaking?

Answer. The Fall 2022 Unified Agenda lists an AFCARS NPRM.[3] HHS is committed to the equitable treatment of all youth in the child welfare system and to address longstanding disparities particularly for LGBTQI+ and Native American youth. We expect that the Unified Agenda for the Spring of 2023 will again include an AFCARS NPRM.

QUESTIONS SUBMITTED BY HON. RON WYDEN AND HON. ROBERT P. CASEY, JR.

NURSING HOME EMERGENCY PREPAREDNESS

Question. On February 23 2023, Chairman Wyden, along with Chairman Casey of the Senate Special Committee on Aging, issued a report *(https://www.finance.*

[2] FY 2024 HHS Budget in Brief, *https://www.hhs.gov/sites/default/files/fy-2024-budget-in-brief.pdf.*

[3] *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0970-AC98.*

senate.gov/chairmans-news/wyden-casey-examine-long-term-care-shortfalls-during-texas-winter-blackout) titled, "Left in the Dark," which examined the impacts of the 2021 Texas blackout on nursing homes and the need for robust emergency preparedness in long-term care facilities. This report tells the story of the older adults and people with disabilities living in long-term care facilities, including skilled nursing facilities or nursing facilities participating in the Medicare and/or Medicaid programs, who were affected by the 2021 Texas winter storm and subsequent blackout. The report also shines a light on other disasters that have affected nursing homes in more than a dozen States since 2018, including our home States of Oregon and Pennsylvania. Lastly, the report also highlights troubling findings by the Inspector General for the Department of Health and Human Services, which identified serious emergency preparedness shortfalls at nursing homes in eight States. This work built on Chairman Wyden's 2018 report *(https://www.finance.senate.gov/ranking-members-news/wyden-finds-nursing-homes-unprepared-for-natural-disasters)*, "Sheltering in Danger," that examined the impacts that Hurricanes Harvey and Irma had on nursing homes in Texas and Florida, respectively.

The report issued eight new recommendations for Federal, State and local governments to improve emergency preparedness in long-term care facilities. The findings and recommendations of this report are critical as the number of disasters and extreme weather events affecting our Nation increases, a trend scientists attribute to climate change. **We ask that HHS detail how it plans to address and carry out each of the recommendations the report directs to it, which are listed below for convenience.**

A. **Improve Inclusivity of Disaster Planning, Preparedness and Management in Communities:** CMS, the Department of Homeland Security, States and local governments should ensure that older adults, people with disabilities and residents of long-term care facilities are substantially involved in emergency planning, response, mitigation, management, and recovery. Congress should pass the Real Emergency Access for Aging and Disability Inclusion (REAADI) for Disasters Act, which would ensure that people with disabilities and older adults have a voice at every stage of disaster management through representation on emergency preparedness planning councils and boards; require accessible information about planning for disasters; and make sure that shelters and temporary housing are accessible to older adults and people with cognitive, sensory, and physical disabilities. In addition, States and local governments should seek to include older adults and people with disabilities as members of emergency preparedness oversight committees and advisory panels.

B. **Improve Staffing—Nursing Homes:** CMS should promulgate mandatory minimum staffing standards for Skilled Nursing Facilities and Nursing Facilities following completion of its study to determine the level of staffing necessary to ensure safe and high-quality care. Congress should pass provisions in the Nursing Home Improvement and Accountability Act of 2021 targeted at improving staffing, such as providing additional Federal resources through Medicaid to increase wages and improve recruitment and retention of staff. Research has repeatedly linked low staffing levels in nursing homes to poor quality care and patient safety violations. Increasing staff levels and reducing staff turnover would better equip nursing homes to respond to emergencies.

C. **Increase the Transparency of Emergency Plans:** CMS should evaluate the feasibility of requiring nursing homes to provide residents and their families with copies of the facility's emergency preparedness plan during intake, and once annually after the facility has completed the federally required update of its emergency plan. CMS should also evaluate the feasibility of posting emergency plans on Care Compare to make them easily accessible for people considering nursing homes for themselves or their loved ones.

D. **Incorporate Climate Change Risks Into Emergency Preparedness:** CMS should evaluate the feasibility of requiring nursing homes to incorporate climate change risks, such as the increasing incidence of extreme weather events, into emergency preparedness planning. If deemed feasible, CMS should issue regulations and guidance that directs nursing homes to consider the effects of climate change into their all-hazards assessment. Such requirements would be in line with findings from the most recent National Climate Assessment, which was mandated by Congress in 1990. The climate assessment notes that "over decades or longer, emergency prepared-

ness and disaster risk reduction planning can benefit from incorporating climate projections to ensure communities are prepared for changing weather patterns."

E. **Incorporate Renewable Energy Into Emergency Preparedness:** CMS and States should ensure emergency power requirements for nursing homes offer flexibility for facilities to use clean energy for secondary emergency power sources, particularly as costs of renewable energy and energy storage continue to decline. CMS should work with the Internal Revenue Service and Department of Energy to offer guidance that educates nursing homes about the availability of Federal tax credits, financing and grants that further reduce the costs of installing clean energy resources and improving energy efficiency through provisions in the Inflation Reduction Act, and other programs.

F. **Ensure Equitable Emergency Preparedness:** CMS should conduct a study that examines the equity of emergency preparedness in and among nursing homes. Such a study should consider factors such as payer mix of residents, racial and ethnic makeup of residents, the percentage of residents reliant on long-term services and supports, geographic location, climate change risks, and the social vulnerability index of the community where facilities are located. CMS should use the study to evaluate ways in which the agency and State partners can improve emergency preparedness for people of color, people living in poverty, and people with disabilities who live in nursing homes.

Answer. Protecting the health and safety of nursing home residents is highest priority of the OIG. OIG has long identified ensuring quality of care in nursing homes as among the Department's top management and performance challenges. While many nursing homes provide excellent care, decades of OIG oversight and enforcement have revealed persistent, entrenched problems in nursing homes ranging from preventable harm to residents to failed emergency preparedness to and gaps in available consumer information, among others. Currently, OIG has a number of audits and evaluations underway to examine emergency preparedness in nursing homes. Below are some examples of ongoing work:

- Nursing Home Capabilities and Collaboration to Ensure Resident Care During Emergencies *(https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000654.asp).*
- State Survey Agency Processes for Overseeing Nursing Home Preparedness *(https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000764.asp).*
- Audit of Nursing Homes' Emergency Power Systems *(https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000784.asp).*
- Medicaid Nursing Home Life Safety and Emergency Preparedness Reviews *(https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000453.asp).*
- Accuracy of Nursing Home Compare Website's Reported Health, Fire Safety, and Emergency Preparedness Deficiencies *(https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000508.asp).*

CMS appreciates Chairman Wyden's and Chairman Casey's leadership on the critical issue of emergency preparedness in nursing homes. The investigation by the majority staffs of the U.S. Senate Finance Committee and the U.S. Senate Special Committee on Aging, "Left in the Dark: The impact of the 2021 Texas Blackout on Long-Term Care Residents and the Need to Improve Emergency Preparedness," is an urgent request for all long-term care facilities to prepare to protect their residents in emergencies no matter the cause of the emergency. As the investigation notes, while the timing and type of disasters cannot always be predicted, the risks can be anticipated and prepared for through robust assessments and plans, frequent training, and maintenance of equipment and supplies.

Improving the inclusivity of disaster planning and preparedness to better meet the unique needs of older adults and people with disabilities, whether they live in the community or a long-term care facility, is an HHS priority. Involving the aging and disability communities in all stages of disaster planning, preparedness, response and recovery is critical to improving the outcomes for these populations when disasters strike.

Monitoring patient safety and quality of care in nursing homes requires coordinated efforts between the Federal Government and the States. Through its survey and certification efforts, CMS works in partnership with State survey agencies to oversee nursing homes and hold them accountable to Medicare and Medicaid Conditions of Participation requirements to ensure safety and quality of care. Additionally, the ACL Long-Term Care Ombudsman Program advocates for older adults and persons with disabilities in long-term care facilities to ensure their rights are protected and any concerns related to health, safety, and quality of life are addressed. Ombudsmen resolve individual complaints, while also advocating for systemic improvements. In 2021, ombudsmen representatives worked on 164,299 resident complaints.

Under CMS requirements, long-term care facilities are required to develop and maintain an emergency preparedness program that includes an emergency plan, policies and procedures, a communication plan, training and testing programs, and emergency and standby power systems. Long-term care facilities must establish policies and procedures that determine, among other things, how required heating and cooling of their facility will be maintained during an emergency situation if there were a loss of the primary power source. CMS took significant steps to update its emergency preparedness guidance for long-term care facilities in 2019, and in 2021, and will use the investigation's findings as we consider additional changes that may be needed to protect nursing home residents during emergencies.

The committees recommend that CMS should issue mandatory minimum staffing standards for long-term care facilities. In February 2022, President Biden announced a comprehensive set of reforms to improve the safety and quality of nursing home care and hold nursing homes accountable for the care they provide. CMS has launched a multifaceted approach aimed at determining the minimum level and type of staffing needed to enable safe and quality care in nursing homes. CMS intends to issue its proposal for minimum staffing requirements using the notice-and-comment rulemaking process—providing further opportunities for all interested parties to weigh in.

The investigation also calls on Congress to increase funding for survey and certification activities. Annual survey and certification budgetary funding levels have been flat since FY 2015 while survey workloads and costs continue to increase due to factors such as a growing number of beneficiaries and surveyor wage growth, as well as an increase in serious complaints against facilities. CMS strongly supports this call for additional survey and certification activities.

As CMS is continually reviewing our programs for improvement, we will consider the investigation's recommendations so that long-term care facilities are held accountable for emergency preparation. No facility should be caught unprepared for an emergency and residents and workers must be adequately protected and cared for.[4]

QUESTIONS SUBMITTED BY HON. MIKE CRAPO

On Inflation Reduction Act (IRA) Price-Setting Program Implementation Guidance

DEFINITION OF "QUALIFYING SINGLE-SOURCE DRUG" FOR PROGRAM PURPOSES

Question. The definition of "qualifying single-source drug" included in CMS's initial guidance for the implementation of the IRA's price-setting program risks dramatically expanding the size and scope of new Federal initiative. Finalized under section 30 of the guidance document, CMS has adopted a seemingly anomalous approach, departing from standard statutory and regulatory definitions of "drug" and "biologic" to treat virtually all medications with the same active ingredient or moiety and the same manufacturer as a single product, regardless of clinically meaningful differences.

Based on this definition, new indications, formulations, strengths, or other differences would prove insufficient to distinguish between two medications with a shared active ingredient, even if approved or licensed pursuant to a distinct New Drug Application (NDA) or Biologics License Application (BLA). The price-setting program would capture all forms of any medicines with the same active ingredient,

[4] Language pulled from CMS reactive statement cleared by OGC.

with eligibility for selection and price-setting determined based on the first approval or licensure date for a product that includes the active moiety (and with the same manufacturer), even if years or decades of high-cost, high-risk, and time-intensive research and development programs separated two different drugs or biologics.

What is the statutory basis for treating drugs or biologics with the same active ingredient/moiety but with approvals or licensure granted pursuant to separate NDAs or BLAs as the same product for eligibility and selection purposes? Where else in statute or in regulation does a Federal agency aggregate multiple different medications in this way?

This definition seems likely to discourage research and development into new indications, formulations, dosage forms, and strengths for any given compound, since even the most clinically meaningful enhancements or novel uses would afford manufacturers no avenue out of the price-setting program. Particularly for active ingredients with earlier initial applications, the law's declining statutory price ceilings could make any potential financial returns from new indications, patient populations, or improvements unfeasible. Has CMS conducted an impact analysis of the effect of this definition on R&D into new indications, formulations, or other developments with respect to existing compounds?

Will CMS consider providing an opportunity for public comment with respect to section 30 of the guidance document, given the far-reaching implications of this definition and of other policies included in the section?

Answer. The initial guidance details the requirements and parameters of the Medicare Drug Price Negotiation Program, including requests for public comment on key elements of the program, and announces the next steps for how the agency will implement the new program for 2026, which is the first year in which the first set of negotiated prices will apply. In the initial guidance, CMS describes the definition we will use to identify a qualifying single source drug for purposes of selection and negotiation for initial price applicability year 2026. This approach to identifying a qualifying single source drug aligns with the requirement in the law to use data aggregated across dosage forms and strengths of the drug, including new formulations of the drug.

As always, CMS broadly welcomes input from the public at all times. In the initial guidance for the Medicare Drug Price Negotiation Program, CMS is voluntarily soliciting comment on a number of key topics related to implementation of the new program. Due to timing constraints and the requirement to publish the selected drug list for initial price applicability year 2026 by September 1, 2023, CMS is issuing guidance on topics related to drug selection as final, without a comment solicitation.

Comments received by April 14, 2023, will be considered for revised guidance. CMS anticipates issuing revised guidance for the first year of negotiation in Summer 2023. CMS is striving for an effective negotiation process with manufacturers that lowers prescription drug prices and ensures people with Medicare have access to innovative therapies, while meeting the ambitious timeframes specified under the law.

IMPLICATIONS FOR RARE DISEASE PATIENTS

Question. While the IRA excludes orphan drugs indicated for just one rare disease or condition from selection for the price-setting program, the narrowness of this exemption risks discouraging drug developers from undertaking the high-cost and high-risk research and development needed to identify new potential uses for products that meet this definition, since even a new indication for a second rare disease would render an orphan drug ineligible for the law's exemption.

Will you commit to working with Congress to remedy this exemption by ensuring that it applies to orphan drugs with indications for multiple different rare diseases, recognizing that the current exclusion structure disincentivizes R&D into additional indications?

The guidance notes that CMS "is considering whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development." What types of actions on this front is the agency considering, and how can Congress support these efforts?

Answer. CMS supports continued drug innovation and believes it is vitally important that beneficiaries have access to innovative new therapies. We are striving to

implement the Negotiation Program in a thoughtful way that both improves drug affordability and accessibility for people with Medicare and supports innovation.

The law requires CMS to exclude certain orphan drugs when identifying qualifying single source drugs, referred to as the orphan drug exclusion. To be considered for the orphan drug exclusion, the drug or biological product must (1) be designated as a drug for only one rare disease or condition by the FDA and (2) be approved by the FDA only for one or more indications within such designated rare disease or condition. As noted in the initial guidance, we are still considering whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development. The agency will continue to keep Congress and stakeholders updated as we move forward.

THE PRICE-SETTING PROCESS

Question. The initial guidance affords affected manufacturers up to three in-person or virtual meetings over the course of the price-setting process, which could help to facilitate and clarify the exchange of offers and information under the program. By stipulating that the first meeting will not occur until after the manufacturer has submitted a counteroffer, however, the guidance document constrains early opportunities for engagement between the agency and manufacturers. Along the same lines, by artificially capping the number of meetings at three, the guidance document fails to provide sufficient flexibility and adaptability for agency officials and manufacturers.

Will CMS consider allowing for more than three in-person or virtual meetings in the course of the negotiation process, given that additional engagement opportunities might inform price offers and counteroffers, in addition to clarifying potential misconceptions and answering outstanding questions?

To that end, will CMS consider allowing for in-person or virtual meetings earlier in the negotiation process (*i.e.,* prior to the counteroffer stage, and ideally prior to the initial offer issuance), since such conversations could better inform and clarify considerations related to the agency's initial offer determination, as well as the manufacturer's counteroffer determination?

Answer. The law requires the Secretary to negotiate directly with manufacturers, in an offer/counteroffer process, in order to arrive at a maximum fair price. For initial price applicability year 2026, the law requires that by February 1, 2024, CMS must provide the manufacturer of a selected drug with a written initial offer and if the manufacturer provides a counteroffer to the initial offer, such counteroffer must be in writing. As described in the initial guidance for 2026, if CMS's written response to the counteroffer rejects the manufacturer's written counteroffer, CMS will extend an invitation to the manufacturer for a negotiation meeting. After this initial meeting, CMS intends to give each party (CMS and the manufacturer) the opportunity to request one additional meeting, resulting in a maximum of three meetings between CMS and the manufacturer.[5]

CMS believes that the negotiation meeting process described in the initial guidance for 2026 allows for a more efficient and effective approach than preparing and exchanging additional written offers and counteroffers. Negotiation meetings would also allow both parties to discuss any new information that may have become available about the selected drug or its therapeutic alternatives, consistent with the negotiation factors described in the statute, that may affect the determination of the maximum fair price. CMS believes that an offer/counteroffer process that includes in-person or virtual meetings would most effectively facilitate the negotiation process to arrive at a maximum fair price and is more consistent with current industry practices for drug price negotiation. In the initial guidance for 2026, CMS solicited comments on this proposed drug price negotiation process, and specifically requested comment on the advantages and disadvantages of this negotiation process, as well as whether there are alternatives that CMS should consider. Comments received by April 14, 2023, will be considered for revised guidance. CMS anticipates issuing revised guidance for the first year of negotiation in Summer 2023.[6]

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[5] Pulled from Medicare Drug Price Negotiation Program Initial Guidance (pp. 55–56), *https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf*.

[6] Pulled from Medicare Drug Price Negotiation Program Initial Guidance (pp. 55–56), *https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf*.

NEGOTIATION VERSUS PRICE-SETTING

Question. While the IRA characterizes the new price-setting program as "negotiation," manufacturers appear to have no meaningful choice except to accept the final offer dictated by the Secretary, regardless of how unrealistically low it might be. Rejecting the offer would require a drugmaker either to incur an impossibly steep penalty of up to 95 percent of all gross sales for a selected drug, or else to pull all drugs from Medicare and Medicaid entirely, an unrealistic proposition for the vast majority of manufacturers, and one with significant access risks for patients. This dynamic minimizes manufacturers' leverage, as the law and guidance document offer them no apparent recourse for an unfairly and arbitrarily low price-point.

Does CMS plan to provide manufacturers with access to any dispute resolution processes or mechanisms over the course of the price-setting process?

What steps can the manufacturer of a selected drug take if CMS presents a final offer with an unfairly and arbitrarily sub-market price? What recourse do the law and associated guidance documents provide, apart from two practical impossibilities (incurring the 95 percent penalty or pulling all drugs from major Federal programs)?

Answer. The initial guidance details the requirements and parameters of the Medicare Drug Price Negotiation Program, including requests for public comment on key elements of the program, for initial price applicability year 2026. Among the key elements that CMS is soliciting comments on is a dispute resolution process for specific issues that are not exempt from administrative and judicial review under the law.

The law requires the Secretary to negotiate directly with manufacturers, in an offer/counteroffer process, in order to arrive at a maximum fair price and consider specific factors in the negotiation process. The government will not set these prices unilaterally. CMS is committed to following the bilateral negotiation process specified by the law.

As described in the initial guidance for 2026, in developing the initial offer, CMS intends to focus on the clinical benefit that the drug provides to people with Medicare as well as whether the drug addresses an unmet medical need and its impact on specific populations compared to its therapeutic alternatives. To formulate an initial offer, CMS intends to: (1) identify therapeutic alternative(s), if any, for the selected drug; (2) use the Part D net price for the therapeutic alternative(s) that are Part D drugs and/or the Part B average sales price for the therapeutic alternatives that are Part B drugs to determine a starting point in developing an initial offer; (3) evaluate the clinical benefit of the selected drug (including compared to its therapeutic alternative(s)), including whether the selected drug meets an unmet medical need and the selected drug's impact on specific populations; and (4) further adjust the preliminary price by the manufacturer-specific factors outlined in the law to determine the initial offer price. CMS will not make or accept any offers for the maximum fair price that are above the statutorily defined ceiling price in the law.

In cases where the selected drug has no therapeutic alternative, or if the price of the therapeutic alternatives identified is above the statutory ceiling for the maximum fair price, CMS intends to determine the starting price for the initial offer based on the Federal Supply Schedule (FFS) or "Big Four" price.[7] If the FSS and Big Four prices are above the statutory ceiling, then CMS intends to use the statutory ceiling as the starting point for the initial offer.

CMS will be considering the negotiation factors outlined in the law very seriously. CMS is striving to implement the Negotiation Program in a thoughtful way that both improves drug affordability and accessibility for people with Medicare and supports innovation.

DETERRING PUBLIC PRIVATE PARTNERSHIPS

Question. The guidance document for the price-setting program specifies that the receipt of Federal financial support at any stage of drug discovery or development will trigger a downward adjustment in the Secretary-mandated price ceiling for a given product. This provision, if finalized, could discourage manufacturers from

[7] The Big Four price is the maximum price that any "Big Four Agency" (the Department of Veteran's Affairs (VA), Department of Defense (DoD), the Public Health Service, and the Coast Guard) is required to pay. *See: https://www.cbo.gov/publication/57007.*

partnering with the Federal Government, thus undermining the core framework for innovation established under the Bayh-Dole Act.

Will CMS commit to reconsidering its interpretation of the Federal financial support factor, given the risk of deterring the types of public-private partnerships that have driven some of our greatest medical advances?

Answer. The Medicare Drug Price Negotiation Program is unrelated and stands separate and apart from march-in authority. CMS is committed to following the bilateral negotiation process specified by the law with manufacturers of the drugs selected for negotiation.

The statute requires that CMS consider certain factors for negotiating the maximum fair price, including certain information provided to CMS by manufacturers, that is specific to the drug that is subject to negotiation. Prior Federal financial support for novel therapeutic discovery and development received by the manufacturer for the drug is one of the factors identified in the law that CMS is required to consider in the negotiation. We are implementing the Negotiation Program in accordance with the law. The initial guidance describes the consistent process CMS is proposing to use when considering all these factors when negotiating a maximum fair price with the manufacturer for a selected drug.

Question. On a related note, will HHS commit to continuing its longstanding policy of rejecting Bayh-Dole "march-in" petitions that rely primarily on pricing dynamics, given that Senators Bayh and Dole repeatedly reaffirmed that their law's march-in rights did not authorize the imposition of de facto price controls?

Answer. 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 committed to implementing the law and upholding these aims to support the innovation needed to deliver new and effective drugs to patients. To that end, HHS has partnered with the Department of Commerce to review the use of march-in authority as laid out in the Bayh-Dole Act. Through this partnership, we have asked an Interagency Working Group to develop a framework for consistent implementation of the march-in provision across the U.S. Government that clearly articulates guiding criteria and processes for making determinations where different factors, including price, may be a consideration in agencies' assessments. HHS will convene a workshop in 2023 to further refine the cases for which HHS could consider exercising march-in authority. HHS will seek input from a diverse array of interested parties—including patient groups, industry, universities, small business firms, and nonprofit organizations, as well as experts in technology transfer and innovation policy. The goal of the workshop will be to assess when the use of march-in rights is consistent with the policy and objectives of the Bayh-Dole Act.

COMMENT PERIODS

Question. CMS's decision to offer opportunities for public comment with respect to the guidance documents governing key programs under the IRA will hopefully help to inform implementation efforts and minimize operational concerns. However, given the complexity of the documents and policies in question, along with the considerable unanswered questions that remain outstanding, the 30-day comment periods provided thus far have proven challenging, as policymakers and stakeholders have attempted to review, consider, and engage on a wide range of policy matters in a short time.

Will CMS consider providing lengthier comment periods for some components of IRA program implementation?

Answer. The Inflation Reduction Act directs CMS to implement the Negotiation Program for 2026, 2027, and 2028 by program instruction or other forms of program guidance. CMS must meet deadlines set forth in statute. Of critical importance, the law requires that CMS publish the selected drug list for initial price applicability year 2026 by September 1, 2023. CMS recognizes that public input will help to achieve successful implementation, and so CMS is electing to voluntarily take comments on certain topics in this initial negotiation guidance. In order to release initial guidance, voluntarily take comments, and issue revised guidance as soon as practicable, CMS must work on an expedited timeline, which necessitates a 30-day comment period.

In order to facilitate the timely implementation of the Negotiation Program, CMS is issuing guidance on identification of selected drugs as final, without a comment

solicitation (with the exception of the Small Biotech Exception Information Collection Request (ICR), for which comments should be made in response to the ICR).

In the revised guidance, CMS may make changes to any policies, including policies on which CMS has not expressly solicited comment, based on the agency's further consideration of the relevant issues.

CMS is committed to collaborating and engaging with the public in the policy-making process. CMS is working closely with patients and consumers, Part D plan sponsors and Medicare Advantage organizations, drug manufacturers, hospitals and health-care providers, wholesalers, pharmacies, and others. CMS is engaging and will continue to engage interested parties through national stakeholder calls, quarterly strategic meetings, and monthly technical calls with CMS staff. In addition, members of the public are welcome to share feedback and input in writing by email at: IRARebateandNegotiation@cms.hhs.gov.

PROPOSED IRA PRICE-SETTING PROGRAM EXPANSION

Question. The President's Budget proposes expanding the prescription drug price-setting program enacted under the IRA to capture more medications each year and to subject drugs to the selection and price-setting process sooner after their launch. While the proposal provides no details beyond these broad concepts, reporting from *Bloomberg Law* [8] cited data from the Centers for Medicare and Medicaid Services (CMS) indicating that under the proposed expansion, drugs and biologics could be subjected to the so-called negotiation process as early as 5 years after FDA approval or licensure, and that the budget proposal would double the number of medications selected for the program each year.

This framework, if adopted, would inevitably slash biomedical research and development, resulting in fewer new drug discoveries and approvals in the coming years. Moreover, the proposed expansion would further erode American intellectual property (IP) protections by substantially weakening potential economic returns for new drugs, which currently tend to benefit from roughly 13 to 14 years of patent protection after FDA approval. With just 5 years of insulation from government-imposed price controls, which the Secretary can set with no floor and no opportunity for judicial or administrative review, drugs and biologics alike would lose crucial incentives for the investments that drive their research and development today.

What is the Biden administration's rationale for subjecting drugs and biologics to the price-setting program after just 5 years?

How does the administration anticipate that the proposed expansion, if codified, would affect private investment in biomedical research and development (R&D), as well as in the number of drugs and biologics that come to market each year?

Have CMS's Office of the Actuary (OACT) or the Congressional Budget Office (CBO) conducted a budgetary analysis of the proposed price-setting program expansion?

When does HHS plan to provide more detailed parameters and specifications of the proposed program expansion to Congress?

Answer. The budget proposal builds on the Inflation Reduction Act by increasing the number of drugs subject to negotiation and making drugs eligible for negotiation sooner after their launch. Expanding the Medicare Drug Price Negotiation Program accelerates the increased gains in access for Medicare beneficiaries to innovative, life-saving treatments enacted by the law, with lower costs for people with Medicare and the program.[9]

THE IRA'S SMALL-MOLECULE PENALTY

Question. Under the IRA, small-molecule drugs receive just 9 years of protection from Secretary-dictated price controls. Given that roughly half of the return on investment for these products tends to come between year 9 and year 13 on the market, the price-setting program thus imposes a de facto penalty on small-molecule medications.

Surveys of manufacturers suggest that many drugmakers plan to steer R&D investments away from small-molecule products in light of this de facto small-

[8] *https://news.bloomberglaw.com/health-law-and-business/biden-puts-drug-pricing-at-center-of-medicare-spending-debate.*

[9] FY 2024 HHS Budget in Brief, *https://www.hhs.gov/sites/default/files/fy-2024-budget-in-brief.pdf.*

molecule penalty. The consequences of forgone innovation in small-molecule development could prove particularly dire for mental health conditions, cancer, and Alzheimer's disease. While even providing for parity between small molecules and biologics under the terms of the price-setting program by extending the small-molecule exemption period from 9 years to 13 would still deter longer-term product enhancements and new indications, alignment would at least mitigate the small-molecule IP erosion imposed by exposing these products to price controls roughly 3 to 4 years (on average) before their patent protections would otherwise end.

Is HHS open to working with Congress to mitigate the aforementioned small-molecule penalty by extending the price-setting program exemption period for these products to more closely align with the exemption period for biologics?

To what extent is HHS tracking private-sector R&D investments in small-molecule and biologic medication candidates in order to monitor potential effects of the IRA's price-setting program?

Answer. The law requires that at least 7 years, for drugs, or 11 years, for biologicals, must have elapsed between the selected drug publication date and the FDA approval or licensure, as applicable. We are implementing the Negotiation Program in accordance with the law.

CMS has been regularly engaging with members of the public to get their feedback so that we are implementing the Negotiation Program in a thoughtful way that both improves drug affordability and accessibility for people with Medicare and supports innovation. We plan to get public input throughout the implementation of the Negotiation Program to make sure that we know what is occurring in the market.

IRA DRUG PRICE-SETTING PROGRAM IMPLEMENTATION FUNDING

Question. CMS has not yet issued a response to a February 22nd letter[10] requesting regular briefings and comprehensive reports on allocation plans regarding the $3 billion in implementation funding provided under the IRA for the law's drug price-setting program. Without answers to the questions outlined in the aforementioned letter, Congress cannot provide meaningful oversight of the initiative's implementation.

Given the importance of accountability and good governance, will CMS provide responses to the questions detailed in the February 22nd letter on a timely basis?

How does CMS plan to ensure meaningful transparency and engagement with Congress on its plans and operational considerations for using the funding appropriated for implementation of the price-setting program?

Answer. CMS is prioritizing transparency and outreach, actively encouraging input and insight from interested parties. We believe that public feedback is an important part of the implementation process, and we welcome it.

To that end, on January 11, 2023, CMS published a memo detailing its approach to implementing the Negotiation Program, including plans for public engagement through stakeholder calls, quarterly strategic meetings, and monthly technical calls with CMS staff; plans for program guidance; a strategy for data collection, including public comment periods; and upcoming key dates and an estimated timeline for implementation. Release of this initial memo set the stage for multiple comment opportunities for members of the public, people with Medicare and their families, beneficiary and consumer advocates, pharmaceutical manufacturers, health-care providers, and other interested parties.

On March 15, 2023, CMS issued initial guidance detailing how CMS intends to implement the Negotiation Program for 2026. Among other items, the initial guidance details how CMS intends to identify selected drugs, consider factors in negotiation, conduct the negotiation process, and establish requirements for manufacturers of selected drugs. Consistent with our commitment to transparency throughout implementation of the Negotiation Program, we are seeking public comment from all interested parties on certain key elements of the guidance through April 14, 2023. After considering the comments, CMS anticipates issuing revised guidance for the first year of the Negotiation Program in Summer 2023.

CMS has kept your staff updated on implementation progress, including through emails and briefings related to agency actions. We received the letter referenced in

[10] *https://www.finance.senate.gov/imo/media/doc/letter_on_ira_implementation_funding1.pdf.*

your question and will provide a response. We will also continue to keep your staff updated as we move forward.

DRUG SHORTAGES AND PRICE CONTROLS

Question. Escalating drug shortages pose a major threat to American patients. According to a recent report from the Senate Committee on Homeland Security and Governmental Affairs (HSGAC), the number of active drug shortages reached a recent peak of 295 at the end of last year,[11] just months after the IRA's inflation-based price controls for Medicare Part D medications first went into effect. For a range of medical conditions, from behavioral health challenges to cancer, these shortages can result in life-threatening consequences.

Experts and government officials from across the political spectrum have long recognized the role that pricing dynamics can play in product shortages, including with respect to prescription drugs. The current Food and Drug Administration (FDA) Commissioner, for instance, recently cited weak price incentives as a driver of medication shortages,[12] in keeping with the findings from a 2019 FDA report, which concluded that "[d]rug shortages persist because they do not appear to resolve according to the 'textbook' pattern of market response," whereby "prices rise after a supply disruption and provide an incentive for existing and new suppliers to increase production until there is enough supply of a product to meet demand."[13] While pricing considerations fall outside of the FDA's purview, other HHS sub-agencies have tools and authorities that could help to mitigate medicine shortages and thus save American lives.

Unfortunately, the price controls codified under the IRA, including both the government price-setting program and the inflation-based price growth penalties for Part B and D drugs, risk exacerbating the shortages that continue to plague our health-care system. A number of studies and reports have linked price control policies to product shortages,[14, 15, 16, 17] as noted by Ranking Member Rand Paul during a recent HSGAC hearing.[18] In the context of prescription drug manufacturing, price controls dull incentives for market entry and hamper drugmakers' ability to adopt conventional and effective market responses to the types of demand fluctuations and supply chain disruptions that trigger medication shortages.

The initial guidance documents recently released by CMS regarding the Part B and D inflation cap policies suggest that the agency plans to deploy an unduly narrow and potentially counterproductive approach to the penalty waiver and reduction policies included in the IRA to account for shortages and supply chain disruptions. Rather than allow for full penalty waivers for medicines in shortage or in the midst of significant supply chain disruptions, which would help to address the shortage risks posed by the inflation rebate policies, CMS's initial guidance materials propose only partial reductions, including one option that would increase penalties over time for drugs remaining in shortage, thus presumably exacerbating, rather than mitigating, the type of strain that often triggers shortages in the first place. In the context of shortages, the market needs flexibility to respond and adapt, not onerous penalties and rigid pricing requirements.

Furthermore, while CMS's guidance documents raise concerns around the potential for manufacturers, in the face of full penalty waivers, to "game" the system by prolonging drug shortages, this worry disregards basic economics. Drugmakers confront major financial, reputational, and regulatory incentives to minimize and address shortages, insofar as they have the tools available to do so. In finalizing its guidance documents, CMS should maximize these tools by ensuring full penalty waivers for drug shortages and severe supply chain disruptions, in keeping with the apparent intent of the relevant IRA provisions.

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[11] *https://www.hsgac.senate.gov/wp-content/uploads/Drug-Shortages-HSGAC-Majority-Staff-Report-2023-03-22.pdf.*

[12] *https://insidehealthpolicy.com/daily-news/low-generic-prices-can-lead-drug-shortages-califf-says.*

[13] *https://www.fda.gov/media/131130/download.*

[14] *https://www.policymed.com/2012/03/increasing-generic-drug-shortages-linked-to-government-price-controls.html.*

[15] *https://www.hsgac.senate.gov/wp-content/uploads/Testimony-Goodman-2023-03-22.pdf.*

[16] *https://alec.org/article/the-truth-about-price-controls-and-prescription-drug-spending/.*

[17] *https://www.cato.org/commentary/problems-price-controls.*

[18] *https://www.hsgac.senate.gov/hearings/drug-shortage-health-and-national-security-risks-underlying-causes-and-needed-reforms/.*

Will CMS commit, in finalizing its guidance for the Part B and D inflation rebate policies, to mitigating drug shortage risks by enabling full penalty waivers for medications in shortage and products facing severe supply chain disruptions?

Answer. The law requires CMS to reduce or waive the rebate amount for certain rebatable drugs, such as those "currently" on the FDA drug shortage list, a Part B or Part D rebatable drug that is a biosimilar biological product and experiencing a severe supply chain disruption, or a Part D rebatable drug that is a generic and experiencing a severe supply chain disruption or if the Secretary determines it is likely to be described as in shortage in the next applicable period without a reduction or waiver.

CMS has requested comment on specific scenarios CMS should consider for purposes of reducing or waiving the rebate in the case of a shortage or severe supply chain disruptions, and approaches CMS could use to reduce or waive the rebate amount. CMS intends to structure this policy such that it does not create incentives for manufacturers to intentionally maintain their drug or biological in shortage.

Question. What other steps do HHS and its sub-agencies plan to take to address the rash of drug shortages currently imperiling patients' access to care?

Answer. Ensuring and increasing the availability of safe and effective medicines are key priorities for FDA. We recognize that not having access to necessary drug products is a serious concern. FDA helps prevent and resolve shortages in various ways, such as through expediting its reviews of new production lines or material sources to increase production, reviewing requests for extensions of product expiration dating, helping manufacturers identify root causes of shortages, and exercising temporary regulatory flexibility for new sources of medically necessary drugs. In addition to working directly with manufacturers, FDA is closely collaborating with Federal Government partners to respond to surges in demand. As a part of the President's Fiscal Year (FY) 2024 budget request, the agency has also requested additional authorities to ensure greater insight and transparency into the supply chain, including requirements for manufacturers to both notify FDA when they will be unable to meet an increase in demand and to enhance their reporting to the agency on drug manufacturing amounts. We look forward to working with Congress on these proposals.

DRUG PRICE-SETTING PROGRAM

Question. Under the IRA's drug price-setting program, the ceiling for Secretary-dictated prices will decline over time, rendering medications affected by the program less and less profitable as they move from one statutory category to the next, regardless of any product improvements or new indications (which the law thus discourages), and irrespective of patent protections and exclusivities (which the law thus weakens). Moreover, given that the IRA includes no floor for the prices imposed under the program, manufacturers could feasibly face "penny-pricing" for older drugs, as drugmakers sometimes currently confront under the 340B Drug Discount Program.

Given the declining window for profitability under the price-setting program, some manufacturers may opt to discontinue certain drugs in the face of unsustainably low government price limits. Meanwhile, these same sub-market maximum fair price (MFP) ceilings will likely deter prospective generic or biosimilar market entrants, given the lack of opportunity for a reasonable return on investment. These dynamics could easily trigger medication shortages by gutting incentives for both the originator drug and potential generic or biosimilar competitors to stay on the market.

In developing initial guidance for the drug price-setting program, has CMS considered and/or addressed the risk of triggering or exacerbating shortages for selected products?

What strategies or tools does the agency plan to employ in order to address or mitigate the shortage risks posed by the implementation of this program?

How, more broadly, do HHS and CMS anticipate that the drug price-setting program will impact the prospective generic and biosimilar markets for selected products? Have the agencies quantified this impact, and if not, do they plan to do so?

Answer. CMS supports innovation and believe it is vitally important that beneficiaries have access to innovative new therapies. The law requires the Secretary to negotiate directly with manufacturers, in an offer/counteroffer process, in order to arrive at a maximum fair price and consider specific factors in the negotiation process. CMS has been regularly engaging with members of the public to get their feed-

back so that we are implementing the Negotiation Program in a thoughtful way that both improves drug affordability and accessibility for people with Medicare and supports innovation. We plan to get public input throughout the implementation of the Negotiation Program to make sure that we know what is occurring in the market.

EXTENDING THE INFLATION-BASED PRICE CONTROLS TO THE COMMERCIAL MARKET

Question. The budget proposes extending the IRA's inflation-based price controls to the commercial market, resulting in a sweeping new private-sector mandate, even as the core policies enacted last year have triggered higher launch prices and other market distortions.[19]

Apart from the catastrophic price controls of the 1970s, which virtually all experts and policymakers now see as a disastrous unforced error,[20] can you point to a precedent for the type of far-reaching price controls that the administration has proposed here?

Answer. The Inflation Reduction Act requires manufacturers to pay rebates to Medicare when drug prices for certain rebatable Medicare Part B or Part D drugs rise at a rate that is faster than the rate of inflation. The budget includes a proposal to revise the formula to calculate these rebates beyond Medicare utilization to include drug units used by commercial plans. Doing so would provide additional savings while discouraging manufacturers from raising drug prices for commercial coverage including employer-sponsored plans, marketplace plans, and other individual and group market plans.[21]

HOME OXYGEN ACCESS

Public Health Emergency Waivers

Question. For many Medicare beneficiaries living with chronic conditions like COPD and ALS, the home respiratory therapy flexibilities provided by CMS in the context of the public health emergency (PHE) have proven pivotal to ensuring access to medically necessary care. As patients, providers, and policymakers prepare for the impending termination of the PHE, many have raised questions regarding the agency's transition plans, particularly for seniors who originally qualified for the home oxygen benefit pursuant to the agency's temporary policy waivers. If required by CMS to requalify for home respiratory therapy once the emergency period concludes, these patients, along with their medical providers, could face significant hurdles, especially in rural and underserved areas with physician shortages.

In light of these substantial burdens, does CMS plan to grandfather initial home oxygen benefit eligibility determinations made during the PHE?

What additional clarity can the agency provide with respect to the upcoming transition for beneficiaries who depend on home respiratory therapy and originally qualified for this benefit pursuant to PHE-related waivers and flexibilities?

Answer. CMS recognizes that it is important for stakeholders to understand how CMS anticipates performing medical review after the Public Health Emergency (PHE) has ended. During the PHE, flexibilities were applied to medical reviews across claim types. For certain DME items, this included the non-enforcement of clinical indications for coverage. Since clinical indications for coverage were not enforced for certain DME items provided during the PHE, once the PHE ends CMS plans to primarily focus reviews on claims with dates of service outside of the PHE, for which clinical indications of coverage are applicable. CMS may still review these DME items, as well as other items or services rendered during the PHE, if needed to address aberrant billing behaviors or potential fraud. The HHS Office of the Inspector General may perform reviews as well. All claims will be reviewed using the applicable rules in place at the time for the claim dates of service. As the PHE comes to an end, CMS will continue to work with stakeholders to ensure beneficiary access.[22, 23]

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[19] *https://www.wsj.com/articles/inflation-reduction-drug-prices-11673628922.*

[20] *https://www.wsj.com/articles/nixon-fight-inflation-price-controls-stagflation-gas-shortages-biden-democrats-reconciliation-bill-federal-reserve-11628885071.*

[21] FY 2024 HHS Budget in Brief, *https://www.hhs.gov/sites/default/files/fy-2024-budget-in-brief.pdf.*

[22] Spotlight | CMS, *https://www.cms.gov/about-cms/components/cpi/cpi-spotlight.*

[23] Medicare Fee-for-Service Compliance Programs | CMS, *https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-ffs-compliance-programs/overview.*

DOCUMENTATION REQUIREMENTS

Question. Many patients who rely on home respiratory therapy have also raised concerns regarding the documentation used to demonstrate medical necessity for these items and services, particularly in light of CMS's elimination of certificate of medical necessity (CMN) requirements in the context of the agency's final national coverage determination (NCD) for Home Use of Oxygen, as issued in September 2021. Given the issues presented by exclusive reliance on physicians' subjective and un-standardized medical record notes to establish medical necessity, some patient advocates have suggested that CMS adopt and implement a standardized home oxygen template incorporating clinical data elements (CDE) to ensure a streamlined, objective, and consistent means of documenting medical necessity.

Given that CMS has already developed a template along these lines, why has the agency opted not to move forward with implementation of a standardized CDE template for home oxygen therapy to this point?

Will the agency consider adopting such a template, to be used in lieu of paper records, moving forward?

Answer. CMS has designed printable clinical templates and suggested clinical data elements (CDEs) to assist providers and IT professionals with data collection and medical record documentation to support coverage of selected items and services. These templates and suggested CDEs are intended to help reduce the risk of claim denials and ensure that medical record documentation is more complete.[24] Specifically, CMS released a clinical template and suggested CDEs for ordering home oxygen therapy. The template is designed to assist a clinician when completing an order for home oxygen therapy to meet requirements for Medicare eligibility and coverage. The template meets the requirements for both the Detailed Written Order and Written Order Prior to Delivery, and is available to the clinician and can be kept on file with the patient's medical record or can be used to develop an order template for use with the system containing the patient's electronic medical record. While completing the "Home Oxygen Therapy Order Template" does not guarantee eligibility and coverage, it does provide guidance in support of home oxygen therapy equipment and services ordered and billed to Medicare. CMS has also released clinical templates and suggested CDEs for documenting the face-to-face encounter for Medicare home oxygen therapy eligibility and coverage and for documenting information regarding home oxygen therapy laboratory test results to meet requirements for Medicare coverage for home oxygen therapy. The home oxygen therapy templates and suggested CDEs are available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Electronic-Clinical-Templates/template-and-CDE-downloads.*[25]

At this time, use of these templates and suggested CDEs is voluntary; however, we welcome provider and stakeholder feedback and suggestions on how to improve all our templates and CDEs.

PATIENT ACCESS TO MEDICATIONS

Question. Numerous health-care providers have raised concerns regarding the potential implications of a guidance document issued by CMS on September 20, 2021, regarding the in-office ancillary services exception under the Physician Self-Referral (Stark) Law. Specifically, many oncology and urology physician practices report having conventionally provided cancer patients with the flexibility, at said patients' election, of receiving outpatient prescription drugs (a designated health service, under the relevant exception) through mail-order services facilitated by a physician practice's pharmacy (or physician-owned pharmacy). Some practices have also traditionally allowed the spouses or caregivers of patients to pick up medically necessary drugs on their behalf through these facilities, under the relevant Stark Law exception.

Some of the language included in the September 2021 frequently asked questions (FAQ) document appears to reflect a substantive departure from the past regulatory treatment of these types of DHS arrangements. To that point, numerous pharmacy boards, for instance, distinguish "dispensing," as included in the applicable regu-

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[24] Clinical Templates—HOME | CMS, *https://www.cms.gov/research-statistics-data-and-systems/computer-data-and-systems/electronic-clinical-templates.*

[25] Home Oxygen Therapy Order Template *(https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Electronic-Clinical-Templates/Downloads/Home-Oxygen-Therapy-Order-Template-Draft-20180619-V42.pdf).*

latory text, from the conduit of delivery (*i.e.,* in these cases, the use of a mail carrier to deliver drugs dispensed by a practice's pharmacy or physician-owned pharmacy). As practices prepare for the end of the PHE and its associated Stark flexibilities, they have expressed concerns over the potential use of the guidance document to prohibit the patient option of mail delivery of drugs from these facilities, which could pose serious access challenges.

Given the access implications and the apparent shift from prevailing regulatory treatment, can CMS clarify whether, under current Stark Law interpretation, mail-order drugs would be excluded from the in-office ancillary exception?

If the agency currently regards mail-order drugs as excluded from the exception, would CMS consider leveraging additional authorities to provide an exception to the Stark Law's relevant location requirement in order to avert potential disruptions to patient access to medically necessary care?

In 2001, CMS issued a regulation enabling mobile facilities used exclusively by a group practice to count under the relevant Stark Law exception. Would the agency consider taking a similar approach here?

Answer. CMS has not changed its policy when it comes to enforcing the Physician Self-Referral Law (PSL) that regulates when referrals may be made for certain services. Congress has specified certain exceptions to the PSL in statute. One exception specified by Congress is known as the in-office ancillary exception. This exception permits physicians to supply services and items, such as drugs, to beneficiaries in the physician office. However, the statute does not allow physicians to mail drugs directly to beneficiary homes without the beneficiary coming into the office. During the COVID–19 Public Health Emergency (PHE), CMS issued a waiver of the terms of this exception to make sure beneficiaries could receive items at home. That waiver will end on May 11th.

CMS does not anticipate or is not aware of any access issues related to the end of this waiver, because beneficiaries have always had options in obtaining Part D drugs, including being able to get them directly via mail order from pharmacies. Part D plans must meet robust requirements aimed at ensuring beneficiaries can obtain the Part D drugs they need.

MULTI-CANCER EARLY DETECTION SCREENING

Question. As the Biden administration has acknowledged, advances in screening technology and uptake will play a key role in efforts to combat cancer. Studies suggest that detecting cancer at an early stage can lead to survival rates roughly 5 to 10 times greater than for late-stage detection.

That said, around 70 percent of cancer deaths in the U.S. occur in conditions with no recommended screening options.

Multi-cancer early detection (MCED) testing technologies have the potential to revolutionize the screening landscape, leveraging rigorous research and cutting-edge scientific developments to detect as many as dozens of different cancer types, often long before symptoms even emerge. Once developed, approved, and brought to market, these tests could increase the cancer survival rate, expand and enhance treatment options, and reduce health-care costs.

Last Congress saw the reintroduction of Medicare Multi-Cancer Early Detection Screening Coverage Act, legislation that would establish a Medicare coverage pathway for FDA-approved MCED screening tests. More than 315 State, local, and national groups, ranging from patient advocacy organizations and labor unions to chambers of commerce and frontline health-care providers, endorsed the proposal, which attained 54 cosponsors in the Senate and 257 in the House, illustrating sweepingly broad bipartisan support.

Will you commit to working with the bill's sponsors in the Senate and House to advance this legislation, given its potentially life-saving effects and its alignment with the President's Cancer Moonshot?[26]

Answer. One year ago, President Biden reignited the Cancer Moonshot and set new national goals to cut the death rate from cancer by at least 50 percent over the next 25 years and improve the experience of people and their families living

[26] *https://www.finance.senate.gov/imo/media/doc/letter_to_president_biden_on_multi-cancer_early_detection_legislation.pdf.*

with and surviving cancer.[27] At HHS, we are doing all we can to make cancer prevention and screening services accessible to everyone in the United States, including taking action to address the estimated 9.5 million cancer screenings missed during the pandemic.[28] The Department looks forward to hearing more from you about how we can explore options to increase access to preventive health services, including cancer screenings. HHS always appreciates the opportunity to provide technical assistance to Congress on important health-care issues.

As a central component of the Cancer Moonshot, in 2024, the National Cancer Institute is launching a new research network to study cancer screening, including evaluating the effectiveness of new blood tests for the detection of one or more cancers to prevent cancer-related deaths. This effort is in addition to other NCI supported research related to MCED tests.

MEDICARE TELEHEALTH COVERAGE

Question. Without additional congressional action, the Medicare coverage flexibilities for telehealth services that are currently in effect will expire at the end of calendar year (CY) 2024, creating an access cliff for beneficiaries.

Does the Biden administration support extending some or all of these coverage flexibilities beyond CY 2024?

Will HHS and its sub-agencies commit to working with Congress on a bipartisan and bicameral basis to develop long-term Medicare coverage solutions that ensure access to telehealth services?

Answer. In response to the COVID–19 public health emergency, which is set to expire in May 2023, flexibilities for Medicare telehealth services were issued through legislative and regulatory authorities to increase access to care for patients and providers. The Consolidated Appropriations Act of 2023 recently extended many of these flexibilities through December 31, 2024. Extended telehealth flexibilities include waiving geographic and site of service originating site restrictions so that Medicare patients can continue to use telehealth services from their home and allowing audio-only telehealth services. Additionally, the expanded list of providers eligible to deliver telehealth services is also extended so Medicare beneficiaries can continue to receive telehealth services furnished by physical therapists, occupational therapists, speech language pathologists, and audiologists, as well as receive telehealth services from Rural Health Clinics and Federally Qualified Health Centers through December 31, 2024. If you are interested in drafting legislation to make these waivers permanent, CMS would be happy to provide technical assistance.

Additionally, recent legislative and regulatory changes made several telehealth flexibilities permanent. Federally Qualified Health Centers and Rural Health Clinics can furnish certain behavioral and mental health services via telecommunications technology. Medicare patients can continue to receive these telehealth services in their home as geographic restrictions on the originating site are eliminated for these telehealth services. Certain behavioral and mental telehealth services can be delivered using audio-only communication platforms, and rural emergency hospitals can serve as an originating site for telehealth services.[29]

TCET AND ACCESS TO BREAKTHROUGH DEVICES

Question. Too often, seniors lack efficient access to medical breakthroughs, due in part to outdated Medicare coverage policies. Disappointingly, in 2021, the Biden administration rescinded the Medicare Coverage of Innovative Technology (MCIT) final rule, which would have created an expedited coverage pathway for FDA-designated breakthrough devices. This decision came in spite of robust bipartisan support for the MCIT regulation.[30, 31]

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[27] Cancer Moonshot | The White House, *https://www.whitehouse.gov/cancermoonshot/*.

[28] On First Anniversary of the President's Reignited Cancer Moonshot, the Biden-Harris Administration Awards Nearly $11 Million to Address Disparities in Cancer Screening and Follow-Up Care, *https://www.hhs.gov/about/news/2023/02/02/on-first-anniversary-presidents-reignited-cancer-moonshot-biden-harris-administration-awards-nearly-11-million-address-disparities-cancer-screening-follow-up-care.html*.

[29] FY 2024 HHS Budget in Brief (p. 69–70), *https://www.hhs.gov/sites/default/files/fy-2024-budget-in-brief.pdf*.

[30] *https://files.constantcontact.com/14c6814f001/f2a3faa1-655d-456f-a1ff-1f7bbb7cfc34.pdf*.

[31] *https://www.dropbox.com/s/c6lsl41ecji4eq9/Letter%20on%20MCIT%20Rule.pdf?dl=0*.

When does the administration plan to issue a formal proposed rule for transitional coverage of innovative technologies, and how will it differ from the MCIT regulation that CMS rescinded in 2021?

Answer. CMS remains committed to expanding access to health-care coverage and services, including new, innovative treatments when they are safe and appropriate. CMS rescinded the Medicare Coverage of Innovative Technology and Definition of "Reasonable and Necessary" (MCIT/R&N) final rule because of concerns that the provisions in the final rule may not have been sufficient to protect Medicare patients. By rescinding this rule, CMS will take action to better address those safety concerns in the future.

Improving and modernizing the Medicare coverage process continues to be a priority, and we remain committed to providing stakeholders with more transparent and predictable coverage pathways. CMS is working as quickly as possible to advance multiple coverage process improvements that provide an appropriate balance of access to new technologies with necessary patient protections. As part of this effort, CMS has conducted several listening sessions to learn about stakeholders' most pressing challenges and to receive feedback from stakeholders about which coverage process improvements would be most valuable.

CMS intends to explore coverage process improvements that will enhance access to innovative and beneficial medical devices in a way that will better suit the health-care needs of people with Medicare. This will also help to establish a process in which the Medicare program covers new technologies on the basis of scientifically sound clinical evidence, with appropriate health and safety protections in place for the Medicare population. HHS looks forward to working with you and hearing your feedback as we move forward with these efforts.

AVERAGE SALES PRICE-RELATED CLARIFICATIONS

Question. Under the multiple best prices reporting option (MBPRO), a manufacturer reports two different "best prices" (BPs): a value-based BP and a non-value-based BP. Patient advocates, providers, and other stakeholders have requested clarity as to whether, for Medicare Part B payment purposes, the average sales price (ASP) for a product leveraging MBPRO should be calculated with respect to the value-based or non-value-based BP.

HHS OIG has cited the lack of clarity on this front as warranting attention, with a recent report noting, "Without clear guidance, manufacturers argue that they will need to adopt varying reasonable assumptions that could create distortions among reported ASPs."[32] Enabling manufacturers to report ASP based on the sales and discounts considered in determining the non-value-based BP, as opposed to the value-based BP, would create more clarity and consistency, mitigating disincentives currently preventing some drugmakers from availing themselves of MBPRO.

Can a manufacturer who elects MBPRO calculate ASP by reference to the sales and discounts considered in the determination of the non-value-based BP? If not, why not?

If a manufacturer may do so, can CMS commit to issuing clarifying guidance promptly to address this issue? If not, why not?

Answer. CMS appreciates the OIG's work on this area and look forward to working collaboratively on this and other issues in the future. In their report, OIG recommended that CMS actively review current guidance related to the areas identified in this report and determine whether additional guidance would ensure more accurate and consistent ASP calculations. CMS agrees with this recommendation and will review the current guidance related to the areas identified in OIG's report and determine whether additional guidance would help to ensure more accurate and consistent ASP calculations. It should be noted that in some cases, additional guidance could be sub-regulatory, and in others, it may potentially require notice and comment rulemaking.

PHYSICIAN PAYMENT REFORM

Question. In recent years, Congress has come together on a bipartisan basis to enact a series of Medicare physician payment increases, mitigating some of the challenges confronted by our front-line providers, particularly as inflation continues to

[32] *https://oig.hhs.gov/oei/reports/OEI-BL-21-00330.pdf.*

flare. While constructive in the short term, this ad-hoc approach creates uncertainty and volatility for clinicians across the country, especially in rural communities.

What specific policies would the administration propose to achieve a sustainable path forward for physician payment reform, driving value-based care and restoring predictability?

Answer. The Biden-Harris administration is committed to protecting and strengthening Medicare so that Americans of every generation can count on it. Ensuring adequate payment rates for physicians and other health-care professionals is essential in maintaining patients' ability to access high-quality and affordable health care. CMS is required to base payments for services under the physician fee schedule on the relative resource costs involved in furnishing a service, and the fee schedule is subject to statutory budget-neutrality requirements. CMS does not have the legal authority to implement increases in payment outside of budget neutrality without additional action taken by Congress.

MEDICAID STATE BURDEN AND THE FEDERAL COMMITMENT TO STATES

Question. Last December, Congress acted on a bipartisan basis to allow States to begin returning their Medicaid programs to post-pandemic normalcy. This effort is essential to protecting hardworking taxpayers' dollars, but it will demand States' attention and resources, as well as HHS's partnership and flexibility.

Unfortunately, last September, HHS proposed a rule that would only complicate States' efforts to rebalance their Medicaid programs and budgets. The new enrollment and eligibility requirements would exacerbate States' administrative and fiscal burden, and risk making an already massive undertaking even more inefficient.

Can you commit that HHS will not finalize this proposed rule until, at a minimum, States have concluded their pandemic-related redeterminations process?

Answer. In September 2022, CMS issued a proposed rule[33] that includes several provisions aimed at simplifying the enrollment process and maintaining continuity of coverage for eligible beneficiaries, including children and individuals dually enrolled in Medicare and Medicaid, many of whom are over 65 and/or have a disability. CMS estimates that this proposed rule would remove barriers to enrollment and increase the number of eligible individuals who obtain coverage and are continuously enrolled in Medicaid and CHIP.[34] Recognizing that most States will require up to 12 months to implement the changes proposed in this rule, we sought public comment on making the final rule effective 30 days after publication with full compliance required 12 months later. The comment period for the proposed rule closed on November 7, 2022. CMS is taking into consideration comments received for final decision making.

PEDIATRIC MENTAL HEALTH

Question. Pediatric mental health providers continue to struggle in their recruitment and retention efforts at a time of immense need. Recently, there has been increased use of FDA-cleared digital technologies that can deliver evidence-based mental health treatments for children. These treatments could be promising and innovative solutions for State Medicaid programs, particularly where there are few pediatric mental providers in a State or region.

Does CMS have a plan to provide technical support to States that want to adopt coverage and payment for these digital technologies under existing Medicaid authorities and payment allowances?

Question. CMS works closely with States as they examine innovative ways to improve their Medicaid programs and address the specific needs of their residents, and CMS works closely with its Federal partners, like FDA, to ensure access to safe and effective interventions for mental health conditions and substance use disorders.

Additionally, States have a great deal of flexibility with respect to covering telehealth services in their Medicaid programs, including mental health services provided via telehealth, and States are not required to submit a State plan amendment

[33] Streamlining Eligibility and Enrollment Notice of Propose Rulemaking (NPRM) | CMS, *https://www.cms.gov/newsroom/fact-sheets/streamlining-eligibility-enrollment-notice-propose-rulemaking-nprm.*

[34] Streamlining Eligibility and Enrollment Notice of Propose Rulemaking (NPRM) | CMS, *https://www.cms.gov/newsroom/fact-sheets/streamlining-eligibility-enrollment-notice-propose-rulemaking-nprm.*

(SPA) to pay for telehealth services if payments for services furnished via telehealth are made in the same manner as when the service is furnished in a face-to-face setting. To establish rates or payment methodologies for telehealth services that differ from those applicable for the same services furnished in a face-to-face setting, a State would need an approved State plan payment methodology and might need to submit a SPA.[35] We look forward to continuing to work with States as they consider these and other innovative coverage decisions in their Medicaid programs.

THE MEDICARE HOSPITAL INSURANCE (HI) TRUST FUND

Question. Transferring general tax revenue into Medicare's hospital insurance trust fund in order to make the program more solvent would be unprecedented. Similar to the Social Security system, the HI portion of the Medicare program was designed to be self-supporting. The Medicare Part A trust fund has a dedicated revenue stream—the HI payroll tax. Beneficiary services are financed through that reserved income source, rather than relying on general tax revenues. Congress only allowed temporary, and time-limited, general transfers to the HI trust fund during the first few years of the Medicare program's implementation. General revenue has never been used for the purpose of expanding Medicare program benefits or extending HI trust fund solvency.

The President's budget request appears to rely solely on massive tax hikes and budget gimmicks to delay Medicare insolvency. Mr. Secretary, are you concerned that transferring general tax revenue into the HI trust fund would undermine the self-financing structure of the trust fund?

The Penn Wharton Budget Model, an organization respected by both sides of the aisle, estimates that almost 40 percent of the revenue attributed to the President's proposal comes from redirecting current-law revenue into the HI trust fund account. Do you agree that shifting tax revenue into the HI trust fund would require tax increases in other areas, new taxes, or deficit increases in order to compensate for the lost revenue streams?

Answer. Medicare is a key pillar of our health-care system and we are committed to strengthening the program both now and in the future. Thanks to our efforts, this year's Medicare Trustees Report estimated that the solvency of the Medicare hospital insurance (HI) trust fund has been extended by 3 years since last year's report. In addition, adoption of the proposals in the President's FY 2024 budget would extend Medicare solvency by at least 25 years, without cutting benefits or raising costs for people with Medicare. The FY 2024 budget also includes a targeted package of Medicare proposals totaling $8 billion over 10 years that supports the administration's priorities such as investing in mental health, strengthening nursing home oversight, and enhancing program benefits. We look forward to continuing to work with Congress to further strengthen this vital program that serves over 65 million Americans.[36]

FAITH-BASED ADOPTION AGENCIES

Question. Public-private partnerships between State child welfare agencies and faith-based organizations help to fill critical gaps in State foster care and adoption programs. In addition to connecting children with safe and loving homes, faith-based organizations provide support, resources and other services to vulnerable children and their families.

Critical to the work of faith-based organizations is ensuring that they can continue to operate, without discrimination, in accordance to the tenants of their faith.

How does your budget ensure that faith-based adoption agencies are supported in their work to serve children and families?

Answer. Faith-based providers are an important part of the Nation's foster care systems, and the budget proposes to expand foster care prevention and other services that are provided by a range of child welfare organizations, including faith-based providers, while ensuring that all children and families involved in the child welfare system are able to access publicly funded services without facing discrimination. The work of the Children's Bureau, including funding programs and providing training and technical assistance supports the faith-based adoption agencies equally

[35] Medicaid State Plan Fee-for-Service Payments, *https://www.medicaid.gov/sites/default/files/2020-03/Medicaid%20telehealth%20services.pdf.*

[36] FY 2024 HHS Budget in Brief, *https://www.hhs.gov/sites/default/files/fy-2024-budget-in-brief.pdf.*

along with the publicly operated agencies. Examples of this support is provided by the following:

The multifaceted national AdoptUSKids Project:

- Featured articles in newsletters and blogs such as: *Partnering With Faith Based Communities To Secure Families.*
- Faith-Based organizations have access to and use the National Photolisting site to highlight children/youth needing an adoptive family and families available to meet the needs of waiting children.
- Recruitment of and highlighting of families and youth with lived experience from faith-based organizations are key member of the project's Speakers Bureau.
- Media Interviews are conducted to highlight the need for adoptive and foster families with faith-based organizations.
- Faith-based organizations can personalize the public service announcements produced by this project each year for their recruitment campaigns.
- The importance of faith-based communities is highlighted on the AdoptUSKids website and in the national and tailored service work conducted through the project's capacity building efforts to include diligent recruitment efforts with all States, tribes, and territories.
- Recruitment occurs on a continual basis that targets faith-based organizations to refer candidates for the Minority Professional Leadership Development program designed to develop leadership within child welfare systems.

Several national projects funded with Adoption Opportunities funds have and continued to make an impact in terms of support for faith-based agencies across the Nation. Examples include:

- National Training and Development Curriculum: This project developed and continues to infuse within public and private (including faith-based) agencies a state-of-the-art, comprehensive training and development curriculum for foster and adoptive families. This training is made free of charge to all agencies and support the pre-service and ongoing developmental training needs for adoptive families to ensure safe and stable permanencies.
- Quality Improvement Center for Adoption/Guardianship Support and Services: This project developed and tested models of post adoption support that involved many faith-based agencies and continues to support the efforts of post adoption support to these agencies.
- Hospital-based training for adoption support among hospital staff has supported many efforts with faith-based agencies.
- National Training Initiative for Adoption-Competent Mental Health Services has developed web-based training that is made available to all child welfare agencies across the Nation including faith-based agencies.

ACA PREMIUM TAX CREDITS

Question. The President's budget proposes permanently authorizing the expanded Obamacare premium tax credits that were most recently extended in the Inflation Reduction Act. Earlier this month, the U.S. Government Accountability Office released a report finding that CMS does not coordinate with States to conduct risk assessments to evaluate the likelihood of improper eligibility determinations for the advance premium tax credit.

Do you agree with these findings, and what steps are you taking to ensure proper oversight of the expanded and enhanced premium tax credits?

Answer. In 2010, the Patient Protection and Affordable Care Act (ACA) established Health Insurance Exchanges through which consumers could submit applications and enroll in health coverage. Under the law, States have the authority to establish their own exchange, a State-Based Exchange (SBE), or use the Federally Facilitated Exchange (FFE). HHS works with all States to address the specific needs of their consumers while also meeting the requirements and responsibilities set by statute. Eligible consumers enrolling in a qualified health plan through the FFE or SBE may receive financial assistance in the form of Advance Payments of the Premium Tax Credit (APTC). HHS is committed to protecting taxpayer funds while reducing the burden on consumers, employers, and other individuals and entities involved in the FFE and SBEs and other insurance affordability programs.

HHS has applied program integrity best practices to the Exchanges based on efforts to prevent and detect fraud, waste, and abuse in its other programs. In addition, HHS has experienced program integrity staff that work to prevent and address

instances of potential fraud. HHS has also made progress toward reporting APTC improper payment estimates by conducting a risk assessment for the APTC program, as required by the Payment Integrity Information Act of 2019 and Office of Management and Budget guidance. HHS also requires SBEs to conduct a defined set of oversight activities, and tracks and monitors how SBEs establish program integrity standards that comply with Exchange-related policy and operational requirements set forth in statute, regulations, and guidance.[37]

In November 2022 HHS for the first time included measurements of the improper payment rate for the APTC program for the FFE in CMS's and HHS's annual 2022 Agency Financial Report. CMS reported the improper payment rate for Benefit Year 2020 (January 1st to December 31, 2020). CMS found that the FFE properly paid an estimated 99.38 percent of total outlays in Benefit Year 2020. The improper payment rate for the program was 0.62 percent.[38] HHS estimated the improper payment rate based on a review of a stratified random sample of applications to determine if the FFE properly performed the required eligibility determinations and paid the appropriate benefits for each sampled application. Most improper payments involve situations where a State or provider missed an administrative step. The vast majority of improper payments are not fraud, and improper payment estimates are not fraud rate estimates. The primary causes of improper payments were manual errors associated with determining consumer eligibility for payments when verification by automated processes was insufficient or not possible. An improper payment could arise, for example, if a consumer is determined eligible for payments based on submitted documentation that did not meet requirements.[39] HHS continues to develop the improper payment measurement program for SBEs and will continue to provide updates on the development status of the SBE improper payment measurement through its annual Agency Financial Report.

THE BROKEN COVERAGE WITH EVIDENCE DEVELOPMENT PARADIGM

Question. Medicare's coverage with evidence development, or CED, paradigm, desperately needs reform, as experts across the political spectrum have contended. In addition to creating access barriers for countless seniors through rigid trial and study requirements, which can also trigger massive costs, with no guarantee of a reasonable return, CED protocols rarely come with a realistic or transparent path to full coverage, even for the most promising medical devices. Underscoring that point, of the 27 CED decisions issued since 2005, only four have ultimately been retired, after a staggering average of 8 years.[40]

Moreover, the application of this pathway to drugs and biologics flies in the face of statute, regulation, and longstanding precedent, exacerbating uncertainty, especially for the small businesses that drive an outsize share of innovative drug development.[41] Unfortunately, rather than defer to FDA's judgment on medications and improve the CED paradigm for devices, CMS has doubled down on its onerous Alzheimer's coverage decision and considered only narrow, and sometimes counterproductive, changes to the CED process more broadly.

What concrete steps will your department and its sub-agencies take to enhance CED and to ensure that seniors can access FDA-approved medicines without needless hurdles and barriers?

Answer. Medicare's Coverage with Evidence Development (CED) is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. In making coverage decisions involving CED, CMS decides after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary. Cov-

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[37] Payment Integrity: Additional Coordination Is Needed for Assessing Risks in the Improper Payment Estimation Process for Advance Premium Tax Credits | U.S. GAO, *https://www.gao.gov/products/gao-23-105577.*

[38] Federally Facilitated Exchange Improper Payment Rate Less Than 1 Percent in Initial Data Release | CMS, *https://www.cms.gov/newsroom/press-releases/federally-facilitated-exchange-improper-payment-rate-less-1-initial-data-release.*

[39] Federally Facilitated Exchange Improper Payment Rate Less Than 1 Percent in Initial Data Release | CMS, *https://www.cms.gov/newsroom/press-releases/federally-facilitated-exchange-improper-payment-rate-less-1-initial-data-release.*

[40] *https://www.agingresearch.org/wp-content/uploads/2023/02/Facade-of-Evidence-CED-2-13-2023.pdf.*

[41] *https://www.finance.senate.gov/imo/media/doc/crapo_letter_to_cms_on_final_coverage_decision.pdf.*

erage in the context of ongoing clinical research protocols or with additional data collection can expedite earlier beneficiary access to innovative technology while ensuring that systematic patient safeguards, including assurance that the technology is provided to clinically appropriate patients, are in place to reduce the risks inherent to new technologies, or to new applications of older technologies.[42]

The FDA performs a vital and an important role. CMS recognizes the important and related—but different—roles of the respective agencies. The FDA determines whether to approve a new medical product based on a careful evaluation of the available data and a determination that the medical product is safe and effective for its intended use. CMS conducts its own independent review to determine whether an item or service is reasonable and necessary for use in the Medicare population and should be covered nationally by Medicare.

ENSURING A ROBUST BIOSIMILAR PIPELINE

Question. Biosimilars present a pivotal opportunity for cost savings, both for patients and for our health-care programs. The FDA has approved at least 40 of these products to date, and in the past 7 years, biosimilars have generated more than $13 billion in savings, with prices averaging just 50 percent of their branded competitors.

In Medicare Part D, however, uptake has proved lower than expected, jeopardizing the biosimilar pipeline and driving up out-of-pocket spending. A recent report from HHS's Office of the Inspector General found that beneficiaries could have realized savings of 12 percent in a single year with greater biosimilar uptake. As a case in point, even with the first Humira biosimilar competitor on the market, and with at least seven more to come before the end of 2023, Part D coverage has been uneven and distorted, with some plans and PBMs advantaging the branded product—or biosimilars with a higher sticker price.

What specific steps does the administration plan to take to promote uptake and access for biosimilars in Medicare Part D?

Answer. HHS is committed to encouraging the use of biosimilar biological products within the Secretary's scope of authority in order to reduce costs to both beneficiaries and the Federal Government. In general, however, a provision in the Part D statute prohibits the Secretary of Health and Human Services from interfering with the private negotiations between drug manufacturers and pharmacies and plan sponsors, requiring a particular formulary, or instituting a price structure for the reimbursement of covered Part D drugs. However, CMS has the authority to review Part D plan formularies to ensure that drug plans provide access to medically necessary treatments and do not discriminate against any particular populations of beneficiaries. CMS uses this authority to review plan formularies for appropriate inclusion of all drug classes. HHS will continue using its authority where possible to seek to promote competition, support increased utilization of biosimilar and generic drugs, reduce the Federal Government's spending on drugs, and achieve greater equity in drug access and affordability for beneficiaries.

RURAL HOSPITAL STABILIZATION PILOT PROGRAM

Question. HHS's Budget in Brief contains a single line item identifying $20 million for a new Rural Hospital Stabilization Pilot Program. The budget describes this proposed pilot program as both providing assistance to rural hospitals at risk of closure and supporting the expansion of hospital service lines that meet rural communities' needs.

What are the detailed policy specifications for this new pilot program, as well as corresponding cost estimates for each component of the proposal?

Answer. As detailed in HHS's Health Resources and Services Administration's Congressional Justification for the Fiscal Year 2024 Budget proposal, the $20 million requested to establish the Rural Hospital Stabilization Pilot Program would enable HRSA to help approximately 25 rural at-risk hospitals each year to expand their services to create new care in the community while expanding revenue streams to stabilize operations and meet local needs.

Specifically, this program would take actions such as:

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[42] Medicare Coverage Document—Guidance for the Public, Industry, and CMS Staff: Coverage With Evidence Development, *https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?MCDId=27.*

- Producing market assessments of participating hospitals to assess gaps in services and those clinical areas where expansion would meet local need and generate additional service volume to improve financial operations; and
- Helping rural hospitals identify and move into services areas that are linked to broader public health needs such as behavioral health, maternity care and those services that could help rural hospitals reduce disparities.

TEMPORARY ASSISTANCE FOR NEEDY FAMILIES

Question. The Temporary Assistance for Needy Families (TANF) program allows States to support programs that promote independence and economic self-sufficiency for low-income families. Unfortunately, TANF has made headlines in recent years due to a lack of accountability and rampant misuse of funds in the program.

The President's budget proposes to include new statutory authority to collect more comprehensive TANF data and to develop an improper payment rate for the program. While this step is necessary to improve program integrity, more must to be done to ensure that TANF continues to successfully lift families out of poverty.

What actions has the Department taken to reduce fraud in the TANF program?

How does the administration plan to engage with Congress to ensure that weaknesses can be addressed in the TANF program?

Answer. The Administration for Children and Families (ACF) is committed to an effective safety net system that ensures funds are spent to achieve their intended purpose and welcomes the opportunity to work with Congress to strengthen TANF. TANF is intended to serve as a critical support to families experiencing economic hardships, providing cash assistance, employment and training assistance, and related services to ensure families can meet basic needs, get access to opportunities in the job market, and remain together.

ACF takes all allegations of fraud and misuse very seriously, as we understand the vital importance of safeguarding taxpayer funds. ACF is working on a number of areas to reduce fraud and strengthen TANF program integrity. The agency proposed new statutory authority, included in the President's FY 2024 budget, that would allow TANF to collect information from States needed to calculate and report an improper payment estimate, identify root causes of improper payments, and develop and monitor corrective actions. In the absence of authority to collect additional data, ACF is exploring the use of existing data sources to strengthen TANF program monitoring and oversight, and we are committed to working with Congress to provide programmatic insight in this area. Additionally, ACF is working to ensure that auditors have the information they need to assess if States have complied with program requirements for areas including allowable costs and sub-recipient monitoring, and to identify areas where States may need additional supports and technical assistance to remediate any weaknesses in internal controls.

The President's budget also notes that the Administration for Children and Families (ACF) "plans to propose a regulation to strengthen TANF as a safety net, make changes to allowable uses of TANF funds, and reduce administrative burden."

The President's budget also notes that the Administration for Children and Families (ACF) "plans to propose a regulation to strengthen TANF as a safety net, make changes to allowable uses of TANF funds, and reduce administrative burden."

Question. What details can you provide about this proposal, and what timeline is ACF working towards to propose the regulation?

Answer. ACF plans to issue a proposed rule to strengthen the TANF program as safety net and work preparation program, make changes to provide additional definitions to allowable uses of TANF funds and reduce administrative burden. The proposed rule will create additional accountability for States to realign their TANF programs to support those who need it most, and build programs centered around what we know works best for families, while maintaining State flexibility and remaining bound by the ways Congress intended for the program to operate. These changes are intended to strengthen TANF to provide the economic and workforce supports to those families and communities with the greatest needs. Under the Workforce Innovation and Opportunity Act (WIOA), except in States whose Governor opted out, TANF is a required partner to WIOA-authorized labor/workforce programs funded by the Departments of Labor and Education.

ACF is currently engaging in listening sessions to ensure a proposed rule is intentional, impactful, and carefully crafted. ACF looks forward to sharing a more concrete timeline once the listening sessions have concluded.

KINSHIP NAVIGATOR PROGRAMS

Question. Kinship navigator programs are critical to ensuring that kin caregivers and their families are well supported, regardless of their involvement in the child welfare system.

A recent report published by the Government Accountability Office (GAO) noted that, as of December 2022, States have not yet accessed Federal matching funds for evidence-based kinship navigator programs due to various challenges in understanding or meeting the evidence-based requirements for evaluating program outcomes. The GAO report noted that HHS officials recognize that more time and resources may be needed to allow for more research on kinship navigator programs to be completed.

What does HHS consider to be an appropriate time frame for States to build evidence supporting the effectiveness of kinship navigator programs?

Answer. We agree that kinship navigator programs are critical supports for kin caregivers and their families. We are pleased that we are making progress in identifying models that are able to be rated as promising or supported by the Prevention Services Clearinghouse, making them available for use by title IV–E agencies under the title IV–E Kinship Navigator program. As of the date of the hearing, seven kinship navigator programs have been reviewed by the Prevention Services Clearinghouse; one of these has been rated as supported and two of these have been rated as promising. Building evidence can be time and resource intensive. Evaluations can take multiple years to plan for and conduct and then often take additional time to ensure findings are disseminated. The timeline for completing evaluations is dependent on a variety of factors including but not limited to funding, evaluation design and sample, and data collection challenges. The funding provided by Congress through annual appropriations under title IV–B, subpart 2 to support the development, enhancement, or evaluation of kinship navigator programs is providing critical resources to assist a number of title IV–E agencies to carry out rigorous evaluations. ACF is also supporting evidence-building through the Notice of Funding Opportunity (NOFO) issued in 2021 for Family Connection Grants: Building the Evidence for Kinship Navigator Programs (HHS–2021–ACF–ACYF–CF–1903). That NOFO estimated a 3-year grant period for evaluation. Therefore, we hope that additional models will be able to be reviewed and rated over the next several years.

QUESTIONS SUBMITTED BY HON. MARIA CANTWELL

BASIC HEALTH PROGRAM

Question. Between 2020 and 2022, 13.5 million additional adults enrolled in Medicaid thanks to enhanced Federal matching subsidies and other COVID–19 relief provisions. The Continuous Enrollment Provision especially increased coverage stability for the most vulnerable population and reduced costs for the government by preventing the Medicaid "churn."

However, the Continuous Enrollment Provision is set to end after this month. The Kaiser Foundation estimates that 5 to 14 million Medicaid beneficiaries could lose coverage in the following months. In addition, the generous Premium Tax Credit extension provided by the Inflation Reduction Act is set to expire after 2025, and it is not certain whether it will be extended again.

We must look for a long-term solution that could both reduce costs for beneficiaries and the government, while ensuring that the most vulnerable population continues to receive affordable, quality coverage after the Public Health Emergency. I believe that the Basic Health Program is the answer to these issues.

The Basic Health Program has produced tremendous results and savings for the two States, New York and Minnesota, which have adopted it. For example in New York, the BHP generated $1 billion in savings for the State in 2019. Compared to benchmark silver plans, the 1 million New York BHP beneficiaries spent $719 million less in premium and out-of-pocket costs. As of 2021, all New York BHP enrollees are paying $0 in premiums. The program is so successful that the State is pursuing a waiver to increase BHP eligibility from 200 percent of the Federal Poverty Level to 250 percent of the Federal Poverty Level.

At the same time, the BHP provides coverage stability by capturing those most susceptible to the Medicaid churn. This ensures that they don't have a lapse in coverage or are subject to unnecessary administrative procedures.

In your budget request, you proposed to make the enhanced Premium Tax Credit permanent. This is projected to cost $183 billion over 10 years. Why do you think that this is the best method to lower health insurance costs?

Do you think that the Basic Health Program could be a more cost-effective alternative to making the expensive Premium Tax Credits permanent?

As States begin to conduct Medicaid eligibility redeterminations next month, we will need to ensure that those who no longer qualify for Medicaid remain insured. How are you ensuring that those who no longer qualify for Medicaid can continue to receive quality, affordable coverage?

Do you believe that the Basic Health Program could be a good way to fill the gap and increase coverage stability?

Last year, the Oregon and Kentucky State legislatures voted to establish their own Basic Health Programs. West Virginia could be next. This shows that States are exploring different options to reduce costs and provide quality health insurance for their residents.

How can we incentivize more States to adopt the Basic Health Program?

Will you work with me to encourage more States to adopt BHPs?

Answer. CMS is committed to using all the levers at our disposal to expand access to high-quality, affordable care, and the President's FY 2024 budget includes a number of proposals that would support this goal. For example, the budget proposes to permanently expand premium tax credit eligibility by eliminating the required contribution for individuals and families making 100 percent to 150 percent of the poverty level and limiting the maximum income contributions towards benchmark plans to 8.5 percent of income. Thanks to these subsidies, for Open Enrollment 2023, four out of five people returning to *HealthCare.gov* were able to find a plan for $10 or less after tax credits.

CMS is also taking steps to make sure the country is prepared for the end of the public health emergency on May 11th. For 2 years, CMS has been working with all States to prepare for the unwinding of this "continuous enrollment" condition in order to ensure that as many people as possible maintain health coverage. That includes helping eligible individuals stay in Medicaid and CHIP, and helping others transition to the Marketplaces, Medicare, or employer-sponsored coverage. CMS is assessing States' compliance with Federal Medicaid eligibility redetermination requirements and, where necessary, developing strategies to address gaps or deficiencies.

CMS has implemented a multipronged approach to improve coverage transitions, including a ramped-up outreach and marketing campaign, and a variety of improvements to Federal marketplace policies and systems to streamline the consumer experience, including a new Marketplace Special Enrollment Period available now on *HealthCare.gov* for qualified individuals and their families who are no longer eligible for Medicaid or CHIP coverage.

This approach also includes enhanced consumer engagement for consumers who lost or will soon lose Medicaid or CHIP coverage. Navigators and other assistance personnel will maintain a critical physical and virtual presence in communities across the U.S. to help consumers understand basic concepts and rights related to health coverage, provide enrollment assistance, and work with individuals to link coverage to care. Specifically, CMS made a historic investment, allocating a total of $100 million to Federal marketplace navigator grantee organizations for the 2022–2023 budget period, including $12.5 million in support of additional direct outreach, education, and enrollment activities for unwinding.

Continuing to expand access to coverage is essential, and I agree there is a real opportunity with the Basic Health Program. CMS works closely with States to identify innovative ways to expand access to high-quality care while reducing healthcare costs. I look forward to continuing to work with Congress, and to hearing from any interested States that want to try the program for themselves.

TITLE X FAMILY PLANNING

Question. The title X program provides essential reproductive services like birth control, STI screenings, and preventative cancer screenings. In 2021, it served about 1.7 million people, two-thirds of whom were living under the Federal poverty level.

Investments in family planning are a proven way to keep people healthy, improve families' financial security, and save taxpayers money. In Washington State, there are over two dozen Planned Parenthood centers that rely on sustained title X funding. Without these clinics, thousands of people would not receive the health care they need.

Since the Supreme Court overturned the constitutional right to abortion last year, access to contraception is more vital than ever. Contraception cannot replace the need for abortion services, but it can help prevent women from having to travel hundreds of miles out of State for basic health care or an abortion.

Additionally, smaller and rural medical facilities are suffering from post-pandemic financial strain and a lack of medical professionals. As a result, some of them, including the Astria Toppenish Hospital in my home State, have opted to close their maternity wards. This is why programs like title X are more critical than ever.

Title X has been funded levelly for the past 8 straight years. This is unacceptable, especially as the program is working to rebuild from the Trump administration's devastating domestic gag rule. Washington State had to opt out of title X funding entirely due to the severity of the domestic gag rule.

According to an *American Journal of Public Health* publication, title X needs $737 million per year to provide family planning services to uninsured, low-income women. The number of funding needs to be even higher to account for other populations that rely on title X services.

Your Fiscal Year 2024 budget includes $512 million for title X. How do you account for the difference between $512 million and the $737 million that researchers say is needed?

Answer. Title X funding remains critical for providing family planning services that are equitable, affordable, client-centered, and high-quality. The ability to access trusted, unbiased information is even more important following the *Dobbs v. Jackson Women's Health Organization* decision and the shifting legal landscape which has led to confusion, misinformation, and disinformation. While data has not yet been collected on the impact of the Supreme Court's ruling, title X clinics have anecdotally reported experiencing an increased demand for family planning services and, correspondingly, a need for additional funding. The FY 2024 budget includes $512 million, a 79-percent increase of the 2023 enacted level.

Question. I welcomed the Biden administration's decision to end the title X domestic gag rule in 2021. Data showed that under the domestic gag rule, title X went from serving 4 million patients in 2018 to 1.7 million patients in 2021. Has the program rebounded since the domestic gag rule was overturned? How many patients did it serve in 2022?

Answer. The data is not yet available to assess the change in services delivered and requested in 2022, but title X clinics have anecdotally reported experiencing an increased demand for services while combating the high turnover of key family planning staff. Additionally, the title X program is still rebuilding its network of clinics following the title X Final Rule and the restoration of funding for clinics nationwide in Fiscal Year (FY) 2022. Once the Family Planning Annual Report (FPAR) data is available in late summer of 2023, HHS will assess the impact of the 2021 Final Rule.

HOME AND COMMUNITY-BASED SERVICES

Question. Home and community-based services are extremely popular in Washington State and across the country. I have worked with my colleagues on both sides of the aisle to increase support for home and community-based care. These services help millions of older adults and people with disabilities avoid high-cost institutional care, while letting them live in the comforts of a surrounding that they are familiar with.

People with disabilities and older adults simply want the same thing we all want—to live independently and age with dignity. Furthermore, home and community-based care can cost as little as one-third of the amount of nursing home care.

One successful program to support home and community-based services is the Money Follows the Person program, which I have championed. This program allows older adults and people with disabilities to leave institutional care settings to live in their communities.

In Washington State, the Money Follows the Person program has been incredibly successful, saving the State Medicaid program millions of dollars. We must support efforts to have sustained funding for this program so that States can effectively use these funds to expand the program. We also need to do more to support caregivers, who offer invaluable support and perform complex work. There are over 850,000 caregivers in Washington State, and the vast majority are unpaid, female, and/or racial minorities.

While I am pleased that the Money Follows the Person program is funded through Fiscal Year 2027 at $450 million per year, I have heard that States are having difficulty planning for the program's future as they are uncertain whether it will be reauthorized.

Do you think the current funding level is sufficient for each State to operate a successful MFP program?

Do you recommend that the program receive permanent funding so that States can better plan for the program in their budgets?

Answer. The Money Follows the Person (MFP) demonstration gives beneficiaries more options for their care and allows them to choose to receive care in the community, rather than institutions. Participating States have demonstrated positive outcomes, including helping individuals in institutions return to the community, improving participant quality of life, and lowering the cost of care.

The budget proposes to invest $150 billion over 10 years in Medicaid home and community-based services, enabling seniors and people with disabilities to remain in their homes, to work, and stay active in their communities. At the same time, the proposal promotes better quality jobs for home-care workers and enhances supports for family caregivers, many of whom are too often forced out of the workforce due to the demands of caring for a loved one.

Question. Home and community-based services cannot exist without a robust caregiving workforce. Home care workers are often low-income, women, underpaid or unpaid, and overworked.

How would the budget support caregivers?

Do you have any plans to increase the availability of the caregiving workforce while providing adequate compensation for these workers?

Answer. The caregiving workforce that helps older adults and people with disabilities live and participate in their communities is comprised of the paid, direct-care workforce and unpaid family caregivers; Within HHS, the Administration for Community Living (ACL)'s budget request for FY 2024 seeks to strengthen both. With respect to the paid direct-care workforce, HHS/ACL is currently funding the development of a Direct Care Workforce Center *(https://acl.gov/news-and-events/announcements/acl-launches-national-center-strengthen-direct-care-workforce)* through which State, private, and Federal entities involved in the recruitment, training and retention of direct-care workers can access model policies, best practices, training materials, technical assistance, and learning collaboratives. Funding in FY 2024 will support continued operations of the Center and establish demonstration grants to develop partnerships across State aging, disability, Medicaid, and labor/workforce agencies and with aging, disability, labor and provider stakeholders to implement recruiting, retention, and training approaches to strengthen job quality in the direct-care workforce at State and local levels. The Direct Care Workforce Center is designed to catalyze change at a systems level that will address the insufficient supply of trained direct-care workers, including Direct Support Professionals to assist individuals with disabilities to become and stay employed and live in the community, promote promising practices at all levels of the service system, and improve data collection to enable a full understanding of the workforce issue. The anticipated outcomes of this effort, include but are not limited to:

- Increasing the availability and visibility of tools and resources to attract, train and retain the direct-care workforce in quality jobs where they earn livable wages and have a voice in their working environment and have access to benefits and opportunities for advancement; and

- Increasing the number of States that develop and sustain collaborations across State systems and workforce agencies to implement strategies that will improve the recruitment, retention, and advancement of high-quality direct-care workforce jobs.

Family caregivers often rely on direct-care workers to augment their efforts to support and assist those for whom they provide care. Over 53 million people are family caregivers, with a growing number of people having to provide care or provide more care due to the direct-care workforce crisis. To address the need for greater recognition, inclusion and support of family caregivers, in September 2022 ACL, in collaboration with the Family Caregiving Advisory Council, delivered to Congress and the Nation the first National Strategy to Support Family Caregivers (the Strategy) *(https://www.hhs.gov/about/news/2022/09/21/hhs-delivers-first-national-strategy-support-family-caregivers.html).*

The strategy addresses five critical priorities areas associated with supporting family caregivers, one of which (Outcome 3.9) addresses the need for "an agile, flexible, and well-trained direct-care workforce . . . to partner with and support family caregivers." Additionally, the Strategy puts forth a series of ideas for action that can be taken by multiple sectors to increase the availability and viability of the direct-care work force.

ACL is beginning some initial steps to implement the Strategy, including establishing technical assistance *(https://www.grants.gov/web/grants/search-grants.html?keywords=caregiver)* to curate best practices and model policies and launching a project to help caregivers access services and supports. Funding in FY 2024 will allow ACL to provide training and technical assistance to the aging, tribal and kinship family caregiver support networks and to establish demonstration grants to enable States and local communities to test solutions and strategies identified in the Strategy to support family caregivers, including by strengthening the paid direct-care workforce and the partnership between that workforce and family caregivers.

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

Question. Please explain the increased role title X plays following the *Dobbs* decision and why it is such a critical part of supporting women's reproductive health?

Answer. For over 50 years, title X family planning clinics have played a significant role in ensuring access to reproductive and preventive health-care services for millions of low-income or uninsured individuals. Following the *Dobbs* decision, expanding and maintaining access to contraception and family planning services under the title X program has become more critical than ever. The shifting legal landscape resulting from the Supreme Court's ruling has led to confusion, misinformation, and disinformation—which has increased the need for evidence-based and high-quality services and information. The title X program supports high-quality, family planning services and preventive care, including breast and cervical cancer screening, contraceptive counseling and care, sexually transmitted infection testing and treatment, and HIV screening. While contraception and related title X-funded services cannot replace the need for abortion, title X-funded clinics remain a critical safety net and important access point for trusted, nonbiased health-care services and information for many people in need of care.

Question. Please explain why title X funding is particularly important to promoting health equity and racial and economic justice?

Answer. Advancing equity for all through the delivery of health-care services is a priority for the title X family planning program. The funding awarded to our vast network of providers and clinics directly supports clients from low-income families, clients of color, and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. Many of the clients served through our network rely on title X providers for their usual source of medical care, including a wide range of preventive services. Moreover, recipients provide title X clients with access to the same quality health care, including full medical information and referrals, that higher-income clients and clients with private insurance are able to access. And, the ability to access high-quality contraception is an important part of helping ensure people can make decisions about their own health, lives, and families. Title X funding has historically been a critically important resource in promoting health equity and racial and economic justice, and it remains a critical source of care for those most in need.

Question. How is the administration ensuring that efforts to address mental health challenges support LGBTQ youth and youth of color?

Answer. Within the Department of Health and Human Services, the Substance Abuse and Mental Health Services Administration (SAMHSA) advances efforts to reduce disparities in mental and/or substance use disorders across populations, including LGBTQI+ youth and youth of color.

The Biden-Harris administration is committed to addressing mental health challenges impacting LGBTQI+ youth in several ways—all of which are grounded in advancing Executive Order 14075 (Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals). SAMHSA is promoting family counseling and support of LGBTQI+ youth by including language in relevant notices of funding opportunities, such as the School-Based Trauma-Informed Support Services and Mental Health Care for Children and Youth program, allowing grantees to provide trauma-informed evidence-based counseling and support services for LGBTQI+ children, adolescents, and their families/caregivers. In addition, SAMHSA began the "press 3" LGBTQI+ youth pilot for LGBTQI+ youth who contact the 988 Suicide and Crisis Lifeline last fall. Currently, 18 percent of texts, 15 percent of chats and 6 percent of calls routed within 988 are for the LGBTQI+ youth-specialized services. Furthermore, SAMHSA supports the LGBTQI+ Behavioral Health Equity Center of Excellence, which provides behavioral health practitioners with vital information on supporting this population.

To address mental health challenges for people of color, SAMHSA administers a number of Centers of Excellence. This includes the Asian American, Native Hawaiian, and Pacific Islander Center of Excellence (AANHPI–CoE). The AANHPI–CoE is tasked with developing and disseminating culturally informed, evidence-based behavioral health information and providing technical assistance on training on issues related to addressing behavioral health disparities in the Asian American, Native Hawaiian, and Pacific Islander communities.

SAMHSA also funds the Centers of Excellence for Behavioral Health Disparities, which establishes three Centers of Excellence to develop and disseminate training and technical assistance for health-care practitioners on issues related to addressing behavioral health disparities. It is expected that the recipients will implement training and technical assistance for practitioners to address the disparities in behavioral health care in three key populations: African Americans, LGBTQ, and the aging population. Additionally, African American Behavioral Health Center of Excellence is a new national Center whose academic home is the National Center for Primary Care, Morehouse School of Medicine. The goal of this Center is to help the field transform behavioral health services for African Americans, making them: **Safer, More effective, More accessible, More inclusive, More welcoming, More engaging, and More culturally appropriate and responsive!**

In addition to these Centers of Excellence, SAMHSA aims to increase the diversity in the behavioral health workforce through the Minority Fellowship Program, which provides stipends to increase the number of culturally competent behavioral health professionals who teach, administer, conduct services research, and provide direct mental illness or substance use disorder treatment services for minority populations that are underserved.

Further, the following SAMHSA grant programs include a focus on youth and young adults with co-occurring conditions and have helped ameliorate some of the gaps in access to care that youth with mental health challenges face: The Infant and Early Childhood Mental Health program (IECMH), Children's Mental Health Initiative (CHMI), the Mental Health Block Grant, the Family Support Technical Assistance Center, and the Statewide Family Network.

Finally, for youth suffering from mental illness or a co-occurring disorder in the juvenile justice system, SAMHSA also operates a grant program to establish or expand programs that divert these youth from the criminal justice system into treatment when it is safe to do so. The Behavioral Health Partnership for Early Diversion of Adults and Youth program supports grantees who provide community-based mental health and substance use disorder services and other supports prior to arrest and booking.

Question. The 988 suicide and crisis line currently provide live crisis center calling services in English and Spanish and uses Language Line Solutions to provide translation services in over 250 additional languages. But, text and chat services are currently only available in English. What are the agency's plans to improve language access to the lifeline?

Answer. The SAMHSA-administered 988 Suicide and Crisis Lifeline plans to add Spanish chat and text services by the end of FY 2023 and is focused on supporting the Spanish crisis center workforce with trainings and webinars conducted in Spanish. SAMHSA also is working to launch video-phone services for individuals who are deaf or hard of hearing and might prefer to interact with 988 in that manner.

The 988 Lifeline currently provides live crisis center calling services in English and Spanish. Further, the 988 Lifeline increased the number of call centers dedicated to taking Spanish calls in 2022. The 988 Spanish subnetwork has seen both an increase in calls along with improvement in response rates (45 percent answered volume increase over previous year). The Spanish call line improved response rates across States and territories from 63 percent in July to 84 percent in March 2023.

The 988 Lifeline also offers crisis services interpreted into over 240 languages and dialects through the call option to 988, increasing accessibility to many people wishing to use the line. Interpreting services are available 24/7 and the average time to be connected to an interpreter is only 17 seconds. The 988 interpreting service allows callers to comfortably connect with crisis counselors in their preferred language outside of English. To connect with an interpreter, callers can dial 988 and ask for an interpreter in English if they are able, or they can simply say the name of the language they need to prompt the crisis counselor to get an interpreter on the line. The 988 interpreting service can also assist crisis counselors in identifying the needed language if the crisis counselor is unsure. Interpreters receive special training to provide effective interpretation over the telephone and follow a code of ethics that includes requirements related to confidentiality, accuracy, and impartiality. Interpretation is only available through calling 988, it is not yet available for 988 text and chat services. SAMHSA is monitoring utilization of Language Line services to understand the demand for live crisis calling services in languages other than English and assess future workforce needs.

QUESTIONS SUBMITTED BY HON. THOMAS R. CARPER

ADDRESSING SDOH

Question. The social drivers of health contribute to more than 80 percent of an individual's health status and have a particularly profound impact on children. Addressing social drivers early in childhood could help reduce avoidable health-care costs across the life span and improve the health of our future generations.

In the FY 2023 omnibus bill, report language related to Whole Child Health Demonstration models was included, which asked the Centers for Medicaid and CHIP Services (CMCS) to provide a report within 180 days to congressional committees containing its plan to design a Whole Child Health demonstration program. Could you provide a status update on that report?

Answer. HHS agrees that addressing the Social Determinants of Health (SDOH, which we are beginning to refer to as Social Drivers of Health to acknowledge that SDOH conditions can be mitigated to improve outcomes) is very important for the health and well-being of the Nation and that addressing SDOH requires engagement and coordination across HHS, as well as with other departments within the Federal Government.

HHS is committed to advancing health equity, expanding coverage, and improving health outcomes for the millions of Americans covered by our programs, including the children enrolled in Medicaid and CHIP. In 2021, CMS released a letter to State Health Officials, entitled "Opportunities in Medicaid and CHIP to Address Social Determinants of Health (SDOH)", to describe opportunities under Medicaid and CHIP to better address SDOH and to support States with designing programs, benefits, and services that can more effectively improve population health, reduce disability, and lower overall health-care costs in the Medicaid and CHIP programs by addressing SDOH.[43] Further, in 2023, CMS began to offer a new Medicaid section 1115 demonstration opportunity to support States in addressing health-related social needs (HRSN), with the goals of improving coverage, access, and health equity across Medicaid beneficiaries. HRSN are an individual's unmet, adverse social con-

[43] *https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf.*

ditions that contribute to poor health and an individual's HRSN are a result of their community's underlying SDOH.[44]

I look forward to hearing from you and from stakeholders across the health-care spectrum as we examine ways to build health equity into new and existing efforts.

MENTAL HEALTH SERVICES

Question. Medicaid and CHIP cover over 40 million children. Therefore, Medicaid and CHIP investments in access to needed mental health services are critical to addressing the national children's mental health emergency.

What are you proposing in your budget to specifically address children's mental health challenges under Medicaid and CHIP?

Answer. The budget provides historic investments in the behavioral health workforce, youth mental health treatment, Certified Community Based Behavioral Health Clinics, Community Mental Health Centers, and mental health research. The budget strengthens access to crisis services by investing in the 988 Suicide and Crisis Lifeline to address 100 percent of estimated contacts, scaling follow-up crisis services, and expanding CDC's suicide prevention program to all States, the District of Columbia, and 18 Tribal and territorial jurisdictions. To address the mental health crisis among adolescents, the budget expands CDC's What Works in Schools program to up to 75 of the largest local education agencies. The budget also accelerates mental health research for promising new treatments and enhanced precision and implementation of existing treatments.

Within Medicaid and CHIP, the administration has taken a number of steps to increase access to children's mental health-care services. On August 18, 2022, CMS issued guidance to remind States about Medicaid's Early and Periodic Screening, Diagnostic and Treatment requirements for most Medicaid beneficiaries under age 21, including in the provision of behavioral health services.[45] The guidance also includes examples of ways that Medicaid and CHIP funding, alone or in tandem with funding from other HHS programs, can be used in the provision of high-quality behavioral health services to children and youth. On that same day, CMS released additional guidance encouraging States to work with schools to deliver on-site health-care services, including behavioral health services, to children enrolled in the Medicaid program.[46]

CMS is also working with States to increase access to behavioral health-care services within schools. In addition to implementing new Medicaid school-based service initiatives made possible by the Bipartisan Safer Communities Act, CMS updated guidance on Medicaid claiming for school-based administrative services and costs; established a technical assistance center in collaboration with the Department of Education to help States advance Medicaid coverage of school-based health services including mental health and substance use disorder services; and awarded $50 million in grants to States to help improve Medicaid coverage of school-based services.

CMS has taken a multifaceted approach to increase access to equitable behavioral health services and improve outcomes for people covered by Medicare, Medicaid, CHIP, and private health insurance, including efforts through the Connecting Kids to Coverage National Campaign. Campaign resources focused on mental health are available on *InsureKidsNow.gov* for organizations to use in their outreach, including short digital videos, live reads, social media messages, graphics, newsletter templates, and more.

In addition, CMS has been working with States to ensure CHIP programs cover services to prevent, diagnose, and treat a broad range of behavioral health symptoms and disorders consistent with SUPPORT Act requirements. CMS works closely with States to implement mental health and substance use disorder parity requirements in CHIP and Medicaid—critical to making sure kids with behavioral health conditions have access to the care they need.

Lastly, in January 2022, CMS launched the 5-year implementation period of the Integrated Care for Kids Model to improve the quality of care for children under

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[44] *https://www.medicaid.gov/medicaid/downloads/addrss-hlth-soc-needs-1115-demo-all-st-call-12062022.pdf.*

[45] *https://www.medicaid.gov/federal-policy-guidance/downloads/bhccib08182022.pdf.*

[46] *https://www.medicaid.gov/federal-policy-guidance/downloads/sbscib081820222.pdf.*

21 years of age covered by Medicaid through prevention, early identification, and treatment of behavioral and physical health needs.[47]

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

MEDICALLY NECESSARY DENTAL CARE

Question. In December 2022, the Centers for Medicare and Medicaid Services (CMS) Medicare Physician Fee Schedule final rule clarified Medicare coverage of medically necessary dental services. I applaud the agency for heeding the call from me and my colleagues by taking this much needed action to improve the health and well-being of Medicare beneficiaries.

When CMS issued the rule, it established a very specific definition in clarifying covered dental services: "dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service." The agency also listed specific services covered under this definition, including, but not limited to, certain services "prior to Medicare-covered organ transplant, cardiac valve replacement, or valvuloplasty procedures," and certain services "performed as a result of and at the same time as the surgical removal of a tumor."

As CMS implements this policy, the agency identified numerous aspects that would require additional guidance. I would appreciate an update from the agency on its plans and timeline with respect to guidance covering the following issues.

In the final rule, CMS stated that it may issue guidance to clarify that CMS Medicare Administrative Contractors "may make claim-by-claim determinations, as necessary." Does CMS plan to issue such guidance and, if so, when does the agency anticipate the guidance will be available?

Further, CMS stated that "integration between the medical and dental professional," would be necessary for Medicare payment. Does CMS plan to issue guidance clarifying requirements with respect to medical and dental integration and, if so, when does the agency anticipate releasing the guidance?

CMS also stated that dentists "would need to be enrolled in Medicare and meet all other requirements for billing" under the Medicare Physician Fee Schedule, and indicated it would "work to provide additional guidance to answer enrollment, billing, compliance, and other administrative questions for dentists as needed." Does CMS intend to provide education and guidance to ensure dentists are aware of enrollment and other requirements so they can meet the needs of their Medicare patients? If so, when would this guidance and educational effort begin?

CMS stated it will "make updates to appropriate Medicare payment data files to ensure that appropriate payments can be made under the applicable payment system" for covered services. Will CMS provide guidance to dentists on payment policies and payment mechanisms, which would be new for dentists who have are not enrolled in Medicare? If so, when would this information be made available?

CMS acknowledged outstanding questions about multiple issues, including: the claims form "dentists would use to submit claims for dental services"; the "procedure code set and diagnostic codes that would be reflected on claims"; whether "National Coverage Determinations (NCDs) will be issued to ensure consistent claim payment"; requirements regarding "frequency limits, documentation requirements, and authorization processes"; and "Medicare enrollment processes for dentists."

The agency cited "the need to address and clarify certain operational issues," and stated it is working to address these issues, including efforts to adopt the dental claim form. CMS stated it plans to provide further guidance on these issues. Can you provide additional details on the process and timeline for issuing this guidance?

Answer. Medicare payment for dental services is generally precluded by statute. However, Medicare has allowed payment for dental services in a limited number of circumstances, specifically when that service is an integral part of specific treatment of a beneficiary's primary medical condition. Some examples include reconstruction of the jaw following fracture or injury, tooth extractions done in preparation for radiation treatment for cancer involving the jaw, or oral exams preceding kidney transplantation.

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[47] *https://innovation.cms.gov/innovation-models/integrated-care-for-kids-model.*

CMS's Calendar Year 2023 Medicare Physician Fee Schedule final rule clarified and codified certain aspects of the current Medicare payment policies for dental services when that service is an integral part of specific treatment of a beneficiary's primary medical condition and outlined other clinical scenarios under which Medicare payment can be made for dental services, such as dental exams and necessary treatments prior to, or contemporaneously with, organ transplants, cardiac valve replacements, and valvuloplasty procedures. Looking ahead to 2024, CMS will begin paying for dental exams and necessary treatments prior to the treatment for head and neck cancers starting in 2024.

Finally, CMS finalized a process to review and consider public recommendations for Medicare payment for dental services in other clinical scenarios. Dentists, as appropriate, can continue to enroll in Medicare according to the current process. Dentists and other qualified practitioners who furnish dental services that are eligible for payment under Parts A and B (because they are inextricably linked to another Medicare-covered medical service) should continue to submit claims using current processes, and can consult with their Medicare Administrative Contractors (MACs) for specific claims submission questions.

As noted in the CY 2023 Physician Fee Schedule final rule, CMS acknowledges the need to address and clarify certain operational issues, and is working to address these issues. CMS anticipates resolving many of the additional operational issues raised by commenters potentially as soon as CY 2024, including efforts to adopt the dental claim form and will also make updates to appropriate Medicare payment data files to ensure that covered dental services can be billed and paid based on the applicable payment system for services furnished. CMS continues to work with the MACs and encourages continued feedback from interested parties to help identify concerns or questions regarding submission and processing of dental claims. CMS also plans to provide guidance and engage in further rulemaking, as necessary, as operational strategies and plans are refined and implemented and will also monitor service utilization to identify any concerns about consistency of claims processing and adequacy of access across the country.

CMS appreciates the feedback and engagement from members of Congress and stakeholders in the dental community during the CY 2023 rulemaking process and looks forward to continuing that engagement as CMS implements this new policy.

NIMHD AND HEALTH DISPARITIES

Question. On President Biden's first day in office, he signed an executive order directing a whole government approach to addressing racial equity and disparities among underserved communities. The President built on that through an additional executive order last month. I applaud his focus on this critical issue. Racial and ethnic minority populations experience higher rates of illness and death from health conditions such as cancer, diabetes, HIV/AIDS, mental health, and obesity.

That is why I have championed legislation throughout my time in Congress to highlight health disparities. In particular, I authored the provision in the Affordable Care Act that elevation of the National Center on Minority Health and Health Disparities to that of an Institute at the National Institutes of Health (NIH). Now known as the National Institute on Minority Health and Health Disparities, NIMHD does critical work to address health disparities. I thank the administration for prioritizing these efforts through previous increases in their funding.

Can you comment on how NIMHD is coordinating health disparities research across NIH?

How is the administration working to ensure eliminating health disparities is a focus of and funded through all Institutes within NIH and across HHS?

Answer. NIH is committed to conducting and supporting scientific research to improve minority health and reduce health disparities. NIMHD led an agency-wide workgroup culminating in the development and publication of the NIH Minority Health and Health Disparities Strategic Plan (2021–2025) (referred to in this response as the "Strategic Plan").[48] The Strategic Plan, which aligns with the NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility,[49] represents a commitment by all of NIH to advance knowledge in three core areas: (1) science of minority health and health disparities, (2) research-sustaining activities, such as training and capacity building, and (3) outreach, collaboration, and dissemination.

[48] *https://nimhd.nih.gov/about/strategic-plan/.*
[49] *https://www.nih.gov/sites/default/files/about-nih/nih-wide-strategic-plan-deia-fy23-27.pdf.*

Following the Strategic Plan's release, NIMHD is leading NIH Institutes, Centers, and Offices (ICOs) to examine progress toward meeting the goals outlined in the Strategic Plan. NIMHD has established an NIH-wide working group that will be evaluating the progress made on the Strategic Plan, identifying gaps to address by 2025, and laying the foundation for the Strategic plan for 2026 to 2030. The working group will develop metrics and a data collection system to track the alignment of activities related to minority health and health disparities with the Strategic Plan priorities.

NIMHD works with NIH ICOs to collectively invest in, integrate, and prioritize health disparities as a topic of interest through collaborative research initiatives, programs, and other activities. For example, the Community Engagement Alliance (CEAL) Against COVID–19 Disparities and the Rapid Acceleration of Diagnostics for Underserved Populations (RADx®-UP) are two initiatives that focus on populations disproportionately impacted by the pandemic. Co-led by NIMHD and the National Heart, Lung, and Blood Institute, the CEAL Initiative actively works in communities in 21 States around the United States and its territories to build trusting relationships and share science-based information. The initiative supports community-engagement activities to address questions about COVID–19 vaccination, therapeutics, and participation in clinical trials among those disproportionately affected by the pandemic. Since its inception, CEAL has recruited over 950 partners across the United States and Puerto Rico, supported over 1,500 local events reaching more than half a million participants, delivered COVID–19 vaccines to around 200,000 people, and enrolled over 600 people to participate in COVID–19-related clinical trials. The CEAL Network is well-positioned to address other critical health disparities in the coming years.

The RADx-UP Initiative is an NIH effort that comprises a consortium of 137 community-engaged projects across the United States, its territories, as well as Tribal Nations to assess and expand COVID–19 testing to communities disproportionately affected by the COVID–19 pandemic. In November 2022, the RADx-UP initiative and NIMHD published a special issue in the *American Journal of Public Health* highlighting peer-reviewed research on interventions to promote testing for SARS–CoV–2, studies on social, behavioral, and ethical issues of the pandemic in underserved populations, and commentaries by NIH leadership on the significance of the initiative.[50] The publication informs and prioritizes key strategies and responses for future public health responses among communities experiencing health disparities. RADx-UP is currently in its final phase of supporting research for improving COVID–19 testing interventions to decrease infections, hospitalizations, and mortality among populations experiencing health disparities.

In FY 2021, NIMHD launched the Structural Racism and Discrimination initiative to understand and address the impacts of structural racism and discrimination on minority health and health disparities. The initiative funded 38 R01 observational and intervention research projects across 14 NIH Institutes. Research findings will provide important insights that can help address the underlying causes of structural racism, discrimination, and social determinants of health to reduce health disparities.

The NIH Common Fund launched the Community Partnerships to Advance Science for Society (ComPASS) program to support innovative structural intervention projects that focus on social determinants of health for community-empowered research. The program will enable communities and researchers to work collaboratively as equal partners in all phases of the research process to enhance the quality of interventions and advance health disparities research.

The ComPASS program intends to improve health outcomes in communities affected by health disparities and inform social policies, systems, and practices to achieve optimal health for all. NIMHD, the National Institute of Nursing Research (NINR), the National Institute of Mental Health, and the NIH Office of Research on Women's Health, serve as co-chairs of the ComPASS working group that directs major ComPASS activities and funding actions.

In efforts to better understand the impact of structural racism and discrimination in causing and sustaining health disparities, NIMHD, NINR, the National Institute of Diabetes and Digestive and Kidney Diseases, and the NIH Office of Disease Prevention released a funding opportunity for community-engaged intervention re-

[50] *https://pubmed.ncbi.nlm.nih.gov/36265091/; https://pubmed.ncbi.nlm.nih.gov/36265090/; https://pubmed.ncbi.nlm.nih.gov/36194852/.*

search to address structural racism to reduce health disparities among individuals living with kidney disease.[51]

In addition to these select research activities and efforts, NIMHD remains committed to working with HHS partners to ensure that the elimination of health disparities remains a priority within NIH and across the HHS.

TELEHEALTH

Question. The last 3 years have shown the benefits of telehealth services. I have been proud to partner with bipartisan colleagues to protect access to telehealth through initiatives, including the CONNECT for Health Act and my work with Senator Thune last Congress in the Senate Finance Committee on tele-mental health.

Together, we secured an extension of telehealth flexibilities until the end of 2024, allowing your department and Congress to continue to ensure the appropriate flexibilities are made permanent.

I want to thank you for working with us throughout the COVID–19 pandemic to make telehealth accessible and predictable for those who came to rely on it. Still, we have seen disparities in access and quality of care.

How is the administration proactively addressing these disparities and ensuring equitable access to high-quality care?

As HHS winds down the Public Health Emergency (PHE) and we look towards permanent telehealth policies, how is HHS ensuring the collection of appropriate data to identify and prevent disparities in access to telehealth across department programs?

How is HHS ensuring that Transformed Medical Statistical Information System (T–MSIS) data is complete and high quality in order to better assess telehealth modalities that have been rapidly deployed during the pandemic.

Answer. In response to the COVID–19 public health emergency, which is set to expire in May 2023, flexibilities for Medicare telehealth services were issued through legislative and regulatory authorities to increase access to care for patients and providers. The Consolidated Appropriations Act of 2023 recently extended many of these flexibilities through December 31, 2024. Extended telehealth flexibilities include waiving geographic and site of service originating site restrictions so that Medicare patients can continue to use telehealth services from their home and allowing audio-only telehealth services. Additionally, the expanded list of providers eligible to deliver telehealth services is also extended so Medicare beneficiaries can continue to receive telehealth services furnished by physical therapists, occupational therapists, speech language pathologists, and audiologists, as well as receive telehealth services from Rural Health Clinics and Federally Qualified Health Centers through December 31, 2024. If you are interested in drafting legislation to make these waivers permanent, CMS would be happy to provide technical assistance.

Additionally, recent legislative and regulatory changes made several telehealth flexibilities permanent. Federally Qualified Health Centers and Rural Health Clinics can furnish certain behavioral and mental health services via telecommunications technology. Medicare patients can continue to receive these telehealth services in their home as geographic restrictions on the originating site are eliminated for these telehealth services. Certain mental telehealth services can be delivered using audio-only communication platforms, and rural emergency hospitals can serve as an originating site for telehealth services.

CMS would be happy to provide technical assistance on legislation to make these waivers permanent or any other legislation you have to expand access to telehealth.

Data about Medicare fee-for-service beneficiaries who used telehealth services between January 1, 2020 and September 30, 2022, and a Medicare telehealth trends report, are available at *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-service-type-reports/medicare-telehealth-trends.* The data will be updated quarterly.

For Medicaid and CHIP, telehealth flexibilities are not tied to the end of the PHE and have been offered by many State Medicaid programs long before the pandemic. Medicaid and CHIP telehealth policies will ultimately vary by State. CMS encourages States to continue to cover Medicaid and CHIP services when they are delivered via telehealth.

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[51] *https://grants.nih.gov/grants/guide/rfa-files/RFA-DK-23-003.html*

Furthermore, The Health Resources and Services Administration (HRSA) supports the telehealth efforts of the Department of Health and Human Services (HHS) to expand access and improve health outcomes. In particular, HRSA's telehealth programs promote and advance telehealth services in rural and underserved areas. HHS oversees *Telehealth.HHS.gov,* which is a one-stop resource for patients, providers, and States for information about telehealth such as telehealth best practices, policy and reimbursement updates, funding opportunities, and more.

In addition, from September 1, 2021 to August 31, 2022, HRSA's Telehealth Resource Centers provided responses to over 6,000 technical assistance requests to assist providers with implementing telehealth and understanding evolving telehealth policy. Further, HRSA's Telehealth Network Grant Program for emergency services promotes rural tele-emergency services by enhancing telehealth networks to deliver 24-hour Emergency Department consultation services via telehealth to rural providers without emergency care specialists. In the most recent reporting cycle, this program served approximately 13,000 patients.

HRSA's Licensure Portability Grant program is another key resource for increasing access to health-care services. It provides support for State professional licensing boards to work together to reduce the burden on clinicians who provide telehealth services in multiple States. Through this program, the Federation of State Medical Boards developed the Provider Bridge to make it easier for professionals to practice across State lines. Over 145,000 providers registered to use the platform.

The FY 2024 budget request would enable HRSA to continue the HHS Telehealth Hub, support the Telehealth Resource Center Program, fund Telehealth Network Grant Program awards, and recompete the Licensure Portability Grant program, among other efforts to proactively address disparities in access and quality of care.

To identify and prevent disparities in access to telehealth, the budget request would help HRSA to track funding, projects, and data for telehealth services and provide a systematic way of capturing data from programs and activities within HRSA's Office for the Advancement of Telehealth that could help inform overall performance of award recipients and their outcomes.

HEALTH SYSTEMS STRENGTHENING

Question. The President's budget includes significant resources to prepare for future pandemics, including bolstering the surveillance, laboratory, and public health workforce capacities of the U.S. Centers for Disease Control and Prevention (CDC).

The CDC has been clear that a disease threat anywhere in the world is a disease threat everywhere in the world. To that end, the CDC has routinely exchanged scientific expertise and data with other nations, worked alongside other agencies, such as the U.S. Agency for International Development and the State Department, to help strengthen health systems and workforces abroad.

How will investments from the FY24 budget allow the Department of Health and Human Services to contribute to global health systems strengthening as a critical component of pandemic preparedness and global health security?

Answer. As the United States' lead public health agency with decades of experience responding to infectious disease threats, CDC works 24/7 to protect the health and safety of Americans. CDC works on behalf of the American people to save lives around the world, partnering with other nations to prevent, prepare for, and respond to infectious disease threats.

CDC is uniquely suited to use its expertise to support partner governments in building health programs, address health threats, enhance sustainable and country-owned public health systems, and improve health outcomes for all. CDC experts work alongside local, regional, and global partners across their global health portfolio to provide unparalleled expertise in data analytics, disease and vector surveillance, diagnostics, laboratory systems, workforce development, emergency preparedness, and outbreak response.

CDC's global health security efforts help detect and contain outbreaks quickly, before they spread, cause deaths, and disrupt the economy. The most effective and least expensive way to protect Americans from diseases and other health threats that begin overseas is to prevent, detect, and respond to outbreaks before they spread to the United States.

In FY 2024, with additional funding requested in the FY 2024 budget, CDC will continue to:

- Build a strong cadre of international disease detectives through expanded education in surveillance, leadership and management, and emergency response through the Field Epidemiology Training Program (FETP). Helping countries to build up their own robust and self-sufficient public health workforce capable of rapidly handling outbreaks within their region is the foundation for sustainable long-term global health security.
- Work side-by-side with countries and partners to strengthen global public health systems, including developing disease surveillance systems that enable disease detection, tracking and reporting, as well as helping to build more effective public health laboratories, both of which can be leveraged to respond to new and emerging threats globally to contain spread.
- Invest in the public health systems needed for HIV testing, prevention, and control. CDC's HIV-focused investments not only build the foundations for an efficient, sustainable, accountable, and high-impact response to HIV, but also, CDC's unique approach to implementing global HIV programs create platforms that play an essential role in the global response to COVID–19 and many other emerging and re-emerging public health threats.
- Build capacity through collaborations with countries experiencing the highest burden of vaccine-preventable diseases to achieve sustainability of their own immunization programs and surveillance systems.
- Help countries establish public health emergency management programs and Emergency Operation Centers (EOCs) to prepare for, respond to, contain, and recover from public health threats. With additional resources, CDC will scale and adapt its emergency management technical assistance to provide more support across regions and to countries at their national and sub-national levels.
- Enhance workforce training, research and diagnostic development, and innovative approaches to surveillance and early detection for rapid outbreak response across areas such as antimicrobial resistance, food and water-borne diseases, high consequence pathogens (viral hemorrhagic fevers, anthrax, etc.) and vector-borne diseases.
- Ensure the access to vaccines for influenza and meningitis and maintain the primary global resource of respiratory laboratory reagents for outbreaks to support global partners to prevent, detect, and respond to respiratory disease threats.

Additionally, in alignment with the Global Health Security Agenda (GHSA) 2024 vision, CDC will enhance ongoing efforts to strengthen global health security, with a focus on strengthening the core public health capacities that countries need to prevent, detect, and respond to infectious disease threats within their border. Building upon CDC country platforms, CDC intends to expand global health security in-country staffing in 19 intensive support countries to strengthen direct collaboration with ministry of health counterparts and provide more hands-on technical assistance and oversight of CDC-supported global health security programs to accelerate progress.

VIOLENCE INTERVENTION PROGRAMS

Question. Gun shot injuries cost the health-care system between $1 billion to $2.8 billion a year. That is without taking into account other costs surrounding these injuries, such as expenses related to police, jails, lost wages to both victims and perpetrators, and more.

Under President Biden's leadership, we have taken significant steps to reduce violent crime from the American Rescue Plan Act to the Bipartisan Safer Communities Act.

In June 2021, the administration announced the White House Community Violence Collaborative of cities using American Rescue Plan Act (ARPA) funding to strengthen community violence intervention (CVI) programs. Baltimore City took part in this, and thanks to funding from ARPA, the city is investing over $50 million in the coming years on a comprehensive violence prevention strategy. This includes CVI programs, victim support services, case management, emergency housing, and reentry services.

Additionally, the administration has placed a focus on hospital-based violence prevention programs and called on States to expand Medicaid to cover these services. I am proud that Maryland General Assembly passed legislation last year to do so.

I was pleased to see the President's continued call for strong investments in community violence intervention programs in the President's budget.

Can you comment on the importance of also having a public health approach to combat violent crime and the administration's commitment to this work?

Answer. Violence is a widespread public health problem that impacts all of us and has a profound impact on lifelong health and well-being. The causes of violence are complex and require a comprehensive public health approach complementary to a public safety and criminal justice approach. CDC's public health approach focuses on early intervention: engaging people in prevention strategies before they intersect with the justice system, with the goal that they never become a perpetrator or victim of violence.

Like disease, violence is preventable. A public health approach uses the same scientific methods to prevent violence that have been used to prevent disease: collecting data to understand trends and differences across groups, supporting research to develop prevention strategies and to understand what works, and taking steps to ensure that proven strategies are implemented in communities nationwide.

Public health draws on a science base that is multi-disciplinary. It relies on knowledge from a broad range of disciplines including medicine, epidemiology, sociology, psychology, criminology, education, and economics. The public health approach also emphasizes input from diverse sectors including health, education, social services, justice, and the private sector. Collective action on the part of these key collaborators is important for addressing problems like violence.

CDC's National Violent Death Reporting System pools information from multiple data sources into a usable, anonymous database describing the circumstances of homicides and suicides in all 50 States, Washington, DC, and Puerto Rico. CDC also currently funds 9 Injury Control Research Centers studying how to prevent injuries and violence and working with community partners to put those findings into action. Additionally, CDC funds 5 Youth Violence Prevention Centers to target youths in communities with high rates of violence. CDC has developed technical packages specifically for preventing adverse childhood experiences, child abuse and neglect, intimate partner violence, sexual violence, youth violence, and suicide for use as tools for communities, States, territories, and partner groups to plan and implement violence prevention efforts.

CDC has a long history of working with multiple sectors at the community level to improve health and well-being. Public health leads violence prevention efforts in the context of underlying contributors that are beyond the reach of the justice sector, such as substance use, community design, and concentrated poverty. As a result, CDC is well positioned to partner with health-care workers, as well as health organizations such as hospitals, mental and behavioral health systems, insurance providers, schools, and others to prevent violence and mitigate its consequences.

HEPATITIS C

Question. As you know, hepatitis C is a liver infection caused by a blood-borne virus that can lead to acute or chronic infection and cause liver disease and cancer. The number of Americans impacted by hepatitis C has more than doubled since 2013, with more than 2.5 million people nationwide infected. This includes over 100,000 Marylanders. However, over 40 percent of people infected are unaware because they are asymptomatic.

Acute and chronic hepatitis C disproportionately affect American Indian and Alaska Natives, Black Americans, people aged 20 to 39 and 55 to 70, those without insurance, and those with substance use disorders.

The President's budget proposes bold action to eliminate hepatitis C through a new 5-year initiative, the National Hepatitis Elimination Program, which would enhance screening, testing, treatment, and prevention efforts with a focus on the highest-risk populations.

Can you discuss the importance of eliminating hepatitis C and why it is within our reach if we choose to invest in it?

Importance of Eliminating Hepatitis C

Answer. Recent published data indicates that the rates of acute hepatitis C quadruped from 2010 to 2020 among adults aged 20–39 years, mirroring increasing rates of overdose deaths fueled by the Nation's opioid and methamphetamine crises. Untreated hepatitis C can lead to cirrhosis, liver failure, liver cancer, and a wide range of extra-hepatic disease processes, such as cryoglobulinemia, depression, and non-Hodgkin lymphoma which often occur in the absence of clinical liver disease and have extensive direct and indirect costs of their own.

One study estimated that a 2-year delay in access to the direct-acting antivirals (DAAs) can lead to increased hepatitis virus-related morbidity and mortality by 15 percent[52] If these patients are left untreated, up to 30 percent will develop liver cirrhosis after 20 years[53] and of these, about 4 percent of patients a year will develop liver cancer (hepatocellular carcinoma). The cost of treating liver complications such as liver failure and transplantation once the disease has advanced far exceeds the costs related to the treatment of HCV before any of these complications occur.

To put it in context using a 2014 data,[54] the proportion of in-hospital stay involving HCV on average were higher in cost ($13,300 versus $11,600); longer (5.8 versus 4.7 days) and more likely to result in death in the hospital (2.9 versus 2.2 percent of stays) compared to the in-hospital stays that did not involve HCV.

Yet, we have safe and effective oral treatment—DAAs that can cure greater than 95 percent of infected people in 8 to 12 weeks. This cure is one of the most dramatic scientific achievements of the last few decades; however, it is not reaching the population who needs it most. Among those diagnosed, only one-third with private insurance and one-quarter with Medicaid and Medicare received timely treatment (within 360 days of diagnosis).[55]

Why it Is Within Our Reach if We Choose To Invest in it

The United States is currently not on track to reach elimination goals outlined in the Viral Hepatitis National Strategic Plan 2021–2025 due to limited investment in hepatitis C. Reasons for the slow progress include low screening and diagnosis of hepatitis C, the disproportionate impact of hepatitis C on marginalized populations, increasing rates of hepatitis C in young adults due to the opioid epidemic, gaps in linking patients to care, and insurance restrictions to treatment.

Broad access to curative hepatitis C medications: Early treatment with the new DAAs offers savings in medical costs, by offsetting part of the initial expense, and improving health status. In a model analysis published in a study, it estimated that waiting to initiate treatment in advanced stages of HCV will cost billions of dollars in medical and treatment expenditure over decades with little reduction in prevalence.[56] The same study also estimated that by front loading expenditures, to treat all HCV diagnosis regardless of the extent of liver damage will substantially lower prevalence within 10 years. In their estimation, over time, cumulative expenditure declines as transmission, prevalence, and incidence of disease decreases.

Innovative testing development: Using the lessons learned from COVID–19, this initiative would accelerate approval of point-of-care RNA tests that are available outside of the U.S. but not in the U.S., by enlisting the Independent Test Assessment Program, an NIH–Food and Drug Administration partnership. Currently, in the U.S., the tests must be processed at off-site labs, forcing patients to return to obtain the results and further delaying their treatment and care.

Population health and health equity: Investment in hepatitis C elimination is also an investment in addressing equity. Hepatitis C disproportionately affects populations experiencing other health and social inequities, including American Indian and Alaska Native persons, non-Hispanic Black persons, individuals without health insurance, justice-involved populations, and people who inject(ed) drugs. Hepatitis C also disproportionately affects baby boomers many of whom are eligible for Medicare. The prevalence of hepatitis C is at least five times higher among baby boomers than in any other group of adults, and baby boomers account for about 75 percent of hepatitis C cases *(https://www.health.harvard.edu/blog/baby-boomers-and-hepatitis-c-whats-the-connection-2019050116532)*. Moreover, the diagnosis and treatment of hepatitis C in this group would result in significant savings for Medi-

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[52] Stärkel P, Vandijck D, Laleman W, Van Damme P, Moreno C, Blach S, Razavi H, Van Vlierberghe H. *Acta Gastroenterol.* The Disease Burden of Hepatitis C in Belgium: An update of a realistic disease control strategy. Belg. June 2015 78(2):228–32. Accessed on April 26, 2023.

[53] Chopra S. Clinical manifestations and natural history of chronic hepatitis C virus infection. Waltham, MA: UpToDate; 2014. Accessed on April 26, 2023.

[54] Ngo-Metzger Q (AHRQ), Mabry-Hernandez I (AHRQ), Heslin KC (AHRQ), Weiss AJ (IBM Watson Health), Mummert A (IBM Watson Health), Bierman AS (AHRQ). Characteristics of Inpatient Stays Involving Hepatitis C, 2005–2014. HCUP Statistical Brief #232. November 2017. Agency for Healthcare Research and Quality, Rockville, MD, *https://hcup-us.ahrq.gov/reports/statbriefs/sb232-Hepatitis-C-Hospital-Stays-Trends.pdf.* Accessed on 04/26/23.

[55] *https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7132e1-H.pdf.*

[56] Van Nuys K, Brookmeyer R, Chou J et al. Broad Hepatitis C Treatment Scenarios Return Substantial Health Gains, But Capacity Is a Concern. *Health Affairs* 34, no.10 (2015):1666–1674 doi: 10.1377/hlthaff.2014.1193. Accessed on April 26, 2023.

care as it would identify those with long-duration chronic disease, who are at highest risk for the most advanced forms of liver disease.

Lessons learned from tested models: The National Hepatitis C Elimination Program was developed by taking lessons learned from innovative programs from across the U.S., including from the States of Louisiana and Washington, the Cherokee Nation, the Veterans' Health Administration (VHA), and the Federal Bureau of Prisons. For example, from 2013 to March 2021, the VHA screened >85 percent of its population for hepatitis C. Of the ~168,000 VHA patients diagnosed with hepatitis C, 90 percent have been treated, with a ~90 percent cure rate. Model pilot programs across the country have provided the evidence base for nationwide scale-up of successful strategies. Investment in these strategies will prevent needless suffering for patients and their loved ones.

It is estimated that the National Hepatitis C Elimination Program will diagnose 92.5 percent and cure 89.6 percent of all people living with hepatitis C within 5 years if we act now.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

FUNDING FOR CHILDREN'S HOSPITALS GRADUATE MEDICAL EDUCATION

Question. The Children's Hospitals Graduate Medical Education (CHGME) program is vital for training the next generation of pediatricians. The children's hospitals that receive this funding train about half of all our Nation's pediatricians and a majority of pediatric specialists. Despite the program's success, CHGME has consistently received far less Federal funding than provided to graduate medical education for adult providers. The President's budget for FY 2024 proposes $385 million for CHGME—the same Congress appropriated for FY 2023. Our Nation is facing a health-care workforce crisis, and we lack the pediatric specialty providers necessary to care for our children. I am concerned that the lack of increase in funding further jeopardizes the ability for our country to maintain a robust pediatric workforce.

Will you work with me to ensure that we prioritize CHGME moving forward to protect children's access to care?

Answer. Thank you for your support of the Children's Hospitals Graduate Medical Education (CHGME) program. We recognize the importance of having an adequate number of pediatric providers and ensuring children have ongoing access to the specialized care they need across provider settings. This important program supports pediatric providers and promote access to health care.

The FY 2024 President's budget proposal for the CHGME program would enable HRSA to continue to support resident physician full-time equivalent placements training in free-standing children's hospitals. We look forward to working with Congress to provide sufficient funding to strengthen the pediatric workforce and expand access to care for children through the CHGME program.

ACCESS TO VACCINES FOR ADULT MEDICAID BENEFICIARIES

Question. When Congress passed the Inflation Reduction Act, it included legislation I sponsored requiring access to all recommended vaccines at no cost for low-income adults who are Medicaid beneficiaries, regardless of what State they live in. The President's FY 2024 budget supports CMS activities to implement this benefit.

Could you share an update on CMS's implementation of section 11405?

How is CMS assisting States in getting ready for the October 1, 2023, effective date for these changes to adult immunization coverage in their Medicaid programs?

Answer. The Inflation Reduction Act addresses longstanding gaps by requiring coverage of vaccinations for adults under Medicaid and CHIP. Starting October 1, 2023, most adults enrolled in Medicaid or CHIP will have coverage of approved adult vaccines recommended by the Advisory Committee on Immunization Practices, and the administration of those vaccines without cost sharing. Increasing access to recommended vaccines is an effective strategy to improve the health of Medicaid adults and, more broadly, the health of communities. CMS is committed to working closely with States to ensure they have the tools and resources they need to ensure they are able to meet these new requirements.

IMPLEMENTATION OF THE TECHNICAL RESET TO ADVANCE THE INSTRUCTION OF NURSES (TRAIN) ACT (SECTION 4143 OF THE CONSOLIDATED APPROPRIATIONS ACT FOR FISCAL YEAR 2023)

Question. Congress included bipartisan legislation I introduced with Senator Capito, the TRAIN Act, as section 4143 of the Consolidated Appropriations Act (CAA) for FY 2023, which was signed into law in December. This provision ensures eligible hospital-based nursing schools and allied health training programs be held harmless for excess funds inadvertently disbursed by the Centers for Medicare and Medicaid Services (CMS) as part of Medicare Advantage Nursing and Allied Health Professional Education Payments in past years. Because this legislation was not enacted until after most of these overpayments had been clawed back, the Centers for Medicare and Medicaid Services (CMS) must now repay these funds to the affected schools.

A March 16, 2023, CMS Transmittal Notice (Transmittal 11904, Change Request 13122), set forth instructions to implement this section, including a complicated formula to calculate the payments owed to schools. However, it is my understanding that a number of schools that have used these instructions to determine what they will get repaid have found that they will only be reimbursed between 29 percent and 37 percent of what was clawed back by CMS. That is not what was intended. My office and Senator Capito's office worked closely with CMS on this provision. Our intention was to ensure that all schools be held harmless—that they have all of the clawed-back funds returned to them.

How did CMS determine the formula for the repayments required under section 4143 of the CAA?

How does CMS intend to ensure these schools are held harmless for the overpayments, as per congressional intent?

Answer. CMS has recently been made aware of this issue, and I know that folks are working to clarify any confusion. CMS is committed to implementing this provision of the CAA correctly.

ACCESS TO CHILDHOOD VACCINES AT PHARMACIES THROUGH THE END OF FISCAL YEAR 2024

Question. Every year, thousands of Ohioans turn to trusted pharmacists in their communities to receive vaccinations. Vaccines are essential in protecting and preserving the health of communities, and health equity depends on vaccine access. Ohioans now expect that they can access vaccines at their local pharmacies, particularly in minority and underserved communities, where the pharmacy may be the easiest, most convenient place to receive vaccinations. The Federal PREP Act included the authority for pharmacists and pharmacy technicians to perform all vaccines recommended by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices for children ages 3–18 until October 1, 2024.

Could you confirm that HHS intends to maintain these authorizations until October 1, 2024?

Answer. If a need is determined, the Secretary is able to amend coverage post the duration of a declared Public Health Emergency for PREP Act coverage for select groups of providers. At the time of the hearing, there are conversations around extending coverage.

HOME RESPIRATORY THERAPY MEDICARE COVERAGE AFTER THE PUBLIC HEALTH EMERGENCY

Question. I understand that CMS plans to continue Medicare coverage without additional documentation for patients who began home respiratory therapy during the COVID–19 pandemic once the public health emergency is ended. Will CMS provide guidance to ensure that these patients continue to receive these services without interruption?

My understanding is that CMS contractors rely on physician notes in the medical record as the only source for determining medical necessity for home respiratory therapy. CMS's data indicates that contractors deny the majority of these claims even when the patient qualifies for services. Though CMS has developed a standardized template form that physicians could use to ensure they are providing the information the contractors need to review claims, CMS does not require its contractors to adopt this approach. This puts patient access to home respiratory therapy at risk. Could you explain why CMS has not implemented a requirement to use this stand-

ardized template and whether the contractors will be required to use this type of documentation when the public health emergency ends?

Answer. CMS recognizes that it is important for stakeholders to understand how CMS anticipates performing medical review after the Public Health Emergency (PHE) has ended. During the PHE, flexibilities were applied to medical reviews across claim types. For certain DME items, this included the non-enforcement of clinical indications for coverage. Since clinical indications for coverage were not enforced for certain DME items provided during the PHE, once the PHE ends CMS plans to primarily focus reviews on claims with dates of service outside of the PHE, for which clinical indications of coverage are applicable. CMS may still review these DME items, as well as other items or services rendered during the PHE, if needed to address aberrant billing behaviors or potential fraud. The HHS-Office of the Inspector General may perform reviews as well. All claims will be reviewed using the applicable rules in place at the time for the claim dates of service. As the PHE comes to an end, CMS will continue to work with stakeholders to ensure beneficiary access.

CMS has designed printable clinical templates and suggested clinical data elements (CDEs) to assist providers and IT professionals with data collection and medical record documentation to support coverage of selected items and services. These templates and suggested CDEs are intended to help reduce the risk of claim denials and ensure that medical record documentation is more complete. Specifically, CMS released a clinical template and suggested CDEs for ordering home oxygen therapy. The template is designed to assist a clinician when completing an order for home oxygen therapy to meet requirements for Medicare eligibility and coverage. The template meets the requirements for both the Detailed Written Order and Written Order Prior to Delivery, and is available to the clinician and can be kept on file with the patient's medical record or can be used to develop an order template for use with the system containing the patient's electronic medical record. While completing the Home Oxygen Therapy Order Template does not guarantee eligibility and coverage, it does provide guidance in support of home oxygen therapy equipment and services ordered and billed to Medicare. CMS has also released clinical templates and suggested CDEs for documenting the face-to-face encounter for Medicare home oxygen therapy eligibility and coverage and for documenting information regarding home oxygen therapy laboratory test results to meet requirements for Medicare coverage for home oxygen therapy. The home oxygen therapy templates and suggested CDEs are available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Electronic-Clinical-Templates/template-and-CDE-downloads.*

At this time, use of these templates and suggested CDEs is voluntary; however, we welcome provider and stakeholder feedback and suggestions on how to improve all our templates and CDEs.

QUESTIONS SUBMITTED BY HON. MICHAEL F. BENNET

ANTIMICROBIAL RESISTANCE

Question. According to the Centers for Disease Control and Prevention (CDC), in just the first year of the COVID–19 pandemic, U.S. hospitals experienced a 15-percent increase in both infections and deaths from drug-resistant bacteria. To prepare for the next pandemic or superbug, we need to address the broken drug pipeline. My legislation with Senator Young, the PASTEUR Act, which we've talked about, would incentivize new antimicrobial drug development at a small fraction of the cost that antibiotic resistance imposes on American patients and consumers and will jumpstart the next generation of drugs that will make that possible. I appreciate that HHS includes a $9 billion proposal in mandatory funding for a subscription model to incentivize the development of novel antibiotics.

Can you tell me more about the administration's proposal for antimicrobial pull incentives included in your budget to tackle this problem?

Can we work together to get it passed this year as part of the Pandemic and All Hazards Preparedness Act (PAHPA) reauthorization?

Answer. To mitigate the threat of antimicrobial resistance, the U.S. Government is taking a multipronged approach that includes surveillance, prevention, stewardship and innovation of new products to treat and prevent infections. However, the value of reduced morbidity, mortality, and disease duration is not currently cap-

tured by many antimicrobial products' current market value, and many large pharmaceutical companies have stopped investing in new antimicrobial products. The majority of products currently in clinical trials are being developed by small companies without the infrastructure and economies of larger firms—these small companies face difficulty self-funding commercialization and Phase 4 studies and the development pipeline is at significant risk of falling short of current and future needs.

The FY 2024 President's budget mandatory proposal is intended to create an incentive for a more robust pipeline of novel antimicrobial products while enhancing stewardship. The proposal would allow for contracts to be established between sponsors of selected products and HHS, valued at between $750 million and $3 billion, paid in annual increments for up to 10 years or through the length of protection or exclusivity. The proposal would establish an interagency committee to identify infections for which new antimicrobial drugs are needed and to develop regulations outlining favored characteristics and assigned monetary values, an application process for product sponsors, how contracts would be established, and how characteristics would be weighed. The proposal addresses patient access to these products by requiring assurances from sponsors regarding supply chain and supply adequacy. Building on the strength ongoing programs like CARB–X, this proposal would allow the HHS Secretary to work with private payors and global partners to participate in a similar mechanism.

We have appreciated the opportunities to provide technical assistance on previous versions of the PASTEUR Act and would be happy to do so in the future. Similarly, we look forward to engaging with you on reauthorization of PAHPA.

Question. The COVID–19 pandemic has intensified the misuse and overprescribing of antibiotics which has increased the spread of antimicrobial resistance in the United States and around the world. Recent examples of resistance include the eye drop recall and the alarming spread of Candida auris—a deadly fungal infection—in hospitals. Diagnostic tests are not adequately being utilized prior to the prescription of an antibiotic.

How will HHS help support efforts to decrease empiric antimicrobial therapy?

What kinds of policies might you propose to help address stewardship and improve the use of diagnostic tests?

Answer. Through the 2020–2025 National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), HHS is working with Federal, State, and local partners to implement a suite of complementary actions to combat antibiotic resistance. The National Action Plan for CARB includes two goals particularly relevant to appropriate antibiotic use. Goal 2 supports antibiotic stewardship, which guides appropriate antibiotic use and thereby reduces the opportunities for resistance to develop. Goal 3 supports the development and appropriate use of diagnostic tests to provide the right antibiotic at the right time in the right dose.

CDC, AHRQ, and CMS support the development, evaluation, and implementation of high-quality antibiotic stewardship programs across a variety of health-care settings. CDC's Core Elements of Antibiotic Stewardship offer providers and facilities a set of key principles to guide efforts to improve antibiotic use and, therefore, advance patient safety and improve outcomes; this guidance has been tailored for hospitals, outpatient settings, nursing homes, and resource-limited settings. The AHRQ Safety Program for Improving Antibiotic Use was developed to help clinicians in hospitals, doctors offices, and long-term care apply the Four Moments of Antibiotic Decision Making and concepts derived from the Comprehensive Unit-based Safety Program (CUSP) to improve antibiotic stewardship by selecting the optimal antibiotic regimens, routes of administration, and durations. AHRQ and partners assessed the Safety Program's impact on patient safety culture and antibiotic prescribing practices across a total of 1,304 participating sites throughout the United States, including 476 units from 402 acute care hospitals, 439 long-term care facilities, and 389 ambulatory care centers. Results indicate that the Safety Program aided participating sites to develop and enhance their Antibiotic Stewardship activities and to reduce antibiotic prescribing. At the end of each intervention, a toolkit was developed that contained materials developed for each cohort as well as additional information to allow sites that did not participate to recreate the Safety Program at their own facilities. CMS works closely with CDC in the development of its antibiotic stewardship program requirements as well as the interpretive guidelines that support these regulations. Through its published rules and guidance, CMS has strongly encouraged health-care facilities to use CDC's Core Elements of Antibiotic Stewardship as a basis for establishing antibiotic stewardship programs

in Medicare-participating facilities. In 2022, CMS published updates to interpretive guidance for hospital requirements under the Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction Final Rule, which revised the regulatory requirements for hospitals related to infection prevention and control and antibiotic stewardship programs.

CDC, AHRQ, NIH, and FDA are working under the National Action Plan for CARB to fund research to better understand the appropriate use of diagnostic testing to address bacterial or fungal infections, and to use that evidence to promote the appropriate use of new and existing diagnostics that determine the presence, severity, or antimicrobial susceptibility or resistance of bacterial or fungal infections in human clinical care. For example, CDC used data from their Gonococcal Isolate Surveillance Project to guide updates to the 2020 gonorrhea treatment recommendations published in the Morbidity and Mortality Weekly Report. These data were used in determining recommended treatment regimens and for test-of-cure testing recommendations.

HHS agencies continue to monitor the implementation of these activities to understand their impact and develop additional proposals to support appropriate antibiotic use, including through improved diagnostic testing. For example, the FY 2024 President's budget includes a proposal for CDC to advance laboratory science through shortening the time to develop diagnostic tests, evaluating and implementing new detection technologies, increasing the number of tests results available per day, ensuring the quality of test results, improving laboratory safety and efficiency, and developing uniform quality practice standards for CDC and other public health labs. The FY 2024 President's budget request for AHRQ includes an investment in research grants and contracts to explore how to address different diagnostic safety challenges and create the infrastructure for continued research to prevent errors and delays in diagnosis.

DIAGNOSTIC TESTING

Question. Due to the Protecting Access to Medicare Act of 2014 (PAMA), laboratory diagnostics and point-of-care testing reimbursement has experienced continued downward reimbursement, reducing common diagnostic testing reimbursement by up to 10 percent year over year. Without congressional intervention, reimbursement reductions are scheduled to continue under PAMA.

Considering the critical role diagnostic testing has in our health-care industry and in combating the COVID–19 pandemic, how do you plan to address reimbursement rates to maintain long-term access to testing?

Answer. The Department shares your desire to protect Medicare beneficiaries' access to laboratory testing services and provide stakeholders with transparency and predictability around reimbursement for laboratory tests. Congress enacted PAMA with a phase-in for reductions such that for CY 2017 through CY 2019, the reduction cannot be more than 10 percent per year, and for CY 2020 through CY 2022, the reduction cannot be more than 15 percent per year. Congress subsequently modified PAMA in legislation four different times to maintain the payment amount for a clinical diagnostic laboratory test for CY 2021 through CY 2023 at the payment amount for CY 2020 and to limit reductions to 15 percent per year for CY 2024 through CY 2026. If Congress wants to make further modifications to the phase-in of reductions under PAMA, we would be happy to provide technical assistance on legislation you draft.

Question. When the Public Health Emergency ends on May 11th, many private payers have indicated they will no longer cover and reimburse COVID–19 tests done at point of care—meaning in pharmacies, urgent care centers and physician office labs.

What is your plan to work with private payers to ensure all Americans have access to point of care COVID–19 testing?

Answer. The requirement for group health plans and health insurance issuers offering group or individual health insurance coverage to cover COVID–19 tests without cost sharing, both for over-the-counter and laboratory tests, will end at the end of the Public Health Emergency (PHE). However, plans and issuers are encouraged to continue to provide this coverage, without imposing cost sharing or medical management requirements, after the PHE ends.

Question. Currently, the Food and Drug Administration (FDA) does not have regulatory oversight of laboratory diagnostic tests, leaving patients at risk of faulty

high-risk tests and increasing the potential of inaccurate diagnosis and treatment. I've collaborated for many years with the FDA and stakeholders on the Verifying Accurate, Leading-edge IVCT Development (VALID) Act, which would create a risk-based regulatory framework at the FDA to oversee these tests. I'm glad that the FDA plans to move forward in their current authority to draft regulations, but I'm also surprised that the FY 2024 HHS Budget did not include the VALID Act as a policy priority.

Under which authorities do you believe that FDA can promulgate regulations on diagnostic test oversight?

Answer. In vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). FDA has authority to promulgate regulations for IVDs under the agency's general rulemaking authorities and statutory authorities relating to devices under the FD&C Act.

Question. Can you provide a timeline of when the public should expect proposed regulations or sub-regulatory guidance?

Answer. At this time, we cannot provide a timeline.

Question. Do you and the FDA support the VALID Act and can you explain why it wasn't included in the budget?

Answer. Yes. FDA supports legislation to establish a modern regulatory framework for diagnostic tests under the Federal Food, Drug and Cosmetic Act, such as the VALID Act. The legislative proposals in the budget FY 2024 summary are legislative proposals originating from FDA, whereas VALID is a legislative proposal originating from Congress. Diagnostic test reform remains one of FDA's top legislative priorities for reauthorization of the Pandemic and All-Hazards Preparedness Act. A modern oversight framework that is specifically tailored to in vitro diagnostics will help us position ourselves for the future—whether it is preparing for the next pandemic or realizing the full potential of diagnostic innovation. The past few years have highlighted the critical need for a modern regulatory framework that strikes the appropriate balance to promote innovation while also ensuring patients have access to accurate and reliable diagnostics. FDA stands ready to continue working with Congress on diagnostic testing reform.

UNACCOMPANIED CHILDREN

Question. For nearly 10 years, Democratic and Republican administrations have failed to care for unaccompanied children who come to the United States. I've continued to raise concerns, when they have been wrongfully detained under *Flores* or held in closed cells intended for medical isolation. As of this week, nearly 8,000 children are under HHS care, but there are likely tens of thousands more who are out of HHS custody in the United States and face high risk of trauma and health conditions. In the past three budgets, HHS has requested the same amount, $5.5 billion, but, as far as I can tell, we haven't seen improved outcomes and care for these children. In fact, we're now hearing reports that employers are exploiting them to work in meat packing facilities and other factories, which is shameful.

What is HHS meaningfully doing to strengthen care for kids in their custody?

Answer. HHS's Administration of Children and Families' (ACF) Office of Refugee Resettlement (ORR) is dedicated to ensuring the safety and well-being of children in our care from the time they enter our custody following a referral from the Department of Homeland Security (DHS) or other Federal entity until they are safely placed with a vetted sponsor.

ORR has made and continues to make significant investments in acquiring additional bed capacity to provide a safe environment and place children in the least restrictive setting appropriate for their needs. Since 2021, ORR has nearly doubled its standard network bed capacity, and has achieved this by safely bringing back online beds that were previously impacted by COVID–19 restrictions, partnering with current providers to provide additional bed capacity through recipient-initiated supplements, engaging non-governmental organizations and governmental jurisdictions to identify ways to expand bed capacity, and publishing notices of funding opportunities (NOFOs) for licensed or soon-to-be-licensed programs.

While ORR's custodial responsibilities end when a child is released from ORR care, ORR provides post-release services (PRS) for children and sponsors who would benefit from ongoing connections to community services. ORR also conducts follow-up by phone with both the sponsor and child after the child is released from ORR

care to help continue and facilitate a child's successful transition into their community and encourage permanency.

ORR is also expanding PRS tailored to the unique needs of each child. In FY 2022, ORR more than doubled the rate of children provided with PRS, serving more than 40 percent of children compared to just over 20 percent in FY 2021. ORR has been developing and progressing with the implementation of expanded PRS, including a pilot project in September 2022. This full rollout is anticipated to start January 1, 2024, and expanded PRS will consist of three levels of services, which may be elevated at any time, ranging from Level 1 (consisting of three check-ins) to Level 3 (involving intensive, in-person case management). Safety and Well-Being Calls will be categorized under "Level 1 Services," where three in-person or virtual comprehensive check-ins are conducted with the unaccompanied child and sponsor at 7 days, 14 days, and 30 days following release from ORR care.

ORR continues to expand access to legal representation to children, consistent with the requirements of law. In FY 2021, 13,579 children received direct representation in their immigration proceedings through ORR's contractor, and in FY 2022, this number increased to 16,299 children. Over the coming year, ORR plans to reach a historic expansion in direct representation by funding an additional 15,000 direct representation cases. ORR will achieve this by bringing on new legal service providers in high release counties, where there has not historically been immigration legal representation. This includes intensive training and language support for these new providers, which will help build long-term capacity in the field. Simultaneously, ORR is working to increase funding and capacity for direct legal representation for unaccompanied children, with the goal of ensuring that all children in ORR care and discharged children can access legal representation by the end of calendar year 2027.

In addition to expanding legal representation through the current and new contracts, ORR developed a legal services recruitment pipeline project in order to build capacity in the field and ensure that ORR can continue to meet increased demand for legal services year after year. ORR estimates that this project will lead the recruitment of over 4,000 new attorneys entering the immigration field over the next 5 years, with more than 100,000 unaccompanied children matched with representation under this program.

Question. How does HHS plan to improve their follow-up procedures for kids who are no longer in HHS custody to ensure they aren't being exploited?

Answer. HHS recognizes that unaccompanied children face unique challenges that require a whole-of-government response, which is why we engage with different entities across the Federal Government and nationally in support of efforts to ensure the safety and well-being of unaccompanied children. Any child being in a dangerous or exploitative situation is cause for concern, and HHS takes action to provide services and referrals, including reports to law enforcement and child welfare authorities, as appropriate, as well as to examine our processes and policies to identify and address any gaps.

On February 28, 2023, ACF finalized a Memorandum of Agreement (MOA) between ORR, the Office on Trafficking in Persons, and the National Center for Missing and Exploited Children where all parties share information on a weekly basis for the purpose of assisting one another to locate and assess the safety and well-being of unaccompanied children, former unaccompanied children, and foreign national minors who are reported missing or who may be subject to trafficking or exploitative activity. The MOA helps bridge data-sharing gaps and allows ORR to receive information on potential trafficking trends or concerns with potential sponsors and document this critical information in ORR's official system of record, the Unaccompanied Children Portal, to inform ORR's case management considerations. The MOA also advances priority actions as outlined in the National Action Plan to Combat Human Trafficking, recommendations articulated by the National Advisory Committee on the Sex Trafficking of Children and Youth in the United States, and recommendations articulated by members of the National Human Trafficking Training and Technical Assistance Center's Human Trafficking Leadership Academy.

ORR's interagency efforts to conduct due diligence to prevent and respond to the child labor issue is ongoing. The recent MOA between the Department of Labor's (DOL) Wage and Hour Division and ACF, formalized on March 23, 2023, expands our collaborative work and will help to identify communities and employers where children may be at risk of child labor exploitation; aid investigations with information that could help identify circumstances where children are unlawfully employed;

and further facilitate coordination to ensure that child labor trafficking victims or potential victims have access to critical services. HHS and DOL are also distributing new materials and trainings to provide information to children and sponsors about child labor laws in the United States so that children and sponsors understand the laws on labor rights and restrictions.

In addition to increasing our efforts to better inform children, sponsors, and providers about child labor exploitation, ORR continues to improve how it prevents and responds to child labor issues, including ensuring follow-up calls to children with reported safety concerns to the ORR National Call Center (ORRNCC) and sharing information with children about where and to whom their concern was reported. ORRNCC is a valuable resource that is available 24 hours, 7 days a week, where children, sponsors, family members, legal service providers, Child Advocates, and other members of the community can request assistance, report concerns, and be referred to essential community services to promote success and community permanence on the child's behalf. ORRNCC is required to document and report any safety concern, in accordance with mandatory reporting laws, State licensing requirements, Federal laws and regulations, and ORR policies and procedures to ORR, as well as to the appropriate local law enforcement agency, State and local child protective services, or both.

Lastly, ORR has invested in proactive program quality and program management capabilities with child safety and well-being at its core. ORR created two new teams that aid its efforts to provide holistic support to children while in care and post-release: the Child Services Team and the Program Quality Team. The Child Services Team is responsible for continuing existing work that ensures children receive legal support; child advocacy, as needed; post-release services; and language access. This team also leads efforts to build out ORR's provision of appropriate education and vocational supports for all children in care as well as to engage with internal and external stakeholders to advance policies and procedures that prioritize child protection and family preservation for unaccompanied children, their caregivers, and broader communities. The Program Quality Team was established as a means of working continuously and collaboratively to use child welfare best practices to achieve and sustain improvement in services and outcomes for the children, youth, and families we serve. Under this team, ORR works on continuous quality improvement and emergent issues, internal monitoring and oversight of the care provider network, prevention of child abuse and neglect, and care provider engagement and performance management. Expanding the breadth of services post-release starts with internal accountability and sustainable program models to ensure the Unaccompanied Children Program continues to develop the tools it needs to serve the best interests of children.

CHILD WELFARE

Question. Just over 5 years ago, in February 2018, Chair Wyden and I successfully led the effort to pass the Family First Prevention Services Act (FFPSA). This legislation provided families with greater access to mental health services, substance use treatment, and/or parenting skills courses so that children, who might normally be placed in out-of-home care, could remain with their families at home. Since then, many States have taken up the option to shift their child welfare systems to better support prevention and reduce the number of kids removed form their home. Currently, there are 39 approved State, jurisdiction, and Tribal title IV–E prevention program plans to date have identified 13 well-supported, 5 supported, and 5 promising evidence-based programs (EBPs) and services for reimbursement in the delivery of prevention services.

Can you provide an update on State implementation of the FFSPA and highlight the resources available for States that want to amend their State child welfare programs?

Answer. States and Tribes are in various stages of development and implementation of title IV–E prevention plans. Currently, 42 jurisdictions have approved title IV–E prevention program plans. The U.S. Department of Health and Human Services (HHS) has made various technical assistance (TA) documents and toolkits available that can support jurisdictions' prevention planning and implementation. For example, the HHS Office of the Assistant Secretary for Planning and Evaluation has developed a toolkit about title IV–E prevention. Similarly, Children's Bureau's Center for States provides TA support. We understand that developing a comprehensive prevention plan takes time. Additionally, we know that many agencies continue to manage unprecedented workforce and leadership challenges and changes. Since the

passage of FFPSA, the Center for States has provided customized support to State and territorial child welfare agencies developing and implementing prevention plans. To support these efforts, the Center for States provides a continuum of TA to jurisdictions, including the following:

- Providing tailored, expert coaching and consultation through direct TA around prevention program plan development and implementation and related efforts;
- Supporting peer groups that allow child welfare professionals to virtually connect with colleagues working in similar practice areas or on common initiatives;
- Developing and disseminating resources, including publications and tools on prevention-focused systems and FFPSA;
- Conducting needs assessments related to prevention service array (identifying candidates, needs, and analyzing service array gaps), including providing support to States in selecting appropriate prevention interventions;
- Refining internal processes related to in-home services and provider relationships, such as effective in-home case planning and service identification in partnership with families, ongoing safety and risk monitoring, collaboration and coalition building among partners, workforce support, training, and coaching;
- Conducting strategic planning related to prevention program plan development (including enhancing key partnerships related to prevention) as well as efforts to come into alignment with the National Model Foster Family Home Licensing Standards; and
- Ensuring children and youth are placed in settings that align with their needs, reducing the use of congregate care, and helping States conduct root cause analyses and strategic planning related to changing the culture and climate of their agencies, including shifts toward a more prevention-based model.

Question. Are there increased resources that the Administration for Children and Families needs to improve or encourage implementation of the FFSPA?

Answer. Our FY 2024 budget proposes to build on the progress noted above by including a suite of proposals to enhance the title IV–E Prevention Services Program. Our proposals would increase Federal reimbursement for the program and, as you note, beginning in FY 2024, make permanent a temporary provision enacted through the Family First Transition Act requiring States to spend at least 50 percent for services that meet the supported and/or well-supported practice criteria (rather than applying that spending requirement to programs meeting the well-supported practice criteria only). The proposal also would allow up to 15 percent of a State's funding to be spent on services that do not currently meet the clearinghouse's evidence standards. As a condition of this, States would be required to evaluate these services and would need to either modify the service (and reevaluate the modified service) or cease using title IV–E funding for it if the evaluation shows the service to be ineffective. Combined, these proposals would further incentivize States to invest and scale up their IV–E prevention programs while giving States the flexibility to provide each child and family with the most appropriate and tailored services for their needs. The proposal also includes $10 million per year to enhance the operation of the Clearinghouse and to support timely evaluations and technical assistance on evaluations to develop additional evidence-based programs. Finally, the proposal includes a change in the law to allow Tribes participating in the program through a State-Tribe title IV–E agreement to use interventions adapted to the culture and context of Tribal communities, exempting them from the requirement to use only programs rated as well supported, supported, or promising. (Currently, this flexibility is available only to Tribes operating the title IV–E Prevention Services program directly, rather than through a State-Tribe agreement.) The proposal would also specifically allow States to use cultural adaptations of interventions that have been rated by the clearinghouse as promising, supported, or well-supported.

QUESTIONS SUBMITTED BY HON. ROBERT P. CASEY, JR.

Question. The Health and Human Services FY 2024 Budget in Brief includes a proposal to "revise the special focus facility program" in the section on Survey and Certification. Can you detail how the special focus facility program will be revised?

Please include a breakdown of how the Survey and Certification funding, including the proposed increase, will address the special focus facility program.

Answer. The President's Fiscal Year 2024 budget requests $566 million for Survey and Certification, an increase of $159 million or 39 percent above FY 2023 enacted. Twenty million of this request supports specific CMS actions outlined in the White House 2022 fact sheet aimed at improving safety and quality of care in the Nation's nursing homes. This includes addressing the backlog of complaints, revising the special focus facility program, and expanding financial penalties for poor-performing facilities.

CMS's Special Focus Facility (SFF) program identifies the poorest-performing nursing homes in the country for increased scrutiny in an effort to immediately improve the care they deliver. The SFF program currently requires more frequent compliance surveys for program participants, which must pass two consecutive inspections to "graduate" from the program. As noted in the White House Fact Sheet, Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes, the SFF program will be overhauled to more quickly improve care for the affected residents, including changes that will make its requirements tougher and more impactful. CMS will also make changes that allow the program to scrutinize more facilities, by moving facilities through the program more quickly. Facilities that fail to improve will face increasingly larger enforcement actions, including termination from participation in Medicare and Medicaid, when appropriate. Additionally, on October 21, 2022, CMS released a SFF Program policy memo revising the SFF program to protect and improve the quality of care that residents living in these facilities receive. These changes aim to address facilities remaining in the SFF program for too long and facilities with "yo-yo" noncompliance after graduating. Additionally, because of the importance of nursing home staffing, CMS is informing State Survey Agencies to consider a facility's staffing levels data when selecting SFFs from the SFF candidate list.

Question. In February, the United Cerebral Palsy and the American Network of Community Options and Resources (ANCOR) published a report entitled "The Case for Inclusion" that contained a number of alarming findings about the home-care workforce. The report documents families and individuals in need of these services being turned away by providers because they do not have sufficient staff. It also documents providers closing complete programs because of lack of staff. What efforts is HHS taking to both improve the recruitment and retention of workers providing home and community-based services?

Answer. Within HHS, the Administration for Community Living (ACL)'s budget request for FY 2024 seeks to strengthen both. With respect to the paid direct-care workforce, HHS/ACL is currently funding the development of a Direct Care Workforce Center *(https://acl.gov/news-and-events/announcements/acl-launches-national-center-strengthen-direct-care-workforce)* through which State, private, and Federal entities involved in the recruitment, training and retention of direct-care workers can access model policies, best practices, training materials, technical assistance, and learning collaboratives. Funding in FY 2024 will support continued operations of the Center and establish demonstration grants to develop partnerships across State aging, disability, Medicaid, and labor/workforce agencies and with aging, disability, labor and provider stakeholders to implement recruiting, retention, and training approaches to strengthen the direct-care workforce at State and local levels. The Direct Care Workforce Center is designed to catalyze change at a systems level that will address the insufficient supply of trained direct care workers, including Direct Support Professionals to assist individuals with disabilities to become and stay employed and live in the community, promote promising practices at all levels of the service system, and improve data collection to enable a full understanding of the workforce issue. The anticipated outcomes of this effort, include but are not limited to:

- Increasing the availability and visibility of tools and resources to attract, train and retain the direct care workforce in quality jobs where they earn livable wages and have a voice in their working environment and have access to benefits and opportunities for advancement; and
- Increasing the number of States that develop and sustain collaborations across State systems and workforce agencies to implement strategies that will improve the recruitment, retention, and advancement of high-quality direct-care workforce jobs.

Question. Late last year, CMS proposed that Medicare cover seat elevation systems for people with disabilities. The final approval of this policy will mean better

physical, emotional, and social development for thousands of people who have serious physical limitations. CMS has not, however started the process to cover standing systems for people with disabilities. Please provide us with an update on the process for considering and approving standing system coverage by Medicare.

Answer. In February 2023 CMS published a proposed National Coverage Determination (NCD) to expand Medicare coverage for power seat elevation equipment for individuals with a Group 3 power wheelchair. The public comment period closed on this NCD last month. CMS plans to consider standing equipment in a separate future national coverage analysis. I'm happy to stay in touch with you as CMS undertakes this process.

Question. I appreciate President Biden's focus on lowering drug costs for all Americans. As you know, Pennsylvania is home to a vital life sciences industry. It is important that we ensure that research and development remain strong, while reducing costs. How are you working to maintain the development of new therapeutics?

Answer. The ecosystem in which FDA operates is rapidly evolving, with unprecedented scale and investment in drug (including biologics) development, increasing complexity in clinical trial designs, and expanding availability of drug development tools. To adapt to these rapid changes, the agency continues to modernize and enhance our core review processes to assure the safety and effectiveness of treatments are meeting the medical needs of the American public most effectively and efficiently. FDA is engaging with industry and other regulatory counterparts in meetings and workshops to share information about novel manufacturing approaches.

FDA aims to grow the scientific expertise of agency staff and foster drug development and approval, particularly in areas of unmet medical need (*e.g.,* disease areas that lack approved treatment options). Through scientific leadership we hope to:

- Develop strategic approaches to address substantive issues in drug development, particularly in areas of unmet medical need;
- Deepen review staff's scientific expertise and support staff's professional development to continually enhance efficient and effective regulatory decisions, informed by the most current science in drug development; and
- Encourage the most efficient and effective drug development approaches to support safe and effective therapeutic options for patients, increase competition, and expand access.

Question. Section 508 of the Rehabilitation Act of 1973 requires Federal departments and agencies to ensure that information and communication technology is accessible for people with disabilities. Over the last year, I have used my position as chairman of the Aging Committee to examine compliance with this law, and assess the accessibility of Federal technology, including Federal websites, for people with disabilities, older adults, and veterans. In December 2022, I released "Unlocking the Virtual Front Door," an investigation that found troubling examples of inaccessible technology across the Federal Government, and which issued 12 recommendations to improve accessibility. In February 2023, the Department of Justice (DOJ) responded to my calls for greater transparency of section 508 compliance, releasing data that confirmed the findings of my report.

I am concerned that people with disabilities are being locked out of government services and are not given a level playing field in Federal workplaces due to inaccessible technology at the Department of Health and Human Services (HHS). According to data HHS submitted to DOJ, 90 percent of the 98,861 Internet webpages that were evaluated are compliant with section 508 accessibility requirements, while 71 percent of 1,430 intranet webpages that were evaluated are compliant. Moreover, 25 years after section 508 was signed into law, HHS reported that two of its program areas—Compliance Process and Training—are not at the General Service Administration's (GSA) highest program maturity level. These data are consistent with the findings of my investigation, which identified examples of inaccessible technology at HHS and its agencies.

Given these concerns, please answer the following question: how does HHS plan to improve section 508 compliance for its external websites, internal websites, and other electronic and information technology?

Answer. HHS has undergone an extensive program maturity exercise within the last 3 years. Efforts included piloting new tools, processes, and accessibility services to improve acquisition, IT development, and web content conformance. The outcomes of these pilot projects have resulted in internal partnerships, and new services contract vehicle that extend digital accessibility resources throughout HHS. Operating

Divisions and Staff Divisions can purchase services offered throughout the agency include options for accessibility tools, testing, remediation, web crawling and calibration, strategic planning, governance activities, section 508 program analytics and process improvements, virtual assistive technology lab, and assistive technology guidance.

Question. Please explain the deficiencies in HHS's complaints process and training that are identified in the DOJ report. How and when does HHS plan to meet GSA's highest program maturity level for these accessibility programs?

Answer. The HHS Digital Accessibility Program is in collaboration with the Office for Civil Rights (OCR), which owns the complaint process, to develop and publish guidance on submitting complaints and helpful steps to ensure conformance of content to avoid future complaints. The OCR process for filing a section 508 complaint is provided in the HHS Policy for section 508 Compliance and Accessibility of Information and Communication Technology (ICT) which is publicly posted on our website.

Question. HHS reported evaluating 98,861 Internet webpages and 1,430 intranet webpages, respectively. What percentage of HHS's total Internet and intranet webpages were evaluated?

Answer. HHS takes a proactive approach to website conformance that validates webpages and content prior to posting online. Then utilizing scanning tools, section 508 programs can audit the content and process. The scans reported represent about 8 percent of the Internet webpages and .3 percent intranet webpages. The HHS Digital Accessibility Program is issuing a new services contract that increases the scanning and calibration of Internet and intranet pages. Once the new contract is in place, the program will begin routinely scanning and calibrating the scan results for all Operating Division homepages. In addition, the HHS Digital Accessibility Program will continue to provide an enterprise solution for Operating Divisions to scan Internet and intranet websites.

Question. Please describe the existing pathways for employees and the public to file section 508 complaints with HHS at a departmental level, as well as at the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, and the Food and Drug Administration. Please provide the number of section 508 complaints HHS as a whole, and CDC, CMS and FDA on an agency level, have received for each of the last 5 fiscal years.

Answer. Formal complaints must either be routed to the Office for Civil Rights (OCR) or the Equal Employment Opportunity (EEO) office. It is up to the party filing the complaint to determine if an OpDiv-level or agency-wide entity will receive the submission. Upon request of an OCR or EEO entity, the respective section 508 program manager or designee will assist in the complaint process. Each OpDiv section 508 program manager or designee is responsible for aiding in complaints pertaining to an OpDiv system, product, content, or service. Assistance may include gathering data, performing evaluations or providing guidance.

Prior to a complaint being submitted, the nature of the complaint must be determined. The OCR investigates complaints related to civil rights, conscience, religious freedom, and health information privacy at covered entities under the follow authorities:

- Federal civil rights laws;
- Conscience and religious freedom laws;
- Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rules; and
- Patient Safety Act and Rules.

Complaints can be filed on behalf of oneself, someone else, or an organization. OCR complaints must be filed using OCR's Complaint Portal Assistant. OCR's procedures will be followed and the applicable parties will be contacted if the complaint refers to an entity within an OpDiv.

The EEO office processes complaints of employment discrimination based on disability. Federal employees and applicants for Federal employment who believe they have been subjected to discrimination must contact an EEO counselor within 45 calendar days of the alleged discriminatory action. EEO contact information can be located on the EEO Programs and Offices website. The complaint will then follow the EEO office's procedures until a determination is reached.

There were four section 508-related complaints processed through OCR in the last year.

QUESTIONS SUBMITTED BY HON. MAGGIE HASSAN

Question. I have previously worked across the aisle to encourage the Department to issue a proposed rule on transitional coverage for emerging technologies (TCET) that addresses coverage for these technologies and balances access with patient protections.

What is the Department's expected timeline for proposing and finalizing a new rule?

Answer. CMS remains committed to expanding access to health-care coverage and services, including new, innovative treatments when they are safe and appropriate. CMS rescinded the Medicare Coverage of Innovative Technology and Definition of "Reasonable and Necessary" (MCIT/R&N) final rule because of concerns that the provisions in the final rule may not have been sufficient to protect Medicare patients. By rescinding this rule, CMS will take action to better address those safety concerns in the future.

Improving and modernizing the Medicare coverage process continues to be a priority, and we remain committed to providing stakeholders with more transparent and predictable coverage pathways. CMS is working as quickly as possible to advance multiple coverage process improvements that provide an appropriate balance of access to new technologies with necessary patient protections. As part of this effort, CMS has conducted several listening sessions to learn about stakeholders' most pressing challenges and to receive feedback from stakeholders about which coverage process improvements would be most valuable.

CMS intends to explore coverage process improvements that will enhance access to innovative and beneficial medical devices in a way that will better suit the health-care needs of people with Medicare. This will also help to establish a process in which the Medicare program covers new technologies on the basis of scientifically sound clinical evidence, with appropriate health and safety protections in place for the Medicare population. HHS looks forward to working with you and hearing your feedback as we move forward with these efforts.

Question. Vaping among children and adolescents continues to be a major public health concern. I am particularly concerned about disposable vapes. In 2020, the FDA announced guidance concerning flavored vapes, but my understanding is that guidance has only applied to flavored vapes that use a refill cartridge, and not to flavored disposable vapes. As a result, disposable vapes have become vastly more popular, including among children using flavored disposable vapes, as shown in the 2022 National Youth Tobacco Survey. And it's clear that the companies manufacturing and marketing disposable vapes are using flavors, packaging, and tactics designed to appeal to children.

What is the administration's plan for addressing this public health threat to our children? Will the FDA take steps to ensure that disposable flavored vapes are treated similarly to flavored vapes that use a refill cartridge?

Answer. Thank you for the opportunity to address this issue. I can assure you that addressing youth use of electronic nicotine delivery systems (ENDS), including disposable e-cigarettes, is a top priority for the Food and Drug Administration (FDA).

FDA takes a comprehensive approach to protecting our Nation's youth from the dangers of and access to tobacco products, including e-cigarettes. Enforcement is an important component to FDA's multipronged approach to regulating tobacco products that also includes review of new products before they come to market, compliance and enforcement actions against illegal products, regulatory policy, and public education.

As background, FDA has regulated e-cigarettes as tobacco products since August 8, 2016. Pursuant to the Tobacco Control Act, as of this date, e-cigarette products generally were required to have FDA authorization prior to marketing. For products that were already on the market when this requirement took effect, FDA deferred enforcement for a period of time. In January 2020, amid alarming levels of youth use of e-cigarettes, FDA issued a final guidance for industry outlining the agency's enforcement priorities for these products.

The final guidance included a policy prioritizing enforcement against certain unauthorized flavored e-cigarette products that appeal to youth.[57] At that time, cartridge-based products, including JUUL, were the most commonly reported product type used among U.S. youth. The guidance also noted that FDA intended to prioritize enforcement of any ENDS product that is offered for sale after September 9, 2020 and for which the manufacturer did not submit a premarket application (or after a negative action by FDA on a timely submitted application). Importantly, the guidance noted that it did not in any way alter the fact that it is illegal to market any new tobacco product without FDA authorization and that FDA may adjust its enforcement priorities over time in light of the best available data.

In September 2020, based on data from the 2020 National Youth Tobacco Survey showing an alarming uptick in use of flavored disposable e-cigarettes by youth, FDA announced that it has taken action to notify companies selling such products to remove them from the market. In a press release, FDA stated: "As we have said many times, the FDA will take action against any ENDS product—regardless of whether it is cartridge-based, disposable, flavored, or otherwise—if it is targeted to kids, if its marketing is likely to promote use by minors, or if the manufacturer fails to take adequate measures to prevent youth access," and "This new data will inform the FDA's enforcement and other actions, and flavored disposable ENDS will be an enforcement priority for the agency."[58]

FDA has refused admission to the U.S. of disposable e-cigarettes for violation of the Federal Food, Drug, and Cosmetic Act;[59] issued warning letters to retailers for illegally selling disposable e-cigarettes to underage purchasers; and issued warning letters to manufacturers for illegally marketing unauthorized disposable products—including Puff Bar,[60] which was the most commonly used e-cigarette brand reported by youth in 2022.

FDA also continues to review premarket tobacco product applications (PMTAs) for all new deemed tobacco products, including disposable e-cigarettes. FDA issued marketing denial orders for certain disposable Hyde products, which was the third most commonly used e-cigarette brand among youth in 2022. Most recently, FDA also issued marketing denial orders (MDOs) to 10 companies, which collectively manufacture and market approximately 6,500 flavored e-liquid and e-cigarette products.[61]

Question. On December 6, 2022, in my role as chair of the Subcommittee on Emerging Threats and Spending Oversight of the Senate Homeland Security and Governmental Affairs Committee, I sent a letter to HHS Acting Chief Financial Officer Norris Cochran and Chief Information Officer Karl Mathias regarding HHS's legacy information technology systems. The deadline to respond was February 6, 2023, but my office has not received HHS's response.

Please report on the status of the response and, if possible, attach it as part of your response to these questions for the record.

Answer. Apologies for the delay. On April 18, 2023 HHS sent a response letter to your staff. It is attached here and summarized below.

We appreciate Congress's continuing efforts to modernize and secure the information technology (IT) infrastructure across the government. HHS shares your goals to update and improve our aging legacy systems.

HHS mainly uses the HHS Nonrecurring Expenses Fund (NEF) to meet the objectives of the Modernizing Government Technology Act of 2017 (MGT Act), rather than an agency specific working capital fund (WCF) for IT modernization. HHS uses the NEF for IT acquisition and modernization consistent with the MGT Act's objectives. HHS manages requests for IT resources through the NEF relying on the CIO and Assistant Secretary for Financial Resources (ASFR) as critical partners that ensure the uses of these funds support the agency mission. As part of an integrated

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[57] This guidance was revised in April 2020 to reflect extensions of certain dates due to the COVID pandemic. This revised guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market.*

[58] *https://www.fda.gov/news-events/press-announcements/national-survey-shows-encouraging-decline-overall-youth-e-cigarette-use-concerning-uptick-use.*

[59] *https://www.fda.gov/news-events/press-announcements/cbp-fda-seize-counterfeit-unauthorized-e-cigarettes.*

[60] *https://www.fda.gov/news-events/press-announcements/fda-notifies-companies-including-puff-bar-remove-flavored-disposable-e-cigarettes-and-youth.*

[61] *https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-denial-orders-approximately-6500-flavored-e-cigarette-products.*

process, the HHS CIO determines which IT projects are needed. The CIO review ensures critical projects receive funding before others are considered and that unapproved requests do not proceed. Next, ASFR determines whether the sponsoring office has alternative funding to cover the project and if central funding from the NEF is needed for the IT project to succeed. The combined process ensures the proper balance of funding sources and IT resources as they support the agency mission.

The NEF authority provided by the Committees on Appropriations enables HHS to recycle funds that would otherwise not be available for IT investments, by allowing HHS to transfer funds to a central account, to remain available until expended for IT and facility investments. The HHS IT Strategic Plan FY 2021–2023 represents the Department's ambition to deliver its core functions with greater agility, security, and effectiveness amidst an evolving public health landscape. The HHS IT Strategic Plan may be found at: *https://www.hhs.gov/sites/default/files/hhs-it-strategic-plan-final-fy2021-2023.pdf.*

Over the past 2 years, the Indian Health Service (IHS) has devoted substantial effort and resources to the program and acquisition planning phases of the agency's multi-year health information technology modernization initiative. Key elements accomplished or under way include:

- Tribal Consultation, Urban Confer, and internal agency analysis of the findings from the 2018–2019 joint HHS/IHS Health IT Modernization Research Project. A final decision memo was issued in April of 2021 committing IHS to full replacement of the Resource and Patient Management System (RPMS) as the most appropriate, realistic, and sustainable option for IHS health IT modernization.
- To accelerate planning and related activities, IHS engaged the CMS Health Federally Funded Research and Development Center (operated by the MITRE Corporation). MITRE has been working with IHS for more than 2 years on multiple fronts, including:
  - Designing a Federal governance structure that ensures ongoing consultation and confer with Tribal and urban Indian partners as well as engagement of health IT users in building and operational management of the new systems.
  - Establishing the Federal Executive Steering Committee (ESC) and structuring the Program Management Office (PMO) responsible for overall day-to-day management of the modernization Program.
  - Establishing the critically important Organizational Change Management (OCM) and Communications branches of the PMO.
  - Conducting a thorough Life Cycle Cost Estimate (LCCE) for health IT modernization across Indian country, in accordance with the rigorous 12-step process published by the Government Accountability Office.
  - Drafting initial concepts for infrastructure architecture, design, and data management; these will be refined in concert with the vendor once the contract for the modernized health IT solution suite is awarded.
  - Clinical and administrative business process and best practice consensus development, modeling, and standardization in preparation for system transition.
  - Acquisition planning support.

QUESTIONS SUBMITTED BY HON. ELIZABETH WARREN

REPRODUCTIVE HEALTH

Question. A Federal lawsuit is currently threatening access to mifepristone, one of two drugs used safely and effectively in medication abortion. Mifepristone has been FDA approved for over 2 decades and is used in more than half of abortion procedures nationwide.

Do you agree that FDA is best suited to determine the safety and effectiveness of drugs, including mifepristone?

Answer. Yes. Congress has charged FDA with determining the safety and effectiveness of drugs. And I have confidence in the FDA staff, who rely on the best available scientific evidence to determine the safety and effectiveness of drugs, and I will continue to defend the FDA's independent, expert authority to review, approve, and regulate a wide range of prescription drugs.

Question. Based on FDA's analysis, which includes review of information from multiple scientific and medical professional societies, do you agree that medication abortion is a safe option for patients to end an early pregnancy?

Answer. The FDA approved Mifeprex (mifepristone 200 mg) more than 20 years ago based on a thorough and comprehensive review of the scientific evidence presented and determined that it was safe and effective for medical termination of early pregnancy. Since 2016, it has been approved for medical termination of pregnancy through 70 days gestation. In this area, as in all others FDA regulates, the best available science has guided agency decision-making.

Taking mifepristone off the market would significantly compromise access across the country—including in California, Illinois, New York, and other States that have secured abortion access.

Question. What is HHS doing to protect access to medication abortion?

Answer. The Biden-Harris administration is committed to protecting access to reproductive health care and has taken several steps to advance this work. Just hours after the Supreme Court's decision in *Dobbs* was released, the Department put up the website *reproductiverights.gov* to help ensure that people had a fact-based website with information on their rights and where they can get coverage for family planning care and birth control. And, based on a comprehensive review of the Mifepristone Risk Evaluation and Mitigation Strategy (REMS) Program, in January 2023 the FDA approved modifications to the REMS so that Mifepristone is no longer required to be dispensed in-person. In addition, the FDA eliminated the previous REMS requirement that did not allow the drug to be dispensed by retail pharmacies; under the REMS, any pharmacy that meets the requirements, and is certified, may dispense mifepristone based on a prescription from a certified prescriber. Protecting access to safe and effective medication abortion is a top priority for me.

Medicaid's free choice of provider requirement is a critical protection that ensures Medicaid beneficiaries can access sexual and reproductive health care at the provider of their choice, including Planned Parenthood. As you know, we have witnessed a disturbing trend in recent years, as hostile Republican Governors and State legislatures have taken action to deny Medicaid patients their Federal legal right to seek services from the provider of their choice. Several States—Missouri, Arkansas, Mississippi, Texas, Louisiana, and South Carolina—have violated this longstanding requirement. These State violations delay and impede timely access to essential services: birth control, sexually transmitted infection testing and treatment, gender-affirming care, annual wellness exams, and other essential care. These violations also disproportionately impact people and women of color, who, due to racism and other systemic barriers that have contributed to income inequality, are more likely to use Medicaid for coverage.

I recently sent a letter highlighting a number of important steps to protect access to reproductive health care, including enforcement of this critical Federal protection, as part of the ongoing response to the Supreme Court's devastating decision in *Dobbs.*

Question. What is HHS's plan to protect everyone's right to access services like birth control, STI testing and treatment, and gender-affirming care at the provider of their choice?

Answer. The Biden-Harris administration is committed to ensuring access to health care and has taken several steps to advance this work. Just hours after the Supreme Court's decision in *Dobbs* was released, the Department published the website *reproductiverights.gov* to help ensure that people had a fact-based website with information about their rights and where they can obtain coverage for family planning care and birth control. The Department also worked to help ensure that people could continue to access birth control through private insurance markets and other Federal programs. Additionally, on July 13, 2022, HHS issued guidance to roughly 60,000 U.S. retail pharmacies, reminding them of their obligations under Federal civil rights laws. This issue is a top priority for me, and one I have tasked the entire Department with taking immediate action to address.

ORGAN PROCUREMENT

Question. Last week HHS announced transformative reforms to break up UNOS's fatal monopoly over the United States organ procurement and transplantation network (OPTN) through HRSA's Organ Procurement and Transplantation Modernization Initiative. OPTN failures also resulted from severe and undisclosed conflicts

among organ donation industry stakeholders who served on OPTN boards and committees.

What specific steps will HHS (including CMS and HRSA) take to ensure that, going forward, any stakeholder serving in any board, advisory, or other capacity in OPTN or Scientific Registry of Transplant Recipients policymaking or oversight fully discloses all financial conflicts of interest, including but not limited to financial relationships with the OPTN, OPOs, tissue recovery and processing companies, organ logistics and transportation companies, or any other organization which does business related to organ donation or transplantation?

Answer. The Organ Procurement Transplantation Network (OPTN) develops and implements policies approved by the OPTN board of directors. On March 22, 2023, HHS announced a multiyear OPTN modernization initiative designed to improve effectiveness across the organ donation, procurement, and transplantation system. The President's budget for Fiscal Year 2024 would more than double HRSA's budget for organ-related work, including OPTN contracting and the implementation of the modernization initiative, to total $67 million. The initiative is intended to strengthen accountability, equity, and performance in the organ donation and transplantation system through a focus on five key areas with the following goals:

- Technology—ensure that the system is reliable, secure, patient-centered, user-friendly, and reflective of modern technology functionality. There is a continuous focus on improved IT system functionality and security, while ensuring continuity of services, protecting patient safety, and accelerating innovation in line with industry-leading standards.
- Data Transparency and Analytics—ensure data is accessible, user-friendly, and patient-oriented. The modernization process provides easily accessible, high-quality, and timely data to make informed patient, donor, and clinical decisions; measure and evaluate program performance; inform oversight and compliance activities; and support the advancement of scientific research.
- Governance—the OPTN board of directors is high-functioning and has greater independence; represents the diversity of communities; and delivers effective policy development.
- Operations—the OPTN is effective and accountable in its implementation of organ policy, patient safety and compliance monitoring, organ transport, OPTN member support, and education of patients, families, and the public.
- Quality Improvement and Innovation—the OPTN promotes a culture of quality improvement and innovation across the network by leveraging timely data and performance feedback, collaborative learning, and strategic partnerships.

The Health Resources and Services Administration (HRSA) has been working to make improvements with these goals in mind. In July 2022, the Scientific Registry of Transplant Recipients convened a consensus conference to make recommendations for better metrics to support organ donation and transplantation and in March 2023, HRSA released an OPTN organ transplantation dashboard to improve transparency of data to the public. Fall 2023 and Spring 2024 OPTN contract solicitations are an opportunity for further advancements in transparency, such as a requirement of the OPTN contractor to improve patient and family understanding of waitlist practices.

As part of the modernization initiative, HRSA will continue to strengthen OPTN contract requirements to ensure members of the OPTN board of directors are separate from OPTN contractor's board. Further, the Fall 2023 OPTN contract solicitation will enable multiple vendors to compete for distinct OPTN functions and will require establishment of an independent OPTN board of directors free from conflicts of interest.

HRSA requires the OPTN board of directors and the Scientific Registry of Transplant Recipients Review Committee members to complete training and sign annual attestations to mitigate conflict of interest concerns and ensure that financial relationships are disclosed.

HRSA will continue to focus on meeting the needs of patients and families by strengthening and providing equitable access to transplantation, improving safety and health outcomes, and empowering patients and providers with the data needed to make informed, shared decisions.

To ensure fair and open competition for the OPTN contract, it is imperative that HHS not allow UNOS or its surrogates to interfere with the business and operations of other potentially interested bidders, including through retaliation or harassment

against patients, doctors, caregivers, or other stakeholders interested in supporting competitive bids.

Question. What specific steps will HHS commit to taking to investigate any and all such allegations, and to remove from all OPTN activities anyone found to be involved in such retaliation and harassment?

How will HHS/HRSA ensure that taxpayer resources—including those that have accumulated at UNOS due to both HRSA appropriations as well as OPTN and UNOS fees, which were funded by taxpayers via Medicare as well as other parts of government—are not used to fund either UNOS's bid for component pieces of the OPTN contract, acquisition of any potential competitors, or its extensive marketing and lobbying activities?

Answer. In the upcoming Request for Proposals (RFP), HHS, through HRSA, will follow all Federal contract policies to ensure that there is equal opportunity for eligible vendors. HRSA also is committed to accountability and intends to work closely with the HHS Office of the Inspector General and others in response to any allegations that warrant such action.

CHILD CARE

Question. Early education expands learning opportunities for our babies and gives parents an opportunity to go to work. But the United States has been underinvesting in child care for decades. Of the 37 richest nations in the world, the U.S. is now number 33 in our spending on our little ones.[62]

Yet, House Republicans are demanding across-the-board funding cuts—at least 27 percent to all government programs.[63] If defense, veterans, Social Security, and Medicare are off the table—as some Republicans now claim—other programs would need to be cut by 78 percent.[64] That includes funding for Head Start and other crucial child-care programs.

You have previously stated that a return to FY 2022 enacted funding levels for Head Start would result in a loss of at least 170,000 slots for children, and a 22-percent reduction in funding from FY 2023 would eliminate over 200,000 slots.[65] How many slots would be lost if Head Start funding were cut by 27 percent? 78 percent?

Answer. Reducing funding for Head Start by 27 percent would eliminate nearly 250,000 slots for children. A 78-percent cut would result in a loss of more than 600,000 slots. With a 78-percent cut, OHS would expect that many programs—particularly Tribal, rural, and smaller programs—would need to close because their programs would no longer be viable due to very small size and they would no longer be able to cover fixed operating costs such as rent.

Question. You have also stated that a return to FY 2022 enacted funding levels would result in a loss of at least 105,000 child-care slots, down from 1,843,000 in FY 2023.[66] And a 22-percent reduction in funding from FY 2023 would eliminate over 101,000 slots.[67] How many slots would be lost if child-care funding were cut by 27 percent? 78 percent?

What would the impacts of these funding cuts mean for parents, families, and children losing access to care?

Answer. Even with the 30-percent increase Congress appropriated to the Child Care and Development Block Grant (CCDBG) in FY 2023, the child-care subsidy system is only funded to serve a small fraction of eligible families to be served—historically supporting just one in seven of those children who are eligible for child-care assistance. Future funding cuts to CCDBG would result in States reducing the

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[62] The Organisation for Economic Co-operation and Development, "Public spending on childcare and early education," OECD Family Database, *https://www.oecd.org/els/soc/PF3_1_Public_spending_on_childcare_and_early_education.pdf.*

[63] Committee for a Responsible Budget, "What Would It Take to Balance the Budget? An Update," February 24, 2023, *https://www.crfb.org/blogs/what-would-it-take-balance-budget-update.*

[64] *Id.*

[65] Department of Health and Human Services, Letter to Representative DeLauro, March 17, 2023, *https://democrats-appropriations.house.gov/sites/democrats.appropriations.house.gov/files/Department%20of%20Health%20and%20Human%20Services%20Letter%20-%20Impact%20of%20Spending%20Cuts.pdf.*

[66] *Id.*

[67] *Id.*

number of families who receive child-care assistance. Funding cuts will also undermine parent choice in care, making it even more difficult for parents to find child care that meets their family's needs. Reducing child-care assistance will also harm employment and family economic stability. In some areas of the country, child-care costs can exceed the cost of college tuition.[68] When families are unable to access child-care subsidies, they may have to patch together less expensive care that could lead to informal, unregulated care that is less reliable, less likely to meet children's developmental needs and to families cutting work hours or exiting the workforce entirely. It's estimated that U.S. parents collectively lose $30 to $35 billion in income due to reducing their work or leaving the workforce entirely when they cannot find affordable child care.[69]

Question. The Child Care Stabilization Grants provided in the American Rescue Plan Act (Pub. L. 117–2) provided crucial relief during the COVID–19 pandemic to allow child-care centers to remain open. However, the expiration of this funding is rapidly approaching, with States facing a funding cliff of over $48 billion.[70] How will the end of this relief funding, coupled with proposed cuts to annual child-care funding affect the child-care industry? What would the impact be on the child-care workforce, which is still down about 60,000 workers compared to pre-pandemic?[71] How many families would lose access to child care? What would the impact be on fees and affordability?

Answer. ARP and other COVID child-care funding has been critical to stabilizing the child-care sector, lowering parent costs, and raising child-care staff compensation. The end of these funds coupled with additional cuts to the CCDF program will harm many children and families. Child-care programs need consistent revenue and financial support to be able to improve quality or raise chronically low wages for the child-care workforce to address high employee turnover and staff shortages. Some States have used ARP funds to pay bonuses or increase salaries, but providers say they still struggle to find staff, and it is uncertain whether these practices will be continued after ARP stabilization funds expire. Due to the staffing shortages, there are providers currently reporting they are hiring people who they would not have even considered for a position prior to the COVID–19 pandemic because of lack of skill, training, or competence.

Additionally, families will lose access to subsidies just as ARP stabilization payments are no longer available to support child-care providers directly. A Kentucky child-care provider recently shared what this means for her business and the families she serves. Before the COVID–19 pandemic, she served two to five children who received a child-care subsidy. Currently, 19 children in her program receive a subsidy, but only for the remainder of this eligibility year. Once ARP stabilization payments to providers expire, the provider expects she will need to raise tuition up to 70 percent to remain open and keep staff. This means the cost to families will increase just as they are losing access to subsidies.

DRUG PRICING

Question. After more than 480 days, the National Institutes of Health (NIH) responded to the petition sent to you by prostate cancer patients Robert Sachs and Clare Love, formally asking HHS to grant march-in rights for the patents on the prostate cancer drug enzalutamide (marketed as Xtandi). The patients' petition referenced a previous request to the Department of Defense (DOD) for it to use march-in rights, as well as the nonexclusive, nontransferable, irrevocable, paid-up licenses held by the U.S. Government to use the enzalutamide patents, to which the DOD never responded.

The response from the NIH to the petition sent to you completely ignored the petitioners' argument that, by definition, meeting practical application requirements

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[68] Example of a local DC private-pay program tuition rate of $20,400 per school year/not including summer months for a 2-year-old for care from 8:30 a.m. to 2:30 p.m. (which does not cover the full work day for a parent). This is a typical, real-life example in Washington, DC; *https://stcolumbasnurseryschool.org/program-tuition/*.

[69] *https://www.ffyf.org/our-child-care-system-is-not-meeting-the-needs-of-families-providers-or-the-economy/*.

[70] Bipartisan Policy Center, "States Face a $48 Billion Child Care Funding Cliff," Linda Smith and Victoria Owens, June 3, 2022, *https://bipartisanpolicy.org/blog/states-face-a-48-billion-child-care-funding-cliff/#:~:text=T%20hroughout%20the%20pandemic%2C%20Congress,fiscal%20cliff%20of%20%2448%20billion.*

[71] *The Wall Street Journal,* "Pricey Child Care Is Keeping Many Parents Out of the Workforce," Harriet Torry, March 18, 2023, *https://www.wsj.com/articles/pricey-child-care-is-keeping-many-parents-out-of-the-workforce-1923f4dd.*

under the Bayh-Dole Act requires that the invention at issue is "available to the public on reasonable terms." I object to HHS, through NIH, continuing to ignore this vital taxpayer protection.

While it is my strongly held view that a prescription drug corporation charging U.S. patients and taxpayers 3–6 times the prices it charges in other wealthy countries for a drug that U.S. taxpayers paid to invent through grants from the NIH constitutes sufficient grounds for exercising march-in rights, the royalty-free right, provided under 35 U.S.C. 202(c)(4), is not subject to practical application or other march-in rights prerequisites. Additionally, the royalty-free right is not subject to appeal before the United States Court of Federal Claims or to being held in abeyance during such an appeal.

Currently, four companies have filed ANDA applications, two of which have already received tentative approval from FDA for generic versions of enzalutamide. Through HHS exercising its royalty-free rights, these manufacturers could readily supply Federal health programs, including Medicare and Medicaid, for a fraction of the price charged by Astellas, saving taxpayers billions of dollars over the remaining patent life of enzalutamide.

Has your office considered exercising the royalty-free rights held by HHS for enzalutamide? If so, what determinations have you made and under what rationale? If not, why not?

Answer. I assure you that HHS and the Biden-Harris administration remain steadfastly committed to increasing all Americans' access to health care and lowering costs for lifesaving treatments and cures.

In support of President Biden's Executive Order on Lowering Prescription Drug Costs for Americans *(https://www.whitehouse.gov/briefing-room/presidential-actions/2022/10/14/executive-order-on-lowering-prescription-drug-costs-for-americans/)*, HHS is pursuing a whole-of-government approach to build on this administration's priorities. As you noted, an important step towards this goal was the passage and signing of the Inflation Reduction Act, which will reduce prescription drug costs for the more than 63 million individuals with Medicare. In addition, the Centers for Medicare and Medicaid Services recently issued initial guidance detailing the requirements and procedures for implementing the new Medicare Drug Price Negotiation Program for the first set of negotiations. The first set of negotiations will occur during 2023 and 2024 and result in prices effective in 2026. The guidance details how Medicare intends to use its new authority to effectively negotiate with drug companies for lower prices on selected high-expenditure drugs, and illustrates the Biden-Harris administration's commitment to lowering high prescription drug costs and improving access to innovative therapies. CMS anticipates issuing revised guidance for the first year of negotiation in Summer 2023.

We know more must be done as too many Americans, particularly the uninsured, find these therapies to be out of reach. March-in authority is indeed a powerful tool designed to ensure that the benefits of the American taxpayer's investment in research and development are reasonably accessible to the public. HHS, the National Institutes of Health (NIH), and other agencies have been petitioned on several occasions to initiate march-in proceedings, but to date have not invoked this authority. Most recently, NIH declined to initiate a march-in proceeding, at the petition of a third party, for the prostate cancer drug Xtandi. In the case of Xtandi, NIH thoroughly reviewed the petition in a manner consistent with the policy and objectives of the Bayh-Dole Act, including an assessment of the relevant intellectual property and applicability of the four statutory criteria. NIH's analyses found Xtandi to be widely available to the public on the market. In addition, given the remaining patent life and the lengthy administrative process involved for a march-in proceeding, NIH did not believe that use of the march-in authority would be an effective means of lowering the price of the drug. For these reasons, NIH determined that initiation of a march-in proceeding was not warranted in this case and HHS concurs with NIH's decision. This decision is consistent with NIH's determination in 2016 in which Knowledge Ecology International and the Union for Affordable Cancer Treatment requested that NIH and the Department of Defense initiate march-in proceedings based on the price of Xtandi, but each declined.

We recognize, however, that there is a need to evaluate how pricing may be a contributing factor when weighing the use of the march-in authority and have committed to working with the Department of Commerce to review the use of march-in authority as laid out in the Bayh-Dole Act. Through this partnership, we have asked an Interagency Working Group to develop a framework for consistent imple-

mentation of the march-in provision across the U.S. Government that clearly articulates guiding criteria and processes for making determinations where different factors, including price, may be a consideration in agencies' assessments. HHS will convene a workshop in 2023 to further refine the cases for which HHS could consider exercising march-in authority. HHS will seek input from a diverse array of stakeholders—including patient groups, industry, universities, small business firms, and nonprofit organizations, as well as experts in technology transfer and innovation policy. The goal of the workshop will be to assess when the use of march-in rights is consistent with the policy and objectives of the Bayh-Dole Act.

UNIQUE DEVICE IDENTIFIERS

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

The process of adding UDIs to Medicare claims is a complex one, but ultimately will require CMS to agree to act on the recommendations of X12, an entity that establishes accredited standards for claims transactions. In June, X12 formally recommended that the device identifier portion of a medical device's UDI be included on the electronic claims transaction. Now, the National Committee on Vital and Health Statistics, an HHS advisory body, must assess the recommendation and make an official recommendation to HHS for adoption.

Will you commit to implementing X12's recommendation and adding UDIs to Medicare claims in a timely manner?

Answer. 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.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. Value-based health-care efforts are important to bending the cost curve of our Nation's health-care spending. In 2019, CBO stated "the available evidence indicates that ACOs have had little or no net effect on Medicare spending." Since then, CBO has communicated they monitor "official evaluations of ACOs from the Center for Medicare and Medicaid Innovation (CMMI) as well as academic research about the performance of ACOs. Since the agency's statement in March 2019 and December 2020 QFRs, CBO's review of the evidence continues to indicate that ACOs have had little or no net effect on Medicare spending." What is the Office of the Actuary at CMS's independent actuarially sound estimate for combined Medicare and Medicaid unrealized savings to the Federal Government from ACOs since the ACA was implemented? Does the administration assume any of the actuarially sound estimate into its mandatory health spending outlays?

Answer. The Medicare Shared Savings Program, through its work with Accountable Care Organizations (ACOs) saved Medicare $1.66 billion in 2021 compared to spending targets. This marks the 5th consecutive year the program has generated

overall savings and high-quality performance results. Over the past decade, the Shared Savings Program has grown to one of the largest value-based purchasing programs in the country. Other ACO models in the Innovation Center have also been found to produce Medicare savings. In particular, the Pioneer ACO Model, which operated from 2012 through 2016, was evaluated to have saved $384 million over the first 2 performance years ($254 million in net savings) and was certified for expansion by the Chief Actuary of CMS in 2015 because expansion was expected to reduce net Medicare spending. In that certification, the Chief Actuary noted that "[b]oth the Pioneer and MSSP ACOs have been shown to produce savings relative to fee-for-service Medicare." In addition, the ACO Investment Model, which operated from 2015 through 2018, was evaluated to have saved $526.4 million in Medicare spending across 3 performance years ($381.5 million in net savings). Elements of both models were subsequently incorporated into the Shared Savings Program through rulemaking. Based on these successes and opportunities to continually improve value for people with Medicare and the health-care system, CMS has set a goal that 100 percent of people with traditional Medicare will be part of an accountable care relationship by 2030.

Financial and quality data for participants in the Medicare Shared Savings Program is publicly available at *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos.* Evaluations of Innovation Center Models can be found at *https://www.cms.gov/priorities/innovation/overview.*

Question. The President's budget seeks to permanently extend enhanced premium tax credits for high-income earners beyond 2025. The budget proposal indicates permanently extending enhanced premium tax credits costs $183 billion over 10 years. CBO has estimated making the subsidies permanent would result in a 2.3 million decrease in enrollment in employment-based coverage. What actions is the administration taking to expand other high-quality, consumer-protected affordable healthcare options, including employer-based coverage options, that do not cost the taxpayers anywhere near $183 billion over 10 years?

Answer. Ensuring that all Americans have access to quality, affordable health care is one of the Biden-Harris administration's top priorities, and HHS has numerous efforts underway to help achieve this goal. The enhanced premium tax credits contributed to a record-setting 16.3 million people enrolling in marketplace coverage in 2023. The President's budget also lowers costs for families with private health coverage by capping insulin costs at $35 for a monthly prescription and extending Medicare drug inflation rebates to commercial plans. In December 2022, CMS released the 2024 Notice of Benefit and Payment Parameters Proposed Rule, which would increase access to health-care services, simplify choice and improve the plan selection process, and make it easier for consumers to enroll in coverage. As required by law, CMS sought public comment on the proposed rule and will take this feedback into account when finalizing the Notice of Benefit and Payment Parameters. CMS received a large number of comments in response to the proposed rule and appreciates the commenters' thoughts and input regarding standards for issuers and marketplaces, as well as requirements for agents, brokers, web-brokers, and assisters that help consumers with enrollment through marketplaces that use the Federal platform.

Question. In February, CMS finalized the Medicare Advantage Risk Adjustment Data Validation (RADV) rule with the goal "to improve program integrity and payment accuracy." I've written to CMS in 2015 and 2017 asking what they are doing to implement safeguards to reduce risk score fraud, waste, and abuse. In the final rule, CMS plans to only attempt to collect $41.1 million in non-extrapolated improper payments from 2011 to 2017, instead of approximately $2 billion in extrapolated improper payments over the same time period. In explaining this decision, CMS cited "certain operational considerations."

Please provide a detailed list of those "certain operational considerations" and their associated costs to the Federal Government to perform.

In 2015, CMS noted to me that it recovered $1.5 billion from 2006 to 2013 in "report and pay" recoveries from Medicare Advantage organizations. The proposed RADV rule stated it would collect $4.5 billion over 10 years. Your agency's final rule goes into great detail about the repeated delay of RADV audits. Your agency estimates in its final rule that it will collect $4.7 billion in overpayments over a 10-year period. Given the agency's track record on RADV overpayment auditing and the delay of this final rule, what assurances can the agency provide that it will meet the estimates for collections in the next 10 years?

CMS has previously stated to me that its RADV audit process for each calendar year was at various stages of review and completion. Please provide a status update and expected timeline for Medicare Advantage overpayment audits by calendar year from 2011 through 2022.

Answer. On February 1st, CMS published a final rule that finalized the policies for the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) program, which is CMS's primary audit and oversight tool of MA program payments. In addition to the CMS RADV audits, the HHS Office of the Inspector General (OIG) also undertakes audits of MAOs, similar to RADV audits, as part of its oversight functions. CMS can collect the improper payments identified during those HHS–OIG audits, including the extrapolated amounts calculated by the HHS–OIG.

The policies in the RADV final rule will help protect the Medicare Advantage program by addressing instances where Medicare paid Medicare Advantage Organizations (MAOs) more than they otherwise should have received because the medical diagnoses submitted for risk adjustment payment were not supported in the beneficiary's medical record. Specifically, this final rule codifies in regulation that, as part of the RADV audit methodology, CMS will extrapolate RADV audit findings beginning with payment year (PY) 2018. As a result, CMS will only collect the non-extrapolated overpayments identified in the CMS RADV audits and HHS–OIG audits between PY 2011 and PY 2017, and will begin the collection of extrapolated overpayment findings for any CMS and HHS–OIG audits conducted in PY 2018 and any subsequent payment year.

We believe this is an appropriate policy because it recognizes our fiduciary duty to protect taxpayer dollars from overpayments and preserves our ability to collect on potentially significant amounts of overpayments made to plans beginning in PY 2018 using an extrapolation methodology. This final rule will also allow CMS to focus on conducting future RADV audits as soon as practicable after an MAO payment year concludes, which was the topic of significant public comment to the proposed rule. Lastly, we have determined that it is in the best interest of all parties to ensure that the contract-level RADV appeals process, which is also referenced in regulation, is able to successfully process all RADV appeals. By not using an extrapolation methodology prior to PY 2018, we expect to better control the total number of active appeals that are submitted in the first few years following finalization of this rule, which will alleviate burden on MAOs and CMS.

When this rule is finalized, we will begin issuing the enrollee-level audit findings from the CMS RADV audits that have been completed (that is, CMS RADV audits for PY 2011–2013, followed eventually by PY 2014 and PY 2015 audits), as well as recovering enrollee-level improper payments identified in HHS–OIG completed RADV audits. The plans for future audit years will be communicated to the MAOs through our standard channels.

Question. HHS recently posted a Notice of Proposed Rulemaking that would allow States to maintain different standards to license non-relative foster parents and kinship care providers, with the goal of reducing barriers for relatives to provide care to children who are in need of foster care. Will ACF issue guidance to States on how decisions related to non-safety related standards for kinship providers could also be applied to non-relative foster parents to reduce barriers to licensing?

Answer. While title IV–E of the act specifically allows title IV–E agencies to waive non-safety licensing standards for relative foster family homes (see section 471(a)(10)(D) of the act), there is no similar waiver for non-related foster family homes. Therefore, ACF cannot provide guidance on how to waive those standards for non-related foster family homes. Subject to the requirements for title IV–E eligibility, State licensing standards for foster homes, whether related or non-related homes, are generally a State issue. ACF is happy to work with States that are interested in exploring potential changes to their State licensing standards to reduce barriers to licensing, but ACF does not generally oversee State licensing standards.

Question. HHS recently posted a Notice of Proposed Rulemaking that would allow States to maintain different standards to license non-relative foster parents and kinship care providers, with the goal of reducing barriers for relatives to provide care to children who are in need of foster care. The definition of kinship provider can include non-relatives who have an existing connection to a child. For the purpose of this rulemaking, how will ACF instruct States to consider licensing for relatives compared to non-relative, "fictive kin?"

Answer. As stated in the February 2023 NPRM, title IV–E agencies have discretion to define "relative" and "kin" when determining to whom they will apply the

relative licensing and approval standards. ACF is currently reviewing and analyzing public comments on the Notice of Proposed Rulemaking. The Department has not yet determined how the final rule will respond to the committee's question.

Question. The Fiscal Year 2024 budget request includes a request to make permanent a temporary provision allowing 50 percent of States' spending on prevention services under the Family First Prevention Services Act to be spent on programs that are rated as well-supported or supported, rather than only well-supported programs. This temporary provision was enacted in 2019 when the Prevention Services Clearinghouse was newly created and there was an extremely limited number of well-supported programs. In your view, how many well-supported programs would need to be listed on the Prevention Services Clearinghouse to return to the original requirement of the Family First Prevention Services Act? Is HHS concerned that supported programs may not be as effective in accomplishing the goals of preventing foster care placement and ensuring child safety and well-being compared to well-supported programs?

Answer. The title IV–E Prevention Services Program, created by the Family First Prevention Services Act (FFPSA), provides a watershed opportunity to create more equitable and positive outcomes for children, youth, and families before they face the tumult and devastating consequences of maltreatment and separation. Working with State and Tribal partners, we are seeking to expand participation in the program and to ensure that agencies are able to offer effective services to meet the needs of all communities and families and we are making progress:

- To date, the Prevention Services Clearinghouse has reviewed 141 programs and services; 17 of these have been rated as well-supported, 18 of these have been rated as supported, and 36 of these have been rated as promising.
- The 42 approved State, jurisdiction, and Tribal title IV–E prevention program plans to date have identified 13 well-supported, 5 supported, and 5 promising evidence-based programs (EBPs) and services for reimbursement in the delivery of prevention services.

It is difficult to determine how many well-supported programs are necessary to address and serve the breadth of issues that children and families present when coming into contact with State child welfare systems. We know from State child welfare agencies that families are bringing high level, complex service needs that often require a more tailored approach to effectively serving each family. Programs and services that carry a promising or supported rating are required to undergo ongoing evaluation in an effort to increase their level of evidence to support a well-supported rating. At this time, we believe it is in the best interest of children and families to provide as wide a range of evidence-based/informed services as possible and to capitalize on all available levers for building evidence.

Question. HHS and the Department of Agriculture have now twice failed to follow the recommendations of a 2017 report from the National Academies of Science, Engineering, and Medicine (NASEM), requested by Congress to evaluate the Dietary Guidelines for Americans development process—which explicitly recommended releasing "any known conflicts—for a reasonable period of time prior to appointment." It is troubling that this recommendation was not implemented in the last two advisory committee selection processes, not to mention the failure to implement several other NASEM recommended reforms designed to bolster transparency.

Will you commit to making any known conflicts of interest reviewed during the selection process public?

In the past, the departments cited privacy concerns for potential nominees to justify their decision not to publicly disclose any known conflicts. If the departments continue to refuse to make public this information, do the departments plan to develop an alternative method for disclosing committee members' conflicts of interest following appointment?

Answer. HHS and USDA have developed procedures to ensure that the advice and recommendations of the Dietary Guidelines Advisory Committee will be the result of the committee's independent judgement and not be inappropriately influenced by the appointing authority or by any special interest group.[72] The FACA statute and FACA regulations are followed throughout the selection process to ensure that the interests and affiliations of committee members are reviewed for conformance with applicable conflicts-of-interest statutes and regulations and to ensure that com-

[72] 5 U.S.C. § 1004(b)(3); 41 CFR § 102–3.105(g).

mittee membership is fairly balanced in terms of points of view represented and functions to be performed. The members of the committee 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 the U.S. Office of Government Ethics (OGE) regulations.[73] Accordingly, committee members are required to file an OGE 450, Confidential Financial Disclosure Report. All members of the committee file an OGE 450 prior to appointment and continue to submit one annually throughout their service on the committee.

The executive branch Confidential Financial Disclosure Reports (OGE 450s) and information contained therein, filed by SGEs, are confidential pursuant to section 107(a) of the Ethics in Government Act, 5 U.S.C. chapter 131, and section[s] 201(d) [and 502(b)] of Executive Order 12674, as modified; see also 5 CFR §§ 2634.604 and 2634.901(d) of the OGE regulations thereunder. Furthermore, the reports are subject to appropriate protections under the Privacy Act, 5 U.S.C. § 552a, as they constitute personal information and are contained in the OGE/GOVT–2 system of records. Additionally, these reports are further protected from disclosure under the Freedom of Information Act (FOIA). In addition to the FOIA exemption, providing for nondisclosure of such information, which is specifically exempted by disclosure by statute, these reports are excluded from required public disclosure under the additional FOIA exemptions for sensitive commercial and financial information and for personal privacy-protected information. See 5 U.S.C. §§ 552(b)(3), (b)(4) and (b)(6). HHS complies with the public disclosure requirements of the Ethics in Government Act, including interpretative guidance from the Department of Justice. Information submitted to HHS in connection with a nomination or application for membership on a Federal advisory committee is in an HHS system of records protected by the Privacy Act. The Privacy Act permits disclosure of information from such systems with the consent of the records subject, but in the absence of consent, the agency may only disclose protected records under specific circumstances set forth in the Privacy Act.[74]

Question. As I stated in my opening comments at the hearing, I thank you for enabling transitional health plans to continue. Approximately 65,000 Iowans are benefiting from this action with many being farmers and small business owners. Letting transitional health plans continue has been a bipartisan priority under Presidents Obama, Trump, and now Biden. The March 23, 2022, bulletin from CMS permitted the nonenforcement policy for CY 2023 and it states the nonenforcement "will remain in effect until CMS announces that all such coverage must come into compliance with the specified requirements." While the nonenforcement creates regulatory certainty in CY 2023, it actually creates uncertainty in CY 2024 and subsequent years. Your answer on this topic to my FY 2023 Health and Human Services budget question for the record stated, "On March 23, 2022, CMS issued a bulletin that extends the policy under which CMS will not take enforcement action against certain non-grandfathered health insurance coverage in the individual and small group market that is out of compliance with certain specified market reforms. The extended nonenforcement policy applies for policy years beginning after October 1, 2022, and will remain in effect until CMS announces that all such coverage must come into compliance with the specified requirements." Given you didn't answer my questions in 2022, I will restate my questions below.

What standard will CMS apply in taking regulatory action to permit transitional health plans to be sold in CY 2024 and subsequent years?

What policymaking process will CMS have in taking regulatory action to permit transitional health plans to be sold in CY 2024 and into the future?

Answer. On March 23, 2022, CMS issued a bulletin that extends the policy under which CMS will not take enforcement action against certain non-grandfathered health insurance coverage in the individual and small group market that is out of compliance with certain specified market reforms. The extended nonenforcement policy applies for policy years beginning after October 1, 2022, and will remain in effect until CMS announces that all such coverage must come into compliance with the specified requirements.

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[73] 5 CFR § 2634, Subpart I.
[74] 5 U.S.C. § 552a(b).

Question. As of March 11, 2023, according to the Rural Health Redesign Center that is serving as the Rural Emergency Hospital Technical Assistance Center, more than 50 hospitals and other organizations have expressed interest in becoming a Rural Emergency Hospital (REH), a new voluntary Medicare designation that provides a lifeline to ensure access to rural health-care services. How many applications has HHS/CMS received from hospitals expressing intent on becoming an REH? How many applications have been approved by HHS/CMS?

Answer. Rural Emergency Hospitals (REHs) are a new provider type established by the Consolidated Appropriations Act, 2021 to address the growing concern over closures of rural hospitals. The REH designation provides an opportunity for Critical Access Hospitals and certain rural hospitals to avert potential closure and continue to provide essential services for the communities they serve. Conversion to an REH allows for the provision of emergency services, observation care, and additional medical and health outpatient services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. This new provider type, effective January 1, 2023 will promote equity in health care for those living in rural communities by facilitating access to needed services. Eligible providers can submit their applications to convert to an REH to their Medicare Administrative Contractor, at which point they will be screened for eligibility and to ensure compliance with all Medicare enrollment requirements. CMS will be posting the number hospitals that have successfully transitioned to REHs on a publicly available CMS website.

Question. Thank you for implementing my Over-the-Counter Hearing Aid Act with Senator Warren. This was a longstanding priority of mine. The Biden administration has stated they plan to end the COVID–19 public health emergency (PHE) on May 11, 2023. While most telehealth provisions under Medicare will remain in effect through the end of CY 2024, Iowa audiologists have communicated to me that telehealth CPT codes they use will no longer be reimbursable under Medicare after May 11th. What is CMS planning to do to address potential access issues to telehealth services after May 11th?

Answer. During the COVID–19 public health emergency (PHE) CMS utilized its regulatory flexibilities to expand access to telehealth services for Medicare beneficiaries. In order to maintain access to audiology services during the PHE, CMS temporarily allowed for Medicare coverage of certain audiology services when provided via telehealth. In the CY 2021 PFS final rule, CMS created a third category of criteria for adding services to the Medicare Telehealth Services List on a temporary basis following the end of the PHE: Category 3. This new category describes services that were added to the Medicare Telehealth Services List during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria. Services added on a temporary, Category 3 basis will ultimately need to meet the criteria under Category 1 or 2 in order to be permanently added to the Medicare Telehealth Services List.

As part of its CY 2023 Medicare Physician Fee Schedule final rule, CMS finalized alignment of availability of services on the telehealth list with the extension time frame enacted in the Consolidated Appropriations Act, 2022 (CAA, 2022), which was for 151 days after the end of the PHE. In addition, in response to comments, CMS finalized the addition of several audiology CPT codes (CPT codes 92550, 92552, 92553, 92555, 92556, 92557, 92563, 92565, 92567, 92568, 92570, 92587, 92588, 92601, 92625, 92626, and 92627) to the Medicare Telehealth Services List on a Category 3 basis. The services CMS temporarily included on the Medicare Telehealth Services List on a Category 3 basis will continue to be included through the end of CY 2023.

The Consolidated Appropriations Act, 2023 further extended the telehealth flexibilities enacted in the CAA, 2022 through December 31, 2024. Given the recent legislative changes, CMS has updated and simplified the Medicare Telehealth Services List to clarify that the services will be available through the end of CY 2023, which is available at *https://www.cms.gov/medicare/medicare-general-information/telehealth/telehealth-codes.* CMS anticipates addressing updates to the Medicare Telehealth Services List for CY 2024 and beyond through our established processes as part of the CY 2024 Physician Fee Schedule rulemaking process. CMS will continue to assess the benefits of the use of telehealth for various services and is happy to provide technical assistance on any legislation you draft on this issue.

QUESTIONS SUBMITTED BY HON. JOHN CORNYN

BIOSIMILARS

Question. How is CMS working to ensure that there is adequate biosimilar uptake in Part D? As a lower cost alternative to pricier biologics, it is imperative that the agency put in place policies to ensure that seniors will have the options for biosimilars as part of their Medicare Part D benefit. With the expected number of new biosimilars expected to come out later this year, decisions about how the agency will create access is crucial.

Is CMS working to ensure that seniors will have access to biosimilars on their Part D plan formularies, including those that are approved midyear?

Answer. HHS is committed to encouraging the use of biosimilar biological products within the Secretary's scope of authority in order to reduce costs to both beneficiaries and the Federal Government. In general, however, a provision in the Part D statute prohibits the Secretary of Health and Human Services from interfering with the private negotiations between drug manufacturers and pharmacies and plan sponsors, requiring a particular formulary, or instituting a price structure for the reimbursement of covered Part D drugs. However, CMS has the authority to review Part D plan formularies to ensure that drug plans provide access to medically necessary treatments and do not discriminate against any particular types of beneficiaries. CMS uses this authority to review plan formularies for appropriate inclusion of all drug classes. HHS will continue using its authority where possible to seek to promote competition, support increased utilization of biosimilar and generic drugs, reduce the Federal Government's spending on drugs, and achieve greater equity in drug access and affordability for beneficiaries.

MEDICAID CMS BULLETIN

Question. CMS recently issued a bulletin on February 17th, "Health Care-Related Taxes and Hold Harmless Arrangements Involving the Redistribution of Medicaid Payments." The bulletin seemed to indicate that it views these arrangements as not permissible.

Does this bulletin represent a change that CMS is looking to implement?

What steps is CMS looking to implement next? Is the agency considering rulemaking?

How as the agency consulted States, and State Medicaid directors as part of this effort?

Has CMS worked with stakeholders, such as safety net providers and children's hospitals?

Answer. In February 2023, CMS issued an informational bulletin reiterating Federal requirements concerning health care-related taxes and hold harmless arrangements involving the redistribution of Medicaid payments. This guidance, which does not establish new policy, was issued as a reminder in response to questions received from several States about complying with this provision of law. CMS recognizes that health care-related taxes often finance critical programs that pay for care provided to Medicaid beneficiaries and shore up the health care safety net, and it will continue to approve permissible health care-related taxes that meet Federal requirements and remains committed to working with States.

EPSDT BENEFIT

Question. Medicaid's Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit is intended to guarantee that children have access to all medically necessary, age-appropriate services, including mental health services. Through the EPSDT benefit, children enrolled in Medicaid should have access to a range of mental health services across the continuum of care. Yet, while it sets an important standard, significant gaps in access persist for some mental health services, particularly for intermediate levels of care such as day programs and intensive outpatient treatment.

As part of the Bipartisan Safer Communities Act, there was language to have HHS review EPSDT implementation and provide updated guidance to States. Can you give us an update on where your review stands and how you are identifying gaps to ensure equitable access to critical mental health services for children?

Answer. The Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit provides comprehensive and preventive health-care services for most children under age 21 who are enrolled in Medicaid. EPSDT is key to ensuring that children and adolescents receive appropriate preventive, dental, mental health, developmental, and specialty services. States are required to provide comprehensive services and furnish all Medicaid coverable, medically necessary services needed to correct and ameliorate health conditions, based on certain Federal guidelines. The Bipartisan Safer Communities Act directs HHS to review State implementation of EPSDT requirements; identify gaps and deficiencies with respect to State compliance with EPSDT requirements; provide technical assistance to States to address such gaps and deficiencies; and issue guidance to States on the Medicaid coverage requirements for such services, including best practices for ensuring children have access to comprehensive health-care services, including children without a mental health or substance use disorder diagnosis. The statute requires HHS to conduct this review by June 2024.

QUESTIONS SUBMITTED BY HON. JOHN THUNE

INDIAN HEALTH SERVICE PROVIDER CREDENTIALING

Question. In January, Cesar Bartell, who worked as an optometrist at an Indian Health Service facility in Sisseton, SD was found to have a history of criminal charges for child molestation. As you know, this is not the first time a provider employed by IHS has been found to have a history of sexual abuse. I have raised concerns about a lack of oversight and transparency at the IHS for many years. My legislation with Senator Barrasso, the Restoring Accountability in the Indian Health Service Act, would modernize the IHS credentialing system and increase transparency. I understand IHS previously implemented a credentialing and privileging system for new applicants and re-applicants at IHS, but clearly there are still issues with identifying issues with existing providers.

What is HHS doing to ensure the IHS has complete information regarding a provider's history? Are there barriers if an investigation occurs outside the State or locality in which the provider is currently practicing?

Answer. The Indian Health Service (IHS) Director, as one of her first actions as IHS Director, was to require all IHS-operated hospitals and health clinics to clearly post information on the Hotline for Reporting Child or Sexual Abuse, and to continue to conduct a review of all provider credentialing information. For example, IHS holds annual mandatory training, along with mandatory reporting on all incidents of inappropriate sexual conduct. Additionally, a credentialing review of providers is completed in regard to any red flags of inappropriate behavior or conduct, and intermittent audits and reports will be completed.

We take prevention of patient abuse extremely seriously and are doing all we can to rebuild that trust. We have a strong patient safety program that is rolling out across the agency, have established mandatory reporting for all IHS staff with emphasis from agency leadership, and have tightened scrutiny of all credentialing of medical providers. The funding requested for the Office of Quality will support critical activities to improve the quality of patient care and support patient safety. The IHS requests $1.2 million for training, technical assistance, and support at the facility level on patient safety issues. Second, the IHS requests about $500,000 to identify patient safety and administrative risks before incidents occur, and to mitigate those risks across the agency.

IHS is currently using the MD-Staff application[75] for credentialing of all licensed providers (LPs) working in Federal facilities. MD staff complete automated primary source verification of multiple elements, including all (active and inactive) State licenses, DEA registration, OIG sanctions, and National Practitioner Data Bank (NPDB) queries. Furthermore, credential verification is automatic and occurs continuously once a provider is hired. For example, should a new adverse report be submitted to the NPDB on an IHS provider, the system would notify the medical staff

[75] The MD-Staff application is a Commercial Off the Shelf (COTS) software solution to automate and standardize the data collection, storage, access, and approval (decision-making) credentialing process for Indian Health Service. Credentialing consists of the validation of licenser, training, education, proficiency, and currency of professional health-care skills. The purpose also includes verifying and auditing reporting systems on compliance with State, Federal, and other applicable regulations.

professional within 24 hours, prompting review. Finally, LPs are privileged at hire, after their first year (provisional privileges), and every 2 years thereafter, which requires a complete review of their credentials.

An implicit barrier in this process are the existing database limitations, wherein reporting bodies or States may or may not report/participate and may, thus, preclude IHS from obtaining complete information regarding a provider's history. Accordingly, IHS is limited by what information is reported or provided to IHS by third parties such as State license boards or the NPDB.

Question. Will you commit to working with me and my staff on the Restoring Accountability in the Indian Health Service Act, in order to solve this persistent problem?

Answer. The Department, as well as the Indian Health Service, is committed to working with you and your staff on this legislation.

TELEHEALTH

Question. Congress extended many of the flexibilities for Medicare telehealth services that were enacted during the pandemic through the end of 2024. We have learned a lot about telehealth during the pandemic, and we should use these lessons and data to inform long-term policy solutions to benefit patients and providers. That is why I'm concerned that your budget does not include any long-term legislative telehealth proposals in Medicare.

I originally authored legislation with my colleagues, the CONNECT Act, prior to the pandemic, in an effort to support permanent access to telehealth services. I am working to use the insights we've gained from the pandemic to ensure the CONNECT Act now reflects the best long-term policies for patients and providers in the future.

Are there specific telehealth policies that your administration wants to work with Congress on to ensure progress isn't lost when the flexibilities expire at the end of 2024? Will you commit to working with me and my colleagues on the CONNECT Act to ensure patients have permanent access to telehealth?

Answer. In response to the COVID–19 public health emergency, which is set to expire in May 2023, flexibilities for Medicare telehealth services were issued through legislative and regulatory authorities to increase access to care for patients and providers. The Consolidated Appropriations Act of 2023 recently extended many of these flexibilities through December 31, 2024. Extended telehealth flexibilities include waiving geographic and site of service originating site restrictions so that Medicare patients can continue to use telehealth services from their home and allowing audio-only telehealth services. Additionally, the expanded list of providers eligible to deliver telehealth services is also extended so Medicare beneficiaries can continue to receive telehealth services furnished by physical therapists, occupational therapists, speech language pathologists, and audiologists, as well as receive telehealth services from Rural Health Clinics and Federally Qualified Health Centers through December 31, 2024. If you are interested in drafting legislation to make these waivers permanent, CMS would be happy to provide technical assistance.

Additionally, recent legislative and regulatory changes made several telehealth flexibilities permanent. Federally Qualified Health Centers and Rural Health Clinics can furnish certain behavioral and mental health services via telecommunications technology. Medicare patients can continue to receive these telehealth services in their home as geographic restrictions on the originating site are eliminated for these telehealth services. Certain behavioral and mental telehealth services can be delivered using audio-only communication platforms, and rural emergency hospitals can serve as an originating site for telehealth services.

CMS would be happy to provide technical assistance on legislation to make these waivers permanent or any other legislation you have to expand access to telehealth.

With respect to HRSA, certain telehealth flexibilities have shown to be beneficial to health-care providers and underserved patients, such as relieving patients of originating site requirements and allowing Federally Qualified Health Centers/Rural Health Clinics to serve as distant site providers so patients can access telehealth services at home. Access to quality audio-only telehealth services has been of assistance to individuals from underserved communities with limited data plans or other constraints that makes video more challenging or costly.

MODERNIZING THE EXCHANGE OF ELECTRONIC HEALTH INFORMATION

Question. In the 21st Century Cures final rule, ONC stated that it intended the rule to be consistent with the privacy right for patients already contained in HIPAA. However, I've heard from providers that there continue to be cases where providers are not able to share EHR data within their own system as is allowed under HIPAA. If the rule works as intended, access to electronic health information should occur while protecting privacy and supporting efficient health-care operations for providers and patients. The FY 2024 budget states that the Office of the National Coordinator for Health Information Technology (ONC) will continue to carry out the 21st Century Cures Final Rule by providing oversight on information blocking practices.

Are you concerned that electronic health record (EHR) vendors may still be limiting the exchange of data, even in scenarios where information sharing is permitted under HIPAA?

How will you ensure there is appropriate oversight of ONC to ensure data is being shared as intended in the final rule?

Answer. Preventing inappropriate interference with access, exchange, or use of patients' electronic health information that is permitted by the HIPAA Privacy and Security Rules and consistent with the patient's privacy preferences is an HHS priority. When the information is needed to support safe, coordinated care, any limits EHR vendors may be imposing for anti-competitive purposes would be a serious concern that HHS will address where it is identified. Survey data and information blocking claims received by HHS suggest hospitals and potentially other health-care providers are not yet reporting possible information blocking as often as they might be experiencing it. HHS continues to promote to health-care providers the opportunity to report information blocking they experience as well as avoiding engaging in it themselves.

The HHS Office of the Inspector General (OIG), in close ongoing coordination with other parts of HHS, including ONC and the Office for Civil Rights (OCR), has the lead on information blocking enforcement. The 21st Century Cures Act gave the HHS Inspector General authority to investigate any claim that a health IT developer, health-care provider, health information network, or health information exchange engaged in information blocking.[76] In the coming weeks, HHS expects to publish our Office of the Inspector General (OIG) final rule establishing procedures necessary to use the 21st Century Cures Act authority to investigate information blocking claims and take enforcement action against certain entities. Statutory authority to determine civil money penalties specific to information blocking by health IT developers (such as EHR vendors), health information exchanges, and health information networks references violations identified through an OIG investigation.[77] OIG and ONC actively coordinate and will continue to do so to ensure that, in addition to any civil money penalty action taken by HHS through OIG, ONC also takes appropriate action under the ONC Health IT Certification Program with respect to any Program-participating EHR vendors (or other Program-participating developers) determined by OIG to have committed information blocking.

MODERNIZATION OF THE IHS ELECTRONIC HEALTH RECORD

Question. Thank you for including more specific information in the budget on the plans to update the Indian Health Service's electronic health record system. As you know, I've continued to ask about the progress and schedule just about every year, as I don't want to lose sight of this important issue. The administration is proposing to make all funding in IHS mandatory starting in 2025, which is a major change in how IHS is funded. That said, the information included in the budget seems to be in the context of a major change in how IHS is funded.

How will the Department continue the efforts on IT modernization if the larger IHS proposal is not adopted?

Answer. The Indian Health Service (IHS) will continue to move forward with modernization. The IHS released the Request for Proposals for the enterprise electronic health record (EHR) system on August 4, 2022, and anticipates selecting a product in Fall 2023. The Health IT Modernization project is significantly ramping up, and

[76] 42 U.S.C. 300jj–52(b) as added by section 4004 of the 21st Century Cures Act (Pub. L. 114–255).

[77] 42 U.S.C. 300jj–52(b)(2)(A), as added by section 4004 of the 21st Century Cures Act (Pub. L. 114–255).

the IHS needs major funding increases to build the system, remediate sites, and deploy the new system. The President's budget fully funds the current $6.2-billion EHR modernization estimate starting in FY 2024, and continues with additional resources in the out years.

The IHS is currently in the one-time capital investment phase of the modernization project. Once costs for ongoing operations and maintenance are understood, the IHS will begin discussing how those recurring costs should be allocated among sites. The current estimate for the modernization project includes the funding necessary to support all Federal, Tribal, and urban sites. The IHS continues to provide a quarterly Tribal Consultation and Urban Confer on the health IT modernization project and has provided a consultation letter to the chair and ranking member of the House and Senate Appropriations Committees in accordance with the bill language included in the IHS appropriation.

If the IHS budget proposal is not adopted, it could substantially slow progress to provide effective digital capabilities, force the IHS to continue development in the Resource and Patient Management System (RPMS), and risk creating confusion and fragmentation among Federal, Tribal, and urban partners. RPMS is unsustainable, as demonstrated by both internal (OIG) and external (GAO) assessments. If the IHS is unable to proceed with meaningful modernization, the agency risks catastrophic failures in health-care delivery, quality outcomes, and third party revenue collections that are critical to the IHS and its tribal and urban partners in achieving our collective mission.

DURABLE MEDICAL EQUIPMENT

Question. As you know, there are no competitively bid areas in South Dakota for the Competitive Bidding Program for Durable Medical Equipment (DMEPOS) in Medicare. However, CMS uses the bidding rates as the basis for payment amounts in the non-bidding areas. In the past, Congress and CMS have addressed low payment rates for Medicare DMEPOS items in non-Competitively Bid Areas (CBAs) by using a blended rate. In the 2020 CARES Act, Congress provided a 50/50 blended rate for rural areas and a 75/25 blended rate for non-rural, non-CBAs. CMS has made the 50/50 blended rates permanent, while 75/25 rates (extended by Congress in the Consolidated Appropriations Act, 2023) are slated to end at the end of this year.

Does the administration plan to take any administrative action to address the rate for non-rural, non CBAs?

What are the administration's plans for the next round of the Medicare Durable Medical Equipment Competitive Bidding Program?

Answer. As you note, the CARES Act increased the payment rates to a 75/25 blend for durable medical equipment (DME) and enteral nutrients, supplies, and equipment furnished in areas other than rural and non-contiguous non-CBAs through the duration of the COVID–19 Public Health Emergency (PHE) period. In the May 2020 COVID–19 Interim Final Rule with Comment Period (IFC), CMS stated its belief that the purpose of this provision of the CARES Act was to aid suppliers in furnishing items under very challenging situations during the PHE. Furthermore, CMS has long maintained that the fully adjusted rates in nonrural non-CBAs are sufficient. CMS will continue to monitor payments in all non-CBAs, as well as health outcomes, assignment rates, and other information.

QUESTIONS SUBMITTED BY HON. TIM SCOTT

Question. South Carolina's seniors and disabled rely on Medicare Advantage to provide them with high-quality and affordable care and especially value the additional benefits and lower co-pays which reduces their out-of-pocket costs.

Have you conducted an analysis on how this proposal would directly impact providers and beneficiaries in each State and territory—including rural versus urban areas?

Have you conducted an analysis on how this proposal will directly impact medically vulnerable patient populations like dual-eligibles, those with chronic conditions (including diabetes), and depression?

Have you conducted an analysis on how this proposal will directly impact diverse beneficiaries?

Have you analyzed how this proposal will impact the national health-care workforce and physician shortage in each State and territory—including rural versus urban areas?

If so, can you share these analyses with the committee?

Answer. The proposed 2024 Advance Notice published on February 1, 2023 includes a series of routine technical updates, improvements, and recalibrations that would result in an increase to MA payments for plans in 2024. MA payments are expected to increase by 1.03 percent from 2023 to 2024, as proposed. This is about a $4-billion increase in MA payments for next year. The proposals in the Advance Notice improve payment accuracy to ensure MA plan payments better reflect the expected costs of care, with higher payments going to plans serving people with greater health-care needs. This helps ensure that people in MA can continue to access the care they need.

Additionally, there are protective features built into the MA risk adjustment system to ensure that plans caring for dually eligible individuals are paid adequately, and nothing in this proposal changes those features. We will continue to pay much more for someone who is dually eligible than someone who is not, even when they have the same diagnoses. These higher payments decrease incentives for plans to favor healthier enrollees or discriminate against sicker patients.

To the extent beneficiaries who are low-income or who are living in rural or underserved areas have greater health-care needs, the proposed model would better compensate plans for that care. Furthermore, Federal law protects most dually eligible individuals from any cost sharing for Medicare services, so specific plans changes in cost sharing cannot be passed onto those dually eligible beneficiaries.

Under the proposed model updates, Medicare, and thus MA plans, will continue to pay for the services beneficiaries need to treat chronic conditions such as diabetes. As part of updating the risk adjustment model, certain diabetes codes were removed because they are not reliable predictors of cost. Over 300 diabetes codes remain in the risk adjustment model. The proposed model would provide extra payments for patients with diabetes who have complications associated with diabetes, like chronic kidney disease, heart disease, and diabetic retinopathy. In addition, there are other payment factors, such as a condition count bump, that increases payment when beneficiaries have more comorbidities. Thus, the 2024 Advance Notice proposals for this aspect of the MA risk model would provide a more targeted and accurate payment increase for a diabetic patient because it adjusts MA payments according to the patient's full health profile, rather than using only a diabetes diagnosis as a proxy for increased health-care costs. This approach would help ensure that higher payments are directed to diabetic patients with the greatest health-care costs.

Medicare, and thus MA plans, would also continue to pay for the services beneficiaries need to treat depression. The proposed model does not impact coverage of Medicare services or requirements for MA plans to deliver covered services. Under the 2024 Advance Notice, MA payments would more accurately reflect the costs of care associated with this condition. While some depression codes were removed from the model because they did not predict cost well or were duplicative or were related to diagnoses in remissions, more than 350 depression codes remain in the risk adjustment model.

Question. My colleague on this committee, Senator Cortez Masto, and I co-led a letter to Centers for Medicare and Medicaid Services (CMS) Administrator Brooks-LaSure expressing bipartisan support for the Medicare Advantage program and the high-quality, affordable care it provides to over 27 million seniors and people with disabilities. In the CHRONIC Care Act, Congress allowed Medicare Advantage plans to cover telehealth more fully. Consistent with that approach, CMS has allowed telehealth encounters to count toward risk adjustment programs so that telehealth can be offered as a benefit without penalty.

Can you assure this committee that CMS will maintain this policy so as not to jeopardize access to care via telehealth for seniors and people with disabilities?

Answer. In January 2021 CMS issued an updated health plan management system memo on the applicability of diagnoses from telehealth services for the purposes of risk adjustment. Under the memo, Medicare Advantage (MA) organizations and other organizations that submit diagnoses for risk adjusted payment are able to submit diagnoses for risk adjustment that are from telehealth visits when those visits meet all criteria for risk adjustment eligibility, which include being from an allow-

able inpatient, outpatient, or professional service, and from a face-to-face encounter. Diagnoses resulting from telehealth services continue to meet the risk adjustment face-to-face requirement when the services are provided using interactive audio telecommunication simultaneously with video telecommunication to permit real-time interactive communication with the beneficiary. This policy remains in effect.

Question. The Centers for Medicare and Medicaid Services (CMS) stated in January 2023: "CMS will seek feedback and insights from a broad range of interested parties throughout implementation of the IRA, including implementation of the Negotiation Program. CMS is committed to collaborating with and engaging the public in the policymaking process. CMS will work closely with patients and consumers, Part D plan sponsors and Medicare Advantage organizations, drug manufacturers, hospitals and health-care providers, wholesalers, pharmacies, and others."

However, in the Part D Negotiation guidance released March 16, 2023, the agency said it will NOT take comments on proposals for selecting the specific drugs to be negotiated, including particulars around the basis for selecting the drugs and the extent to which drug manufacturers may appeal CMS's decisions. These seem like pretty important factors that could significantly affect a company's operations and the patients they serve.

Given the IRA legislation has NOT afforded affected stakeholders no judicial or administrative review in many areas, why would the agency suppress the voice of impacted stakeholders, when they specifically pledged they would seek feedback?

Answer. CMS recognizes that public input will help to achieve successful implementation and broadly welcomes input from the public at all times. In the initial guidance for the Medicare Drug Price Negotiation Program, CMS decided on key topics to seek comment where CMS would like specific input from the public to operationalize the new program. Due to timing constraints and the requirement to publish the selected drug list for initial price applicability year 2026 by September 1, 2023, CMS is issuing guidance on topics related to drug selection as final, without a comment solicitation.

CMS has sought and will continue to seek feedback and insights from a broad range of interested parties throughout the implementation of the Inflation Reduction Act, including but not limited to comment on initial guidance. CMS is committed to collaborating and engaging with the public in the policymaking process. CMS is working closely with patients and consumers, Part D plan sponsors and Medicare Advantage organizations, drug manufacturers, hospitals and health-care providers, wholesalers, pharmacies, and others. CMS is engaging and will continue to engage interested parties through national stakeholder calls, quarterly strategic meetings, and monthly technical calls with CMS staff. In addition, members of the public are welcome to share feedback and input in writing by email at: *IRARebateandNegotiation@cms.hhs.gov*.

Question. Since the bipartisan Orphan Drug Act was enacted 40 years ago, rare disease and cancer patients have benefited from the development of over 600 new treatments. This is a tremendous achievement, though there's more work to be done. Too many patients living with rare diseases and cancers still have no treatments available to them. Unfortunately, the Inflation Reduction Act threatens the continued success of the Orphan Drug Act. Specifically, it does not protect therapies that treat two or more orphan diseases from government price setting. As a result, we already know of two companies that have cited the IRA as a reason not to continue rare disease drug development.

Will you commit to doing what you can via guidance and rulemaking to ensure that the pipeline of life-altering therapies continues for patients living with rare diseases (like Sickle Cell, Parkinson's, ALS, et cetera) and cancers?

Answer. FDA remains strongly committed to doing what we can via guidance for industry and stakeholder engagement activities to maintain and promote the robustness of the development pipeline for safe and effective drugs and biological products to treat patients with rare diseases, including rare cancers. FDA has published more than 18 guidance documents since 2018 on topics that are highly relevant to drug and biological product development for rare diseases, including rare cancers. Some recent examples include:

- 2023 Draft Guidance for Industry: *Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics.*[78]
- 2023 Draft Guidance for Industry: *Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products.*
- 2022 Guidance for Industry: *Human Gene Therapy for Neurodegenerative Diseases.*
- 2022 Draft Guidance for Industry: *Tissue Agnostic Drug Development in Oncology.*

Of note, with regard to promoting the development of treatments for more than one rare disease at a time, both FDA and NIH, along with several other entities, are working collaboratively to expedite development of gene therapies for rare diseases that are caused by a single genetic mutation and for which there is no commercial interest in developing therapies due to each disease's rarity. This effort, the Bespoke Gene Therapy Consortium, focuses on developing common gene therapy platforms and standards that can be used in the manufacture of several different gene therapies, each for a different rare disease, and thus would increase efficiency overall.

Further, NIH and NCATS remain committed to supporting research to find treatments and cures for rare diseases and conditions without a treatment, and to increase the speed of therapeutic and diagnostic development. At NIH, NCATS's Division of Rare Diseases Research Innovation provides leadership, coordination and collaboration on rare disease research programs across the NIH. Research on specific rare diseases is supported by many NIH Institutes, Centers, and Offices (ICOs) as falls within their respective missions.

NCATS supports rare disease research projects with applicability to many diseases at a time, and works with other HHS operating divisions to ensure appropriate resources and expertise are being applied. One such program involving cross agency collaboration and targeting rare diseases is the Bespoke Gene Therapy Consortium (BGTC), a partnership with the Food and Drug Administration (FDA) and the Foundation for the National Institutes of Health (FNIH), NCATS and 10 other NIH Institutes and Centers (ICs), and several pharmaceutical companies and nonprofit organizations, that will streamline gene therapy development and products for rare disorders of no commercial interest. For BGTC clinical trials, scientists will develop strategies for streamlining the regulatory processes for FDA approval of safe and effective gene therapies, and they will develop standardized approaches to preclinical testing. BGTC has narrowed the potential diseases to be studied to 14, and proposals for clinical trials are being reviewed, with the 5–6 chosen trials to be announced in May 2023.

Another collaborative research initiative is the NIH Common Fund's Somatic Cell Genome Editing (SCGE) program, led by NCATS and the National Institutes of Neurological Disorders and Stroke (NINDS). Phase 1 of the program aims to develop high-quality tools for performing safe and effective genome editing in humans and then make these tools widely available to the research community to reduce the time and cost of developing new therapies. Based on the success of Phase 1, the Common Fund approved a second phase of the program, which will be focused more on accelerating somatic genome editing clinical trials. Applications have been reviewed, and funded projects will be announced shortly. FDA collaborated with the SCGE program throughout Phase 1, and given the greater focus on clinical trials in Phase 2, the NIH and FDA plan to establish a memorandum of understanding (MOU) to efficiently translate the results from Phase 2 projects into the clinic.

Question. Diabetes is a major health crisis in our country, with continuing significant increases particularly in the rate of type 2 diabetes, which can be prevented. In South Carolina, over 500,000 adults have been diagnosed with diabetes, another 120,000 people have diabetes but are unaware, and 1.4 million have prediabetes. In total, that's over half the population of my State. Evidence shows that Diabetes Prevention Programs (DPP) delivered by all modalities of care are effective, and the Centers for Disease Control and Prevention (CDC) recognized DPPs served hundreds of thousands of privately insured Americans in 2022 alone. In contrast, the Medicare Diabetes Prevention Program (MDPP), which severely restricts the number of suppliers, has served only 4,848 beneficiaries since 2018 according to a recent Centers for Medicare and Medicaid Services evaluation report.

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[78] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-trial-considerations-support-accelerated-approval-oncology-therapeutics.* This draft guidance, when finalized, will represent FDA's current thinking on this topic.

With the potential of MDPP now recognized in the administration's budget, what is HHS doing to expand access to these important services through the online and distance learning modalities that have already been validated by the evidence base, by CDC and by the commercial market?

Answer. CDC continues to implement, scale, sustain, and evaluate the National Diabetes Prevention Program (National DPP) and projects that support its implementation. The National DPP relies on results-based partnerships with State health departments, private organizations, insurers, and community-based organizations to deliver and pay for the National DPP.

The National DPP has allowed virtual delivery since 2015. At the start of the pandemic, CDC helped lifestyle change program providers shift from in-person to virtual delivery. Since then, CDC has helped providers maintain and expand their capabilities to deliver the program virtually. For instance, CDC developed a Guide for Using Telehealth Technologies *(https://www.cdc.gov/diabetes/pdfs/programs/E_Telehealth_translation_product_508.pdf)* to provide users with information to help inform their decisions regarding implementation of different telehealth technologies and to provide specific implementation considerations for each technology.

CDC remains focused on increasing access to the National DPP lifestyle change program and funds national organizations to expand the program in medically underserved areas and communities at high risk for diabetes, including Medicare beneficiaries. For example, CDC has worked with the National Association of Chronic Disease Directors and other partners to implement a Medicare Diabetes Prevention Program (MDPP) Enrollment Project. This project supports MDPP suppliers in promoting the program to Medicare beneficiaries; increasing health-care provider referrals to the program; and obtaining and using billing software to process and submit claims to CMS, which supports program sustainability.

CDC has also collaborated with National Association of Chronic Disease Directors, Centers for Medicare and Medicaid Services, and the American Medical Association to develop MDPP resources in its coverage toolkit (Medicare Diabetes Prevention Program (MDPP) Implementation Resources—National DPP Coverage Toolkit, *https://coveragetoolkit.org/medicare/mdpp-implementation-resources/*). Examples of these resources include a recorded webinar, frequently asked questions, and a fact sheet for MDPP suppliers to navigate changes to their programs during the public health emergency, such as flexibilities for virtual sessions.

Additionally, as detailed by the White House National Strategy of Hunger, Nutrition, and Health, the administration set a goal of ending hunger and increasing healthy eating and physical activity by 2030 so fewer Americans experience diet-related diseases—while reducing related health disparities. Integrating nutrition and health can optimize Americans' well-being and reduce health-care costs. Currently, only a limited number of Medicare beneficiaries are seeking nutrition and obesity counseling services. The President's FY 2024 budget includes a proposal to expand access to additional beneficiaries with nutrition or obesity-related chronic diseases and make additional providers eligible to furnish services.

Medicare covers an array of services that aim to address obesity. For example, obesity screenings, intensive behavioral therapy for obesity for the prevention or early detection of illness or disability, bariatric surgical procedures, and diabetes screenings and participation in a diabetes prevention program are covered under Medicare in certain cases. Under current law, the Medicare statute excludes "agents when used for anorexia, weight loss, or weight gain" from the definition of a Part D drug in section 1860D–2(e) of the Social Security Act. Despite this statutory exclusion, Part D sponsors wishing to provide coverage of prescription weight loss agents may do so as a supplemental benefit to enhanced alternative Part D plans, as they can with other prescription drugs that are excluded from the definition of a Part D drug.

Question. During the COVID–19 public health emergency (PHE) the Centers for Medicare and Medicaid Services (CMS) provided flexibility to allow the virtual supervision of drug infusions by nurse practitioners through real-time audio/video technology. Providers have been expediently utilizing this flexibility throughout the PHE, when appropriate, which has increased access to care, maintained patient safety, and enabled patients to follow their treatment plans more easily without interruptions due to staffing shortages or canceled appointments. This flexibility is especially important and can be beneficial as the country continues to face widespread health-care workforce shortages and access issues for rural patients. In the Calendar Year 2023 Physician Fee Schedule (PFS), CMS declined to extend this

flexibility beyond the PHE, though they said they would consider comments received from the proposed rule for potential future PFS rulemaking.

Has CMS done any further evaluation of this vital flexibility, and do you plan on extending or making it permanent?

Answer. During the public health emergency (PHE) for COVID–19, CMS temporarily modified the regulatory definition of direct supervision, which requires the supervising physician or practitioner to be "immediately available" to furnish assistance and direction during the service, to include "virtual presence" of the supervising clinician through the use of real-time audio and video technology. Under our currently finalized policies, CMS will continue to permit direct supervision through a virtual presence through the end of the year in which the PHE ends (through December 31, 2023). We continue to gather information on this topic, and we appreciate the information provided by commenters in the CY 2023 Physician Fee Schedule Rule. We believe allowing additional time to collect information and evidence for direct supervision through virtual presence will help us to better understand the potential circumstances in which this flexibility could be appropriate permanently, outside of the PHE for COVID–19.

Question. Medicare physician payments, which were dramatically altered following the passage of the Medicare Access and CHIP Reauthorization Act (MACRA) in 2015, and its impact on patient access to care remains a major issue for my constituents. In fact, adjusted for inflation in practice costs, Medicare physician pay actually declined 26 percent from 2001 to 2023, or by 1.8 percent per year on average. Congress has been forced to provide annual payment patches to prevent, in part, budget neutrality driven cuts to the Medicare Physician Fee Schedule. It is clear that the Medicare physician payment system is broken.

What is HHS doing administratively to make the Medicare payment system run more smoothly? Does HHS to have the necessary authority to make improvements to the MACRA program?

Answer. Ensuring adequate payment rates for physicians and other health-care professionals is essential in maintaining access to high-quality and affordable health care. HHS appreciates Congress' leadership in the Consolidated Appropriations Act of 2023 to provide temporary, 1-year increases in payment amounts for all services under the physician fee schedule by 2.5 percent in 2023 and 1.25 percent in 2024. HHS also appreciates Congress's work to extend incentive payments for clinicians who are qualifying participants in advanced alternative payment models through 2025. CMS does not have the legal authority to implement increases in payment outside of budget neutrality without additional action taken by Congress. Annual Medicare physician payment updates have been set in statute since 2015. CMS does not have the authority to use a different update. If Congress wants to change the law, we would be happy to provide technical assistance on legislation you draft.

Question. The fall 2022 Department of Health and Humans Services Unified Agenda regulatory calendar currently lists April 2023 as the target date for Centers for Medicare and Medicaid Services (CMS) to release the Medicare Transitional Coverage for Emerging Technologies (TCET) proposed rule (CMS–3421, *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0938-AU86*), which would provide transitional Medicare coverage for new medical technologies.

Can you assure this committee that CMS will issue the TCET proposed rule by April 2023, particularly given that this rule was initially scheduled for release in 2022, and originally discussed over 2 years ago when the Medicare Coverage of Innovative Technology rule was repealed? Assuming that CMS publishes the TCET proposed rule in April 2023, when does the agency expect to release and implement the final rule?

Answer. CMS remains committed to expanding access to health-care coverage and services, including new, innovative treatments when they are safe and appropriate. CMS rescinded the Medicare Coverage of Innovative Technology and Definition of "Reasonable and Necessary" (MCIT/R&N) final rule because of concerns that the provisions in the final rule may not have been sufficient to protect Medicare patients. By rescinding this rule, CMS will take action to better address those safety concerns in the future.

Improving and modernizing the Medicare coverage process continues to be a priority, and we remain committed to providing stakeholders with more transparent and predictable coverage pathways. CMS is working as quickly as possible to advance multiple coverage process improvements that provide an appropriate balance

of access to new technologies with necessary patient protections. As part of this effort, CMS has conducted several listening sessions to learn about stakeholders' most pressing challenges and to receive feedback from stakeholders about which coverage process improvements would be most valuable.

CMS intends to explore coverage process improvements that will enhance access to innovative and beneficial medical devices in a way that will better suit the health-care needs of people with Medicare. This will also help to establish a process in which the Medicare program covers new technologies on the basis of scientifically sound clinical evidence, with appropriate health and safety protections in place for the Medicare population. HHS looks forward to working with you and hearing your feedback as we move forward with these efforts.

Question. Unfortunately, South Carolina ranks towards the bottom of U.S. States when it comes to maternal mortality rates. A March 2022 legislative brief from the South Carolina Maternal Mortality Review Committee showed that in 2021, South Carolina completed the review of pregnancy-related deaths occurring in 2018 which resulted in the first report of the South Carolina Pregnancy-Related Mortality Ratio (PRMR)—35.3 pregnancy-related deaths per 100,000 live births in 2018. This number is well above the national average. This is clearly an issue impacting my constituents.

The birthing-friendly hospital designation was implemented to show the public what hospitals were meeting the guidelines set out, but what are the administration's next steps beyond publishing that list?

Answer. Medicaid is the largest single payer of pregnancy-related services and covers over 42 percent of births nationally. The Children's Health Insurance Program (CHIP) also covers pregnant adolescents and, in some States, low-income pregnant individuals with income over the Medicaid income limit. Together, Medicaid and CHIP play a critical role in ensuring access to care for pregnant and postpartum individuals, improving the quality of maternal health care, and addressing disparities in health outcomes and pregnant and postpartum care. The American Rescue Plan Act of 2021 gave States a new option to provide 12 months of continuous postpartum coverage to pregnant individuals enrolled in Medicaid and CHIP beginning April 1, 2022, for a period of 5 years.[79] The Consolidated Appropriations Act, 2023, made permanent this State option. To date, more than 30 States and the District of Columbia have elected to extend postpartum coverage, including South Carolina.[80]

Additionally, in July 2022, CMS released its Maternity Care Action Plan *(https://www.cms.gov/files/document/cms-maternity-care-action-plan.pdf)* to support the implementation of the Biden-Harris administration's Blueprint for Addressing the Maternal Health Crisis *(https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/24/fact-sheet-president-bidens-maternal-health-blueprint-delivers-for-women-mothers-and-families/#:~:text=The%20Blueprint%20outlines%20five%20priorities,outcomes%20in%20the%20United%20States%3A&text=Increasing%20access%20to%20and%20coverage,services%2C%20including%20behavioral%20health%20services)*. The action plan takes a holistic and coordinated approach across CMS to improve health outcomes and reduce inequities for people during pregnancy, childbirth, and the postpartum period. CMS's implementation of the action plan will support the Biden-Harris administration's broad vision and call to action to improve maternal health.[81] CMS is always happy to receive feedback from stakeholders on additional ways the agency can advance equity and reduce disparities in maternity care.

Question. Due to the complexity of the pharmacy practice, many pharmacy students undertake a residency in a hospital. According to Federal regulation, pharmacy residency programs operated by hospitals that are affiliated with or owned by a health system or academic medical center are required to be directly controlled by those hospitals (42 CFR § 413.85). These hospitals receive pass-through payments from Medicare. However, due to a lack of clarity and Medicare Administrative Contractors' (MACs) inconsistent interpretation of what is needed to meet the "direct control" requirement, hospitals and affiliated health systems need greater clarity

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[79] *https://www.medicaid.gov/federal-policy-guidance/downloads/sho21007.pdf.*

[80] *https://www.medicaid.gov/federal-policy-guidance/downloads/image-maternity-care-expansion.png.*

[81] *https://www.cms.gov/newsroom/press-releases/cms-releases-maternity-care-action-plan-implement-biden-harris-maternal-health-blueprint-launches.*

from the Department of Health and Humans Services and the Centers for Medicare and Medicaid Services (CMS) to ensure compliance.

Can hospitals share or contract for administrative functions the health systems, without violating 42 CFR §413.85(f)(1)(i)–(v)? What documentation would assist CMS in confirming that the hospital retains control of the residency program?

Answer. Under Medicare regulations, Pharmacy Residency Programs must meet certain requirements in order to claim pass-through payments from Medicare. These regulations (42 CFR §413.85) require providers to meet a number of requirements with respect to training costs, curriculum, instruction, and program administration. Specifically, with respect to program administration, the regulations state that the operator must "control the administration of the program, including collection of tuition (where applicable), control the maintenance of payroll records of teaching staff or students, or both (where applicable), and be responsible for day-to-day program operation. (A provider may contract with another entity to perform some administrative functions, but the provider must maintain control over all aspects of the contracted functions.)"

Question. Many osteopathic medical students choose to actively pursue careers in primary care, strengthening the backbone of our Nation's health-care system. Fifty-seven percent of osteopaths practice in primary care (including family medicine, internal medicine, and pediatrics). Osteopathic medical education also has a proven history of establishing educational programs for medical students and residents that target the health-care needs of rural and underserved populations. Sixty percent of colleges of osteopathic medicine are located in health professional shortage areas, 64 percent require their students to go on clinical rotations in rural and underserved areas, and 88 percent have a stated public commitment to rural health. Further, 41 percent of graduating 2020–2021 osteopathic medical students plan to practice in a medically underserved or health shortage area; of those, 49 percent plan to practice in a rural community.

What role will osteopaths and the osteopathic medical education community serve in the HHS Initiative to Strengthen Primary Health Care?

Answer. Thank you for your question regarding the HHS Initiative to Strengthen Primary Health Care and the role of osteopathic physicians and the osteopathic medical education community. The HHS Initiative to Strengthen Primary Health Care was launched in September 2021 to strengthen the Federal foundation for the provision of whole person primary care for all, to improve: access to health care, the health and well-being of people, families and communities, and health equity. Primary care is the foundation and entry way of our health-care system and strong primary care has been documented to improve health, longevity, and health equity.

A first deliverable of the HHS Initiative to Strengthen Primary Health Care is an HHS Action Plan to Strengthen Primary Care. This has been collaboratively developed by 14 HHS Operating and Staff Divisions and coordinated by the Office of the Assistant Secretary for Health. The action plan, which outlines actions HHS will take in FY 2023 and 2024, under current funding and statutory authority, is in the final stages of HHS clearance and will be released later this year. The HHS Action Plan focuses on increasing investment in primary care and advancing effective payment models, strengthening the workforce, improving equitable access to primary care, advancing digital health to support primary care, and advancing primary care research and its translation into practice.

Primary care clinicians are physicians, nurse practitioners, physician assistants, and clinical nurse specialists who practice primary care. They often practice in a team that may include nurses, medical assistants, case managers, community health workers, and other staff members. With integration of other clinical services and primary care, such as behavioral health, oral health and clinical pharmacy, the team expands its multiple disciplines. For physicians, the major specialties of primary care are family medicine, general internal medicine, general pediatrics, and geriatrics.

Osteopathic physicians are important members of the primary care physician workforce and, as you note, are particularly important for the primary care workforce in medically underserved and rural areas. In addition, the osteopathic medicine approach, which focuses on health and well-being and holistic, person-centered care, is completely aligned with the aims and vision of the HHS Action Plan to Strengthen Primary Care. Osteopathic medical education is also very much community-based, which the HHS Initiative aims to foster. Thus, osteopathic physicians

and osteopathic medical education are integral to the HHS Initiative to Strengthen Primary Health Care and the HHS Action Plan to Strengthen Primary Care.

In the process of developing the HHS primary care action plan, the American Association of Colleges of Osteopathic Medicine (AACOM) responded to the HHS Initiative to Strengthen Primary Health Care Request for Information and the OASH Primary Health Care team held a listening session with AACOM to discuss osteopathic medical and graduate medical education.

QUESTIONS SUBMITTED BY HON. JAMES LANKFORD

UNACCOMPANIED CHILDREN

Question. In Fiscal Year 2022, the Department of Homeland Security referred 128,904 unaccompanied children to the Office of Refugee Resettlement. That is more than triple the number of unaccompanied children that arrived to the United States in fiscal year 2017. In response to this dramatic increase in vulnerable children coming to the border, *The New York Times* reports that the Department of Health and Human Services has prioritized speed over safety when placing unaccompanied children with sponsors.

Moreover, myself and six other Senators sent a letter to you last year that has gone unanswered expressing our concern with ORR's dependence on Field Guidance #21 which instructs staff to place pregnant unaccompanied children in ORR facilities based on the State's abortion laws in which the facility is located. A child's referral to ORR is an opportunity to treat them with care while searching for appropriate, vetted sponsors, not an opportunity to encourage the taking of unborn life. Every life is worthy of protection, born or unborn. In light of these concerns, please answer the following questions.

How many abortions has HHS ORR facilitated for unaccompanied minors in its custody? Please include a breakdown of chemical abortions and surgical abortions and whether such abortion took place at an ORR facility.

Answer. ORR has strict confidentiality policies related to sharing health-care information of the children it serves, including regarding their reproductive health. ORR policy requires, to the greatest extent possible, placement of pregnant unaccompanied children requesting an abortion in ORR programs that are State licensed to care for pregnant children and in an appropriate location to support the child's health-care needs. This includes access to an appropriate medical provider who is able to legally perform the requested abortion. The particulars of the abortion procedure are the purview of medical providers, not ORR.

Question. How much Federal funding has HHS spent on facilitating abortions for minors including, staff time, transportation and accommodation costs? Please provide a breakdown of the costs by type.

Answer. ORR complies with Federal law, including Federal appropriation restrictions regarding payment for abortions as passed by Congress.

Question. Please provide a list of all States and localities where HHS ORR has transported pregnant unaccompanied minors in order to facilitate their access to abortion.

Answer. ORR does not capture this information in a reportable format. As a matter of policy, travel to access comprehensive medical services is permissible and routine for unaccompanied children in ORR care and custody (see ORR Unaccompanied Children (UC) Program Policy Guide Sections 3.4, 3.4.3 and 3.4.4, *https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-section-3*).

Question. What steps is HHS taking to coordinate with law enforcement to identify and remove children from unsafe sponsorships? How many children has HHS removed from such unsafe sponsorships since January 2021? Please share with the committee a breakdown of the number and reasons for such termination?

Answer. ORR's custodial authority over unaccompanied children ends when a child is released from ORR care. ORR does not have the authority to remove a child from a household once released—that authority resides with each State's child protective services.

ORR conducts a minimum of three safety and well-being calls to children and sponsors after ORR releases a child from its care. ORR cannot require children and sponsors to participate in safety and well-being calls, and they may choose not to answer a call for a variety of reasons. Also, upon their release, ORR provides children with information on the ORR National Call Center (ORRNCC), a 24-hour, 7 days a week, resource. Care providers, post-release services (PRS) providers, and ORRNCC staff are required to document and report any safety concern, in accordance with mandatory reporting laws, State licensing requirements, Federal laws and regulations, and ORR policies and procedures to ORR, as well as to the appropriate local law enforcement agency, State and local child protective services, or both. Over the last 2 months, ORR has implemented a requirement for the ORRNCC to provide children who call the helpline and express safety concerns with information regarding the authorities to which their safety concerns will be reported. It also connects children directly with the appropriate authority when possible and place an additional follow-up call to the child to confirm if any further actions are needed. If a placement is found to no longer be safe for a child, ORR and its grant recipients and contractors alert the necessary law enforcement entities and child protective services, which have the legal authority to take appropriate action—an authority that does not rest with the U.S. Department of Health and Human Services (HHS).

Question. What is the extent of Interagency Coordination with HHS Office of Refugee Resettlement, DHS, and DOL on ensuring the welfare of unaccompanied children at the border?

Answer. Under the Homeland Security Act of 2002 and the Trafficking Victims Protection Reauthorization Act (TVPRA) of 2008, ORR is legally required to provide for the care and custody of all unaccompanied children from the moment they enter ORR's custody following a referral from the U.S. Department of Homeland Security (DHS) or other Federal entity until they are appropriately and safely released to a vetted sponsor. For additional information about ORR's vetting policies, see ORR UC Program Policy Guide section 2, *https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-section-2*.

ORR and DHS coordinate the transfer of unaccompanied children from DHS custody to ORR custody. At the time of referral, DHS shares all pertinent information related to the unaccompanied child to facilitate the child's placement into ORR's custody. This information includes basic biographical data on the child; situational factors such as health, pregnancy, travel companions; human trafficking indicators; and any known criminal records or behavioral issues. DHS enters all information via the Unaccompanied Children Portal—ORR's system of records. ORR uses this information to make a placement designation within 24 hours and notifies both the referring agency and the care provider by email when a suitable placement becomes available, which by statute must occur within 72 hours of DHS's determination of the child's unaccompanied child status. DHS's Immigration and Customs Enforcement (ICE) is responsible for the physical transfer of unaccompanied children to ORR-funded care provider facilities. The ICE transportation contractor coordinates directly with U.S. Customs and Border Protection (CBP) and ORR for operational arrangements and estimate time of arrival notices.

Coordination between HHS and the U.S. Department of Labor are ongoing. On March 23, 2023, the Department of Labor's Wage and Hour Division (DOL/WHD) and HHS's Administration for Children and Families signed an agreement to formalize a partnership between the agencies and outline procedures the agencies will follow as they work together to deepen information-sharing, coordination, training, and education. The Memorandum of Agreement (MOA) seeks to maximize DOL/WHD's enforcement of the child labor protections within the Fair Labor Standards Act and to enhance HHS/ACF's ability to protect children from exploitation and to connect individuals to needed benefits and services. The MOA includes unprecedented steps for greater collaboration between the two agencies to prevent and address illegal child labor.

Question. On February 27th, HHS announced a 4-week audit of their vetting process for sponsors for unaccompanied children. Will you commit to providing the committee a copy of the written report describing the outcome of your audit and provide an interagency briefing for the committee following the HHS audit of sponsor vetting processes?

Answer. ORR looks forward to providing more information on the outcome of the audit soon, which will inform ongoing process improvements to ORR's UC program. Further information regarding the audit is anticipated soon.

HEALTH IN AMERICA

Question. In your opening statement, you mentioned that HHS is working on policies that would help our health system not be an "illness care" system, but a "wellness care" system instead.

What efforts has HHS taken to address health problems in America through healthy eating and lifestyle changes instead of solely focusing on increased funds to public health programs?

Answer. By far, the greatest burden of disease in the United States is attributable to diseases related to poor nutrition and low rates of physical activity. At the most foundational level, HHS leads the development of evidence-based nutrition and physical activity guidelines, which are the basis for numerous initiatives designed to advance health and prevent disease in America. These foundational documents have been iteratively produced for decades. A description of the *Dietary Guidelines for Americans* and the *Physical Activity Guidelines for Americans* can be found below, along with examples of initiatives that HHS has created to implement these guidelines, to help improve healthy eating and physical activity among diverse populations.

HHS also works with Federal partners to develop national objectives related to healthy eating and physical activity through its longstanding Healthy People *(https://health.gov/healthypeople)* initiative, as congressionally mandated. By focusing action across public health and related sectors of government and civil society toward achieving these key Healthy People objectives, we can improve health and well-being.

Through the COVID–19 pandemic, HHS has coordinated a whole of government initiative—Equitable Long-Term Recovery and Resilience *(https://health.gov/our-work/national-health-initiatives/equitable-long-term-recovery-and-resilience)*—to develop and implement a Federal plan that has the potential to orient most extant Federal resources to favorable outcomes in individual and community resilience, as defined in the framework of Vital Conditions for Well-being. This broader initiative is designed to affect longitudinal change at a systems level such that the conditions for healthy living and thriving are enhanced equitably across communities.

Improving Healthy Eating Through Evidence-Based Guidance: Dietary Guidelines for Americans

The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) work together to update and release the statutorily mandated *Dietary Guidelines for Americans (Dietary Guidelines, https://www.dietaryguidelines.gov/)* every 5 years. The *Dietary Guidelines* provides advice on what to eat and drink to meet nutrient needs, promote health, and prevent disease. Each edition of the *Dietary Guidelines* reflects the current body of nutrition science and is developed and written for a professional audience, including policymakers, health-care providers, nutrition educators, and Federal nutrition program operators.

On January 19, 2023, the HHS and USDA announced the appointment of 20 nationally recognized nutrition and public health experts to serve on the 2025 Dietary Guidelines Advisory Committee. The Committee is tasked with reviewing the current body of nutrition science on specific topics and questions and developing a scientific report that includes its independent, science-based advice for HHS and USDA to consider. The Committee's review, along with public comments on its scientific report and agency input, will help inform HHS and USDA as they develop the *Dietary Guidelines for Americans, 2025–2030.*

Examples of HHS efforts to implement the Dietary Guidelines:

1. **Toolkit for Health Professionals:** Health professionals play a key role in encouraging healthy food and beverage choices. To assist health professionals in implementing the evidence-based nutrition guidance found in the *Dietary Guidelines for Americans, 2020–2025,* the HHS Office of Disease Prevention and Health Promotion developed a suite of materials *(https://health.gov/our-work/nutrition-physical-activity/dietary-guidelines/current-dietary-guidelines/toolkit-professionals)* to help health professionals start a conversation and share key messages with patients, clients, and peers.
2. **Updated definition of the "healthy" claim:** On September 28, 2022, the Food and Drug Administration issued a proposed rule to update the definition of the nutrient content claim "healthy" to align with the *Dietary Guidelines for Americans, 2020–2025* and the updated Nutrition Facts label. The

"healthy" claim can act as a quick signal on food package labels to help empower consumers, including those with lower nutrition knowledge, with information to identify foods that will help them build healthy eating patterns.

Diet-related chronic diseases in the United States are the leading causes of death and disability. Healthy eating patterns, which include fruits, vegetables, lower-fat dairy, and whole grains, are associated with improved health, such as reduced risk of cardiovascular disease, type 2 diabetes, certain types of cancers, and being overweight or obese. Providing informative and accessible food labeling empowers consumers and may help foster a healthier food supply for all if some manufacturers include more fruits, vegetables, dairy, and whole grains and limit saturated fat, sodium, and added sugars in their products to qualify to use the updated claim.

Improving Physical Activity Through Evidence-Based Guidance: Physical Activity Guidelines for Americans

The *Physical Activity Guidelines (https://health.gov/our-work/nutrition-physical-activity/physical-activity-guidelines/current-guidelines)* is an essential resource for health professionals and policymakers. It includes recommendations for Americans ages 3 years and over—including people at increased risk of chronic disease—and provides evidence-based advice on how physical activity can help promote health and reduce the risk of chronic disease. The *Guidelines* serves as the primary, authoritative voice of the Federal Government for evidence-based guidance on physical activity, fitness, and health for Americans.

HHS released the first edition of the *Guidelines (https://health.gov/our-work/physical-activity/previous-guidelines/2008-physical-activity-guidelines)* in 2008, followed in 2013 by the *Physical Activity Guidelines for Americans Midcourse Report: Strategies to Increase Physical Activity Among Youth (https://health.gov/our-work/physical-activity/previous-guidelines/2013-midcourse-report).* The current version—the second edition of the *Physical Activity Guidelines for Americans*—was released in 2018. A midcourse report for this iteration will be released in June 2023, focused on strategies to increase physical activity among older adults.

Examples of HHS efforts to implement the physical activity guidelines for Americans:

1. **Move Your Way® Campaign:** The HHS Office of Disease Prevention and Health Promotion developed the Move Your Way® *(https://health.gov/our-work/nutrition-physical-activity/move-your-way-community-resources)* campaign to promote recommendations from the second edition of the *Physical Activity Guidelines for Americans.* Rather than a one-size-fits-all approach, Move Your Way emphasizes personalized, practical strategies that people can use to fit more activity into their busy lives, while clearly communicating the amount and types of physical activity Americans need to stay healthy. The campaign includes a partner toolkit with materials in English and Spanish to promote the benefits of physical activity among a wide variety of audiences.
2. **National Youth Sports Strategy (NYSS):** According to the *Physical Activity Guidelines for Americans,* youth ages 6 to 17 years need at least 60 minutes a day of moderate-to-vigorous physical activity. Playing sports is one way youth can get the physical activity they need. Sports also provide opportunities for youth to experience the connection between effort and success, and may enhance their academic, economic, social, and health prospects.

In 2019, ODPHP launched the National Youth Sports Strategy (NYSS, *https://health.gov/our-work/nutrition-physical-activity/national-youth-sports-strategy/about-national-youth-sports-strategy*) with the goal of uniting the U.S. youth sports culture around a shared vision: that one day, all youth will have the opportunity, motivation, and access to play sports. The Strategy is based on research and best practices from the scientific community and successful youth sports programs across the United States. It offers actionable ideas for parents, coaches, organizations, communities, and policymakers to support youth sports participation for all.

Following the release of the NYSS, the Office of Disease Prevention and Health Promotion (ODPHP) created the NYSS Champions program as a way to recognize organizations that promote youth sports in their communities and help achieve the NYSS vision: that one day, all youth will have the opportunity, motivation, and access to play sports.

3. **Active People, Healthy Nation℠:** Active People, Healthy Nation *(https://www.cdc.gov/physicalactivity/activepeoplehealthynation/about-active-people-*

healthy-nation.html) is a national initiative led by CDC to help 27 million Americans become more physically active by 2027. To achieve this goal, CDC has created tools for action *(https://www.cdc.gov/physicalactivity/activepeoplehealthynation/everyone-can-be-involved/index.html)* so that communities can implement evidence-based strategies to increase opportunity for greater physical activity across a variety of sectors and settings.

The NIH Office of Nutrition Research (ONR) is leading a cross-government initiative on Food is Medicine research, which would integrate nutrition science and health care. Through this initiative, supported by funding requested in the FY 2024 President's budget, healthy eating and lifestyle changes to reduce the burden of diet-related chronic diseases, including diabetes and obesity, which are some of the most deadly and costly in this country, will be emphasized. ONR has developed a comprehensive Food is Medicine Networks or Centers of Excellence program that aims to support clinical nutrition research on the effectiveness of increasing attention to healthy diets and lifestyles within the medical enterprise. It aims to expand clinical nutrition science and lifestyle medicine training in medical school curricula and across health professions. Working in partnership with other Federal agencies, these NIH Networks or Centers of Excellence will aim to develop the evidence-base and identify the most effective approaches to healthy eating and lifestyle medicine to both prevent and treat diet-related chronic diseases.

"INFLATION REDUCTION ACT" IMPACT ON CANCER

Question. The administration, including the President himself during his State of the Union speech, has been touting the Cancer Moonshot initiative and the goal to "cut cancer death rates in half in the next 25 years." Oklahoma has a state-of-the-art NCI-designated cancer research and treatment facility.

However, **I am wondering how the administration is taking into account its own actions in actually keeping itself from reaching its own goals?** As I am sure you have seen, several drug manufacturers have noted that they will likely be forced to remove drugs, nearly all of them mentioning cancer drugs specifically, from production because of the impacts of the IRA drug price setting policies. So at the same time, the administration is claiming they are going to cure cancer, the companies that actually do the R&D on possible cancer cures, are saying that they are having to pull back because of a policy that same administration supported.

How many more tax-payer dollars will have to be spent to make up for the cancer treatments that the private industry was already working on?

Answer. FDA is not involved in drug pricing, nor does it control the business decisions made by pharmaceutical companies. We will continue to work with the pharmaceutical industry to expedite the development of cancer products through our expedited programs and Oncology Center of Excellence regulatory review pilots.

Question. How much faster could cancer treatments that were already in the pipeline get to patients if their manufacturers were incentivized to produce them instead of if they are disincentivized as they are now?

Answer. FDA is committed to working with all drug stakeholders including the pharmaceutical industry to modernize evidence generation throughout all phases of development and use FDA expedited programs to speed access and approval of products to diagnose and treat patients with cancer.

ALZHEIMER'S

Question. One in three seniors die from Alzheimer's or a related form of dementia. Bipartisan groups of members in Congress have written to the administration about concerns over the CMS National Coverage Determination (NCD) policy and its impact on access to Alzheimer's therapeutics and diagnostics. This new class of Alzheimer's treatments gives families hope that they will have more quality time with their loved ones before the disease takes hold. Since then, CMS has declined to open the NCD to increase access for patients and families in need.

Why is your agency treating patients with Alzheimer's differently than others with life-threatening conditions?

What gives CMS more authority than the FDA to decide if a drug is safe and effective?

Answer. Alzheimer's disease is a devastating illness that affects millions of Americans and their families. CMS is committed to helping people get timely access to treatments and improving care for people with Alzheimer's disease and their fami-

lies. CMS has a responsibility to ensure that people with Medicare have appropriate access to therapies that are reasonable and necessary for use in the Medicare population.

The FDA performs a vital and an important role. CMS recognizes the important and related—but different—roles of the respective agencies. The FDA determines whether to approve a new medical product based on a careful evaluation of the available data and a determination that the medical product is safe and effective for its intended use. CMS conducts its own independent review to determine whether an item or service is reasonable and necessary for use in the Medicare population and should be covered nationally by Medicare.

NURSING HOMES

Question. Recently, CMS has suggested placing some additional requirements on nursing homes with the stated goal of increasing patient safety, including the implementation of Federal staffing ratio requirements. Most States have their own staff ratios to account for their individual populations and what needs and workforce looks like in their State. While we have the same goal of helping nursing homes keep patients safe, Federal standardized staff requirements will not help quality of care. In fact, it may actually decrease it by causing some facilities to close their doors. SNFs in rural Oklahoma are already caring for a large variety of patients, both with long term and short term needs—sometimes because they are one of the only Medicaid providers in the area. By placing Federal requirements on a system that is not one-size-fits-all, you are actually hurting the most vulnerable patients in the system.

What type of real stakeholder engagement has CMS engaged in to create proposals like the Federal staffing requirement, besides opening a comment period in the Federal Register?

Were nursing home workers and patients in rural America taken into consideration when crafting this policy? What did outreach to this population specifically look like?

Why did the administration choose to not extend its COVID Public Health Emergency policy which allowed nursing homes to train Temporary Nurse Aides (TNAs) and allow for extra time for those TNAs to acquire full training certification?

Answer. Understaffing continues to be a concern despite existing requirements. For that reason, CMS believes it essential to patient safety that it conduct new rulemaking to propose more specific, detailed, and quantitative minimum staffing requirements.

CMS initially published a Request for Information (RFI) soliciting public comments on minimum nursing home staffing requirements in April 2022, within the Fiscal Year (FY) 2023 Skilled Nursing Facility Prospective Payment System Proposed Rule. CMS received over 3,000 comments from a variety of interested parties including advocacy groups; long-term care ombudsmen; industry associations (providers); labor unions and organizations; nursing home staff and administrators; industry experts and other researchers; family members; and caretakers of nursing home residents. The vast majority of comments received from members of the public who identified themselves as family members or caretakers of residents living in nursing homes voiced concerns related to residents not receiving adequate care because of chronic understaffing in facilities. Multiple commenters stated that residents can go entire shifts without receiving toileting assistance, leading to falls or increased presence of pressure ulcers. One commenter, whose parents live in a nursing home, noted that they visit their parents on a daily basis to ensure the provision of quality care and reported that staff in the facility have stated that they are overworked and understaffed.

The feedback received has and will be used to inform the research study design for the mixed methods study that CMS is conducting with qualitative and quantitative elements to help to inform the minimum staffing proposed requirements. CMS seeks to consider all feedback from the RFI responses, listening sessions, and mixed methods study in crafting proposals for minimum direct care staffing requirements in nursing homes. We expect to propose such requirements to advance the public's interest in safe, quality care for residents in a 2023 rulemaking. CMS intends to seek workable, implementable solutions that ensure safe, quality care for residents. CMS appreciates the interest shown by so many stakeholders to date and looks forward to robust response from stakeholders when the proposed rule is issued.

INFLATION CAPS

Question. Your budget calls for the expansion of several Inflation Reduction Act policies from Medicare to the private market, one of which is inflation caps on drug prices. I have been arguing for several years at this point about the negative repercussions from placing inflationary caps on drug prices—namely how they will almost surely incentivize companies to launch their drugs at much higher prices than they otherwise would have. Even CBO agrees—they said, "the inflation-rebate and negotiation provisions would increase the launch prices for drugs that are not yet on the market relative to what such prices would be otherwise."

Why does HHS continue to move forward with the expansion of policies that are proven to increase drug prices when the stated goal is to decrease prices?

Answer. The Inflation Reduction Act requires manufacturers to pay rebates to Medicare when drug prices for certain rebatable Medicare Part B or Part D drugs rise at a rate that is faster than the rate of inflation. The budget includes a proposal to revise the formula to calculate these rebates beyond Medicare utilization to include drug units used by commercial plans. Doing so would provide additional savings while discouraging manufacturers from raising drug prices for commercial coverage including employer-sponsored plans, marketplace plans, and other individual and group market plans.

CMS cannot predict behavioral changes by drug manufacturers in response to implementation of the inflation rebates for Part B and D drugs. Our understanding is that manufacturers typically set their drugs' launch prices to be competitive with other therapeutic and non-therapeutic competitors.

"NOT SCORABLE" SECTIONS IN THE BUDGET

Question. In going through the HHS budget in brief, I noticed several instances that policy proposals are followed by "[Not Scorable]." **Would you be able to explain to me what that means to you?** Most of the time a section that ends in "not scorable" is filled with promises of increased access to certain health services, meaning that it is likely that additional resources are to be spent. I feel certain that each of your proposed policies will surely increase Federal spending in one way or another, meaning that they would "score."

Are the proposed and "not scorable" policies simply not detailed enough to be able to receive full cost information or is HHS assuming that these policies will not cost the Federal Government additional funds? What measures are used to make such assumptions?

Answer. All proposals in the FY 2024 President's budget reflect the official legislative agenda of the Biden administration. For the Centers for Medicare and Medicaid Services (CMS), the Office of the Actuary provides official estimates for legislative proposals affecting Medicare, Medicaid, and other CMS programs. A proposal may not be scorable due to multiple factors, in limited circumstances. For example, the evidence supporting the policy may indicate a range of potential effects on spending, both direct and indirect, that make it difficult to provide a pinpoint estimate. In other instances, the proposal leaves certain implementation details for future development to account for stakeholder and other valuable input on how it would be carried out, which also affects the ability to provide a pinpoint estimate at the time of Budget publication.

The proposals in the FY 2024 President's budget each improve these vital programs. The administration stands ready to work with Congress on refinements and additional details that will support enactment.

RULING IN *FDA V. ALLIANCE FOR HIPPOCRATIC MEDICINE*

Question. As you know, last week, the U.S. District Court for the Northern District of Texas held a hearing in the case *FDA v. Alliance for Hippocratic Medicine,* which challenges the FDA's approval and deregulation of a chemical abortion drug, mifepristone. Although a decision has not been issued in that case yet, there have been some calls for the FDA to ignore an injunction or a decision that would restrict access to mifeprex while the litigation continues, should that occur, and continue to distribute chemical abortion drugs regardless of the Federal court's decision.

If a decision is issued in that case and that decision restricts the distribution of chemical abortion drugs in any way, will you ensure HHS's compliance with the decision of the Federal district court?

Answer. The FDA has determined that mifepristone is safe and effective for medical termination of early pregnancy and we continue to believe that patients should have access to FDA-approved medications that FDA has determined to be safe and effective for their intended uses. We stand by FDA's approval of mifepristone and will continue to do everything we can to prevail in the courts. That said, HHS will comply with all court orders.

FEDERAL FUNDING FOR ABORTION

Question. I'm concerned by the priority HHS seems to be placing on the taking of unborn human life, as opposed to providing actual health care to save lives. Once again, the President's FY 2024 budget proposes to eliminate the longstanding Hyde Amendment. Since it first became law in 1976, the Hyde Amendment has saved over 2.4 million lives. The law has been renewed every year since 1976 on a bipartisan basis, and nearly 60 percent of Americans agree that taxpayer dollars should not be used to fund abortion.

Assuming that Congress continues to maintain the Hyde Amendment, like it has done for the last 47 years, will you commit to ensuring that zero Federal dollars are used for elective abortion?

Answer. As HHS Secretary, my role is to implement the law. The Department will follow all applicable laws as they relate to abortion and any other issue.

TITLE X FUNDING

Question. In addition to Hyde, funding for the title X family planning program, which under current regulation continues to fund abortion-providers like Planned Parenthood, increased to by $225 million—from $286 million to $512 million.

Will you ensure that any amount appropriated by Congress to title X is not used for abortion, consistent with Federal law prohibiting title X dollars from being used for abortion? Considering title X dollars are awarded to abortion providers, how will you ensure compliance with the law?

Answer. The Department will follow all applicable laws as they relate to abortion and any other issue. Title X recipients are required to ensure that non-title X abortion activities are separate and distinct from title X project activities. Where recipients conduct abortion activities, the recipient must ensure that the title X-supported project is separate and distinguishable from those other activities. OPA monitors title X recipient compliance by conducting ongoing monitoring calls and recipient correspondence, reviewing recipient progress reports and continuation applications.

CONSCIENCE PROTECTIONS

Question. We have had a number of conversations on protecting conscience rights of individuals. Since 2004, Congress has continued to include language on annual funding bills that prohibits funding to entities that discriminate against institutions or individuals that do not provide, pay for, provide coverage of, or refer for abortions. Although you once referred to enforcement of this law as "illegal," the President's budget includes the rider. Notably, the Proposed Rule recently issued by HHS significantly walks back much of the clarity and standards for implementation and enforcement of both the Weldon Amendment and other conscience protection laws enacted by Congress that the 2019 rule provided.

How much involvement did you have with issuing the rule? What steps were taken to ensure the rule was issued manner free of conflicts of interest?

Answer. HHS met with many faith-based leaders and stakeholders to help inform work on this rule. In 2019, HHS issued a regulation that provided broad definitions, created new compliance regulations, and created a new enforcement mechanism for a number of statutes related to the conscience rights of certain federally funded health-care entities and providers. This regulation was held unlawful by three Federal district courts. In light of these court decisions, and consistent with the administration's commitment to safeguard the rights of Federal conscience and religious nondiscrimination while also protecting access to reproductive health care, HHS issued a proposed rule to partially rescind the provisions of this rule that were deemed illegal in Federal court, while reinforcing other processes previously in place for the handling of conscience and religious freedom complaints. The proposed rule issued in 2022 notably maintains provisions from the 2019 rule issued by the Trump administration that provided clarity and standards for enforcement of the Weldon Amendment, among the conscience statutes the Department enforces.

Question. Recently, HHS Office for Civil Rights issued a reorganization that appears to dissolve the Conscience and Religious Freedom Division, among other divisions, and enfold that work into separate, broader divisions.

What impact do you expect this reorganization will have on investigating and enforcing conscience protection laws?

Answer. HHS expects this reorganization to have a positive impact on our enforcement of conscience protection laws. In fact, the former Deputy Director of the Conscience and Religious Freedom Division, Luis Perez, is now the Deputy Director of the newly formed Enforcement Division. In this role, he will be able to help OCR strategically carry out enforcement activities and prioritize its needs, which importantly includes enforcing Federal conscience protections. Further, the 2022 conscience proposed rule that OCR published proposed maintaining all of the conscience statutes that were previously delegated to OCR for enforcement.

Question. What impact do you expect this reorganization will have on investigating and enforcing other civil rights laws, including protections for individuals with disabilities?

Answer. HHS expects the reorganization to have a positive impact on our enforcement of disability laws and other civil rights laws. The former Deputy Director of the Conscience and Religious Freedom Division, Luis Perez, is now the Deputy Director of the newly formed Enforcement Division. He is a trained lawyer and litigator and will help improve OCR's enforcement work, bring forward high impact matters that help people, and help OCR enforce regulations including the HIPAA Security Rule, which is an issue of national security.

Question. There has been much media coverage about the State of California threatening to cut out health-care entities from partnership with the State because they are not providing abortions either in California or in other States, based on the laws in those areas or Federal law, such as prohibitions on mailing chemical abortion drugs.

Has HHS OCR initiated an investigation into whether such discrimination would violate the Weldon amendment?

Answer. OCR generally does not confirm or deny pending investigations to protect the integrity of the investigation and work.

NEW YORK TIMES REPORT

Question. During the hearing, you testified that you were unaware of the reporting that HHS could not locate at least 85,000 unaccompanied minors through their safety and well-being calls. This number was reported in *The New York Times,* and the Departments of Labor and Health and Human Services—within 2 days of this number being reported—announced that they would be taking additional labor enforcement efforts to ensure that unaccompanied minors are labor trafficked.

Your Department took action in response to *The New York Times* report, and you provided a statement in a joint DOL and HHS press release on the matter.

Since February 23, 2023, were you briefed on *The New York Times* report (Hannah Dreier, "Alone and Exploited, Migrant Children Work Brutal Jobs Across the U.S.", *New York Times,* February 25, 2023, *https://www.nytimes.com/2023/02/25/us/unaccompanied-migrant-child-workers-exploitation.html*)? Please answer "yes" or "no."

If yes, did you receive any briefing regarding this matter in your prep materials for this hearing? Please answer "yes" or "no."

Did you receive any briefings on the labor trafficking initiative the Biden administration announced on February 27, 2023, either prior to or subsequent to the rollout? Please answer "yes" or "no."

Did you receive any information on this labor trafficking initiative in your prep materials for this hearing? Please answer "yes" or "no."

If you did receive information regarding *The New York Times* report or the labor trafficking initiative, please explain to the committee why you testified that you were unaware that HHS could not locate the reported 85,000 unaccompanied minors.

Answer. The February 23, 2023, *New York Times* article that you reference demonstrated the terrible ways that employers are exploiting the economic situation

that many children and families in the United States find themselves in, including children who have previously been in ORR care. HHS takes the issue of child labor very seriously. To that end, we are committed to taking additional action to educate children and our providers about child labor exploitation, ensure sponsors understand the hazards of child labor, and collaborate with the Department of Labor to do everything we can to reduce the likelihood that children will end up in a situation where they are exploited. Our principal responsibility is to care for unaccompanied children while they are in our custody, and then make sure we can place the child to a safe, vetted sponsor. HHS looks forward to partnering with Congress to advance the shared mission of protecting children and continue to strengthen the quality and depth of services we offer.

The Department does not believe it is accurate to say that 85,000 children are lost. ORR's custodial authority ends when a child is released from ORR care. Per ORR policy, care providers must make at least three safety and well-being calls to speak with the child and the sponsor individually. Children and sponsors are not required to answer these calls, and some do not. It is important to note that many sponsor families may not answer a call from an unknown phone number or may choose not to answer a call for a variety of reasons. Despite the voluntary nature of the child's and sponsor's participation in safety and well-being calls, in FY 2022, ORR care providers made contact with either the child, the sponsor, or both in more than 81 percent of households.

MEMORANDUM OF AGREEMENT

Question. In 2018, HHS and DHS entered into a memorandum of agreement to, in part, require ICE to share with HHS information contained in ICE databases on the criminal and immigration histories of potential sponsors and all adult members in sponsor households. The intent of this MOA was to allow for HHS use additional information to make more complete suitability determinations prior to placing a child with an adult sponsor.

The Biden administration terminated this agreement and waived background check requirements for household members living with prospective sponsors. At the time, the Biden administration argued that the old MOA "undermined the interests of a child" and that the new MOA "promotes the safe and timely transfer of children."

In light of the recent *New York Times* story (Hannah Dreier, "Alone and Exploited, Migrant Children Work Brutal Jobs Across the U.S.", *New York Times,* February 25, 2023, *https://www.nytimes.com/2023/02/25/us/unaccompanied-migrant-child-workers-exploitation.html*), will you be updating your guidance regarding the vetting of sponsors? Please answer "yes" or "no."

If no, why not?

Answer. In June 2018, ORR, ICE, and CBP entered into an MOA that set forth the expectations of the parties as they pertained to sharing information about unaccompanied children at the time of referral from ICE or CBP to ORR, while in the care and custody of ORR, including during the vetting of potential sponsors, and upon release from ORR care and custody. Section V of the 2018 MOA specified that ORR would transmit sponsor fingerprints to ICE as part of its sponsor assessment process. DHS would then perform criminal and immigration status checks for all sponsor categories and provide the results to ORR prior to a child's release from care. Prior to the 2018 MOA, ORR already transmitted sponsor and other required subjects' fingerprints to the Federal Bureau of Investigation (FBI) for adjudication in accordance with its policies and procedures. This made the ICE biometric background checks duplicative of ORR's FBI checks.

In late 2018, ORR reviewed the effects of the ICE biometric background checks required under the MOA. The review assessed whether they yielded any new information that enabled ORR to identify child welfare risks that it would not have found under its standard policies, including the FBI fingerprint background checks that were already formerly part of ORR's vetting process for sponsors who were not previously the child's primary caregiver. ORR also examined whether a correlation existed between the ICE biometric background checks and a child's length of stay in ORR care. ORR determined that none of the information gleaned from duplicative ICE biometric background checks yielded automatic sponsor disqualification or additional child safety and welfare concerns, and in fact, had a negative influence on sponsors coming forward to take custody of a child. Moreover, the sheer number of sponsors and their household members requiring ICE biometric checks resulted in

lengthier time in care for children in ORR custody while background check requests surged, creating long wait times to schedule fingerprint appointments, and for those checks to be adjudicated. For instance, median length of care for unaccompanied children discharged to Category 1 sponsors increased from 20 days to 73 days between January 5, 2018, and July 7, 2018. Based on its child welfare expertise, ORR assessed that the ICE fingerprint checks were not in the best interests of unaccompanied children in care.

In light of these findings, between December 2018 and June 2019, ORR issued four operational directives that updated its background checks processes to be consistent with pre-MOA policies. FBI fingerprint background checks would only be required for all sponsor categories and adult household members in cases where there were risks to the child, the child was especially vulnerable, and the case was being referred for a home study. Without such instances, Category 1 sponsors and Category 2A sponsors no longer required biometric-based background checks. Lastly, close adult relative sponsors in Category 2 were broken into sub-classes of Category 2A and 2B, which affected background check requirements for each. FBI fingerprint background checks were and still are required for all Category 2B sponsors.

In March 2021, ORR formally rescinded the 2018 MOA. ORR, ICE, and CBP signed a replacement MOA on consultation and information-sharing policies. Its terms were the same as the 2018 version apart from the removal of section V as it related to ORR sharing information with ICE. ORR and DHS ensured that the information sharing provisions were relevant to the safe and timely placement and transfer of children to ORR care and ORR's discharge process.

ORR is dedicated to ensuring the safety and well-being of children in its care from the moment they enter its custody, to when they are safely placed with a vetted sponsor. ORR also understands the importance of providing children and their sponsors with the PRS tools and resources necessary to promote their safety. ORR provides PRS to facilitate a continuum of care to unaccompanied children who would benefit from ongoing assistance and to help them transition into their new communities. PRS include timely referrals and connection to community resources, as well as intensive services in cases where support is needed to address a child's specific needs. These referral and case management services are offered by a network of ORR-funded non-profit providers across the United States. ORR has doubled the rate of the total number of cases of PRS worked on in FY 2021 to more than 40 percent in FY 2022—all while receiving an unprecedented number of referrals beginning in Calendar Year 2021. ORR continues to build PRS capacity and is on track to provide nearly 50 percent of children released from ORR care with PRS in CY 2023. These services are fundamental in helping children and their sponsors establish resiliency and access resources in their communities.

In order to fulfill its mission, ORR continuously evaluates its unification policies and procedures to ensure that ORR is pursuing the best interest of each child. Additionally, ORR conducted an audit of the UC Program's current sponsor vetting requirements for potential sponsors who have previously sponsored unaccompanied children to make quality improvements where deemed appropriate without unnecessarily keeping children in government-funded, congregate care settings. ORR looks forwards to sharing the findings of the audit with the committee.

Question. Do you believe that a child, who has encountered significant trauma during his or her journey to the border, should be placed with unvetted sponsors? Please answer "yes" or "no."

Answer. No. Every child discharged from ORR care is vetted in compliance with statute and in adherence to ORR's policies and procedures. The safety and well-being of an unaccompanied child is the primary factor in ORR release decisions. ORR's legal responsibility to provide for the care and custody of unaccompanied children includes robust sponsor vetting. Safe and timely release of unaccompanied children to vetted sponsors is a multilayered process that involves the identification of a sponsor, which is typically a parent or other family member. The sponsor must then complete a robust screening process that includes a sponsor application, interviews, sponsor suitability assessments and reviews of supporting documentation, background checks, and in some cases as required by ORR UC Program Policy Guide section 2.4 *(https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-section-2#2.4)*, home studies prior to release and PRS.

Question. Does the Department believe that it should vet *every adult individual* who lives in a sponsor's household? Why or why not?

Answer. Pursuant to the TVPRA, ORR conducts background checks on every sponsor to determine whether the proposed release is safe and the sponsor can provide for the child's physical and mental well-being. The process includes a public records background check of criminal history and sex offender registry databases. Under current policy, if a public records check reveals possible disqualifying factors under ORR UC Program Policy Guide section 2.7.4 *(https://www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied-section-2#2.7.4)*—such as a documented risk to the safety of the unaccompanied child, the child is especially vulnerable, or the case is being referred for a home study—parents and legal guardians (also known as Category 1 sponsors) and non-parent immediate family relatives (or Category 2A sponsors) are fingerprinted, and the information is submitted to the FBI prior to the child's release from ORR custody. All other potential sponsors, like extended family members (Category 2B sponsors) or unrelated sponsors and distant relatives (Category 3), are fingerprinted and their information is submitted to the FBI for a criminal history background check prior to a child's release from ORR care. See ORR UC Program Policy Guide section 2.2.1 *(https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-section-2#2.2.1)*.

In addition to verifying a sponsor's identity through background checks, ORR conducts a thorough assessment of potential sponsors' suitability in accordance with its statutory responsibilities. ORR's policies with respect to the release process are described in its online UC Program Policy Guide section 2 *(https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-section-2)* and in Field Guidance 10 *(https://www.acf.hhs.gov/sites/default/files/documents/orr/FG-10%20Expedited%20Release%20for%20Eligible%20Category%201%20Cases%202021%2003%2022.pdf)* and 11 *(https://www.acf.hhs.gov/sites/default/files/documents/orr/FG-11%20Temporary%20Waiver%20of%20Background%20Check%20Requirements%202021%2003%2031.pdf)*. Requirements include proof of the sponsor-child relationship, as well as the sponsor's ability to provide protection from abuse, abandonment, neglect, and other harm. ORR and care provider staff also evaluate a child's risk and resiliency factors and their unique needs such as medical conditions or past experiences in home country to determine a release decision based on child welfare principles. These sponsor suitability assessments give ORR, through its Federal Field Specialists, case managers, and field staff, the individual decision-making and operational flexibility necessary to make case-by-case determinations of what is in the child's best interest and whether certain potential sponsors that are not Category 2B and 3 sponsors and adult household members needed to be fingerprinted. Fingerprint background checks are still required for all Category 2B and 3 sponsors.

In some cases, ORR also requires adult household members to undergo a background check search of State child abuse and neglect (CA/N) registries maintained by individual States. ORR routinely relies on its State partner agencies to facilitate and adjudicate CA/N checks. States independently own and operate their respective CA/N registry databases and provide relevant information upon request to the agencies that ask for them. As a result, timely CA/N check adjudication varies widely, and ORR care providers' ability to vet every adult household member with an additional check can depend on whether a particular State partner can promptly facilitate the CA/N check without compromising timely unification of children with their sponsors.

The *Flores* Settlement Agreement requires that children be released from ORR care without unnecessary delay and to make prompt and continuous efforts toward unification and the release of the child. Once a sponsor is thoroughly vetted, due process protections entitle a suitable sponsor to take custody of the unaccompanied child without undue delay or procedural hurdles in line with child welfare best practices. However, safety remains at the forefront of ORR's policies and procedures, so without sacrificing safe and effective sponsor vetting procedures, Case Managers also obtain information on adult household members for purposes of such things as alternate caregiver plans to ensure that the child is cared for if the sponsor ever becomes unavailable. Case Managers are also trained to identify any safety risks or vulnerability flags that would necessitate additional background checks on adult household members, but that does not mean, as a threshold matter, that children are unsafe should a sponsor live with adult household members. Children experience better educational, social, developmental, and health outcomes when they are surrounded by familiar support systems that can often include extended family and other individuals living within the same household, and have access to comprehensive community resources, as opposed to being in more restrictive, unfamiliar con-

gregate care settings where they are more likely to feel lonely, isolated, and confused about their circumstances.

QUESTIONS SUBMITTED BY HON. STEVE DAINES

DRUG PRICE NEGOTIATION PROGRAM AND SMALL MOLECULE INNOVATION

Question. The recent, partisan Inflation Reduction Act created the Medicare Drug Negotiation Program, granting the HHS Secretary the ability to negotiate drug prices in Medicare-covered drugs. The negotiation process allows for small molecule drugs that are approved as NDAs to become eligible for negotiation at 7 years after they receive FDA approval, whereas biologics become eligible at 11 years.

This arrangement is questionable in light of the fact that small molecule medicines accounted for a majority of new, life-saving medicines and cures approved by the FDA in recent years. This drug negotiation program would appear to stunt and disadvantage the development of small molecule medicines which, notably, much of the research and development for new oncology medicines is on small molecules.

Is the administration concerned that the negotiation program as currently designed will disadvantage or deter small molecule advancements?

Given the promise shown for small molecules in the oncology space, is the administration concerned that the negotiation program could severely undermine the administration's own Cancer Moonshot initiative?

Small molecule drugs are more often dispensed at the pharmacy counter, or sent to patients through mail orders, whereas biologics are often physician-administered. Has HHS considered the impact of the drug price negotiation program favoring biologics over small molecules in light of the ongoing provider shortages across the country, especially in more rural States like Montana?

How does the Department expect this will impact patient access to medicines?

What analysis has the Department done to assess this dynamic?

Many small molecule medicines have the potential to address more than one disease or treat broader patient populations, perhaps in earlier lines of therapy, than solely the initial diseases and populations approved at launch. Do you think CMS has the authority to begin the "negotiation" eligibility clock upon the receipt of an indication for a subsequent indication, after having received an orphan drug negotiation exception for previous indication? Why or why not?

Answer. CMS supports continued drug innovation and believes it is vitally important that beneficiaries have access to innovative new therapies. The statute provides that drugs that have been approved by the FDA for at least 7 years, or biologicals that have been licensed by the FDA for at least 11 years, are eligible for negotiation. Any drugs or biologicals selected for negotiation will have been on the market for quite some time.

The law requires CMS to exclude certain orphan drugs approved or licensed when identifying qualifying single source drugs, referred to as the orphan drug exclusion. To be considered for the orphan drug exclusion, the drug or biological product must: (1) be designated as a drug for only one rare disease or condition by the FDA; and (2) be approved by the FDA only for one or more indications within such designated rare disease or condition. As noted in the initial guidance, we are considering whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development.

CMS has been regularly engaging with members of the public to get their feedback so that we are implementing the Negotiation Program in a thoughtful way that both improves drug affordability and accessibility for people with Medicare and supports innovation. We plan to get public input throughout the implementation of the Negotiation Program to make sure that we know what is occurring in the market.

QUESTIONS SUBMITTED BY HON. TODD YOUNG

MEDICARE COVERAGE FOR INNOVATIVE MEDICAL DEVICES

Question. The Fall 2022 HHS Unified Agenda regulatory calendar currently lists April 2023 as the target date for CMS to release the Transitional Coverage for

Emerging Technologies (TCET) proposed rule, which would provide transitional Medicare coverage for new medical technologies.

Can you assure us that CMS will issue the TCET proposed rule by April 2023, particularly given that this rule was initially scheduled for release in 2022, and originally discussed over 2 years ago when the Medicare Coverage for Innovative Technology (MCIT) rule was repealed?

CMS indicated in the Medicare Coverage for Innovative Technology (MCIT) repeal rule that "breakthrough" designation from the Food and Drug Administration (FDA) alone would not necessarily result in a technology having eligibility to undergo the TCET process.

Please describe the technologies CMS is considering could be potentially eligible for coverage under the TCET.

How complex would eligible devices need to be? Would follow-on devices potentially be eligible for Medicare coverage under the TCET?

Answer. CMS remains committed to expanding access to health-care coverage and services, including new, innovative treatments when they are safe and appropriate. CMS rescinded the Medicare Coverage of Innovative Technology and Definition of "Reasonable and Necessary" (MCIT/R&N) Final Rule because of concerns that the provisions in the Final Rule may not have been sufficient to protect Medicare patients. By rescinding this rule, CMS will take action to better address those safety concerns in the future.

Improving and modernizing the Medicare coverage process continues to be a priority, and we remain committed to providing stakeholders with more transparent and predictable coverage pathways. CMS is working as quickly as possible to advance multiple coverage process improvements that provide an appropriate balance of access to new technologies with necessary patient protections. As part of this effort, CMS has conducted several listening sessions to learn about stakeholders' most pressing challenges and to receive feedback from stakeholders about which coverage process improvements would be most valuable.

CMS intends to explore coverage process improvements that will enhance access to innovative and beneficial medical devices in a way that will better suit the health-care needs of people with Medicare. This will also help to establish a process in which the Medicare program covers new technologies on the basis of scientifically sound clinical evidence, with appropriate health and safety protections in place for the Medicare population. HHS looks forward to working with you and hearing your feedback as we move forward with these efforts.

MEDICARE ADVANTAGE

Question. CMS is considering policy to eliminate over 2,200 codes, many of which are used to diagnose and treat chronic diseases commonly experienced by low-income seniors and people with disabilities, including depression, vascular conditions, and heart disease. The American Medical Association (AMA) and over 2 dozen patient disease groups have raised concerns about the elimination of these codes and asked for a delay in the implementation of this new model under further stakeholder engagement is conducted.

Have you conducted an analysis on how this proposal would directly impact providers and beneficiaries in each State and territory? Have you analyzed how this proposal will impact the national health-care workforce and physician shortage in each State and territory? Can you share this analysis?

Will the administration provide assurances that the proposed policy changes will not lead to increased beneficiary costs or disruption for Medicare Advantage seniors in 2024?

Answer. In February, CMS proposed routine technical updates to improve the accuracy of MA payments in the 2024 Advance Notice. The proposed adjustments in some codes help to ensure that the risk adjustment of MA payments better reflects a beneficiary's costs of care, which means MA plans serving beneficiaries with greater health-care needs would receive appropriately higher payments. The proposed model updates do not impact coverage of Medicare services or requirements for MA plans to deliver covered services; rather, these proposed changes improve the accuracy of payments made to MA plans for covering care for enrollees.

As required by law, CMS sought public comment on the CY 2024 Advance Notice and will take this feedback into account when finalizing the Rate Announcement.

CMS received a large number of comments in response to the CY 2024 Advance Notice and appreciates the commenters thoughts and input regarding payments under the MA program.

SOCIAL DETERMINANTS OF HEALTH

Question. The Social Determinants Accelerator Act would establish a Federal interagency council to better leverage existing programs and address the barriers to coordination between health and social services programs. The bill would also help States and localities to develop innovative strategies to address social determinants in their communities.

Have you considered establishing some sort of commission or interagency council, like in the Social Determinants Accelerator Act, to address potential SDOH barriers?

Answer. HHS agrees with the committee that addressing social determinants of health is critical for improving health and well-being. HHS is continuing our work with an intra-agency workgroup of multiple HHS agencies and is also engaging in a White House-led Interagency Policy Committee, which involves participation of multiple Federal agencies to develop whole-of-government approaches to addressing social determinants of health. A particular focus of the IPC's efforts has been identifying opportunities to support the development and sustainability of infrastructure needed to improve coordination of health and social care services at the local level.

MEDICAID

Question. Last month, CMS released an Informational Bulletin titled, "Health-Care-Related Taxes and Hold Harmless Arrangements Involving the Redistribution of Medicaid Payments" which clarified CMS's position on the use of health-care-related taxes as a permissible source of Medicaid funding.

Can you discuss what prompted CMS to release this bulletin at this time?

Does this bulletin reflect existing policy or is it a shift in policy?

Can you confirm that the policies reflected in the bulletin will be directed and applied to all States?

Answer. Recently, CMS has been approached by several States with questions regarding the statutory and regulatory requirements applicable to health-care-related taxes, including in connection with proposals to implement or renew Medicaid managed care State directed payments (SDPs). Many of these questions have focused on whether health-care-related tax arrangements involving the redistribution of Medicaid payments among providers subject to the tax would comply with the statutory and regulatory prohibition on hold harmless arrangements, as specified in section 1903(w)(1)(A)(iii) and (w)(4) of the Social Security Act (the Act) and implementing regulations.

In response to these questions, in February 2023, CMS issued an informational bulletin reiterating Federal requirements concerning health-care-related taxes and hold harmless arrangements involving the redistribution of Medicaid payments. This guidance, which does not establish new policy, was issued as a reminder in response to questions received from several States about complying with this provision of law. CMS recognizes that health-care-related taxes often finance critical programs that pay for care provided to Medicaid beneficiaries and shore up the health care safety net, and it will continue to approve permissible health-care-related taxes that meet Federal requirements and remains committed to working with States.

QUESTIONS SUBMITTED BY HON. THOM TILLIS

Question. The President's budget requests an additional $100 million for the Food and Drug Administration's Center for Tobacco Products to be paid for by extending user fees to manufacturers of electronic cigarettes. This is in addition to the over $700 million the FDA already receives from tobacco industry user fees on an annual basis. The Family Smoking Prevention and Tobacco Control Act of 2009, legislation which you supported during your tenure in Congress, gave FDA the authority to regulate the tobacco industry. The act also intended such user fees facilitate regulatory pathways that evaluate alternative nicotine containing products and only those products determined to be less harmful than continued cigarette smoking could be sold in the marketplace.

However, since the law was enacted, FDA has only authorized 23 products or components of those products. Those authorizations were granted well after the 180-day statutory deadline and there are still literally hundreds of thousands of product applications pending at the agency.

What assurances can you provide that these additional user fees will improve CTP's regulatory review process? Unlike the other Centers at the FDA that must achieve certain performance measures in order to receive industry user fees, CTP does not have such requirements. Should FDA take steps to align CTP with the other Centers, or should Congress act to help ensure CTP is operating more effectively?

Answer. Since its inception, FDA has taken many actions to reduce tobacco-related disease and death, including taking steps to prevent and reduce youth use of tobacco products, proposing tobacco product standards, reviewing applications before new tobacco products can be legally marketed, pursuing compliance and enforcement actions to hold companies accountable, and educating the public about the risks of tobacco products.

Last summer, to strengthen FDA's tobacco program, FDA Commissioner Califf commissioned an external evaluation to be conducted by a panel facilitated by the Reagan-Udall Foundation (RUF). The panel was asked to assess the tobacco program's regulatory processes and agency operations relating to regulations and guidance, application review, compliance and enforcement, and communication with the public and other stakeholders. The evaluation was completed in December 2022, and the panel's report gave FDA helpful recommendations to build on CTP's existing foundation and continue to grow and mature the program. The RUF report included a specific recommendation for FDA to pursue securing user fees from each sector regulated by the Center, including, for example, Electronic Nicotine Delivery Systems. FDA is committed to addressing all the recommendations outlined in the report, including developing and implementing a comprehensive 5-year strategic plan, which builds upon the foundation of CTP's previous strategic priorities. FDA is committed to being transparent about our key activities, which will ensure external stakeholders have a clear view of our plans.

Your question raises concerns with the premarket application process and timeliness in reviewing applications. CTP has made important progress in reviewing Premarket Tobacco Applications (PMTA) for tobacco products. To date, FDA has received PMTAs for nearly 26 million products, the vast majority of which are for e-cigarette products, and successfully completed review of 99 percent of them. This includes the applications for nearly 6.7 million products that were received by the September 9, 2020, court-ordered submission deadline (FDA has also completed review of 99 percent of those applications as well). FDA continues to review the remaining one percent of applications submitted by the September 9, 2020, deadline and is committed to completing this as quickly as possible while making sure final decisions are legally defensible and grounded in science.

FDA acknowledges that there are opportunities to enhance the PMTA review process and has started developing a more efficient framework for high-quality tobacco product application reviews, which will, for example, improve review times. CTP's goals are to work internally and through engagement with external stakeholders to: better communicate scientific issues and review processes to support efficiency, effectiveness, and transparency; hire additional staff to enhance program management and implementation, including for application review; and increase internal communication to improve scientific engagement and deliberation. These efforts include activities such as resuming posting of scientific policy memos and reviewer guides, when appropriate, and communication through public events, such as workshops and listening sessions.

FDA is committed to transparency and accountability and regularly reports to the public and Congress on premarket review progress.

This important work cannot be done without sufficient resources. Currently, section 919 of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 387s) authorizes FDA to assess user fees on tobacco products that fall within the following six product classes: cigars, pipe tobacco, cigarettes, snuff, chewing tobacco, and roll-your-own tobacco. Section 919 also authorizes the total amount of user fees FDA must assess and collect each year. For the first 10 years of the FDA tobacco program, the total amount of user fee collection increased each year; however, beginning in Fiscal Year 2019, the authorized amount of $712 million is fixed for each subsequent fiscal year and is not indexed to inflation. Further, section 919 of the

FD&C Act does not provide FDA the authority to assess and collect user fees for ENDS, which includes e-cigarettes, and certain other deemed products. Thus, FDA has had to spend a significant portion of the $712 million in user fees it collects annually from the existing six product classes to properly regulate deemed products, especially ENDS.

FDA's request to extend user fees to ENDS and deemed products would ensure a more equitable distribution of user fees across industry. In addition, the request for an additional $100 million in user fees, indexed to inflation, is in line with ensuring comprehensive regulation of the changing tobacco product marketplace. The additional $100 million will enable FDA to expand much-needed activities in the critical areas of compliance and enforcement, product review, scientific research, regulation and guidance development, and public education.

Question. Recently, the National Center for Advancing Translational Sciences (NCATS) and the Food and Drug Administration have publicly acknowledged an urgency to speed solutions for rare disease patients by developing treatments for more than one rare disease at a time. However, the limited nature of the Inflation Reduction Act's orphan drug exemption would discourage future research programs of existing rare disease therapies into additional orphan indications due to the risk of losing the exemption.

Please detail how HHS plans to take a "whole agency approach" to ensure future research and development for patients with rare diseases and conditions without a treatment.

Answer. FDA remains strongly committed to doing what we can via guidance for industry and stakeholder engagement activities to maintain and promote the robustness of the development pipeline for safe and effective drugs and biological products to treat patients with rare diseases, including rare cancers. FDA has published more than 18 guidance documents since 2018 on topics that are highly relevant to drug and biological product development for rare diseases, including rare cancers. Some recent examples include:

- 2023 Draft Guidance for Industry: *Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics*.[82]
- 2023 Draft Guidance for Industry: *Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products*.[83]
- 2022 Guidance for Industry: *Human Gene Therapy for Neurodegenerative Diseases*.[84]
- 2022 Draft Guidance for Industry: *Tissue Agnostic Drug Development in Oncology*.[85]

Of note, with regard to FDA and NIH "developing treatments for more than one disease at a time," both agencies, along with several other entities, are working collaboratively to expedite development of gene therapies for rare diseases that are caused by a single genetic mutation and for which there is no commercial interest in developing therapies due to each disease's rarity. This effort, the Bespoke Gene Therapy Consortium, focuses on developing common gene therapy platforms and standards that can be used in the manufacture of several different gene therapies, each for a different rare disease, and thus would increase efficiency overall.

Further, NIH, and NCATS remain committed to supporting research to find treatments and cures for rare diseases and conditions without a treatment, and to increase the speed of therapeutic and diagnostic development. At NIH, NCATS's Division of Rare Diseases Research Innovation provides leadership, coordination and collaboration on rare disease research programs across the NIH. Research on specific rare diseases is supported by many NIH Institutes, Centers, and Offices (ICOs) as falls within their respective missions.

NCATS supports rare disease research projects with applicability to many diseases at a time, and works with other HHS operating divisions to ensure appropriate resources and expertise are being applied. One such program involving cross

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[82] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-trial-considerations-support-accelerated-approval-oncology-therapeutics.*

[83] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-design-and-conduct-externally-controlled-trials-drug-and-biological-products.*

[84] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/human-gene-therapy-neurodegenerative-diseases.*

[85] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tissue-agnostic-drug-development-oncology.*

agency collaboration and targeting rare diseases is the Bespoke Gene Therapy Consortium (BGTC), a partnership with the Food and Drug Administration (FDA) and the Foundation for the National Institutes of Health (FNIH), NCATS and 10 other NIH Institutes and Centers (ICs), and several pharmaceutical companies and nonprofit organizations, that will streamline gene therapy development and products for rare disorders of no commercial interest. For BGTC clinical trials, scientists will develop strategies for streamlining the regulatory processes for FDA approval of safe and effective gene therapies, and they will develop standardized approaches to preclinical testing. BGTC has narrowed the potential diseases to be studied to 14, and proposals for clinical trials are being reviewed, with the 5–6 chosen trials to be announced in May 2023.

Another collaborative research initiative is the NIH Common Fund's Somatic Cell Genome Editing (SCGE) program, led by NCATS and the National Institutes of Neurological Disorders and Stroke (NINDS). Phase 1 of the program aims to develop high-quality tools for performing safe and effective genome editing in humans and then make these tools widely available to the research community to reduce the time and cost of developing new therapies. Based on the success of Phase 1, the Common Fund approved a second phase of the program, which will be focused more on accelerating somatic genome editing clinical trials. Applications have been reviewed, and funded projects will be announced shortly. FDA collaborated with the SCGE program throughout Phase 1, and given the greater focus on clinical trials in Phase 2, the NIH and FDA plan to establish a memorandum of understanding (MOU) to efficiently translate the results from Phase 2 projects into the clinic.

Question. The Inflation Reduction Act exempts an orphan drug indicated for a single rare disease/condition from Medicare price negotiation.

Please clarify when the Medicare negotiation eligibility clock begins for a drug that loses the orphan drug exemption due to approval for an additional indication.

Answer. CMS supports continued drug innovation and believes it is vitally important that beneficiaries have access to innovative new therapies. We are striving to implement the Negotiation Program in a thoughtful way that both improves drug affordability and accessibility for people with Medicare and supports innovation.

The law requires CMS to exclude certain orphan drugs approved or licensed when identifying qualifying single source drugs, referred to as the orphan drug exclusion. To be considered for the orphan drug exclusion, the drug or biological product must (1) be designated as a drug for only one rare disease or condition by the FDA, and (2) be approved by the FDA only for one or more indications within such designated rare disease or condition. As noted in the initial guidance for the Medicare Drug Price Negotiation Program for initial price applicability year 2026, CMS is still considering whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development. The agency will continue to keep Congress and relevant stakeholders updated as we move forward.

Question. Value-based care is a bipartisan issue and a model many of us on this committee support as one way to meet our obligations to seniors but also to bring down costs. The administration has set a goal of having as many Medicare beneficiaries as possible in value-based care by 2030.

I'm concerned about the potential chilling effect of the Medicare Advantage Advance Notice on risk adjustment for providers that take on full risk—as MA is the primary place that can happen—particularly in underserved areas in NC.

How do you see the risk adjustment changes affecting value-based provider access for Medicare beneficiaries in underserved areas, particularly for duals? There are several provider organizations, including ones that operate in my State, saying the proposed changes will reduce resources for dually eligible Medicare beneficiaries.

Answer. The proposals in the Advance Notice improve payment accuracy to ensure MA plan payments better reflect the expected costs of care, with higher payments going to plans serving people with greater health-care needs. This helps ensure that people in MA can continue to access the care they need.

Additionally, there are protective features built into the MA risk adjustment system to ensure that plans caring for dually eligible individuals are paid adequately, and nothing in this proposal changes those features. We will continue to pay much more for someone who is dually eligible than someone who is not, even when they have the same diagnoses. These higher payments decrease incentives for plans to favor healthier enrollees or discriminate against sicker patients.

To the extent beneficiaries who are low-income or who are living in rural or underserved areas have greater health-care needs, the proposed model would better compensate plans for that care. Furthermore, Federal law protects most dually eligible individuals from any cost sharing for Medicare services, so specific plans changes in cost sharing cannot be passed onto those dually eligible beneficiaries.

CMS anticipates stable premiums and benefits for beneficiaries in 2024, as seen previously in years with comparable updates. For example, in 2015, MA plans experienced a payment increase of 0.4 percent compared to 2014. Following those payment updates, the MA market remained strong and continued to grow. Historical experience shows plans compete in this highly competitive market to keep premiums down and maintain supplemental benefit levels, with beneficiary choice remaining strong.

Question. As you are aware, the President's budget proposes further expanding the price-setting program to 5 years after approval for all drugs. This is concerning as some studies show that a full 50 percent of investments in all drugs are recouped in years 9 through 13.

Can the administration provide data that shows R&D investments in complex drugs (like those aimed at treating diseases like cancer and Alzheimer's) can be recouped in just 5 years?

What is the Department's estimate of the number of fewer new drugs as a result of the expansion of the negotiation program?

Answer. The President's budget proposal builds on the Inflation Reduction Act by increasing the number of drugs subject to negotiation and making drugs eligible for negotiation sooner after their launch. Expanding the Drug Price Negotiation Program accelerates the increased gains in access for Medicare beneficiaries to innovative, life-saving treatments enacted by the law, with lower costs for people with Medicare and the program.

Question. My State is home to some of the strongest universities in the Nation, and the research and development they undertake every day creates scores of new jobs, bolstering our economy and advancing our global leadership in biomedicine, along with numerous other fields. The expansion of the negotiation program included in the President's budget could demolish or downsize many of the public-private partnerships that enable these institutions to innovate.

How would your administration's proposal impact biomedical research and development—in numerical terms—and what would the downstream effects be for public-private partnerships and research hubs like the ones North Carolina?

Answer. On March 15, 2023, CMS issued initial guidance detailing the requirements and parameters of the Medicare Drug Price Negotiation Program, including requests for public comment on key elements, and announced the next steps for how the agency will implement the new program for 2026. In the initial guidance, CMS laid out an approach to negotiation that will focus on key questions, including but not limited to the selected drug's clinical benefit, the extent to which it fulfills an unmet medical need, and its impact on people who rely on Medicare. The statute requires that CMS consider certain manufacturer-specific data, including research and development costs and recoupment of those costs, and available evidence about alternative treatments, as the basis for determining offers and counteroffers for a selected drug under the Negotiation Program. We are going to be considering the negotiation factors outlined in the law very seriously. **We are striving to implement the Negotiation Program in a thoughtful way that both improves drug affordability and accessibility for people with Medicare and supports innovation.**

Question. The administration has allocated additional funding to expand access to telehealth, especially in rural and underserved areas. Further, through the passage of the Consolidated Appropriations Act of 2023, Congress extended pandemic expanded telehealth access to the end of 2024.

What changes in law are required to continue providing flexibility to enable expanded access beyond 2024 in rural and underserved areas?

Answer. In response to the COVID–19 public health emergency, which is set to expire in May 2023, flexibilities for Medicare telehealth services were issued through legislative and regulatory authorities to increase access to care for patients and providers. The Consolidated Appropriations Act of 2023 recently extended many of these flexibilities through December 31, 2024. Extended telehealth flexibilities in-

clude waiving geographic and site of service originating site restrictions so that Medicare patients can continue to use telehealth services from their home and allowing audio-only telehealth services. Additionally, the expanded list of providers eligible to deliver telehealth services is also extended so Medicare beneficiaries can continue to receive telehealth services furnished by physical therapists, occupational therapists, speech language pathologists, and audiologists, as well as receive telehealth services from Rural Health Clinics and Federally Qualified Health Centers through December 31, 2024. If you are interested in drafting legislation to make these waivers permanent, CMS would be happy to provide technical assistance.

Additionally, recent legislative and regulatory changes made several telehealth flexibilities permanent. Federally Qualified Health Centers and Rural Health Clinics can furnish certain mental health services via telecommunications technology. Medicare patients can continue to receive these telehealth services in their home as geographic restrictions on the originating site are eliminated for these telehealth services. Certain mental health telehealth services can be delivered using audio-only communication platforms, and rural emergency hospitals can serve as an originating site for telehealth services.

For Medicaid and CHIP, telehealth flexibilities are not tied to the end of the PHE and have been offered by many State Medicaid programs long before the pandemic. Medicaid and CHIP telehealth policies will ultimately vary by State. CMS encourages States to continue to cover Medicaid and CHIP services when they are delivered via telehealth.

QUESTIONS SUBMITTED BY HON. MARSHA BLACKBURN

Question. We have a profound responsibility, through our Federal health-care programs, to address the needs of Americans with disabilities, as well as seniors and those living with debilitating conditions—including rare diseases.

Unfortunately, several bureaucratic and controversial measures—such as using so-called quality-adjusted life years, or QALYs—undermine that broadly bipartisan mission. As explained by the National Council on Disability, "QALYs place a lower value on treatments which extend the lives of people with chronic illnesses and disabilities." Patient advocates across the board have echoed these concerns for years, especially given the access gaps and barriers created by the use of these discriminatory metrics in other countries, particularly in Europe.

For that reason, I recently joined a group of my colleagues in urging your department—and the administration more broadly—to eliminate the use of QALYs and other similar measures, both directly and indirectly, across our Federal health-care programs.

Given the long history of bipartisan opposition to QALYs, can you commit to working with me and my colleagues, as well as your counterparts in other departments, to prevent the application of these types of metrics across all Federal programs?

Answer. It has been a longstanding policy that Medicare does not use QALYs, in accordance with the law. We are happy to provide technical assistance on any legislation you draft.

Question. The price controls imposed under the Inflation Reduction Act (IRA) have the potential to damage biomedical research and development, erode access to future treatments, and hand a competitive edge to our other global rivals. The law's impact on innovation in small-molecule drugs, which hold promise for addressing diseases like Alzheimer's and cancer, will prove particularly devastating. In fact, the majority of manufacturers have already reported plans to shift R&D away from these types of products due in part to the shorter exemption period for these drugs under the IRA's government price-setting program. I strongly support efforts to extend this exemption period from 9 years to 13, ensuring parity between small molecules and biologics.

To that end, last month, I joined Senator Menendez in introducing the Maintaining Investments in New Innovation Act, which would provide this type of extension for gene-targeting therapies. I hope we can find bipartisan support for an even broader proposal to capture the full range of life-saving small-molecule drugs. If Congress fails to act on this front, patients—and especially seniors—will inevitably suffer.

Can you commit to working with Congress to mitigate the harmful effects of the IRA's government price-setting program?

Answer. We are striving to implement the Negotiation Program in a thoughtful way that both improves drug affordability and accessibility for people with Medicare and supports innovation. We are happy to provide technical assistance on your legislation.

Question. The "maximum fair price" (MFP) risks spillover beyond Medicare ("commercial spillover") in two ways: (1) diversion, when Medicare and 340B status may not be established and when the organization dispenses/administers to a patient contrary to law; and (2) reimbursement challenges, when commercial payers may seek to adjust to MFP-based reimbursement for non-MFP-eligible individuals, thus compromising patient access to therapies. MFP is also explicitly included in Best Price reporting, which could lead to price erosion in non-Medicare markets.

Given that the IRA is intended to apply solely to Medicare and its beneficiaries, how will the administration assure that its mandated prices will not "spill over" and manipulate commercial and other non-Medicare markets?

As the administration works to implement the IRA's government price-setting program, will CMS commit to providing multiple notice and comment rulemaking periods, with reasonable time constraints, and assurance that CMS will respond to public comments to allow patient groups, manufacturers, and other stakeholders to have the ability to provide meaningful input?

Answer. The Inflation Reduction Act requires manufacturers to provide access to the prices negotiated (*i.e.,* maximum far prices) for the selected drugs when Medicare beneficiaries receive these drugs. There is no requirement for manufacturers to provide access to the maximum fair prices (MFPs) when commercially insured individuals receive these negotiated drugs.

On March 15, 2023, CMS issued initial guidance detailing the requirements and parameters of the Negotiation Program, including requests for public comment on key elements, and announced the next steps for how the agency will implement the new program for 2026. As described in the initial guidance, CMS intends to require the manufacturers ensure that entities that dispense drugs to those MFP-eligible individuals, including pharmacies, mail order services, and other dispensers, have access to the MFP for the selected drug, in accordance with the law. CMS intends to define "providing access to the MFP" as ensuring that the amount paid by the dispensing entity for the selected drug is no greater than the MFP. As part of the initial guidance, CMS is seeking comment on how such a process would operate most effectively, including suggestions on ways that CMS could provide technical assistance to entities to ensure they are able to provide the MFP to MFP-eligible individuals and ways to ensure that MFP-eligible individuals whose cost-sharing was not consistent with MFP are made whole.

The Inflation Reduction Act requires that CMS implement the Negotiation Program for 2026, 2027, and 2028 by program instruction or other forms of program guidance. CMS recognizes that public input is essential for successful implementation. CMS has sought and will continue to seek feedback and insights from a wide range of interested parties throughout the implementation of the Inflation Reduction Act, including but not limited to comment on this initial guidance. Public feedback will contribute to the success of the Negotiation Program, and the initial guidance is one tool, among many, CMS will use to ensure interested parties' voices are heard on implementation of the new drug law. More information on how to submit comments can be found in the initial guidance. Comments received by April 14, 2023, will be considered for revised guidance. CMS anticipates issuing revised guidance for the first year of negotiation in Summer 2023. Additionally, this guidance is only for implementing drug price negotiation for initial price applicability year 2026. CMS is continuing to take feedback for future years of the program.

Question. For decades, robust competition from generic drugs has cut costs for American patients from all walks of life. Generics currently account for 90 percent of all prescriptions filled in the U.S. and our generic drug prices are lower than virtually any other developed nation. Biosimilars have the potential to drive similarly strong cost savings among higher-cost medications. The FDA has approved at least 40 biosimilars, driving down prices for patients at the pharmacy counter and the doctor's office.

However, I am concerned that the IRA's government price-setting program will reverse this trend and destroy the growing biosimilar market, resulting in higher

health-care spending for consumers and taxpayers. During consideration of the IRA, I filed an amendment to shore up the biologic delay provision under the price-setting program, given that the current language seems entirely unworkable for biosimilar development timelines. This is not a partisan proposal but rather a technical improvement that I hope to introduce as standalone legislation in partnership with my colleagues on both sides of the aisle.

Can you commit to working with me and with Congress more broadly to fix the IRA's special rule for delaying price-setting for biologics subject to impending competition, given the importance of promoting biosimilars?

Answer. CMS acknowledges and prioritizes the importance of promoting biosimilars. We are implementing the Drug Price Negotiation Program under the Inflation Reduction Act, including the special rule to delay the selection and negotiation of certain biological products when there is a high likelihood that a biosimilar biological product (for which such biological product will be the reference product) will be licensed and marketed within 2 years in accordance with the law. We are happy to provide technical assistance on your legislation.

Question. Patent protections are enshrined in our Constitution and have provided the driving incentive for most life-saving medical breakthroughs. The IRA's government price-setting program risks eroding intellectual property protections for American inventors, small businesses, and entrepreneurs. I have serious concerns with efforts to weaponize Federal programs and laws to undermine IP.

Attempts to repurpose and distort the Bayh-Dole Act framework to seize American patents and impose sweeping price controls would destroy the partnerships responsible for many of our most groundbreaking treatments and cures. Senators Bayh and Dole both asserted as much for years, making clear that the so-called "march-in" provisions under their landmark law were never intended to enable Federal price-fixing.

Can you commit to adhering to the law—and the express intent of its bipartisan drafters—and reject efforts to misuse march-in rights to dictate price controls for medications?

Answer. 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 committed to implementing the law and upholding these aims to support the innovation needed to deliver new and effective drugs to patients. To that end, HHS has partnered with the Department of Commerce to review the use of march-in authority as laid out in the Bayh-Dole Act. Through this partnership, we have asked an Interagency Working Group to develop a framework for consistent implementation of the march-in provision across the U.S. Government that clearly articulates guiding criteria and processes for making determinations where different factors, including price, may be a consideration in agencies' assessments. HHS will convene a workshop in 2023 to further refine the cases for which HHS could consider exercising march-in authority. HHS will seek input from a diverse array of interested parties—including patient groups, industry, universities, small business firms, and nonprofit organizations, as well as experts in technology transfer and innovation policy. The goal of the workshop will be to assess when the use of march-in rights is consistent with the policy and objectives of the Bayh-Dole Act.

Question. Many therapies initially approved for a single indication go on to secure multiple indications, which is common among oncology drugs. The IRA arbitrarily applies the government price-setting mandate on a drug after the applicable exclusivity period regardless of follow-on indications. I am concerned that this disincentivizes manufacturers from performing additional clinical trials and pursuing other indications.

How will CMS ensure that innovation is unaffected, and manufacturers can continue post-approval development to realize the full breadth of a drug's potential benefit?

Answer. CMS supports continued drug innovation and believes it is vitally important that beneficiaries have access to innovative new therapies. We are striving to implement the Negotiation Program in a thoughtful way that both improves drug affordability and accessibility for people with Medicare and supports innovation.

The law requires CMS to exclude certain orphan drugs approved or licensed when identifying qualifying single source drugs, referred to as the orphan drug exclusion. To be considered for the orphan drug exclusion, the drug or biological product must

(1) be designated as a drug for only one rare disease or condition by the FDA, and (2) be approved by the FDA only for one or more indications within such designated rare disease or condition. As noted in the initial guidance, we are still considering whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development.

Question. In enacting the No Surprises Act, Congress included the Qualifying Payment Amount (QPA) as only one of the several factors to be considered in the IDR process. The Federal Courts have twice admonished HHS about the bias toward the QPA. Yet, the administration has not taken basic corrective action against this tilting of the playing field in favor of insurers.

Do you now agree to clarify through guidance that the rates used to calculate the QPA must be the median of the contracted rates "paid" by the plan in January 2019?

Because regulation gives primacy in the dispute resolution process to these QPAs, insurance companies have uniformly refused to negotiate with providers during the 30-day negotiation period established in the law.

In your opinion, which party is better prepared to weather long periods of cashflow delay, doctors or insurers?

While audits will not solve the manipulation of median prices, they are critical to ensuring a full and fair arbitration process.

Why has HHS not yet moved forward with implementing section 102 of the No Surprises Act, which requires establishing an auditing process for health insurers effective October 1, 2021?

Answer. CMS is committed to implementing the No Surprises Act (NSA) consistent with the law. Certified Independent Dispute Resolution (IDR) entities are required to consider the qualifying payment amount (QPA) and certain additional factors when selecting between the offer submitted by a plan or issuer and the offer submitted by a facility, provider, or provider of air ambulance services when determining the total out-of-network payment rate for items and services subject to the Federal IDR process. The QPA for a given item or service generally is the median contracted rate on January 31, 2019 for the same or similar item or service, increased for inflation.

The standards governing a certified IDR entity's consideration of information when making payment determinations for disputes involving items or services furnished on or after October 25, 2022 are provided in the August 2022 final rules, as revised by the opinion and order of the U.S. District Court for the Eastern District of Texas in *Texas Medical Association, et al. v. United States Department of Health and Human Services et al.,* Case, No. 6:22–cv–372 (February 6, 2023). As of March 17, 2023, the Departments have completed the necessary updates to the Federal IDR portal and Federal IDR process guidance documents to reflect these revised payment determination standards.

Additionally, consistent with section 102 of the No Surprises Act, the Departments outlined the QPA auditing requirements in Requirements Related to Surprise Billing, part 1 (July 13, 2021) and CMS is conducting QPA audits on behalf of all departments to ensure that plans and issuers are complying with requirements related to the calculation and disclosure of the QPA. The NSA requires the departments to submit a report to Congress for each year in which audits were conducted. The departments are actively conducting QPA audits as required under the statute and intend to produce the reports to Congress required in the law.

Question. Over half of the Medicare care beneficiaries in Tennessee rely on Medicare Advantage plans—around half a million Tennesseans. Many of these beneficiaries are low-income and in rural parts of the State where the extra benefits, like health programs and additional support for those with disabilities, are especially important. This administration seems dead set on pushing policies that harm the Medicare Advantage program, like the recently proposed cuts to the program, which will decrease benefits for some of Tennessee's most vulnerable, like those in special needs plans.

Is the Department concerned that its recent payment determinations will affect care for Medicare Advantage beneficiaries, which account for more than half of all Medicare enrollees nationwide?

Answer. As required by law, CMS adjusts payments to health plans offering MA to reflect the expected health-care costs of enrollees based on health status and de-

mographic characteristics through a process known as "risk adjustment." This ensures CMS pays more for enrollees with greater health-care needs and reduces incentives for plans to favor healthier beneficiaries. CMS routinely makes updates to the MA risk adjustment model to reflect more recent utilization and cost patterns and to ensure MA payments accurately reflect the costs of care for MA enrollees. In February, CMS proposed routine technical updates to improve the accuracy of MA payments in the 2024 Advance Notice. CMS received public feedback on these proposals, and will take this feedback into account when finalizing the 2024 Rate Announcement.

Question. The President's budget proposes to increase funding for the title X family planning program from $286 million to $512 million. The title X program has been called a slush fund for abortion providers, like Planned Parenthood, who are expected to receive tens of millions annually from this program now that your rule, allowing grantees to be collocated with abortion clinics, has taken effect.

A January 2023 Marist poll found that 60 percent of Americans oppose using tax dollars to fund abortions. Why do you continue to subsidize the abortion industry despite most Americans opposing using their tax dollars for this purpose?

How much Federal funding have abortion groups like Planned Parenthood received from HHS since you became the Secretary?

Answer. As HHS Secretary, my role is to implement the law. The Department will follow all applicable laws as they relate to abortion and any other issue.

Question. Millions of Americans are living with limb loss and limb difference. Despite the robust size of this population, policymakers know very little about how the health care delivery system serves individuals as they navigate the unique challenges they confront. To address this shortcoming, with Senator Duckworth and Representatives Guthrie and Butterfield, I introduced the Triple-A Study Act in the last Congress, asking GAO to study how Medicare and Medicaid are meeting the needs of the limb loss and limb difference community. GAO has begun its work, and we expect the study to be completed later this year.

As we learn more from GAO regarding gaps in care and opportunities for improvement, can we count on you to work with us to ensure that the limb loss and limb difference community has access to the high-quality care they expect and deserve from the Medicare and Medicaid programs?

Answer. CMS looks forward to reviewing this study from the working with the GAO on this review and we would be happy to work with you on this issue, including providing technical assistance on any legislation you draft.

Question. I've written to CMS Administrator Chiquita Brooks-LaSure about the need to provide coverage of important technologies for people with serious disabilities like ALS, MS, and spinal cord injuries. I appreciate your team proposing that Medicare cover seat elevation systems for people with disabilities, but I encourage you to finalize this important coverage decision.

Will you commit to issuing a similar coverage proposal for standing systems that help people with disabilities perform activities of daily living and avoid costly complications?

Answer. In February 2023 CMS published a proposed National Coverage Determination (NCD) to expand Medicare coverage for power seat elevation equipment for individuals with a Group 3 power wheelchair. The public comment period closed on this NCD last month. CMS plans to consider standing equipment in a separate future national coverage analysis. I'm happy to stay in touch with you as CMS undertakes this process.

Question. In your first 2 years as Secretary leading the department responsible for overseeing the Federal response to the COVID–19 pandemic that has claimed the lives of over 1 million Americans, have you ever spent an extended period working from California?

What percentage of your time have you spent in California in your 2 years as Secretary?

Can the Department commit to proactively sharing documents released through FOIA related to the Secretary's calendars and travel that are "frequently requested" (described in subsection (a)(2) of § 552 as records having been requested three or more times) with my office?

Answer. HHS is incredibly proud of the work that HHS has accomplished during this administration. This is a 24/7 job and I treat it as such, whether I am in an office building, on domestic or international official travel, or teleworking. As always, our north star will continue to be delivering on our mission which means building on the innovations and technology that we have put to work to ensure we are enhancing the health and well-being of all Americans.

HHS is committed to transparency and to working in good faith to address members' requests for information.

Question. Digital health technologies, including clinical decision support software, software as a medical device, patient remote monitoring, and AI-enabled services, have already improved patient outcomes and provider efficiency.

What is CMS's strategy to address this emerging field of medicine and adequately incorporate digital health technologies into the Medicare payment systems across all settings?

Answer. Thank you for your interest in expanding access to digital technologies in Medicare. President Biden's Fiscal Year 2024 budget includes a proposal that would allow for Medicare coverage of evidence-based digital applications and platforms that facilitate greater access to behavioral health services, especially for beneficiaries who live in rural or health professional shortage areas. If you are interested in drafting legislation to address Medicare's coverage of digital technologies, CMS would be happy to provide technical assistance.

Question. Section 218(b) of the Protecting Access to Medicare Act of 2014 directed the HHS Secretary to establish AUC program by January 1, 2017 with a relevant clinical decision support mechanism (CDSM) to assess the appropriateness of imaging services based on a patient's needs. Congress intended for the AUC program to ensure the best possible high-value imaging to patients, while avoiding unnecessary or duplicative procedures. It has been over 8 years since PAMA was enacted. After several delays, CMS indicated this past July that full implementation of the AUC program was delayed until further notice.

What are the specific reasons for the persistent delays in implementation? Is CMS considering a new implementation timeline? If so, what is the new timeline?

CMS has indicated that significant concerns related to improperly denying claims that may not be subject to the AUC consultation requirement (*e.g.,* imaging performed in critical access hospitals) still exist and preclude full implementation.

Is this concern expressed by CMS still valid? Does CMS envision a solution to this concern?

Would CMS be open to working with Congress and other stakeholders to identify AUC implementation difficulties, and then amend PAMA to alleviate those concerns and successfully implement this program?

Answer. The Protecting Access to Medicare Act (PAMA) directed CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. CMS has taken steps to implement this program over several years, and codified the AUC program in our regulations. In Calendar Year 2020, CMS began conducting an educational and operations testing period for the claims-based reporting of AUC consultation information. This operations and testing period has been extended until further notice.

Further, to incentivize the use of qualified clinical decision support mechanisms (CDSMs) to consult AUC, CMS established in the CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstances Policy for the Transition Year final rule and interim final rule, a high-weighted improvement activity under the Merit-based Incentive Payment System (MIPS). This activity can be selected under MIPS by ordering professionals who consult specified AUC using a qualified CDSM. The activity was implemented with the performance period that began January 1, 2018.

CMS is continuing to evaluate the AUC program, as well as other quality and value-based care initiatives that may help with appropriate utilization of advanced diagnostic imaging services. In previous rulemaking, CMS has raised operational and administrative issues with the AUC program and solicited additional information from stakeholders on mechanisms to ensure that only appropriate claims are subject to AUC claims processing edits. The identification of claims that are or are not subject to the Medicare AUC Program must be precise to avoid inadvertently denying claims that should be paid. CMS would be happy to work with Congress

and provide technical assistance on any potential amendments related to this program.

SUBMITTED BY HON. MARSHA BLACKBURN,
A U.S. SENATOR FROM TENNESSEE

From *The New York Times,* February 25, 2023

ALONE AND EXPLOITED, MIGRANT CHILDREN WORK BRUTAL JOBS ACROSS THE U.S.

By Hannah Dreier

Arriving in record numbers, they're ending up in dangerous jobs that violate child labor laws—including in factories that make products for well-known brands like Cheetos and Fruit of the Loom.

Cristian works a construction job instead of going to school. He is 14.

Carolina packages Cheerios at night in a factory. She is 15.

Wander starts looking for day-labor jobs before sunrise. He is 13.

It was almost midnight in Grand Rapids, MI, but inside the factory everything was bright. A conveyor belt carried bags of Cheerios past a cluster of young workers. One was 15-year-old Carolina Yoc, who came to the United States on her own last year to live with a relative she had never met.

About every 10 seconds, she stuffed a sealed plastic bag of cereal into a passing yellow carton. It could be dangerous work, with fast-moving pulleys and gears that had torn off fingers and ripped open a woman's scalp.

The factory was full of underage workers like Carolina, who had crossed the southern border by themselves and were now spending late hours bent over hazardous

machinery, in violation of child labor laws. At nearby plants, other children were tending giant ovens to make Chewy and Nature Valley granola bars and packing bags of Lucky Charms and Cheetos—all of them working for the processing giant Hearthside Food Solutions, which would ship these products around the country.

"Sometimes I get tired and feel sick," Carolina said after a shift in November. Her stomach often hurt, and she was unsure if that was because of the lack of sleep, the stress from the incessant roar of the machines, or the worries she had for herself and her family in Guatemala. "But I'm getting used to it."

Hearthside Food Solutions, one of the United States' largest food contractors, makes and packages products for well-known snack and cereal brands. Kirsten Luce for The New York Times

These workers are part of a new economy of exploitation: migrant children, who have been coming into the United States without their parents in record numbers, are ending up in some of the most punishing jobs in the country, a *New York Times* investigation found. This shadow work force extends across industries in every state, flouting child labor laws that have been in place for nearly a century. Twelve-year-old roofers in Florida and Tennessee. Underage slaughterhouse workers in Delaware, Mississippi and North Carolina. Children sawing planks of wood on overnight shifts in South Dakota.

Largely from Central America, the children are driven by economic desperation that was worsened by the pandemic. This labor force has been slowly growing for almost a decade, but it has exploded since 2021, while the systems meant to protect children have broken down.

The Times spoke with more than 100 migrant child workers in 20 states who described jobs that were grinding them into exhaustion, and fears that they had become trapped in circumstances they never could have imagined. *The Times* examination also drew on court and inspection records and interviews with hundreds of lawyers, social workers, educators and law enforcement officials.

In town after town, children scrub dishes late at night. They run milking machines in Vermont and deliver meals in New York City. They harvest coffee and build lava rock walls around vacation homes in Hawaii. Girls as young as 13 wash hotel sheets in Virginia.

Oscar Lopez, a ninth grader, works overnight at a sawmill in South Dakota. On this day, he skipped school to sleep after a 14-hour shift. Kirsten Luce for *The New York Times.*

In many parts of the country, middle and high school teachers in English-language learner programs say it is now common for nearly all their students to rush off to long shifts after their classes end.

"They should not be working 12-hour days, but it's happening here," said Valeria Lindsay, a language arts teacher at Homestead Middle School near Miami. For the past 3 years, she said, almost every eighth grader in her English learner program of about 100 students was also carrying an adult workload.

Migrant child labor benefits both under-the-table operations and global corporations, *The Times* found. In Los Angeles, children stitch "Made in America" tags into J. Crew shirts. They bake dinner rolls sold at Walmart and Target, process milk used in Ben & Jerry's ice cream and help debone chicken sold at Whole Foods. As recently as the fall, middle-schoolers made Fruit of the Loom socks in Alabama. In Michigan, children make auto parts used by Ford and General Motors.

The number of unaccompanied minors entering the United States climbed to a high of 130,000 last year—three times what it was 5 years earlier—and this summer is expected to bring another wave.

These are not children who have stolen into the country undetected. The federal government knows they are in the United States, and the Department of Health and Human Services is responsible for ensuring sponsors will support them and protect them from trafficking or exploitation.

But as more and more children have arrived, the Biden White House has ramped up demands on staffers to move the children quickly out of shelters and release them to adults. Caseworkers say they rush through vetting sponsors.

While H.H.S. checks on all minors by calling them a month after they begin living with their sponsors, data obtained by *The Times* showed that over the last 2 years, the agency could not reach more than 85,000 children. Overall, the agency lost immediate contact with a third of migrant children.

An H.H.S. spokeswoman said the agency wanted to release children swiftly, for the sake of their well-being, but had not compromised safety. "There are numerous places along the process to continually ensure that a placement is in the best interest of the child," said the spokeswoman, Kamara Jones.

Far from home, many of these children are under intense pressure to earn money. They send cash back to their families while often being in debt to their sponsors for smuggling fees, rent and living expenses.

"It's getting to be a business for some of these sponsors," said Annette Passalacqua, who left her job as a caseworker in Central Florida last year. Ms. Passalacqua said she saw so many children put to work, and found law enforcement officials so unwilling to investigate these cases, that she largely stopped reporting them. Instead, she settled for explaining to the children that they were entitled to lunch breaks and overtime.

Sponsors are required to send migrant children to school, and some students juggle classes and heavy workloads. Other children arrive to find that they have been misled by their sponsors and will not be enrolled in school.

The federal government hires child welfare agencies to track some minors who are deemed to be at high risk. But caseworkers at those agencies said that H.H.S. regularly ignored obvious signs of labor exploitation, a characterization the agency disputed.

In interviews with more than 60 caseworkers, most independently estimated that about two-thirds of all unaccompanied migrant children ended up working full time.

A representative for Hearthside said the company relied on a staffing agency to supply some workers for its plants in Grand Rapids, but conceded that it had not required the agency to verify ages through a national system that checks Social Security numbers. Unaccompanied migrant children often obtain false identification to secure work.

"We are immediately implementing additional controls to reinforce all agencies' strict compliance with our long standing requirement that all workers must be 18 or over," the company said in a statement.

At Union High School in Grand Rapids, Carolina's ninth-grade social studies teacher, Rick Angstman, has seen the toll that long shifts take on his students. One, who was working nights at a commercial laundry, began passing out in class from fatigue and was hospitalized twice, he said. Unable to stop working, she dropped out of school.

"She disappeared into oblivion," Mr. Angstman said. "It's the new child labor. You're taking children from another country and putting them in almost indentured servitude."

On the Night Shift

Children being processed by the U.S. Border Patrol in Roma, Texas. In the past two years alone, 250,000 unaccompanied minors have come into the country. Kirsten Luce for The New York Times

When Carolina left Guatemala, she had no real understanding of what she was heading toward, just a sense that she could not stay in her village any longer. There was not much electricity or water, and after the pandemic began, not much food.

The only people who seemed to be getting by were the families living off remittances from relatives in the United States. Carolina lived lone with her grandmother, whose health began failing. When neighbors started talking about heading north, she decided to join. She was 14.

"I just kept walking," she said.

Carolina reached the U.S. border exhausted, weighing 84 pounds. Agents sent her to an H.H.S. shelter in Arizona, where a caseworker contacted her aunt, Marcelina Ramirez. Ms. Ramirez was at first reluctant: She had already sponsored two other relatives and had three children of her own. They were living on $600 a week, and she didn't know Carolina.

When Carolina arrived in Grand Rapids last year, Ms. Ramirez told her she would go to school every morning and suggested that she pick up evening shifts at Hearthside. She knew Carolina needed to send money back to her grandmother. She also believed it was good for young people to work. Child labor is the norm in rural Guatemala, and she herself had started working around the second grade.

One of the nation's largest contract manufacturers, Hearthside makes and packages food for companies like Frito-Lay, General Mills and Quaker Oats. "It would be hard to find a cookie or cracker aisle in any leading grocer that does not contain multiple products from Hearthside production facilities," a Grand Rapids-area plant manager told a trade magazine in 2019.

General Mills, whose brands include Cheerios, Lucky Charms and Nature Valley, said it recognized "the seriousness of this situation" and was reviewing *The Times's* findings. PepsiCo, which owns Frito-Lay and Quaker Oats, declined to comment.

Three people who until last year worked at one of the biggest employment agencies in Grand Rapids, Forge Industrial Staffing, said Hearthside supervisors were sometimes made aware that they were getting young-looking workers whose identities had been flagged as false.

"Hearthside didn't care," said Nubia Malacara, a former Forge employee who said she had also worked at Hearthside as a minor.

In a statement, Hearthside said, "We do care deeply about this issue and are concerned about the mischaracterization of Hearthside." A spokesman for Forge said it complied with state and federal laws and "would never knowingly employ individuals under 18."

Kevin Tomas said he sought work through Forge after he arrived in Grand Rapids at age 13 with his 7-year-old brother. At first, he was sent to a local manufacturer that made auto parts for Ford and General Motors. But his shift ended at 6:30 in the morning, so he could not stay awake in school, and he struggled to lift the heavy boxes.

"It's not that we want to be working these jobs. It's that we have to help our families," Kevin said.

By the time he was 15, Kevin had found a job at Hearthside, stacking 50-pound cases of cereal on the same shift as Carolina.

"So Many Red Flags"

Cristian, 14, has been working in construction in North Miami for two years instead of going to school. Federal law bars minors from a long list of such jobs. Kirsten Luce for The New York Times

The growth of migrant child labor in the United States over the past several years is a result of a chain of willful ignorance. Companies ignore the young faces in their back rooms and on their factory floors. Schools often decline to report apparent labor violations, believing it will hurt children more than help. And H.H.S. behaves as if the migrant children who melt unseen into the country are doing just fine.

"As the government, we've turned a blind eye to their trafficking," said Doug Gilmer, the head of the Birmingham, Ala., office of Homeland Security Investigations, a federal agency that often becomes involved with immigration cases.

Mr. Gilmer teared up as he recalled finding 13-year-olds working in meat plants; 12-year-olds working at suppliers for Hyundai and Kia, as documented last year by a Reuters investigation; and children who should have been in middle school working at commercial bakeries.

"We're encountering it here because we're looking for it here," Mr. Gilmer said. "It's happening everywhere."

Children have crossed the southern border on their own for decades, and since 2008, the United States has allowed non-Mexican minors to live with sponsors while they go through immigration proceedings, which can take several years. The policy, codified in anti-trafficking legislation, is intended to prevent harm to children who would otherwise be turned away and left alone in a Mexican border town.

When Kelsey Keswani first worked as an H.H.S. contractor in Arizona to connect unaccompanied migrant children with sponsors in 2010, the adults were almost always the children's parents, who had paid smugglers to bring them up from Central America, she said.

But around 2014, the number of arriving children began to climb, and their circumstances were different. In recent years, "the kids almost all have a debt to pay off, and they're super stressed about it," Ms. Keswani said.

She began to see more failures in the vetting process. "There were so many cases where sponsors had sponsored multiple kids, and it wasn't getting caught. So many red flags with debt. So many reports of trafficking."

Now, just a third of migrant children are going to their parents. A majority are sent to other relatives, acquaintances or even strangers, a *Times* analysis of federal data showed. Nearly half are coming from Guatemala, where poverty is fueling a wave of migration. Parents know that they would be turned away at the border or quickly deported, so they send their children in hopes that remittances will come back.

In the last 2 years alone, more than 250,000 children have entered the United States by themselves.

The shifting dynamics in Central America helped create a political crisis early in Mr. Biden's presidency, when children started crossing the border faster than H.H.S. could process them. With no room left in shelters, the children stayed in jail-like facilities run by Customs and Border Protection and, later, in tent cities. The images of children sleeping on gym mats under foil blankets attracted intense media attention.

The Biden administration pledged to move children through the shelter system more quickly. "We don't want to continue to see a child languish in our care if there is a responsible sponsor," Xavier Becerra, secretary of health and human services, told Congress in 2021.

A detention site in the Rio Grande Valley in March 2021. The Biden administration has faced pressure to move unaccompanied children through the system quickly. Pool photo by Dario Lopez-Mills

His agency began paring back protections that had been in place for years, including some background checks and reviews of children's files, according to memos reviewed by *The Times* and interviews with more than a dozen current and former employees.

"Twenty percent of kids have to be released every week or you get dinged," said Ms. Keswani, who stopped working with H.H.S. last month.

Concerns piled up in summer 2021 at the Office of Refugee Resettlement, the H.H.S. division responsible for unaccompanied migrant children. In a memo that July, 11 managers said they were worried that labor trafficking was increasing and complained to their bosses that the office had become "one that rewards individuals for making quick releases, and not one that rewards individuals for preventing unsafe releases."

Staff members said in interviews that Mr. Becerra continued to push for faster results, often asking why they could not discharge children with machine-like efficiency.

"If Henry Ford had seen this in his plants, he would have never become famous and rich. This is not the way you do an assembly line," Mr. Becerra said at a staff meeting last summer, according to a recording obtained by *The Times.*

The H.H.S. spokeswoman, Ms. Jones, said that Mr. Becerra had urged his staff to "step it up." "Like any good leader, he wouldn't hesitate to do it again—especially when it comes to the well-being and safety of children," she said.

During a call last March, Mr. Becerra told Cindy Huang, the O.R.R. director, that if she could not increase the number of discharges, he would find someone who could, according to five people familiar with the call. She resigned a month later.

He recently made a similar threat to her successor during a meeting with senior leadership, according to several people who were present.

"It Was All Lies"

Migrant children were among the day laborers who gathered on a school day in Homestead, Fla., to find roofing, landscaping or other work. Kirsten Luce for The New York Times

While many migrant children are sent to the United States by their parents, others are persuaded to come by adults who plan to profit from their labor.

Nery Cutzal was 13 when he met his sponsor over Facebook Messenger. Once Nery arrived in Florida, he discovered that he owed more than $4,000 and had to find his own place to live. His sponsor sent him threatening text messages and kept a running list of new debts: $140 for filling out H.H.S. paperwork; $240 for clothes from Walmart; $45 for a taco dinner.

"Don't mess with me," the sponsor wrote. "You don't mean anything to me."

Nery began working until 3 a.m. most nights at a trendy Mexican restaurant near Palm Beach to make the payments. "He said I would be able to go to school and he would take care of me, but it was all lies," Nery said.

His father, Leonel Cutzal, said the family had become destitute after a series of bad harvests and had no choice but to send their oldest son north from Guatemala.

"Even when he shares $50, it's a huge help," Mr. Cutzal said. "Otherwise, there are times we don't eat." Mr. Cutzal had not understood how much Nery would be made to work, he said. "I think he passed through some hard moments being up there so young."

Nery eventually contacted law enforcement, and his sponsor was found guilty last year of smuggling a child into the United States for financial gain. That outcome is rare: In the past decade, federal prosecutors have brought only about 30 cases involving forced labor of unaccompanied minors, according to a *Times* review of court databases.

A handwritten ledger, in Spanish, of Nery Cutzal's debts to his sponsor, including money for tacos and clothes. The child owed more than $4,000, plus interest. Court information has been redacted for privacy.

Unlike the foster care system, in which all children get case management, H.H.S. provides this service to about a third of children who pass through its care, and usually for just 4 months. Tens of thousands of other children are sent to their sponsors with little but the phone number for a national hotline. From there, they are often on their own: there is no formal follow-up from any federal or local agencies to ensure that sponsors are not putting children to work illegally.

In Pennsylvania, one case worker told *The Times* he went to check on a child released to a man who had applied to sponsor 20 other minors. The boy had vanished. In Texas, another case worker said she had encountered a man who had been targeting poor families in Guatemala, promising to help them get rich if they sent their children across the border. He had sponsored 13 children.

"If you've been in this field for any amount of time, you know that there's what the sponsors agree to, and what they're actually doing," said Bernal Cruz Munoz, a caseworker supervisor in Oregon.

Calling the hotline is not a sure way to get support, either. Juanito Ferrer called for help after he was brought to Manassas, VA, at age 15 by an acquaintance who forced him to paint houses during the day and guard an apartment complex at night. His sponsor took his paychecks and watched him on security cameras as he slept on the basement floor.

Juanito said that when he called the hotline in 2019, the person on the other end just took a report. "I thought they'd send the police or someone to check, but they never did that," he said. "I thought they would come and inspect the house, at least." He eventually escaped.

Asked about the hotline, H.H.S. said operators passed reports onto law enforcement and other local agencies because the agency did not have the authority to remove children from homes.

The Times analyzed government data to identify places with high concentrations of children who had been released to people outside their immediate families—a sign that they might have been expected to work. In northwest Grand Rapids, for instance, 93 percent of children have been released to adults who are not their parents.

H.H.S. does not track these clusters, but the trends are so pronounced that officials sometimes notice hot spots anyway.

Scott Lloyd, who led the resettlement office in the Trump administration, said he realized in 2018 that the number of unaccompanied Guatemalan boys being released to sponsors in South Florida seemed to be growing.

Jose Vasquez, 13, photographed at the church he attends in Grand Rapids, Mich. He works 12-hour shifts, six days a week, at an egg farm outside the city. Kirsten Luce for The New York Times

"I always wondered what was happening there," he said.

But his attention was diverted by the chaos around the Trump administration's child separation policy, and he never looked into it. The trend he saw has only accelerated: For example, in the past 3 years, more than 200 children have been released to distant relatives or unrelated adults around Immokalee, FL., an agricultural hub with a long history of labor exploitation.

In a statement, H.H.S. said it had updated its case management system to better flag instances when multiple children were being released to the same person or address.

Many sponsors see themselves as benevolent, doing a friend or neighbor a favor by agreeing to help a child get out of a government shelter, even if they do not intend to offer any support. Children often understand that they will have to work, but do not grasp the unrelenting grind that awaits them.

"I didn't get how expensive everything was," said 13-year-old Jose Vasquez, who works 12-hour shifts, 6 days a week, at a commercial egg farm in Michigan and lives with his teenage sister. "I'd like to go to school, but then how would I pay rent?"

Occupational Hazards

Carolina Yoc, back right, worked on math problems after a night shift at a Grand Rapids food plant. The 13-year-old girl sitting next to her said she also worked nights at a factory. Kirsten Luce for The New York Times

One fall morning at Union High School in Grand Rapids, Carolina listened to Mr. Angstman lecture on the journalist Jacob Riis and the Progressive Era movement that helped create federal child labor laws. He explained that the changes were meant to keep young people out of jobs that could harm their health or safety, and showed the class a photo of a small boy making cigars.

"Riis reported that members of this family worked 17 hours a day, 7 days a week," he told the students. "The cramped space reeked of toxic fumes." Students seemed unmoved. Some struggled to stay awake.

Teachers at the school estimated that 200 of their immigrant students were working full time while trying to keep up with their classes. The greatest share of Mr. Angstman's students worked at one of the four Hearthside plants in the city.

The company, which has 39 factories in the United States, has been cited by the Occupational Safety and Health Administration for 34 violations since 2019, including for unsafe conveyor belts at the plant where Carolina found her job. At least 11 workers suffered amputations in that time. In 2015, a machine caught the hairnet of an Ohio worker and ripped off part of her scalp.

The history of accidents "shows a corporate culture that lacks urgency to keep workers safe," an OSHA official wrote after the most recent violation for an amputation.

Underage workers in Grand Rapids said that spicy dust from immense batches of Flamin' Hot Cheetos made their lungs sting, and that moving heavy pallets of cereal all night made their backs ache. They worried about their hands getting caught in conveyor belts, which federal law classifies as so hazardous that no child Carolina's age is permitted to work with them.

Hearthside said in a statement that it was committed to complying with laws governing worker protections. "We strongly dispute the safety allegations made and are proud of our safety-first culture," the statement read.

Federal law bars minors from a long list of dangerous jobs, including roofing, meat processing and commercial baking. Except on farms, children younger than 16 are not supposed to work for more than 3 hours or after 7 p.m. on school days.

But these jobs—which are grueling and poorly paid, and thus chronically short-staffed—are exactly where many migrant children are ending up. Adolescents are twice as likely as adults to be seriously injured at work, yet recently arrived preteens and teenagers are running industrial dough mixers, driving massive

earthmovers and burning their hands on hot tar as they lay down roofing shingles, *The Times* found.

Unaccompanied minors have had their legs torn off in factories and their spines shattered on construction sites, but most of these injuries go uncounted. The Labor Department tracks the deaths of foreign-born child workers but no longer makes them public. Reviewing state and federal safety records and public reports, *The Times* found a dozen cases of young migrant workers killed since 2017, the last year the Labor Department reported any.

The deaths include a 14-year-old food delivery worker who was hit by a car while on his bike at a Brooklyn intersection; a 16-year-old who was crushed under a 35-ton tractor-scraper outside Atlanta; and a 15-year-old who fell 50 feet from a roof in Alabama where he was laying down shingles.

In 2021, Karla Campbell, a Nashville labor lawyer, helped a woman figure out how to transport the body of her 14-year-old grandson, who had been killed on a landscaping job, back to his village in Guatemala. It was the second child labor death she had handled that year.

"I've been working on these cases for 15 years, and the addition of children is new," Ms. Campbell said.

In dairy production, the injury rate is twice the national average across all industries. Paco Calvo arrived in Middlebury, VT when he was 14 and has been working 12-hour days on dairy farms in the 4 years since. He said he crushed his hand in an industrial milking machine in the first months of doing this work.

"Pretty much everyone gets hurt when they first start," he said.

Targeting the Middlemen

Charlene Irizarry, the human resources manager at Farm Fresh Foods, an Alabama meat plant that struggles to retain staff, recently realized she was interviewing a 12-year-old for a job slicing chicken breasts into nuggets in a section of the factory kept at 40 degrees.

Ms. Irizarry regularly sees job applicants who use heavy makeup or medical masks to try to hide their youth, she said."Sometimes their legs don't touch the floor."

Other times, an adult will apply for a job in the morning, and then a child using the same name will show up for orientation that afternoon. She and her staff have begun separating other young applicants from the adults who bring them in, so they will admit their real ages.

Ms. Irizarry said the plant had already been fined for one child labor violation, and she was trying to avoid another. But she wondered what the children might face if she turned them away.

"I worry about why they're so desperate for these jobs," she said.

In interviews with underage migrant workers, *The Times* found child labor in the American supply chains of many major brands and retailers. Several, including Ford, General Motors, J. Crew and Walmart, as well as their suppliers, said they took the allegations seriously and would investigate. Target and Whole Foods did not respond to requests for comment. Fruit of the Loom said it had ended its contract with the supplier.

One company, Ben & Jerry's, said it worked with labor groups to ensure a minimum set of working conditions at its dairy suppliers. Cheryl Pinto, the company's head of values-led sourcing, said that if migrant children needed to work full time, it was preferable for them to have jobs at a well-monitored workplace.

The Labor Department is supposed to find and punish child labor violations, but inspectors in a dozen states said their understaffed offices could barely respond to complaints, much less open original investigations. When the department has responded to tips on migrant children, it has focused on the outside contractors and staffing agencies that usually employ them, not the corporations where they perform the work.

In Worthington, MN, it had long been an open secret that migrant children released by H.H.S. were cleaning a slaughterhouse run by JBS, the world's largest meat processor. The town has received more unaccompanied migrant children per capita than almost anywhere in the country.

Outside the JBS pork plant last fall, *The Times* spoke with baby-faced workers who chased and teased one another as they came off their shifts in the morning. Many had scratched their assumed names off company badges to hide evidence that they were working under false identities. Some said they had suffered chemical burns from the corrosive cleaners they used.

Not long afterward, labor inspectors responding to a tip found 22 Spanish-speaking children working for the company hired to clean the JBS plant in Worthington, and dozens more in the same job at meat-processing plants around the United States.

But the Labor Department can generally only issue fines. The cleaning company paid a $1.5 million penalty, while JBS said it had been unaware that children were scouring the Worthington factory each night. JBS fired the cleaning contractor.

Many of the children who were working there have found new jobs at other plants, *The Times* found.

"I still have to pay back my debt, so I still have to work," said Mauricio Ramirez, 17, who has found a meat processing job in the next town over.

"Not What I Imagined"

It has been a little more than a year since Carolina left Guatemala, and she has started to make some friends. She and another girl who works at Hearthside have necklaces that fit together, each strung with half a heart. When she has time, she posts selfies online decorated with smiley faces and flowers.

Mostly, though, she keeps to herself. Her teachers do not know many details about her journey to the border. When the topic came up at school recently, Carolina began sobbing and would not say why.

After a week of 17-hour days, she sat at home one night with her aunt and considered her life in the United States. The long nights. The stress about money. "I didn't have expectations about what life would be like here," she said, "but it's not what I imagined."

She was holding a debit card given to her by a staffing agency, which paid her Hearthside salary this way so she did not have to cash checks. Carolina turned it over and over in her palm as her aunt looked on.

"I know you get sad," Ms. Ramirez said.

Carolina looked down. She wanted to continue going to school to learn English, but she woke up most mornings with a clenched stomach and kept staying home sick. Some of her ninth grade classmates had already dropped out. The 16-year-old boy she sat next to in math class, Cristian Lopez, had left school to work overtime at Hearthside.

Cristian lived a few minutes away, in a bare two-room apartment he shared with his uncle and 12-year-old sister, Jennifer.

His sister did not go to school either, and they had spent the day bickering in their room. Now night had fallen and they were eating Froot Loops for dinner. The heat was off, so they wore winter jackets. In an interview from Guatemala, their mother, Isabel Lopez, cried as she explained that she had tried to join her children in the United States last year but was turned back at the border.

Cristian had given his uncle some of the money he earned making Chewy bars, but his uncle believed it was not enough. He had said he would like Jennifer to start working at the factory as well, and offered to take her to apply himself.

Cristian said he had recently called the H.H.S. hotline. He hoped the government would send someone to check on him and his sister, but he had not heard back. He did not think he would call again.

https://www.nytimes.com/2023/02/25/us/unaccompanied-migrant-child-workers-exploitation.html

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PREPARED STATEMENT OF HON. MIKE CRAPO,
A U.S. SENATOR FROM IDAHO

Thank you, Mr. Chairman, and thank you, Secretary Becerra, for being here today.

I do want to respond to the question of the debt ceiling negotiations. I want to make it very clear, the Republicans are asking for negotiations on the debt ceiling

process, to add some fiscal restraint into the debt ceiling extension. I ask you, Secretary Becerra, to take back to the President my plea that he engage with us in negotiations.

I want to make it clear, we are not talking about trying to reduce benefits in Medicare or Social Security for our seniors. What we are talking about is reasonable reforms that can help us get to some kind of fiscal restraint on our spiraling debt. I encourage all of my colleagues in the Senate, but particularly the President, to engage with those kinds of negotiations.

I want to start my formal remarks on the positive. You have testified before and talked to me privately about the fact that although we have our differences on a lot of different policy areas, we want to find those areas where we can work together, and we found some last year.

Late last year, we came together on a package of bipartisan reforms to produce common-sense solutions, ranging from mental health improvements to comprehensive telehealth coverage for seniors and working families. Moreover, we accomplished all of this while reducing the deficit by billions of dollars.

Fortunately, the administration supports these policies, and I look forward to partnering with the U.S. Department of Health and Human Services (HHS), as well as with my colleagues on both sides of the aisle, to advance additional reforms that improve health-care access, affordability, and choice for all Americans. That being said, I do have concerns with the budget the President has put forward.

Unfortunately, many of the proposals in the President's budget run directly counter to these types of initiatives. I have serious concerns with the focus on partisan policies that risk harming health-care access and affordability, for both current and future patients. The budget's central proposal, for instance, would dramatically expand the size and scope of the bureaucratic, government-run drug price-setting program enacted under last year's Inflation Reduction Act (IRA).

Prior to that law's passage, my Republican colleagues and I warned repeatedly that imposing sweeping price controls would prove disastrous for patients, biomedical research and development, and domestic manufacturing jobs. Many of our fears have already come to pass.

We pointed to the risk of higher launch prices and distorted pricing practices, based on projections validated by the nonpartisan Congressional Budget Office. And sure enough, *The Wall Street Journal* reported in January, and I quote, "The impact in 2023 may actually be higher drug prices." We also expressed concerns around lifesaving R&D, as a University of Chicago study estimated the IRA would result in 135 fewer new drug approvals in the next 2 decades. That figure would inevitably skyrocket under the budget's proposed expansion. Already, numerous manufacturers have signaled plans to table certain projects in light of the uncertainty created by the IRA.

In recent months, we have also seen a rash of drug shortages, which even leading U.S. Food and Drug Administration (FDA) officials have attributed to pricing dynamics. Doubling down on the IRA's price controls would exacerbate the law's most harmful consequences. Americans deserve better and more affordable access to prescription drugs, and we can find bipartisan, results-oriented solutions this year to advance that goal. Government price mandates, however, are a step in the wrong direction.

I also have profound concerns with the budget's bold claims of averting the Medicare hospital insurance trust fund's looming insolvency, largely through massive tax hikes and budget gimmicks. This unbalanced approach does nothing to address Medicare's cost drivers. It would also punish the small business job creators and entrepreneurs who drive our economy.

Unfortunately, the budget takes a similarly shortsighted approach to Medicaid, reviving a number of rejected policies from past proposals, including hundreds of billions in new spending, tied to burdensome conditions and efforts to circumvent State leaders.

The Federal Government should focus on supporting States as they work to return Medicaid to post-pandemic normalcy, rather than imposing new top-down mandates. Instead of turning to one-size-fits-all solutions, we should look to proven models for Federal programs, such as Medicare Advantage. With sky-high patient satisfaction rates, Medicare Advantage shows that consumer choice and market forces can produce more benefits and better outcomes.

As we move forward, I encourage your Department, Mr. Secretary, to focus on our many shared goals, from cost-cutting competition to sustainable telehealth access, rather than on partisan priorities.

Thank you again for being here today, and thank you, Mr. Chairman.

SUBMITTED BY HON. THOM TILLIS,
A U.S. SENATOR FROM NORTH CAROLINA

From *The Washington Post*

OUR LAW HELPS PATIENTS GET NEW DRUGS SOONER

By Birch Bayh and Bob Dole*

As co-authors of the Bayh-Dole Act of 1980, we must comment on the March 27 oped article by Peter Arno and Michael Davis about this law.

Government alone has never developed the new advances in medicines and technology that become commercial products. For that, our country relies on the private sector. The purpose of our act was to spur the interaction between public and private research so that patients would receive the benefits of innovative science sooner.

For every $1 spent in government research on a project, at least $10 of industry development will be needed to bring a product to market. Moreover, the rare government-funded inventions that become products are typically five to seven years away from being commercial products when private industry gets involved. This is because almost all universities and government labs are conducting early-stage research.

Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.

The article also mischaracterized the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.

The law we passed is about encouraging a partnership that spurs advances to help Americans. We are proud to say it's working.

From *Endpoints News,* November 1, 2022

UPDATED: ELI LILLY BLAMES BIDEN'S IRA FOR CANCER DRUG DISCONTINUATION AS THE NEW PHARMA PLAYBOOK TAKES SHAPE

By Max Gelman,† Senior Editor

Eli Lilly laid blame Tuesday afternoon on President Joe Biden's Inflation Reduction Act as the reason it scrapped a $40-million cancer drug.

As part of its third quarter update earlier Tuesday morning, the Big Pharma revealed it had removed a Phase I drug licensed from Fosun Pharma, a BCL2 inhibitor that had been undergoing studies for a variety of blood cancers. Though the reasoning had been initially unclear, an Eli Lilly spokesperson told Endpoints News in an email that "in light of the Inflation Reduction Act, this program no longer met our threshold for continued investment."

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*The writers are, respectively, a former Democratic senator from Indiana and a former Republican Senator from Kansas.

†*https://endpts.com/author/max-gelman/*.

Asked to explain how the IRA impacted this specific drug, the spokesperson highlighted the law's impact on small molecule R&D.

"The IRA changes many dynamics for small molecules in oncology and when we integrated those changes with this program and its competitive landscape, the program's future investment no longer met our threshold," the spokesperson told Endpoints in a follow-up email.

The Inflation Reduction Act, which Biden signed into law over the summer, contains provisions allowing Medicare to negotiate prices for certain high-cost drugs. Starting in 2026, the HHS Secretary will select drugs from a list of the highest-selling Medicare Part D and, later on, Part B medicines for which the agency will be allowed to set a "maximum fair price."

For small molecules, the government can begin negotiating prices after the drugs have been on the market for at least 9 years. The drugs would also have to be among the top therapies Medicare pays for. Critics of the law have said beginning negotiations at the nine-year mark will hamper innovation, because pharma companies obtain 13 years of market exclusivity—a threshold which remains in place with the IRA.

Lilly's decision comes a few days after Alnylam noted the IRA in a press release, tying it to the legislation to a decision ending Phase III plans for vutrisiran in the rare Stargardt disease. In this instance, Alnylam emphasized the orphan drug exemption for the IRA's drug price caps, in which therapies are exempt from Medicare negotiations if approved for only one designation.

Earlier this year, the FDA approved vutrisiran, branded as Amvuttra, to treat hereditary transthyretin-mediated (hATTR) amyloidosis. Alnylam lists the price at $463,500 per patient per year, and the drug pulled in about $25 million in its first quarter on the market.

The Lilly drug, dubbed LOXO–338, was far from any regulatory decision. Researchers were testing it as a monotherapy in Phase I studies and it would have progressed to a combination cohort had safety and efficacy been confirmed, according to the federal government's clinical trials database.

Lilly expected to enroll more than 300 patients, as of the trial's most recent update on October 12.th Started in August 2021, the study was supposed to observe patients' response rates over the course of two years and report data in 2024. But with Lilly dropping the program, it's not clear what will happen to patients who have already taken the experimental drug.

Lilly licensed LOXO–338 from Fosun Pharma in October 2020, nabbing the rights to the drug everywhere but China for $40 million. On top of that, Fosun had been eligible for up to $400 million in milestones and mid-to-high single-digit royalty payments on any approvals.

Additionally, Lilly abandoned another pipeline program Tuesday, a PACAP38-targeting antibody known as LY3451838. According to previous SEC filings, researchers had been testing the drug in a Phase II study for chronic pain since November 2020. But in August, Lilly updated the indication to migraines.

Per the trial database, the Phase II trial was completed this past September. A press release from Lilly Neuroscience said the study "did not meet pre-specified critical success factors."

With earnings season in full swing, Lilly isn't the only Big Pharma company to cull programs from its pipeline. Last month, Roche chopped a Phase II eye disease candidate after a biotech tossed a similar drug the day before, and Novartis indefinitely postponed plans to submit an FDA pitch for its PD–1 drug. GSK made a broad retreat from NY–ESO as a cancer target when it pulled out of two cell therapy 2.0 alliances, while AbbVie discarded an autoimmune drug, the product of a 10-year discovery partnership.

From *Bloomberg,* October 27, 2022

ALNYLAM HALTS WORK ON EYE DRUG, CITING NEW U.S. LAW OVER PRICING

By Angelica Peebles [1]

- Drugmaker had planned to expand drug's use for eye disease
- New drug-price negotiation law cited as disincentive

Alnylam Pharmaceuticals Inc.[2] said it's stopping work on a treatment for a rare eye disease because of a new U.S. drug-pricing law with the potential to limit how much it could charge for the medication in the future.

Alnylam will not begin a planned late-stage trial of its drug Amvuttra for Stargardt disease, which causes blindness, while it examines the Inflation Reduction Act, the company said Thursday in its third-quarter earnings statement.[3] The shares fell 2.7% as of 10:47 a.m. in New York.

Under the act, the U.S. Government will be able to negotiate prices for a small subset of drugs in the Medicare program for seniors. The law targets drugs that Medicare spends the most money on and have been on the market for years, and drug companies like Alnylam have argued that it discourages investment in new medicines.

Amvuttra is already approved to treat a rare disease called transthyretin-mediated amyloidosis, and Alnylam was exploring Stargardt disease as a second indication. The company charges $463,500 per patient a year for the drug and in the third quarter, its first full quarter on the market, the company reported $25 million in revenue from it.

Alnylam isn't moving forward with adding the second indication because the act exempts drugs with one rare-disease use from price negotiations. The list of drugs subject to negotiations is limited to the 50 Medicare spends the most money on by 2029, and it's not clear whether Amvuttra would fall into that category.

Alnylam is "still digesting the legislation," said Yvonne Greenstreet, chief executive officer of the Cambridge, Massachusetts-based company, said Thursday on a call discussing the earnings results. Management has considerable concerns about the legislation, she said.

Greenstreet said Alnylam remains interested in Stargardt disease, which is estimated [4] to affect fewer than 200,000 people in the U.S. and causes progressive vision loss. She said the company is still trying to figure out the best path forward.

PREPARED STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON

The Finance Committee meets this morning with Secretary Becerra to discuss the year ahead for the Department of Health and Human Services. The President's budget comes down to a simple proposition: helping working families and the middle class get ahead and reducing the deficit are not mutually exclusive.

When it comes to health care, that means protecting Medicare for the next generation by asking the wealthy to pay their fair share in taxes; strengthening Medicare's negotiating power for the cost of prescription drugs; and investing in priorities like mental health care, home-based care, and the health-care workforce.

That's a sharp contrast to the Republican approach to the Federal budget since the beginning of this year, which amounts to demanding secret negotiations on unspecified cuts to Federal programs while holding hostage the full faith and credit of the United States Government.

Budget Committee Chair Whitehouse and I asked the nonpartisan Congressional Budget Office to run the numbers, and it's clear that Republican promises to spare certain parts of the budget like Social Security and Medicare just don't add up. Sparing essential lifelines for seniors in addition to Republican priorities like ex-

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[1] *https://www.bloomberg.com/authors/AUdOqwkfIrY/angelica-peebles.*
[2] *https://www.bloomberg.com/quote/ALNY:US?leadSource=uverify%20wall.*
[3] *https://www.bloomberg.com/news/terminal/RKEUO0MEWG7T.*
[4] *https://rarediseases.info.nih.gov/diseases/181/stargardt-disease.*

tending the Trump tax law means essentially zeroing out everything else in the Federal budget.

I want to take a moment to address reports that some members are considering proposals that cut earned benefits in Medicare or Social Security for those who are not yet at retirement age. Let me be very clear: as long as I'm chairman of the Finance Committee, I will fight any effort to engage in intergenerational warfare. There are plenty of ideas to improve the financial health of these programs that do not include forfeiting the earned benefits of current workers.

Now I'm going to take a minute to talk about what cuts like these mean in practical terms, starting with Medicaid. Contrary to popular belief, Medicaid acts as the Nation's backstop for nursing home care, not Medicare. That means when your parents are in their 80s or 90s and require nursing home care, Medicaid is there to help cover the cost once they've spent down their hard-earned savings over the course of their retirement.

If Republicans go after Medicaid the way they did in 2017, by cutting Federal support to State Medicaid programs and giving States free reign to pare back benefits, that guaranteed backstop of nursing home care in old age is ripped away. That means a return to times from distant memory before the social safety net was created, when older Americans who ran out of savings and couldn't count on a family member for help were consigned to poor farms or almshouses.

Colleagues, none of us wants America to return to that time. So let's look for ways to work together to take on the big health challenges of the day, rather than pursuing reckless cuts that imperil American seniors.

I want to briefly tick through some important priorities in the President's HHS budget.

First, on prescription drugs, the President's budget has several bold proposals to build on the Inflation Reduction Act that will hold big pharma accountable for years of high prices, while lowering costs for seniors. That includes speeding up Medicare negotiation and increasing the number of drugs subject to negotiation each year. I support this approach, especially as the Centers for Medicare and Medicaid Services (CMS) continues to steadily implement the laws that are already on the books.

Just last week, the Biden administration announced that the anti-price-gouging law written in this committee on a bipartisan basis in 2019 will lower coinsurance payments for 27 drugs in Medicare Part B. Part B pays for prescription drugs to treat diseases like cancer and rheumatoid arthritis administered in the doctor's office. That includes Humira, which is Exhibit A for why drug pricing reforms were needed in the first place. Important steps like these—coinsurance reductions, free vaccines, and the insulin cost cap in Medicare—are just the beginning of the big league impact this law will have on Americans' health costs.

Next, mental health care. Last Congress, this committee wrote black letter law to move the country towards a reality where all Americans can get quality mental health care when and where they need it, and I thank Senator Crapo for making sure it was a bipartisan effort throughout. I'm proud that this committee included a number of important policies in bipartisan bills, like improved mental health care in schools, funding for community behavioral health centers—a longstanding priority for Senator Stabenow—coverage for therapists in Medicare, and new GME slots for psychiatrists. Despite that important work last year, every member of this committee knows there is more to be done. I intend to work with Ranking Member Crapo to enact the remaining policies that members of this committee put so much sweat equity into.

When it comes to mental health parity, Congress passed a landmark law in 2008 based on the proposition that mental health and physical health should be treated equally. That's not happening today. Fifteen years after the law was written, insurance companies are still finding ways to drag their feet. So the challenge for this committee is to stop the foot-dragging under current law, and develop fresh approaches to give Americans what they thought they were getting in 2008. The President's budget takes important steps in that direction, and I'm proud to be working with Senator Bennet to put mental health care on a better footing.

I'm also pleased to see the President's budget take a big step when it comes to postpartum coverage for new mothers in Medicaid. At the end of last year, Congress came together on a bipartisan basis to create an option for every State to cover postpartum care for new mothers for 12 months. The President's budget takes the next step to make that coverage available across the entire country. That's critically

important at the time when maternal mortality is rising, particularly for Black women.

Before I wrap up, I want to talk about one more critically important priority—long-term care. Right now, millions of seniors and Americans with disabilities are falling through the cracks, as recently reported in *The Washington Post.* It's high time to develop smart policies that provide several long-term care options to families to get the care that's best for their loved ones. One option is home and community-based care, which the President's budget proposes to expand in Medicaid. For too many of our fellow Americans who count on Medicaid for long-term care, it's not possible to receive that type of care with the current laws on the books. Senator Casey has been a champion of this effort on the Finance Committee, and I'm proud to call myself his partner. It's long past time to expand this coverage under Medicaid.

I'm pleased to see so many smart investments in this budget in high-priority policies that will improve health care for Americans with coverage under Medicare, Medicaid, and ACA marketplaces.

Thank you for joining the committee this morning, Secretary Becerra. There's a lot to discuss today, so I look forward to speaking with you in the Q&A.

COMMUNICATIONS

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Statement of Michael G. Bindner

Chairman Wyden and Ranking Member Crapo, thank you for the opportunity to submit these comments for the record on the HHS FY 2024 budget request.

I have put out previous comments on orphan drugs, examining lessons learned from the pandemic that need to be noted, mental health hospitalization, getting to single-payer and establishing a Medicare Part E for Senior Medicaid and other long term care in the attachments.

These comments will restate my upcoming testimony to the Labor, HHS and Education Appropriations Subcommittee and the House Budget Committee. I have not pulled any punches.

From LHHSE:

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. 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. Healthcare reform should only be done in this way. Among our other proposals is to fund healthcare spending through an employer paid subtraction value added tax. This would allow for the repeal of the ACA–SM surtax on higher-income individuals enacted as part of the Affordable Care Act.

From the Budget Committee Comments (PB proposals are in boldface):

Extend ACA premium support permanently, extend low cost care in states that have not expanded Medicaid

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 also 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.

Extends Medicare Solvency: Strengthen Medicare by increasing NIIT (ACA–SM) and limiting pass through income reforms

As above, 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' health care and overseas military and ocean deployments.

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 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.

The way to fully fund healthcare is through an employer-paid subtraction value-added tax.

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.

The President has punted on reforming Social Security. This is a mistake—although Chairman Smith and the Majority will not like this proposal—probably because it would work and take the topic off of the table.

Individual payroll taxes. A floor of $20,000 would be instituted for paying these taxes, with a ceiling of $75,000. This lower ceiling reduces the amount of benefits received in retirement for higher-income individuals. The logic of the $20,000 floor reflects full time work at a $10 per hour minimum wage offered by the Republican caucus in response to proposals for a $15 wage. **Any increase to the minimum wage must fully cover tipped workers.** The White House/Senate Majority/House Minority needs to take the deal. Doing so in relation to a floor on contributions makes adopting the minimum wage germane in the Senate for purposes of Reconciliation. The rate would be set at 6.25%.

Employer payroll taxes. Unless taxes are diverted to a personal retirement account holding voting and preferred stock in the employer, the employer levy would be replaced by a goods and receipts tax of 6.25%. Every worker who meets a minimum hour threshold would be credited for having paid into the system, regardless of wage level. All employees would be credited on an equal dollar basis, rather than as a match to their individual payroll tax. The tax rate would be adjusted to assure adequacy of benefits for all program beneficiaries.

Appropriations Subcommittees

Labor, Education, Housing and Related Agencies

Add Housing and Urban Development and Veterans Affairs Housing functions to reinforce synergies between housing, education and workforce development.

Transfer out Health and Human Services to decrease the size of the LHHSE Appropriation package.

Health and Human Services and Veterans Affairs

Create synergies between human services and veterans' health and other DVA functions.

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 One—HHS Budget FY 2023

Orphan 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 16, 2022, 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.

Pandemic Lessons

On the pandemic, we urge that there be a public examination of lessons learned—particularly mistakes. The largest mistake was to not identify COVID–19 as being spread like a cold.

Subsequent variants identified sneezing and a runny nose as early signs of the virus. This was true in the first round, but to save face, it was not mentioned and is still not admitted. Job one of preparing for the next coronavirus pandemic is to list cold or supposed allergy symptoms as the signal to self-quarantine (if not be quarantined).

Donald Trump did not kill a million people. Trying to downplay original symptoms did—which led to a loss of credibility among some populations. This social aspect must also be explored—especially if these populations are to comply with later instructions.

Mental Health Hospitalization

The President's proposals to expand behavioral health are most welcome, although only a start. Replacing mental health facilities—as well as policies which allow longer-term mandatory stays are what is needed—including conditions whereby readmission to a more controlled environment is automatic in the event of relapse or medication non-compliance.

Such a change in the rules of the game will demand 50-state cooperation, as local laws are impacted. The Department of Justice and state and local police agency participation is also required. Reform cannot only be for those with insurance—it must be for everyone. Parity is not enough—and is impossible without not only more beds—but more dedicated hospitals.

Attachment Two—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 protection 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 are 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.

CHRONIC CARE POLICY ALLIANCE
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Re: Full Committee Hearing: "The President's Fiscal Year 2024 Health and Human Services Budget"

Dear Chairman Wyden and Ranking Member Crapo:

On behalf of patients with chronic conditions, the Chronic Care Policy Alliance urges the Finance Committee to utilize hearings on the 2024 Health and Human Services Budget as an opportunity to ensure accountability and oversight as that department implements the health policies included in the 2022 Inflation Reduction Act (IRA). Additionally, we recommend that legislators prevent further changes to the new Medicare Drug Price Negotiation Program, including those proposed by the Biden Administration in the budget for fiscal year 2024, until the IRA has been fully implemented and the impact of these policy changes are known and understood.

The health policies in the IRA took great strides to lower patient costs and included many beneficial policies that will provide immediate relief to patients including out-of-pocket caps, capping the costs of insulin, and eliminating cost sharing for vaccines. However, the long-term impact of other provisions of the law, including the Medicare Drug Price Negotiation Program, remains unknown and could impede the development of new treatments and limit patients' ability to access new therapies in years to come.

We were joined by 36 organizations in sending the below letter to Congress and the Centers for Medicare and Medicaid Services (CMS) further explaining these concerns and urging that CMS ensure patient advocates have ample opportunity to weigh-in throughout and after IRA implementation to limit any negative impact on patients.

Further, given the uncertainty around the Medicare Drug Price Negotiation Program and other provisions of the IRA, we would urge that Congress reject any proposals to accelerate the scope of the negotiation program. The Biden Administration's proposed budget included proposal to substantially increase the number of drugs on which CMS can negotiate starting in 2026, and making drugs subject to negotiation much sooner. According to press reports, this proposal could double the number of drugs negotiated each year and make drugs subject to negotiation after only 5 years after FDA approval instead of the current 9–13 year time frame.

This expansion of an untested policy could lead to disastrous results for patients by significantly limiting access to current and future therapies. The impact could also significantly hinder research for patients with complex or rare diseases that require intricate treatment regimes.

We appreciate the Finance Committee's ongoing work and oversight to ensure that patients are protected as these new policies are implemented and look forward to staying in close touch throughout the implementation process.

Sincerely,

Liz Helms
Founder/Director

In a letter to Congress and the Centers for Medicare & Medicaid Services (CMS), the Chronic Care Policy Alliance (CCPA) was joined by 36 organizations urging Congress and the Administration to ensure that patient advocates have a seat at the table throughout the implementation of the Inflation Reduction Act's health policies.

CCPA and its partners want to protect patient interests and avoid any unintended consequences by asking for patient input in the planning phase before implementation. Read the full letter:

Dear Congress:

As patient representatives, we advocate on behalf of patient interests and interpret how certain policies will positively or negatively affect them. Patients know firsthand the benefits of a strong health care system that provides access to new and groundbreaking treatments. In recent years, we have seen great strides in the treatment of ALS, cancer and Alzheimer's disease that have increased life span, slowed the ravage of disease and improved the quality of lives.

Last year, Congress passed significant policies within the Inflation Reduction Act (IRA) focused specifically on patient costs. We were especially pleased by the improvements to Medicare Part D that included adding an out-of-pocket cap, establishing a $35 limit on monthly insulin costs, and eliminating cost sharing for vaccines. These policies will provide immediate relief to patients. Thank you.

However, other policies around prescription drug prices faced significant debate during the legislative process. Policymakers must keep in mind the unknown long-term impacts on the development of new treatments—especially those for complex and rare diseases—and patients' ability to access those new therapies.

Now it is time for the real work as the Administration begins the lengthy process of implementing IRA's policies. We urge Congress to continue oversight throughout the implementation process and insist that patient voices are heard.

The Medicare Drug Price Negotiation Program contained in the law seeks to establish negotiated rates, or the Maximum Fair Price (MFP), for medications. While focused on reducing drug costs, the unintended negative consequences for drug coverage, formulary priority, access and further research and development could harm patients. For example, as new prices are determined, payors may favor products on their formularies that have a negotiated price. This could ultimately make other medications more difficult to access as payors encourage use of these negotiated price medications and discourage others. Payors already utilize cost saving measures that negatively impact patients such as restrictive formularies, step therapy and strict prior authorizations. Patients need access to the correct treatments, or they will suffer. The addition of products with artificially lowered prices is likely to create yet another restrictive process for patients.

We urge Congress to ensure that regulators at CMS create specific opportunities for patient advocates to participate in the regulatory process.

Our specific recommendations include:

- **Host regional roundtables to solicit feedback from patients.** We strongly recommend that CMS create a structure similar to that used to implement the Affordable Care Act (ACA) and utilize the CMS regional staff to hold patient-centered roundtable discussions throughout the country to ensure that patients have the opportunity to share their experiences and insights directly with CMS, regardless of their physical location. Providing regional opportunities is particularly important in the patient community where resources may make participation at the federal level more of a challenge than in their state and local communities.
- **Release draft guidance, solicit written comments.** We are pleased that CMS has announced that it will issue draft guidance that seeks public input on key provisions of the MFP program. We hope that the draft guidance includes and seeks feedback on the process, including the methodology CMS uses to determine the MFP. Soliciting written comments from the public is critical.
- **Develop patient-centered criteria.** CMS should also develop, with significant input from patients, patient-centered criteria that must be adhered to as CMS implements the drug pricing provisions. This will ensure patient perspectives are heard and patient needs are prioritized. The ACA required that the Center for Medicare and Medicaid Innovation develop similar criteria.
- **Meaningfully engage patients in determining the MFP for each drug.** Patient advocates can offer both substantial and critical perspectives as CMS considers what a price should be for a specific drug. CMS should create a process through which it will consistently and meaningfully engage with patients determining each drug's price, and ensure they have a say in the outcome.
- **Study the impact of the drug pricing provisions on patients.** CMS should study the impact that negotiation has on patients prior to negotiation, focusing

on issues related to access to current and future therapies. For example, CMS should study the impact of the drug pricing provisions on Medicare Part D coverage, including formulary placement and utilization management.

Should you have any questions or comments, please contact Liz Helms, Founding Director, CCPA at lizh@chroniccarealliance.org. Thank you for your time and attention to these critical issues.

Sincerely,

Chronic Care Policy Alliance (CCPA)

Alliance for Aging Research; ALLvanza; American Behcet's Disease Association (ABDA); American Cancer Society Cancer Action Network—Nevada; Applied Pharmacy Solutions; Autoimmune Association; Axis Advocacy; Black, Gifted & Whole Foundation; Cancer Support Community; Chronic Disease Coalition; Coalition of Wisconsin Aging and Health Groups; Colorado Gerontological Society; GO2 for Lung Cancer; Healthy Men Inc.; Hereditary Neuropathy Foundation; HIV + Hepatitis Policy Institute; ICAN, International Cancer Advocacy Network; International Foundation for AiArthritis; Lazarex Cancer Foundation; Let's Talk About Change; Looms For Lupus; Men's Health Network; MLD Foundation; National Association of Nutrition and Aging Services Programs (NANASP); National Hispanic Medical Association; National Patient Advocate Foundation; National Puerto Rican Chamber of Commerce; Neuropathy Action Foundation (NAF); Nevada Chronic Care Collaborative; Partnership for Innovation and Empowerment; Partnership to Fight Chronic Disease; Patients Rising Now; RetireSafe; Southern Christian Leadership Global Policy Initiative (SCL–GPI); Support for People with Oral and Head and Neck Cancer, Inc. (SPOHNC); The National Puerto Rican Chamber of Commerce

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DIGITAL THERAPEUTICS ALLIANCE
https://dtxalliance.org/

April 5, 2023

U.S. Senate
Committee on Finance
Hon. Ron Wyden
Chairman
Hon. Mike Crapo
Ranking Member
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Wyden and Ranking Member Crapo:

On behalf of the Digital Therapeutics Alliance (DTA), we want to take this opportunity to thank you and the members of the Senate Committee on Finance for convening a committee hearing on Wednesday, March 22, 2023 on "The President's Fiscal Year 2024 Health and Human Services Budget." During the hearing the committee focused on various aspects of President Biden's HHS budget.

We write to the committee today to voice our support for key aspects of the President FY 2024 budget,[1] specifically a legislative proposal to establish Medicare coverage of evidence-based digital applications and platforms that facilitate the delivery of behavioral health services, especially for beneficiaries who live in rural or health professional shortage areas.

Digital therapeutics (DTx), a relatively new category of medicine that—as HHS requests, "enables Medicare coverage of evidence-based digital applications and platforms that facilitate the delivery of mental health services"—deliver therapeutic interventions directly to patients using scientifically developed, clinically evaluated software to treat, manage, and prevent diseases and disorders.

We therefore respectfully ask the Department of Health and Human Services to respond to Chairman Wyden's previously submitted questions for the record on whether CMS can currently reimburse for DTx products under existing national or local coverage determination processes, potential or existing criteria for DTx product reimbursement, and necessary steps to create a new benefit category.

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[1] *https://www.hhs.gov/sites/default/files/fy-2024-budget-in-brief.pdf.*

DTx products are subject to rigorous patient-centered core principles and are used independently, alongside medications, or in tandem with clinician-delivered therapy. They differ from pure lifestyle, wellness, adherence, diagnostic, and telehealth products, and are distinct from the over 350,000 digital health apps available online.

Digital therapeutics' benefits, however, are currently available in the United States only to patients covered by certain private payors and select Medicaid plans, and are not available to patients (and their clinicians) who receive insurance coverage through Medicare. Without a dedicated Medicare benefit category for digital therapeutics, as proposed through the Access to Prescription Digital Therapeutics Act (S. 723 and H.R. 1458), this healthcare inequity will continue to grow, while also limiting the scalability of DTx access to patients covered by other commercial and state coverage plans.

We again thank the committee for holding this important hearing and for considering the important issues raised during the hearing and by the Digital Therapeutics industry. Should you have any further questions or issues you would like to discuss, we would be delighted to discuss them further with you.

Sincerely,

Megan Coder, PharmD, MBA
Chief Policy Officer

Sara Elalamy
Director of U.S Government Affairs

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U.S. Senate
Committee on Finance

The President's Fiscal Year 2024 Health and Human Services Budget
Wednesday, March 22, 2023

UNOS supports Health Resources and Services Administration's (HRSA) plan to introduce additional reforms into the nation's organ donation and transplantation system. We also stand united with HRSA in our shared goal to get as many donor organs as possible to patients in need while increasing accountability, transparency and oversight.

We welcome a competitive and open bidding process for the next Organ Procurement and Transplantation Network (OPTN) contract to advance our efforts to save as many lives as possible, as equitably as possible. We believe we have the experience and expertise required to best serve the nation's patients and to help implement HRSA's proposed initiatives.

Numerous components of HRSA's plan also align with our new action agenda, which is a list of specific proposals we outlined earlier this year aimed at driving improvement across the system.

We are committed to working with HRSA, U.S. Department of Heath and Human Services (HHS), Congress and others who care about this system so deeply to assist in carrying out these reforms and to do our part to improve how we serve America's organ donors, transplant patients and their families.

Dr. Maureen McBride
Interim UNOS CEO

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