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THE PRESIDENT'S FISCAL YEAR 2025 HEALTH AND HUMAN SERVICES BUDGET

HEARING

BEFORE THE

COMMITTEE ON FINANCE UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

SECOND SESSION

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THE PRESIDENT'S FISCAL YEAR 2025 HEALTH AND HUMAN SERVICES BUDGET

THURSDAY, MARCH 14, 2024

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

The hearing was convened, pursuant to notice, at 10:06 a.m., in Room SD–215, Dirksen Senate Office Building, Hon. Ron Wyden (chairman of the committee) presiding.

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

Also present: Democratic staff: Shawn Bishop, Chief Health Advisor; Kripa Sreepada, Senior Health Advisor; Joshua Sheinkman, Staff Director; and Tiffany Smith, Deputy Staff Director and Chief Counsel. Republican staff: Kellie McConnell, Health Policy Director; Gregg Richard, Staff Director; and Charlotte Rock, Senior Health Policy Advisor.

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

The CHAIRMAN. The Finance Committee will come to order. Today we meet to discuss the year ahead for health care in America. Thank you, Secretary Becerra, for joining us.

I am going to start off, colleagues, with a little bit of history. Topic 1: drug prices. In July 2020, Donald Trump said, and I quote: "Since the day I took office, I have made reducing drug prices one of my highest priorities." For 4 straight years, Donald Trump complained about high drug prices, did lots of finger-pointing at others about the problem, and repeatedly talked about how he was the best friend seniors who depend on Medicare could have. What was actually accomplished over his 4 years? Exactly nothing.

Fast forward to the Biden administration. From the time Joe Biden took office, President Biden made it clear that he was committed to lowering drug prices and health-care costs for families.

I remember him having a conversation with me shortly after his election, and he said the Finance Committee is the place where things happen, and everybody has been talking about doing something about drug prices forever. Now it's time to get something done, and to actually help seniors—not just talk about it, because there has been plenty of talk, but actually get results that provide real pocketbook relief to seniors and consumers.

Two years later, President Biden—because Senator Stabenow and many colleagues who are on this side of the aisle worked very hard to get results to lower prices on medicine—President Biden signed the Inflation Reduction Act into law.

For the first time, under the law, Democrats and President Biden gave Medicare the authority to negotiate better drug prices. Understand what that means. It means that seniors beat big pharma. Big pharma's holy grail, what they cared about more than anything, is prohibiting negotiation for a better deal on medicine.

Look at what they are doing right now, going to court trying to stop any negotiation. But we have it written into law that there is going to be negotiation, and on top of it, most Americans have access to free vaccines. Insulin costs for seniors were capped at $35 a month. And as we said—Senator Stabenow and I talk about it all the time—when the government leads on these issues, particularly the showpiece of American health care, Medicare, almost always the private sector copies it.

And so, we have seen some real progress in the private sector as well—not as much. We want everybody in America to get that pricing relief, but we are making real progress. We also created price-gouging penalties for the first time, to hold big pharma accountable for high drug costs. Those are already benefiting patients and taxpayers.

We have plenty more to do. For example, it is essential that finally, after all this debate, we get pharmacy benefit management reforms across the finish line and that Congress finish this crucial change that is going to help all these wonderful people in their white coats—because they are here to keep the small pharmacies going—and to lower drug costs for patients and protect community pharmacies.

So that is the difference, folks, on the first issue, drug prices, between Donald Trump and President Biden.

Topic 2: health insurance. In March 2019, Donald Trump tweeted, "The Republican Party will become the party of health care." With the help of Senate Republicans, his number one health-care goal stated again and again, number one goal, repeal the Affordable Care Act. Just get rid of the whole thing. On that one he failed, fortunately, as well.

Under President Biden's leadership, the Democrats boosted tax credits for health insurance, saving millions of Americans an average of $800 per year on their coverage and expanding access to care. So, when you look at President Biden's health-care budget for the upcoming year, what you see is a clear focus, which is to build on the progress that the Biden administration has made.

So, with all these health challenges in mind, the next question is, what do Donald Trump and the Republicans have planned when they talk about health care? The American people are wondering, because not once during the ACA repeal and replace crusades, not once did we see an actual replacement.

Seven years after the effort to repeal the ACA crashed and burned, nothing has changed. Donald Trump still says, "Let's get rid of it." He still lacks a plan to take care of all the people whose health-care coverage his doing that would actually rip away. And now apparently, he is even talking about gutting Americans' hard-

earned Social Security and Medicare benefits. No plan for keeping seniors out of poverty and illness either.

So that is the difference, folks, between what Senate Democrats and President Biden are talking about, and what Donald Trump is talking about. The Republican health-care plan is, shred the programs that exist today that countless Americans rely on, and just pretend, just pretend everything is going to be fine.

So, on these issues, I think it is clear that there is a gap between President Biden and Senate Democrats and Donald Trump, with respect to health care. The gap between those Trump promises and Biden action on health care, the difference on the actual record between the two, is as deep as Crater Lake. Democrats made promises to the American people, and we got results; we delivered.

I am going to wrap up by saying there is another issue today that is pending that is very important for kids and health care, and that is to get our bipartisan tax deal with Congressman Jason Smith passed in the Senate. It would help 16 million kids and immediately lift 400,000 kids out of poverty. Now, you do not have to take my word for this. Here is what the president of the American Academy of Pediatrics had to say about this. By the way, in case anybody is interested, he is from Oregon, Dr. Ben Hoffman.

He is a doctor at Oregon's very own Oregon Health Sciences Center, and I guess his night job is president of the Academy of Pediatrics. He has said, and I quote here: "There's an inextricable link between poverty and child health." An inextricable link, folks, between poverty and child health.

What we are trying to do—it got 357 votes in the House of Representatives—is help those 16 million kids be healthier, and 400,000 of them would get out of poverty right away. So, we want everybody to know this morning we are all in in terms of getting it done. We want to pass that bill—the Child Tax Credits and the help for companies with their research and development—before the April 15th filing deadline.

So, hearing from the American Academy of Pediatrics, as we wrap up this discussion, as far as I am concerned is about as good as it gets. But we are still going to have some more very good input today from Secretary Becerra about how President Biden is going to continue to lower costs and improve care for more families. But first we will hear from 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 before I begin my formal remarks, I will say there is one thing you and I agree on. That is, we have to control drug prices, and you already referenced that.

You see a number of folks here in the audience in white coats. Those are pharmacists, and we met on the grass out in front of the Capitol today, Senator Wyden and I did, with hundreds and hundreds of them to talk about one of the most important things we can do, which we need to do right now, which is to get the PBM legislation, which passed this committee 26 to 0, on the books, so

that we can start one of the most significant things that can be done to help control drug prices.

So I want to focus on that. We do have our disagreements still on what we consider to be a price-control program and the impact of it. But we have places where we have agreement, and I am hopeful that we can make progress on that right away.

Back to my formal remarks. Thank you, Mr. Chairman, and thank you, Secretary Becerra, for being here today. Over the course of the past year, the Finance Committee has taken bipartisan action to tackle a range of health-care challenges, leveraging collaboration and consensus to advance common-sense solutions for seniors and working families.

Our pharmacy benefit manager reforms, which I have already referenced, would modernize Medicare's prescription drug benefits, driving down costs at the pharmacy counter and netting billions in savings for taxpayers. Moreover, the committee's mental health proposals would build on previous efforts to shore up patient access to critical services, especially in rural communities.

These policies received nearly unanimous support from across the dais, all through regular order. Your department and its subagencies, Mr. Secretary, have offered essential technical assistance throughout these processes, and that support has ensured alignment between our legislation and its intended goals, and I thank you for that. As we move forward, further action on these overdue patient-focused proposals must become an urgent priority, not just for our committee but also for the administration. We have a responsibility to patients, community pharmacies, and front-line health-care providers to deliver on these commitments, regardless of policy differences on other fronts.

The President's budget request, unfortunately, falls severely short of that aim. On prescription drug affordability, for instance, the document makes virtually no mention of the robust bipartisan, bicameral efforts to reform PBM practices, instead opting to double down on a price-control policy that polarizes members in both chambers. Bipartisan bills in the Senate and the House would address unintended consequences spurred by the Inflation Reduction Act's pricing provisions, particularly for patients with rare diseases who will likely see fewer treatment options under that law.

Rather than embrace these avenues for viable reform, however, the budget seeks to expand the program's scope, with no attempt at improved transparency, certainty, or mitigation. Further, the President's budget request affirms an overreaching mandate that would force more nursing homes to close their doors, and result in less access to home and community-based services for Medicaid beneficiaries. This document highlights divisions and misses vital opportunities for productive patient-driven partnerships with Congress. We will continue engaging with your department on a host of health-care hurdles that demand policymakers' attention. You have rightly raised concerns, for instance, around the ongoing surge in medication shortages, including for lifesaving therapies.

The chairman and I recently released a white paper outlining potential solutions to prevent and mitigate this crisis, and we look forward to working with HHS and CMS to develop legislation designed to achieve these goals. We also stand ready to partner on

proposals aligned with the President's Cancer Moonshot, including by ensuring that seniors can access innovations like multicancer early detection screening. Those tests can be invaluable for a Cancer Moonshot. Earlier this Congress, I joined Senator Bennet in reintroducing our bill to grant Medicare coverage for these technologies, and bipartisan majorities in both chambers—bipartisan majorities in both chambers—have joined as cosponsors for this legislation.

More broadly, while the administration erred in rescinding regulations aimed at expediting access to medical breakthroughs, your department could take a range of steps to restore patients' trust in reliable coverage for medical devices, including by expanding and enhancing the proposed pathway that CMS published last year.

Before closing, let me emphasize the importance of timely communication with respect to the cyberattack on Change Healthcare. While your department has recently taken important steps to issue guidance and flexibility to insurers, providers, and contractors to mitigate the effects of this hack, the over-2-week delay resulted in unavoidable uncertainty. Already financially vulnerable rural hospitals and providers with little to no cash reserves required immediate action by the administration to ensure payrolls could be met and services could be continued without interruption.

In the coming days and weeks, HHS should continue to update members and stakeholders on efforts to limit further disruption. We have an obligation to build on longstanding legacies of bipartisanship and bolster the clinician workforce, drive value-based care, improve broken payment systems, and ensure long-term access to telehealth.

With these joint goals in mind, thank you again for being here, Mr. Secretary, and thank you, Mr. Chairman.

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

The CHAIRMAN. Thank you, Senator Crapo. As Senator Crapo noted, and I think I talked about this with Senator Cornyn—I cannot see him down there—getting a 26-to-nothing vote from the Senate Finance Committee on a major piece of legislation involving enormous sums of money is just about impossible around here.

It is hard to get a 26- or 27-to-nothing vote for ordering soda pop. So I thank my colleagues for their work on that.

Secretary Becerra?

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

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

When President Biden took office in January 2021, COVID was ravaging our families and our economy, and Americans were dying at the rate of two to three 9/11s every day. I will repeat that: every day, we were losing Americans at the rate of two to three 9/11s every day.

In January 2021, the number of Americans with health insurance was, like our jobs and the economy, down and on the canvas. Prescription drug prices were skyrocketing, with patients and their pocketbooks at the mercy of big pharma and its profits.

Today, 3 years later, nearly 700 million shots of COVID vaccine have gone into the arms of Americans, and we can now manage COVID like the flu. Today, more than 300 million Americans, a record number, can go to the doctor or hospital and not go bankrupt, because they have their own health insurance. More than 21 million of those Americans can count on the Affordable Care Act marketplace for their insurance, another record. Today, while big pharma is still big, the President's new prescription drug law has brought down the price of insulin to $35 per month for Americans on Medicare, and as we speak, we are negotiating with drug companies to lower the prices of even more prescription drugs, even as they sue us to stop us.

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

This budget continues our shift from a health system that treats illness to one that sustains wellness. All told, the Fiscal Year 2025 budget proposes $130.7 billion in discretionary and $1.7 trillion in mandatory funding to advance our mission and invest in key priorities. Let me share some of the highlights. The budget provides Medicaid-like coverage to low-income individuals in the outlier States that have not expanded Medicaid under the Affordable Care Act. When that happens, another 1.5 million Americans will have health-care coverage and the peace of mind that comes with it.

This budget builds on the largest investment in behavioral health in a generation. It bolsters a 988 suicide and crisis lifeline. It gives young people support at home and school. That means boosting our behavioral health workforce with 12,000 new psychiatrists, psychologists, clinical social workers, marriage and family therapists, counselors, and peer-support specialists.

Across HHS, the budget tackles the maternal health crisis by improving access to pre- and postnatal care, supporting emergency care services, and expanding maternal care in rural and underserved communities. We are making child care more affordable for working families, and more available where families live and work.

This budget would provide increased wages for early childhood education workers, and it would fund more than 750,000 slots for children in Head Start. It funds universal preschool for our Nation's 4 million 4-year-old children, and will eventually include our 3-year-olds as well.

Our budget grows and strengthens our cybersecurity initiatives to ensure patient safety and privacy, and to keep our hospitals and providers, especially smaller ones and those in rural communities, running and secure. Finally, this administration has made tremendous strides in preparedness capabilities since the pandemic, and we keep building.

This budget invests in countermeasures to combat antimicrobial-resistant drugs, to expand our monitoring of supply chains, and to integrate 200 data sources across Federal, State, and local governments, to improve information sharing.

We cannot reduce the health and well-being of Americans to a line on a budget spreadsheet, but we can transform the numbers on that balance sheet into investments and services that sustain health and promote wellness for all Americans. President Biden has presented a forward-leaning budget. I look forward to taking your questions.

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

The CHAIRMAN. Thank you, Mr. Secretary.

Let me start with the lower prescription drug costs for seniors issue. Again, I went through some of what former President Donald Trump said. He said pharma companies were getting away with murder. He said that would change under his presidency, that he would create a fair and competitive bidding process, and prices would come way, way down. And, colleagues, these are exact quotes from Donald Trump.

And I am quite certain, Mr. Secretary, when you came in, none of that had been actually accomplished. I described that conversation I had with President Biden after the election, where he said he was going a very different route: Medicare drug price negotiation, stop the price gouging if they raise the prices over inflation, cap out-of-pocket costs for seniors. He took on big pharma and won; not just talk, delivery.

So, Mr. Secretary, one that I was very involved in, stopping this price gouging—is it correct that some seniors are now saving $618 per dose on a drug that they get in their doctor's office?

Secretary BECERRA. Senator, that is correct, and it is going to grow even more in terms of savings because, as we move through the years, many of the provisions that you all helped pass are kicking in. So today, a senior will not have to worry about these enormous costs if they are on a drug medication, because there is a limit now on what they will pay, their capped spending.

So, it might be about $3,500 this year, but next year the limit on expenditures out of pocket for a senior, $2,000.

The CHAIRMAN. Now for the first time, in addition to the price-gouging penalty and the out-of-pocket costs and these priorities that I mentioned, for the first time Medicare is negotiating drug prices. And on this one, as I say, we beat pharma and took away their holy grail, which is trying to prohibit negotiation.

I would like to hear more about the 10 high-cost drugs that you are negotiating. How many people with Medicare take the drugs that you are negotiating this year? I do not believe I have seen an aggregate number on this. I think the American people would like to know how many people with Medicare take these drugs that you are fighting to lower the prices on. What is the number?

Secretary BECERRA. So, Mr. Chairman, let me work down. So we know there are 65, 66 million Americans who receive health care through Medicare. Not all of them take the 10 drugs that were negotiated, but for many they are lifesaving, and they need them.

Suffice it to say that in 2022, the costs of just these 10 drugs, just for Medicare, the 66 million—not the 330 million Americans, just the 66 million Americans on Medicare—the cost of those 10 drugs in 2022 alone was $46 billion; out of pocket from those very seniors who were using those drugs, about $3.5 billion.

And so, it is big money for just those 10 drugs, and the next year, when we get to negotiate for 15 more drugs, we will get to save Americans even more.

The CHAIRMAN. And what is the ballpark number, Mr. Secretary, in terms of how many people with Medicare are taking these drugs?

Secretary BECERRA. I could not give you the specifics on all the 10. I do not have that before me, or for any one of the particular ones. But they are very well-known drugs, and for seniors they treat principally issues like cancer, heart disease, and kidney failure. It is the kind of chronic disease that we know quite a bit about. I could try to get you specific numbers——

The CHAIRMAN. Why don't you get us that for the record? But you are saying that the amount of money involved in this area—I thought I heard you say $46 billion.

Secretary BECERRA. Forty-six billion dollars in 1 year for 10 drugs.

The CHAIRMAN. Okay.

Secretary BECERRA. Just for Medicare.

The CHAIRMAN. In 1 year; okay.

Let's talk about this cybersecurity breach, which is, you know, so serious. I am of the view that it also relates to the fact that these facilities are getting bigger and bigger, and then I think they become really a systemic kind of risk. We have to get on top of this.

For a long time, these private companies have been allowed to set their own standards, and it does not seem very surprising that neither UnitedHealth Group nor Federal agencies were prepared for the attack on Change Healthcare and its fallout.

My view is that the health-care sector is a prime target for criminals and foreign adversaries, and as I say, as these companies have become so large, it is creating a systemic cybersecurity risk. Today, there are no Federal mandatory technical cybersecurity standards for the health-care industry, even though people have been talking about this for ages, I mean, something like 2 decades.

I want to make it clear that has got to change now. Now, I understand that in your budget, you are going to increase penalties for compliance violations and make the first actual concrete proposal to require real mandatory cybersecurity standards for hospitals.

Mandatory standards are a great first step, but we have got to do more, and the next step has got to be the fines and accountability for negligent CEOs, for example, which will enable HHS to better protect patients and our national security. Will you work with me, Mr. Secretary, to start holding these executives who are not doing their job in line with the kind of safety standards the American people have a right to expect on cyber? Will you work with me so we start holding the negligent CEOs accountable?

Secretary BECERRA. Mr. Chairman, we look forward to working with you and every member on this dais on these issues.

The CHAIRMAN. All right.

Senator Crapo?

Senator CRAPO. Thank you, Mr. Chairman.

Mr. Secretary, last year this committee, as we have said, voted nearly unanimously to pass two bipartisan PBM reform bills, which

we have already described here, so I will not do that again. Together, these provisions would generate billions in taxpayer savings, in addition to bringing down costs for seniors with chronic conditions.

These bipartisan bills reflect, by far, the most comprehensive and consensus-driven solution to a range of challenges raised by members in both chambers across the political spectrum. That said, this legislation and this issue is absent, as I see it, in the President's budget, sending a troubling signal to the patients and community pharmacies and front-line health-care providers across the country.

Secretary Becerra, what concrete steps does the administration plan to take to support our efforts to get this legislation moved expeditiously and put into law?

Secretary BECERRA. Senator, we are absolutely prepared to work with you. I have said this for about over a year, both in this chamber and the other chamber, that we are absolutely ready to work with you on PBM reform. We want to find that there will be more transparency in the way these PBMs operate, and certainly I think we all agree there is no reason to have middlemen in the health-care system if they are not going to provide health care.

And so, we very much look forward to working with you on this, and we appreciate that there is bipartisan support.

Senator CRAPO. Well, and I did say in my opening statement that you have given very good technical support as we developed this legislation. I am asking now that the President step up and use the bully pulpit to get this legislation moved in this Congress. Please, I would ask you to please take that request back to him.

Secretary BECERRA. And you are probably aware, Senator, that we just did an event at the White House on this very issue, to really highlight it for the American people.

Senator CRAPO. Good news.

When the IRA passed nearly 2 years ago, Mr. Secretary, your department praised the law unconditionally. As implementation proceeds, however, American seniors have experienced the consequences of the law. A growing number of clinical trials for medical breakthroughs have been canceled, particularly for rare disease drugs. Part D plans exclude more and more medications from coverage, and subject others to prior authorization and step therapy, delaying critically needed care. Copays continue to skyrocket, often tied to inflated sticker prices, which exclude any rebates or discounts. In short, the system's flaws have gotten worse, not better.

Secretary Becerra, can you commit to working with Congress on a bipartisan basis to remedy these issues and improve the Part D program, rather than prioritizing IRA expansion, which remains both a partisan and unrealistic endeavor?

Secretary BECERRA. Senator, we absolutely look forward to working with you on a bipartisan basis. I will say that the President is very clear and is doubling down on the IRA, and making it work even more effectively. But we absolutely look forward to working with you on a bipartisan basis.

Senator CRAPO. Well, that is disappointing. It has been disappointing to hear, but we received the President's message, and I am just asking you to help us try to find some bipartisan solutions to move forward.

On telehealth, telehealth coverage has proven critical for seniors and working families across Idaho and the rest of the country. Unfortunately, without additional action, Medicare beneficiaries and Americans with high-deductible health plans risk losing access to telehealth services overnight at the end of this year.

Patients and front-line providers currently face profound uncertainty as we move closer to this coverage cliff. Secretary Becerra, what actions do your department and its subagencies plan to take in order to avert this unacceptable outcome, as well as to reassure millions of Americans who rely on telehealth for core coverage every day?

Secretary BECERRA. Senator, we continue to work with you and your colleagues here and in the House of Representatives on the extensions of some of those flexibilities. As you know, statutorily we are constrained in being able to extend some of those flexibilities on telehealth. We need your support. We are working also with our State and local partners because, as you know, many of those issues involved State rules and laws.

So, for example, a practitioner practicing out beyond State lines through telehealth, that has to be done with the concurrence of States before a doctor in your State can practice in my State. So we are working with them as well, so we can extend these telehealth flexibilities.

Senator CRAPO. Well, we understand that part of that ball is in our court. It really helps when we have a mutual activity to try to get those kinds of resolutions to the finish line. So thank you for your attention to that.

Secretary BECERRA. Yes.

Senator CRAPO. With that, thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Crapo.

Senator Stabenow?

Senator STABENOW. Well, thank you so much, Mr. Chairman and Ranking Member. And, Secretary Becerra, welcome. It is always good to see you. I appreciate all the work you are doing, you and your department, and I really appreciate the critical investments to expand health-care access and affordability for communities, for families across the Nation, that is proposed in the President's budget. This really does build on the investments and the work that we have done as Democrats with the President in the last 3 years.

You know, I do want to say, Mr. Chairman, I want to correct one thing you were talking about——

The CHAIRMAN. Please.

Senator STABENOW [continuing]. That former President Trump did not do anything on prescription drugs. What I would say is, he did not do anything for people on prescription drugs. But President Trump and Republican colleagues did give a 40-percent tax cut to big pharma in their tax law.

The CHAIRMAN. You got it.

Senator STABENOW. That 40-percent tax cut did not translate to a 40-percent reduction in prices for the seniors in Michigan or for anybody on medication in Michigan. So we have been focused, working with the President and with you, on cutting prescription drug costs for Americans who have been paying the highest prices

in the world, even though we have major investments we do as taxpayers to support the development of these new drugs.

So the bills that we have been working on together have delivered lower costs as we know, improved access, and transformed the way we provide behavioral health care in this country, which is so important, and as you know, is something I care deeply about.

We have over 21 million people now receiving health care through the Affordable Care Act. That is a record, right? Over 21 million people signed up for insurance—very, very affordable insurance—and that is including 418,000 Michiganders, many getting a good policy for $10 a month, $20 a month. I mean, it has transformed families' lives to be able to have that health care.

The health-care premiums have gone down hundreds of dollars for 271,000 Michigan residents who are using the Affordable Care Act. And of course, the $35 cap on insulin is lowering out-of-pocket costs for seniors in Michigan and across the country, not counting the inflation caps on cancer drugs that are used in doctor's offices or hospitals; not counting the cap this year on out-of-pocket costs or next year, when it goes to a permanent $2,000.

And so, there is a lot of—you know, it is a big deal. It is a big deal what we have been doing. So I want to just ask you a question and speak to what I like to call "health care above the neck," because we need to make sure health care above the neck is the same as health care below the neck for people.

We have made historic investments in mental health, behavioral health, on a bipartisan basis. It has been really terrific to see that happen, and I appreciate partnering with you and with the President to lower costs and create more access, as you have talked about. But particularly in this budget, the President included significant investments in the future of community care, which is Certified Community Behavioral Health Clinics, which we are funding through the health-care system, not through grants that stop and start.

And as you know, this is something that keeps people out of the hospital, out of the jail unnecessarily, people off the streets who have been homeless, and gets them the care that they need. So we expanded CCBHCs nationwide through the Bipartisan Safer Communities Act. States are stepping up to participate. We have more States this Spring that will be coming into the full program.

I know that the budget not only supports CCBHCs' expansion, but makes it permanent, and I also want to give a shout-out to Senator Cornyn. Thank you for being my partner in moving forward the definitions on CCBHCs, to make sure they are permanently a part of Medicare and Medicaid, so this program is permanent. So, thank you for partnering on that.

Can you elaborate on your plans to make this a permanent foundation for how we provide behavioral health care in communities across our country?

Secretary BECERRA. Senator, first to you and Senator Cornyn, thank you for putting in place something that has proven to be a great success, and that now everyone wants to do, because mental health conditions do not surface only between 9 to 5. They occur at any hour, any part of the day, and you have to be ready.

And what you all did in making Certified Community Behavioral Health Clinics available, critical care centers available 24–7, was a God-saving measure for so many people. So, we are going to try to encourage other States to buy in, because the more we have these centers, the quicker we cut the cost of care for taxpayers because, at the end of the day, many of these folks end up using the emergency room to get the care that they need.

And so, what you have done is—by establishing these centers that are specific for them, for mental health conditions, it gives them a chance to see professionals that could treat them right away. And so we are going to build on that. The President's budget commits to that, and thank God you all came together on a bipartisan basis to address what 9 in 10 Americans say is a growing mental health crisis in this country.

Senator STABENOW. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. I thank my colleague.

Next is Senator Grassley.

Senator GRASSLEY. I am going to bring up a problem with your department, the very same problem I recently had with the EPA. So, it is not just your department that this might be a problem with, but last month, I wrote oversight letters to 15 HHS contractors and grantees. Those 15 organizations receive some of the largest contract awards for the care and placement of unaccompanied children. My oversight work is based on new information that shows many children may have been placed in a very dangerous situation. I want to know what these contractors are doing to ensure children's safety.

In response to my 15 letters, your department sent an email to contractors and grantees on February 28th, that I want to quote: "Kindly direct Senator Grassley's office to HHS's Office of Assistant Secretary for Legislation for this request."

My staff have been told by contractors that they are ready to respond to me, but HHS instruction has so far caused them not to. Do you accept the premise that recipients of congressionally appropriated taxpayers' money must respond directly to congressional oversight requests, and I hope you can answer that positively that they should?

If you would agree with me, when would you direct your staff to clarify to recipients of my letter that they must respond to Congress? Now, we had EPA saying these letters I sent to other groups spending taxpayers' money, that they could respond directly to me. So, can you say that for your department?

Secretary BECERRA. Senator, as a former member, I too wanted to be able to conduct oversight when I was in the House of Representatives, and so, absolutely. These contractors, these various entities, Americans, have every opportunity and right to respond directly to you. We offered to provide them with some guidance if they wished to have it. They were under no obligation to get it. But you are absolutely within your rights, and they are as well, to be in communication.

Senator GRASSLEY. Okay. So as a follow-up, just let me be very clear. These folks that I wrote to have received together billions of dollars of taxpayers' money. When I and my colleagues send them

requests for information, they have an obligation to respond, and this administration's interference, which evidently we are not going to have anymore, at least for a while, has been obstructive.

Then another question: if HHS receives a law enforcement request for information relevant to a child's trafficking investigation, does the HHS provide that information to law enforcement without requiring a subpoena?

Secretary BECERRA. We work on an ongoing basis with law enforcement throughout the country, because again, we care for, we have custody, temporary custody for minors. And so we continue to work with law enforcement throughout the country. We follow the rules. In some cases, we are dealing with very private, sensitive, confidential information, and so we make sure we follow the rules so we do not violate any individuals' privacy. At the same time, we are fulfilling our obligations to respond to law enforcement.

Senator GRASSLEY. Are you saying in some cases you can reply directly to law enforcement without a subpoena, and then are you saying in other cases you might need a subpoena?

Secretary BECERRA. We try to make sure that we are complying with the law when it comes to providing information. Some information is more confidential than other pieces of information. So we make sure that we are not violating any privacy rights, any protections in providing information, whether it is to law enforcement or any other entity.

Senator GRASSLEY. This would have to be my last question, and then I will submit questions in writing for the record. At last year's budget hearing, you and I discussed supporting rural health care, including the need for CMS to fully utilize the Rural Community Hospital Demonstration program.

Right now, CMS is only using 25 of its statutory 30 hospital spots for this program. You told me last year that HHS would, quote-unquote, "do more to support rural hospitals in need." Following our discussion, I wrote the CMS Administrator. Then at my request, the CMMI Director met with two rural hospitals interested in joining the program, but that is where the progress stalled.

CMS explained that in order to fill the open spot, it would require 12 months of work, and too many hospitals would be interested. If CMS has the tools to help one rural hospital and it is not, you should be doing something about it.

I realize you might not know about every program at HHS, but why doesn't your department want to help five rural hospitals through this program? It is budget-neutral, and Congress has reauthorized it three times since 2003.

Secretary BECERRA. I know time has expired, but, Mr. Chairman, may I respond?

The CHAIRMAN. Just briefly.

Secretary BECERRA. Briefly, Senator, let us follow up on this. But what I will tell you is, if you take a look at the President's budget—and we can get back to you with a number of the projects that we have undertaken in rural America—we are doing a great deal, especially with many facilities that are on the verge of closing, and that would be even worse for many parts of rural America.

But let me follow through with you on your particular concerns, because we have quite a bit to talk about when it comes to our work in health care for rural America, and this budget, as you will see, makes major investments in rural America.

The CHAIRMAN. We are going to have to move on.

Senator Menendez is next.

Senator MENENDEZ. Mr. Secretary, for years communities across the country have struggled to fill major provider workforce gaps, a growing crisis exacerbated by the pandemic. Based on my legislation, Congress authorized the creation of 1,000 new Medicare-funded graduate medical education slots in the Consolidated Appropriations Act of 2021, and outlined specific, specific criteria for distributing these slots. However, CMS has repeatedly included additional criteria not specified in the law, which unfairly disadvantages many States, including New Jersey. Since enactment, there have been two rounds of distribution for these slots, meaning we are 40 percent of the way through the program, and New Jersey continues to be completely shut out.

It has been years, and we still do not have an answer as to how we get positions to teaching hospitals in my State. The law clearly specifies that "the Secretary shall," not may, "shall distribute residency positions to each of four specified categories of providers." So, what can you commit to doing to help ensure that States are no longer unfairly shut out of the program, in contravention to the way the law is written?

Secretary BECERRA. Senator, I appreciate the question, because I know that this has been one you have worked on for quite some time, and our team has been trying to be responsive to your staff as well. As you know, in New Jersey, like California, the circumstances sometimes make it difficult for some regions to be able to qualify for some of the resources, and in this case, GME slots.

We are more than willing to work with your team, but the resolution is not so simple because, as you try to resolve the issues that affect States like New Jersey or California, you create other issues for other States.

Senator MENENDEZ. Well, let me interrupt you, because it is not so difficult. The law is clear. It is CMS, the kingdom of CMS, that has decided to add additional criteria that Congress did not stipulate. I am sure when you were a member in the House Ways and Means Committee, you really appreciated it when Federal agencies changed the law that you helped pass, and enacted it in a way that was not your intention. That is exactly what is happening here; exactly what is happening here. I think you have the power to fulfill the law, as it says "the Secretary shall" distribute residency provisions in accordance with the law. This is not happening in accordance with the law, and so this suggestion that the Department is trying to be cooperative and helpful falls far short on me. I hope we can find a better way forward.

Last month, your agency's Inspector General issued a concerning report, finding that over a few months' period, 16 percent of unaccompanied migrant children files lacked any kind of sponsor background checks. It also found that in nearly 20 percent of cases where unaccompanied minors were released to sponsors pending a background check, there was no documentation confirming those

checks were ever completed. Given the alarming problem of unaccompanied migrant children being released into situations where they are ruthlessly exploited for their labor, this is a glaring blind spot that needs to be addressed.

Extrapolating from the report, we are talking about potentially thousands of migrant children who are sent to unvetted sponsors. As the report concludes, "The failure to complete background checks increased children's risk of being released to unsafe sponsors." What specific actions has your agency taken in response to the finding of the Inspector General's report, and how is your agency working to ensure that expeditiously finding sponsors for unaccompanied minor children does not come at the cost of their safety and well-being?

Secretary BECERRA. Senator, I can assure you that most of the recommendations that were made by the Inspector General for incidents—you are referring to incidents that occurred back in Spring of 2021, a 2- or 3-month period. I can assure you that what was being observed by the Inspector General back then is not the case today. If you recall, at that point we had an infrastructure that had been virtually dismantled. We had to stand it up, and at that point we were dealing with an influx of children.

Senator MENENDEZ. So today we would find none of this is what you are telling me?

Secretary BECERRA. You would find that we are now doing all of the background checks. We are doing a thorough assessment of anyone who is seeking to become a vetted sponsor.

Senator MENENDEZ. All right. I look forward to seeing that as a reality.

Finally, a recent Supreme Court decision has upended vital protections for ESRD patients, protections that Congress passed 40 years ago through the Medicare Secondary Payer Act. I am proud to partner with Senator Cassidy on a bill to amend that act and protect patients living with ESRD from discrimination by private health insurance plans. But unfortunately, we are not able to get your agency to work with us to fix this problem. Will you commit to CMS working with my staff, and Senator Cassidy's staff, to have the appropriate information we need to address this problem?

Secretary BECERRA. I absolutely commit to make sure that our staff is working with your and Senator Cassidy's staff, and I know that we have been engaged with some of the folks on this particular issue.

Senator MENENDEZ. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Cornyn?

Senator CORNYN. Thank you, Mr. Chairman.

Mr. Secretary, in August your department recommended the reclassification of marijuana to a Schedule III for the Drug Enforcement Administration. Previous administrations had used a five-factor test to determine what the scheduling of a drug should be, but this administration, your office, has created a new two-factor test to determine currently accepted medical use. What is the reason for the change?

Secretary BECERRA. Senator, thank you for the question, and as you will see from the report that has now been made public, there has been a lot of science that has been collected over the years on

cannabis. We have far more information now. As you know, throughout the country many States have moved much farther than the Federal Government has. Even in places like Texas, you see where action has been taken on cannabis. What we are doing is simply reflecting what the science is showing.

Senator CORNYN. You have compared it to heroin in terms of its potential for abuse. Why didn't you compare other types of drugs that are scheduled by your office?

Secretary BECERRA. I am going to try not to speak directly for the FDA, because the FDA did this assessment analysis independently from HHS. They are the agency that has been tasked with that job, with their scientists, and I will not try to speak for them.

But what I will tell you is that the rigorous work that was done to come to these conclusions was based on the science and the evidence they had before them.

Senator CORNYN. Did they do additional research into adolescent brain development or mental health consequences, or the impact on pregnant women?

Secretary BECERRA. I am sure they took into consideration all the information out there on both the effects and the evidence that there is on cannabis use.

Senator CORNYN. You are saying that for a fact?

Secretary BECERRA. Senator, as I was saying, I do not want to try to speak for the FDA and its scientists, because I did not do the actual assessment. But I am pretty——

Senator CORNYN. But you announced the recommendation. I assume you would take into account impact on adolescent brain development, on mental health consequences, or pregnant women?

Secretary BECERRA. As I said, I am sure that the FDA would have taken into account all of the different circumstances involved. I did not make the recommendation. It was made by FDA.

Senator CORNYN. I want to follow up on some of the questions that Senator Menendez and Senator Grassley asked. Your department is responsible for the administration of the Office of Refugee Resettlement, correct?

Secretary BECERRA. That is correct.

Senator CORNYN. And that means that any unaccompanied children who come to our border are basically transferred to your care by the Border Patrol, correct?

Secretary BECERRA. That is correct.

Senator CORNYN. And you identify a sponsor for them in the interior of the United States, correct?

Secretary BECERRA. That is our obligation, yes.

Senator CORNYN. Yes. And there have been about 400,000 of these unaccompanied children who have come to the United States during President Biden's term of office. Can you tell us where they are now?

Secretary BECERRA. We can give you information on the vetting process and——

Senator CORNYN. No; I asked you, do you know where they are now?

Secretary BECERRA. As I said to you, we can tell you who the vetted sponsors were that received——

Senator CORNYN. That is not what I asked you. I know that you have interviewed sponsors to some extent, although not adequately. I agree with Senator Menendez. But do you have any responsibility for their welfare as you sit here today?

Secretary BECERRA. While they are in our custody, we have jurisdiction to provide them with——

Senator CORNYN. I am talking about now that they are in custody of your vetted sponsors.

Secretary BECERRA. Senator, you and your colleagues did not give us jurisdiction to provide the oversight of these children once they left our care.

Senator CORNYN. So that is not your responsibility? Is that what you are saying?

Secretary BECERRA. We do not have jurisdiction. We cannot spend money on things we do not have jurisdiction over.

Senator CORNYN. So you do not know whether they are being trafficked for sex, whether they are being forced into dangerous jobs of child labor? You do not know whether they are going to school? You do not know whether they are getting the health care they need? You simply do not know, correct?

Secretary BECERRA. Well, while they are in our care, we know all those things and they do not happen.

Senator CORNYN. Well, they are no longer in your care once you transfer them to the sponsors, right?

Secretary BECERRA. As I said, Senator, the statutes that you all passed do not give us the authority to monitor these kids once they are out of our custody.

Senator CORNYN. So, whose responsibility is it to look after the welfare of these children?

Secretary BECERRA. My understanding is the statutes that you all passed left that open for the communities where they enter.

Senator CORNYN. Say that again?

Secretary BECERRA. My understanding is the statutes that you all enacted that said that our jurisdiction over these kids ends once we have delivered them to a vetted sponsor, is that the communities where they reside will now be in charge of providing for their services.

Senator CORNYN. So, as a result of the broken border policies of the Biden administration, these kids have been placed with sponsors. You do not know where they are, you do not know what is happening to them. You do not think that is your responsibility, and you frankly do not care?

Secretary BECERRA. No, that is not accurate, and these laws preceded President Biden taking office. This system has been broken—as you know and I know—for more than 40 years, or close to 40 years. You and I have been in Congress for quite some time. I started in Congress back in 1993——

Senator CORNYN. Well, you have a job to do right now. You have about a $1.8-trillion budget, and you have the responsibility for taking care of these children, and you simply hand them off to sponsors, to homes where you do not know the conditions they are living in.

Secretary BECERRA. That is not true.

Senator CORNYN. You do not know where they are going to school, whether they are being sold for sex or forced into labor. You do not know, and you do not think it is your responsibility, correct?

Secretary BECERRA. No, I would dispute pretty much what you just said, Senator.

The CHAIRMAN. The time of the gentleman has expired. I am going to go to Senator Lankford in just a minute. But we just got some information from the Department of Health and Human Services here at the committee. The number of Medicare beneficiaries who are going to save money because of Medicare negotiation is 9 million. That would be 1 out of 7 Medicare beneficiaries.

Senator Lankford, you are next.

Senator LANKFORD. Mr. Chairman, thank you.

Let me do a quick follow-up on this, Secretary Becerra, on what Senator Cornyn was just talking about at this point. Individuals who are placed in HHS custody with ORR, who are unaccompanied minors, are they always placed in a home with someone who is legally present in the country, or could they be also placed in a home of someone who is not legally present in the country and we do not know their legal status?

Secretary BECERRA. Our authority is to place them with someone whom we vet, who will provide a safe shelter, and——

Senator LANKFORD. Do you have any idea of what percentage of children are placed in the home of someone who is not legally present in the country at the time?

Secretary BECERRA. I could not tell you that right now, no.

Senator LANKFORD. So, we do not know that? These are individuals who are vetted, but they are not vetted for their legal status in the country?

Secretary BECERRA. We vet—our responsibility is for the care and safety of the child——

Senator LANKFORD. Yes. I am just asking the question. Just are individuals vetted if they are legally present in the country? Do we know children are placed in the home of someone legally present?

Secretary BECERRA. And, Senator, I do not want to be—I do not want to evade the question. What I am trying to tell you is that our focus is on what are the elements that would make this a safe placement for the child.

Senator LANKFORD. But legally present is not on that list of what is safe?

Secretary BECERRA. I would not say to you that that is a particular object. That does not mean it does not get considered.

Senator LANKFORD. But we do not know what percentage of kids are placed there? I have a lot of other questions, but it is my understanding that is not a consideration on it.

There is a new rule that has come out on nursing homes that I will tell you my rural nursing homes are extremely concerned about. My State is extremely concerned that HHS is creating a rule that is going to cause the closure of a lot of our rural nursing homes.

I understand the good intent that is here, but what this is going to cause is a dramatic rise in prices, and a difficulty of getting R.N.s into those difficult locations. I would just encourage you to reconsider that rule. My State is half rural, half urban, and for

those areas that are rural, they still want to maintain their nursing home. A rule that I did not vote on, that was created by HHS, is about to cause the closure of a lot of those rural nursing homes, and I think that is very significant for us.

So, I am just going to challenge you to reconsider that, so that our rural nursing homes can stay open in the days ahead.

You know this is coming, because your office contacted us at 11 p.m. last night to try to answer a question on this. So let me ask for a little more clarity. Last year, you created a rule on title X funding that in my State—and my State currently has laws that protect the lives of every child, born and unborn—that if my State did not put on our health pamphlets, brochures, whatever it may be, a way for people to get access to an abortion, if they did not put that 1–800 phone number on there, we would lose title X funding.

You followed through on your threat, and you took away title X funding from my State, which takes away from my rural counties AIDS testing, cancer screenings. All of those things you took away from my State, because my State would literally not put a phone number in our health brochures of where people could go to get an abortion.

First of all, let me start—that violates Federal law, because obviously title X funding is not about abortion. That is specifically in Federal law, so you have created something entirely new with that. The second thing I would say is, why would you take away that funding, and is that true?

Would you be willing to put—the funding has been taken away; my State has lost that money for AIDS testing and cancer screenings in our county health departments because of that.

Secretary BECERRA. So, Senator, I am not surprised by your question, and you are not going to be surprised by my answer, in that I do not agree with the way you framed this. Because if it were as you framed it, we would be in court right now losing. But the——

Senator LANKFORD. We are in court right now. There is an appeal that is going on.

Secretary BECERRA. And so far, we are able to enforce the law as it stands. All the law says is, individuals who are going in for services should know what services they are entitled to. We are not saying anything about abortion. We are just simply saying a person should be informed of the services that could be available to them under title X, and if a State wants to not abide by the law, they understand the consequences. They will not get their money.

Senator LANKFORD. So, the specific law that you are stating there is, if we do not put a 1–800 number where to go to get an abortion——

Secretary BECERRA. That is not the case.

Senator LANKFORD. That is the case. So we have verified this; we have walked through the process. That is the one issue when we ask, if we added this one phone number to brochures, does that fulfill——

Secretary BECERRA. To get information——

Senator LANKFORD [continuing]. And we were told "yes," that would fulfill everything. It is just a phone number of where to go

to get an abortion, because you cannot get it in the State. So what has happened then is AIDS testing goes away in my State, cancer screening goes away.

I mean, that is a pretty big bully tactic, to be able to say, "I am going to remove all these things if you do not do what we are asking you to do," which is not in the statute.

Secretary BECERRA. Senator, we follow the law. We expect those who want Federal dollars to follow the law.

Senator LANKFORD. Well, we are also following the law.

Secretary BECERRA. Then they will get their money. If they follow the law, they will get their money.

Senator LANKFORD. Well, clearly, we are being withheld from that. I would ask you just a quick "yes" or "no" question, because there is another decision that is coming down from the Supreme Court next week, as they hear about chemical abortions. There have been some rumors out there to say, and some individuals saying that if the Supreme Court determines something about chemical abortions, that HHS and FDA should just ignore it.

So my "yes" or "no" question is—we do not know what direction the Supreme Court is going to take on that decision, but when the Supreme Court makes that decision, will HHS abide by that decision, whatever it is?

The CHAIRMAN. Briefly, Mr. Secretary. My colleague's time is up.

Secretary BECERRA. Senator, you are asking me to speculate on something. We are going to do everything we can——

Senator LANKFORD. I am asking you if you are going to follow the Supreme Court and the United States Constitution. That should not be a hard question. You have been a member of Congress and a member of the executive branch.

Secretary BECERRA. We always follow the law.

Senator LANKFORD. That is all I need to know: yes, you will follow the law.

The CHAIRMAN. The time of the gentleman has expired.

Senator Carper?

Senator CARPER. Thanks. Thanks, Mr. Chairman. Mr. Secretary, welcome to the Finance Committee. So, I am intrigued by this exchange between the two of you.

When it comes to drug pricing reforms, my principles are pretty simple: much lower costs for American families. We need to encourage innovation, we need to improve transparency, and we need to curb rising costs to the Federal Government. Over the past several years, I think we have pretty much accomplished those things. As you know, we passed, and the President signed into law, the Inflation Reduction Act. This landmark legislation included many provisions to lower the high cost of prescription drugs.

The IRA capped the cost of insulin, for example, at $35 a month for Medicare beneficiaries; made recommended vaccinations available at no cost; capped out-of-pocket spending for Medicare Part D beneficiaries at $2,000 annually; and authorized Medicare to negotiate drug prices with manufacturers for certain high-expenditure drugs.

We made, I think, historic progress in making health-care accessible and more affordable. We are not done, but we are heading in the right direction. We have an opportunity to continue tackling

the rising costs of health care by addressing the growing public health crisis of obesity. Despite obesity being formally recognized as a disease, access to medical treatment for obesity remains limited. The economic and social impact of obesity has risen to almost $1.7 trillion. That is trillion, with a "t," dollars per year. The cost of doing nothing is way too high; too high for American families and way too high for the Federal Government as we wrestle with deficits.

That is why I reintroduced the Treat and Reduce Obesity Act with Senator Cassidy in this Congress. This legislation would expand Medicare coverage of intensive behavior therapy for obesity, and would authorize a Medicare prescription drug benefit to cover medications that are used for the treatment of obesity.

I have been a proud champion for the Treat Obesity Act now for over a decade. Investments in obesity as a disease are long overdue. Mr. Secretary, how will you and your team at HHS work with us to invest in this prevention and treatment of obesity in this Congress?

I like to say bipartisan solutions are lasting solutions. We think this is one of those, and this is a good one. Go ahead.

Secretary BECERRA. Senator, we look forward to working with you because we know that more and more, with the innovation and sophistication of technology and science, we are going to have opportunities to really make a difference in the lives of a lot of Americans. So we very much look forward to working with you so that programs like Medicare and Medicaid can be at the forefront of making sure Americans have access to the treatment they need.

Senator CARPER. Thanks.

The COVID–19 pandemic taught us a lot of lessons. One of those we now have the opportunity to learn from and grow upon. One such example lies in the acute hospital care and home waiver program known as Hospital at Home. We saw the demand for home-based care rise during the pandemic, when hospitals and healthcare facilities were over capacity and patients preferred to receive their care at home. The Hospital at Home program was established under the public health emergency to meet this demand by allowing Medicare beneficiaries to receive hospital-level health-care services at their home.

Since its enactment, we have seen the Hospital at Home program become a true success story. It has proven to deliver higher reported patient satisfaction along with positive patient outcomes, and potential cost savings. To ensure that patients and their providers would have access to the Hospital at Home program for 2 years—beyond the duration of the COVID–19 public health emergency—last Congress, Senator Tim Scott and I introduced the Hospital Inpatient Services Modernization Act. I am proud the Congress passed this bipartisan bill. It was signed into law by President Biden last year.

Mr. Secretary, what lessons have we learned from the success of the Hospital at Home program?

Secretary BECERRA. Senator, I hope that we are able to report pretty soon on all the lessons, because the study that was required by the legislation will give us an opportunity to see how we can do this. But no doubt, I share your interest in making sure that people

in America can receive the care they need where they can get it, and as efficiently as they can and when they need it.

And so, the studies that we are going to be putting forward should help us understand how we can try to move in a good direction for folks who need care. Oftentimes, it could be in their home. So we look forward to working with you on that.

Senator CARPER. All right. Well, we look forward to it as well. My colleagues hear me say often, "find what works; do more of that." We think this is something that works and that we are going to want to do more of. We look forward to working with you, and again, this is one of those pieces of legislation that has bipartisan support.

I am grateful to Senator Cassidy, Dr. Cassidy, and everyone who has joined us in this effort. Thank you so much.

The CHAIRMAN. I thank my colleague.

Next is Senator Casey.

Senator CASEY. Mr. Chairman, thanks. Mr. Secretary, good to have you back here, and thanks for your service to the country at a difficult time.

I want to start with the issue of prescription drugs. I am grateful for your work and the work of the administration on efforts to lower the cost of prescription drugs. We all know that prescription drug costs in our country are significantly higher than so many of our competitor nations. I voted for the Inflation Reduction Act, which had a provision to allow Medicare, for the first time, to negotiate for lower prices. It also had that $35-a-month cap on insulin for Medicare Part D beneficiaries.

I am just holding up here—it is an enlarged version of a piece of paper I put out a couple of months ago now to summarize the benefits of the Inflation Reduction Act prescription drug provisions, just in Pennsylvania, just to give you an example. There is a lot you cannot see from where you are sitting.

But just the capping of insulin at $35 a month, 80,200 Pennsylvanians will benefit from that. And then another one, just for highlight, we know that less than a year from now, the $2,000 out-of-pocket cost cap will go into effect. That will impact nearly 829,000 Pennsylvanians. So, big numbers just in one State.

I wanted to ask you to give us a state of play: what is already in effect and how it is working, and then what has the administration proposed in the budget to further expand policies and measures that will continue to ratchet down the cost of prescription drugs?

Secretary BECERRA. Senator, we may ask you for a copy of that document that you just put up, because we could always use anything that helps convey information to consumers. Thirty-five dollars a month for insulin is lifesaving in many cases for many people. But for folks on fixed incomes—you know how important that is for seniors who have to depend on their Social Security check to pay for things.

The fact is that today, if a pharmaceutical company tries to raise the price of its drug beyond the rate of inflation, we now get to yank back the extra that they are charging beyond the rate of inflation. That is a big one. Today, we are in the midst of negotiating for the 10 costliest drugs in the Medicare program, which in 2022

cost Americans just in Medicare, 65 million people on Medicare, $46 billion.

We are going to finish that, the negotiation, by August. We will be announcing what the price will be come September. That is already in effect. Those prices would then come into play at the beginning of 2026. Next year, we will get to negotiate another 15 drugs. And as you have heard, President Biden would like us to negotiate not just another 15, but another 50, because we are going to be saving a ton of money.

The Congressional Budget Office has said we are probably going to save at least $100 billion in just negotiating for better prices in those first 10 drugs. On top of that, you are aware—and this is very important for a lot of seniors in Pennsylvania and throughout the country—the cap on how much they will have to spend out of their own pocket, it has already begun this year, a cap of about $3,500 for catastrophic costs. But by next year, when people are paying for these drugs, if they are on a cancer drug or have kidney failure—tens of thousands of dollars, today, they pay out of pocket, because their cap is really high. Next year, the cap will be $2,000 overall. A game-changer for so many Americans.

Senator CASEY. And that $2,000 cap goes into effect January 1st, correct?

Secretary BECERRA. Yes, next year.

Senator CASEY. And then, can you just briefly walk through proposals for some of them you mentioned? You said the President proposed 50 more prescription drugs to be negotiated.

Secretary BECERRA. We know what works. If CBO, the Congressional Budget Office, is telling us for just these 10 drugs, we will save $100 billion for taxpayers, why do we limit it to 10? You all were good enough to help make sure that next year it is 15 we negotiate. But the President is saying, why stop a good thing? Let's negotiate more of these, because we know in America we are paying two or three times the cost for these drugs than other people around the world.

Senator CASEY. Well, I appreciate that.

And the second issue that I wanted to note is how grateful I was that the President's budget includes a provision to allow States to provide continuous Medicaid eligibility for children under the age of 6. This continuous eligibility will reduce gaps in coverage and access to essential care services for kids, such as preventive care.

Ensuring kids have access to high-quality, affordable health care is of course one of our number one priorities. And I introduced legislation, the Medicaid for Every Child Act, which would automatically enroll all children, all children through the age of 18, in Medicaid.

How is HHS working to expand access to health care for children? I know I do not have much time, but just a brief summary.

Secretary BECERRA. Well, you have mentioned a very important aspect to it that the President has in his budget. We are also trying to make sure that we provide care from the very moment of birth, in fact beyond, because we are focusing on maternal health. Because too many women in America, believe it or not, in the richest country in the world, are dying, or their babies are dying at the time of birth or within the first year.

And so today, we offer a woman who is on Medicaid not just 60 days of postpartum care, but 365 days. Fortunately, so far, 45 of the 50 States have adopted that. And so, that is going to help kids moving forward to start off on the right track. There are any number of things we could mention Senator, but I know your time is short.

Senator CASEY. Thanks so much. I appreciate it.

Secretary BECERRA. Thank you.

The CHAIRMAN. I thank my colleague.

Let's just consult the board here. Senator Johnson is next.

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

Secretary BECERRA. Thank you.

Senator JOHNSON. I think you may be aware, I have written over 60 oversight letters having to do with our response to COVID, the vaccine, vaccine injuries, to your agency and to your subagencies. I want to talk about three of those primary requests.

The first is on the origin of COVID and Anthony Fauci's emails. In June 2021, 4,000 pages of his emails were released under a FOIA request. Within a week of that, I had five members of the Homeland Security and Governmental Affairs Committee sign a letter requesting those 4,000 pages unredacted.

Let me first ask the question. You do agree to the fact that under FOIA, those requests can be redacted for a host of reasons. But congressional oversight, we are not subject to those redactions, correct?

Secretary BECERRA. Senator, I do not want to speak out of turn. But we continue to make sure that we protect confidential information, the privacy of information, and we try to do the best we can to respond to congressional requests.

Senator JOHNSON. But again, we are not subject to those same redactions, and the U.S. Code—5 U.S.C. section 2954—states that an executive agency on request of the Committee on Governmental Affairs, any five members there, shall submit—shall submit—information requested of it.

So as an accommodation, we went from 4,000 pages, requested 400 pages unredacted. Over the course of a number of months, we were allowed in a reading room. We got 350 pages, we were able to look at them; could not take copies, could take notes. We are down to the last 50 pages of the Fauci emails. [Holding up a series of completely blacked-out pages.] I was hoping that you would bring these unredacted, because last year, in this similar hearing, I asked you about these, and you said, "You are absolutely entitled to the information that by law a member of the Senate or the House should get."

Again, the law is 5 U.S.C. 2954. It states you shall turn those over to us. Why haven't you turned those over to us here a year later?

Secretary BECERRA. And, Senator, you know, I will try to make this as clear as I can, because Secretaries before me and others who have testified before me have tried to answer this question that many Senators and House members have asked in the past.

It is an accommodation process, where we try to make sure that we fulfill the request as best we can, without undermining national security, confidentiality, and the interests of——

Senator JOHNSON. So, Mr. Secretary, you realize if you are withholding information from Congress required under law, that at a minimum you should be providing me a privilege log justifying the reason you are withholding this information. This has been a year since you said that I was entitled to the information that is required by law.

We have not gotten a response from you. We have not gotten a privilege log. Why not? Why haven't you listed the privilege you are claiming to withhold these 50 pages unredacted? What privilege is it that you are claiming to withhold this information, not only from Congress, but from the American public? What is the privilege being claimed?

Secretary BECERRA. And, Senator, I know that your staff has been engaged with our team when it comes to trying to respond to some of the requests. We will continue to try to respond the best we can.

Senator JOHNSON. Well, you have not responded. You should have provided us a privileged list, a log, so we can understand what privileges you are asserting in withholding this information from the American public. So, I am expecting that privilege log post haste, okay?

Now let me move on to two other things. There was a standard operating procedure issued in January 2021, shortly after the vaccine got its emergency use authorization, laying out the analysis that FDA and CDC were going to do on the Vaccine Adverse Event Reporting System.

First, reporting ratio—we have gotten the run-around on that. Finally, you said it was going to be empirical Bayesian analysis. I have written, I think, five or six oversight letters, trying to obtain that analysis on the VAERS system. I have not gotten bubkis. I have not gotten anything on this whatsoever.

Why is the FDA, and CDC, why are they withholding their analysis of their Vaccine Adverse Event Reporting System? We fund the agencies. We pay their salaries. That data should be made available to the American public. Why is it not? Why are your agencies withholding that information?

Secretary BECERRA. Senator, I will try to make sure I can get back to you. I cannot speak directly for the actions of FDA, but what I will tell you is that we try to be responsive to any requests we get——

Senator JOHNSON. You have not; your agencies have not been responsive at all. They are giving me the middle finger. They have been giving me the middle finger for a year. So, Mr. Secretary, I would request a phone call within a week or 2. You check into this.

I have also got—I have run out of time—some significant questions about hot lots, that the agencies are completely ignoring. I mean, things like over 5,000 adverse events with one lot of COVID vaccine versus the most adverse events associated with one flu lot, 137. These are serious issues, and the American public deserves this information. So I would expect a phone call personally from you with the privilege log and responding to why you are not re-

leasing the analysis on VAERS. Why can't I get a legitimate response in terms of hot lots that have been identified repeatedly by a number of outside researchers?

The CHAIRMAN. The time of the gentleman has expired.

Senator Cortez Masto?

Senator CORTEZ MASTO. Thank you. Thank you, Mr. Chairman. Mr. Secretary, thanks for being here. I appreciate it.

First of all, thank you for the incredible work that you and your team are doing around prescription drug negotiation as authorized by the Inflation Reduction Act. It is so important for seniors and so many across the country, to lower drug prices. So, thank you. I also recognize that big pharma is in court right now trying to challenge your authority under that legislation, which unfortunately is happening. In addition to the Inflation Reduction Act negotiation, we also imposed caps on out-of-pocket spending for seniors for the first time.

And so, how is the initial out-of-pocket cap, which was put in place just January of this year—it is just the initial—benefiting seniors right now, and how might that change when the $2,000 cap is in full effect next year?

Secretary BECERRA. Senator, thank you for the question, and thank you for your work. I know Nevadans are able to keep a little extra money in their pocket because of the work that you and your colleagues have done to lower the cost of prescription drugs.

Many Americans, especially those who are in Medicare who are getting older, have very high costs for medication. They are perhaps suffering from cancer. Maybe they are having kidney failure. But oftentimes, their costs are extremely high, and while Medicare provides a lot of support and pays for a lot, out-of-pocket costs can be very high for some individuals. It can be into tens of thousands of dollars.

Today, this year, the catastrophic cost limit kicked in as a result of the President's lower-cost prescription drug law, which means that no senior today, for those catastrophic costs, pays more than about $3,500 out of pocket. Next year, starting in 2025, the most for those medications that any senior will pay out of pocket will be $2,000. That is a lifesaving measure for many people.

Senator CORTEZ MASTO. And that is true, as I have heard from so many of my seniors. How do they become aware of it though? Is your agency pushing information out so seniors are aware?

Secretary BECERRA. We are trying to get that information out, but a really quick story. I had a senior come up to me and say, "I went back to my pharmacist because when I saw what they had charged me for my insulin, I felt guilty that they had undercharged me. So, when I went back to the pharmacist, I said, 'You undercharged me,' and the pharmacist said, 'No, that is the new price, $35.'"

She was just up in the clouds, because this is a senior on a fixed income who had been paying, I think, $117 a month. Thirty-five dollars—that is real money in her pocket.

Senator CORTEZ MASTO. Yes, it makes a difference. It makes a difference for so many of my seniors as well.

Let me jump to mental health. Every single one of Nevada's 17 counties is designated a health professional shortage area, also

known as HPSA, as you well know. All 17 counties are primary care shortage areas, and 16 out of 17 Nevada counties are designated as mental health shortage areas. The President's budget proposes to extend the 10-percent incentive payment for physician services provided in shortage areas to include a broader range of clinicians and behavioral health practitioners.

This committee has also passed a bipartisan package allowing more mental health providers to receive an increased bonus for practicing in shortage areas. Should this increase in shortage area bonuses become law, providers across Nevada would see an increase in their Medicare reimbursement.

My question to you is, many shortage areas lack a physician, but Nevadans may have access to a nurse practitioner or a clinical social worker. So, has HHS evaluated how extending the range of clinicians eligible for the HPSA bonuses might impact our workforce challenges, particularly in our rural communities?

Secretary BECERRA. Yes. Great question, Senator, because you are right. We learned that, especially as a result of COVID, there are health professionals who may not be physicians who can do some of the work that right now they are prohibited from doing. So we are working with States, because the licensing issue is at the State level. So, for certain practitioners, a nurse practitioner for example, to do things beyond what is currently provided by State law, we have to have the States make amendments.

And so, we are working with them, because COVID taught us that a lot of health professionals are ready to go. They just have to be free from those constraints.

Senator CORTEZ MASTO. Well, I appreciate that, and it is one thing I know, working in my State, and you as a former Attorney General recognize, that at a Federal level, there is only so much jurisdiction you have, and it does require either State or local community government partnership here when it comes to looking out for the best interest of our kids, or whether it comes to opening the door for access to more physicians or doctors or mental health clinicians coming into the State.

There is a role for the States to play as well, and I appreciate that work that you and your staff are doing, that partnership. Thank you.

Secretary BECERRA. Thank you.

The CHAIRMAN. I thank my colleague.

Senator Cassidy is next.

Senator CASSIDY. Secretary Becerra, thank you for being here.

First, Senator Menendez and I have requested a TA for coverage for dialysis patients. I have a TA request in for the Connected MOM Act, to allow mothers at risk for problems in their pregnancy to get stay-at-home monitoring.

We have—it is outstanding for months. Now, I know your staff is incredibly busy. You get lots of requests, but this actually will save lives. So can I ask that you ask your staff to get these fulfilled ASAP?

Secretary BECERRA. I agree with you, these are important. Let me ask. As you know, CMS is right now besieged with so many different things, the latest being this Change Healthcare cybersecu-

rity attack. But let me get to them and say that this is important, and see if they can work with you to double the speed.

Senator CASSIDY. I appreciate that.

Now let me next ask about HHS data modernization. Is that an in-house data platform that HHS is using, or do you do like the Department of Defense does and contract with others who are cloud-based like AWS or Palantir or somebody like that?

Secretary BECERRA. You know, Senator, I will be honest with you. I want to get back to you, because I do not want to give you misinformation. But if you give us the name after this hearing of who your person is on staff, we will make sure we are in communication to get you that correct information.

Senator CASSIDY. Sounds great. Related to that, there was this recent finding by the—an acronym—the National Association of ACOs, which published data suggesting that seven fraudulent companies stole $2 billion in Medicare payments in 2023, and they did that using a virtual research data center to find the fraud.

Now that is all good. Of course, I would like for CMS to have been on top of it, and that is why I would like to talk to you about data modernization at some point in time. I am also told that academics have used this data. They do not have the ability to purchase it, so they have relied upon CMS to stream it.

And so, I was a little surprised when CMS announced last month that it would discontinue sharing data with institutions beginning August 19th, and require all researchers to move to the fee-based virtual research data center. That is fee-based, right? [Turning to staff.] Yes. Now I understand the per-user price for that is quite high.

So, I do not know if you are going to lower the price for the academics, or if you continue, have you done an analysis on how many fewer researchers and students will be able to access the data if you go to this, et cetera?

Secretary BECERRA. Senator, we are in the process of reviewing this. We are in fact—we have a solicitation for information to get responses back. As you know, this is a fairly new area. We want to be more aggressive in getting everyone on board. Every sector within health care has to get into this, because no one can keep their data doors unlocked with these cyberattacks that are occurring. So, we are trying to get the best information we can to know exactly how to proceed.

Senator CASSIDY. Sounds good. So, I think, I think you are open to allowing researchers to have it either at a discounted price or some way, but they would not pay the full freight of somebody who is doing it as a for-profit?

Secretary BECERRA. Yes. I will not speak to where we will go. I will tell you we are open, because we are trying to learn as everyone else is trying to learn.

Senator CASSIDY. Okay. Would you give me a follow-up on that——

Secretary BECERRA. Absolutely.

Senator CASSIDY [continuing]. Because the researcher who approached me has been incredibly helpful to this committee, whether the committee knows it or not, because she is just fed into our office, and the fact that she might not have it will be deleterious.

Secretary BECERRA. I would invite you or your team to help, because we are trying to get everyone to give us their best information, because we do not want to miss anything, especially for the little guys. The big guys could probably afford to do some of these things, but for the little guys, it could be very expensive. So, any information you are getting, we would love to have it.

Senator CASSIDY. Sounds great.

You know I have been interested in return to work. Can you tell me what percent of HHS employees and CMS employees are currently 4 days a week or more in the office?

Secretary BECERRA. Sure. What I could tell you is that, as you know, because HHS was involved with COVID, we have been working from Day One, and we continue to have folks come into the office to work. I can tell you that we are complying with the Office of Management and Budget's guidance when it comes to in-office work levels. We have a variety of——

Senator CASSIDY. And what is that right now?

Secretary BECERRA. I'm sorry?

Senator CASSIDY. What is that requirement?

Secretary BECERRA. The requirement is not a straightforward requirement, because there are a lot of different work schedules and work——

Senator CASSIDY. But just at HHS, typical employee. Would it be 1 day a week, would it be 3 days every month? Would it be 4 days a week?

Secretary BECERRA. Yes. NIH researcher, every day. IHS caregiver, every day.

Senator CASSIDY. But the HHS building, that one down the street?

Secretary BECERRA. The HHS building. Most of us probably almost every day because we are in——

Senator CASSIDY. Those are political appointees. What about the nonpolitical appointees?

Secretary BECERRA. There, where you have some flexibilities for some of the career staff, it could be 3 out of 5 days a week; it could be 4 out of 5 days. It depends on what their job is.

Senator CASSIDY. What is the least amount it could be?

Secretary BECERRA. Well, there are some folks who get to telework altogether, because their job is essentially in front of a computer. And so, what we are trying to do is make sure——

Senator CASSIDY. Now, are you monitoring VPN data or anything else to measure productivity?

Secretary BECERRA. Yes. We could use your help, because the systems we are using to monitor are from back in the 1970s and 1980s. So it has been difficult to really get the dots connected.

The CHAIRMAN. The time of my colleague has expired.

Next is Senator Cardin.

Senator CARDIN. Mr. Secretary, welcome. It is wonderful to have you before our committee.

I want to ask you first in regards to some of the actions you have taken in regards to oral health. As you know, oral health is critical to overall health, and you have provided some additional medically necessary determinations in regards to coverage under both Medicaid and Medicare.

And I guess I want you to be able to continue to recognize that a lot of the services are medically necessary that traditionally have not been covered under these programs. So, can you tell us how you are using the authorities that you have to expand access to medically necessary oral health?

Secretary BECERRA. So, Senator, I know that we are trying to expand access to health in rural communities, because we now see a contraction. And what we are trying to do is, where you all have given us authorities to actually provide flexibilities in the way some of these providers operate, we will do so.

Sometimes it is difficult because there are consequences, especially if you have a net neutral system of funding, to make some of those resources available. But we try to stretch where we can. We could certainly use your help in making sure that the authorities we have allow us the flexibility to really reach most of rural America when it comes to health care.

Senator CARDIN. We want to work with you in a process within CMS to evaluate clinical evidence for additional dental services, to determine when they are medically necessary for beneficiaries. We know that sometimes this is a struggle in interpretation, and I know Senator Stabenow and I have been working on this issue, and we will be glad to try to give you the additional authorities if you need additional authorities.

But we think under the Affordable Care Act, you have certain abilities that you can use to deal with medically necessary services, and you can use that in order to try to expand care.

Let me ask you, in regards to the issues concerning—this committee has been very concerned about the transplant issues and the quality issues. Can you tell us the status of making sure that we can have fair competition and quality in regards to the system reforms related to transplantation of organs?

Secretary BECERRA. We are trying to move aggressively with the reforms that Congress enacted, which really reflected the reforms that we had proposed in regulatory channels. What we will need though is resources, because we are trying to set up a new, independent board that will monitor the transplant activities.

We are trying to create a robust system of competition, just to see who will operate the system, and we need help to make sure that we can get this done as quickly as possible, because I think everyone agrees that the resources we need to bring us up to date are not there. I hope that in this budget process, we are able to get some of the resources that the President has proposed in his budget.

Senator CARDIN. So, let me ask you about another subject that I have been raising for a long time, and that is dealing with drug shortages. It is amazing in the wealthiest country in the world, that spends the most by far on medicines, that we have relatively inexpensive drugs that are in short supply and are compromising the quality of health care in America.

I find that outrageous. We have tried to deal with shelf life and to give some flexibility, so that drugs that are still effective—that we do not have those shortages. But we find that without some system of carrot and stick, we are going to always have these shortages, and that is unacceptable.

So, can you tell me the strategy that you are deploying in order that Americans have access to critical medicines that are not difficult or expensive to produce, but because of the manner in which our market works, these drugs are in short supply?

Secretary BECERRA. Absolutely, Senator, and thanks for the work that you have been doing on this subject. Our problem is, our current statutory authorities really only give us sight at the end stage when, at the retailer level, we start to see the shortage: people cannot find the drug on the shelf, they cannot get it from the pharmacy.

We are asking for authority so we can actually see a shortage or a constriction occurring at the early stage, when that medicine is being manufactured. Waiting until the retailer says, "I do not have enough," is way too late. So we are asking to be allowed to have greater insight into what the manufacturer sees, so the manufacturer has to alert government whether or not they see shortages occurring at their stage.

The second thing we would like to do is make sure that we try to bring home much of that manufacturing, because we should not be dependent on China and other countries for the materials that it takes to create these pharmaceutical medications. And so, we would like to bring some of that manufacturing back home. The President includes about $95 million to make it possible to actually have manufacturers base their operations here in the U.S.

Senator CARDIN. Thank you.

Mr. Chairman, I will have a question for the record in regards to orphan-type drugs or drugs that are taking a long time under FDA, where the life expectancy is short. I will have a question for the record in that regard.

The CHAIRMAN. Senator Cardin, thanks for your good work on the drug shortage issue, and it has been good to work with you on it.

Senator Brown?

Senator BROWN. Thanks, Mr. Chairman. Mr. Secretary, nice to see you again. Thank you. So much in the IRA mattered in people's lives. It's something in Toledo, on a whole other subject, that mattered to people there.

I want to thank you specifically for your work on prescription drugs, one of the most important things we did. Thirty-five-dollar insulin—72,000 Ohio seniors will benefit; 219,000 older Ohioans who rely on the ACA will benefit. We want to expand, as I know you do, and Senator Whitehouse and I have worked on this, to expand the insulin cap to everyone, not just Medicare beneficiaries.

The Federal Government is negotiating better prices for patients. Many years ago, when you and I served in the House together, I used to take buses to Canada, about 3 hours away. People would be able to fill their prescriptions with negotiated prices the way our own VA does, saving 50, 60, 70 percent. We can do that now, and thanks for your work on that.

So, walk through briefly, because I have another topic I want to talk about, how this will all work. How can you, how can HHS work to implement the law to ensure lower prescription drug costs?

Secretary BECERRA. So, Senator, it is already in effect, as you mentioned, with insulin. We see how it is working. I have had any

number of conversations with a lot of seniors who rely on their Social Security check, essentially for their day-to-day living. When they hear that $35 is all they will pay now for their insulin, where before they were paying $100, $150, $250, it is a godsend for them. The fact that today, we can yank back the extra profits that a pharmaceutical company is making if they try to raise the price of that drug by more than the rate of inflation, that is a great thing for Americans on Medicare as well.

The fact that today, the out-of-pocket costs for a senior are now being limited, so that even if you have to use that expensive cancer drug, you will not pay more than about $3,500 out of pocket. That is still a lot of money——

Senator BROWN. And that number comes down.

Secretary BECERRA. And next year it comes down to $2,000 total. And for folks who are paying tens of thousands right now, that's real money.

Senator BROWN. When you think about what this Congress and the last two have done in terms of restoring, in my State, 100,000 union workers' pensions; what the Child Tax Credit did temporarily—we keep moving on it—dropping poverty rates by 40 percent; and what we are doing on drug prices, I mean, it affects huge, huge numbers of people who need a little bit of help in their lives. Thank you for that.

I want to shift to East Palestine. You and I have talked on the phone about it, the site of the train derailment in eastern Ohio, just slightly into western Pennsylvania. Senator Casey is on this committee.

I made my ninth trip there this week. The administration has announced a few NIH grants to get some work underway on health monitoring. That is a really good first step. I have asked HHS to set up a voluntary disease registry for the residents of that community, and I just wanted you to commit to working with my office and the residents of East Palestine and its surrounding communities, including Senator Casey's impacted constituents, on a voluntary disease registry and additional resources for long-term health monitoring.

Secretary BECERRA. Senator, look. I thank you for your leadership on this, on East Palestine. You know, I feel like you are always nipping at my behind on this one, and making sure we are doing something. I am glad we were able to get $250,000 to that local community health center right after the incident occurred, to help them out.

We are glad we sent CDC out there to do the in-person surveys, to help find out what the health status was of people. NIH now, this year, announced six grants that are going out to help understand what is going on there for the folks in East Palestine, and we are absolutely prepared to work with you and State and local partners on this issue, on a registry and these other matters.

Senator BROWN. Thank you.

Two other quick things. I appreciate the commitment you made, when we talked during last year's budget hearing, to use a project labor agreement during the construction of the new CDC NIOSH facility. NIOSH is an institution—the National Institute for Occupational Safety and Health—unlike any in the world—in Cin-

cinnati, OH. They make a huge difference for workers, by studying and understanding workers' illnesses and diseases and injuries and other matters for—I mean, it really is about the dignity of work. Thank you for that, and I look forward to working with you to make sure we have the resources to see this project through to completion, and to get that PLA in as quickly as possible.

The other thing is, we spoke recently about the financial issues of the Salem Regional Medical Center. It happens to be in the same county where East Palestine is. The train going through Salem was actually on fire before it derailed 8 miles later in East Palestine.

So that regional medical center faces problems because of an error by one of Medicare's regional contractors. I need your commitment to continue working with me to ensure that we deliver timely solutions, to ensure that we can keep providing care through the Salem Regional Center, if you would.

Secretary BECERRA. We are prepared to continue to work with you, Senator.

Senator BROWN. Good. Thank you, Mr. Secretary.

The CHAIRMAN. Senator Brown, I thought you would be interested. A couple of years ago, you were enormously helpful in our creating that price-gouging penalty, you know, where drugs were way over inflation.

The Secretary confirmed that just one of those drugs—and they are of course in the doctor's offices, Part B of Medicare—is saving $600, more than $600 per dose. So I just wanted to say "thank you" for your efforts on that.

Senator Barrasso?

Senator BARRASSO. Thanks, Mr. Chairman.

Mr. Secretary, thanks for being here. Good to see you again.

I wanted to turn to the crisis at the southern border, and how it is overwhelming our health-care system here in the United States. What we see on the news, reported and written, and on video and television, hospitals in sanctuary cities right now—New York City, Denver, San Diego, Chicago, Boston—tell us that they are at risk of collapsing financially due to the overwhelming number of illegal migrants flooding their emergency rooms and their clinics, and essentially getting free care, having the American people pay for their care.

A clinic in Chicago reported seeing nearly 16,000 migrants last year, illegal immigrants. The cost of their care totals over $30 million. This is what the hospital is reporting, paid for by American taxpayers. Denver Health was in the headlines in 2023, reporting over 20,000 hospital visits from migrants. The hospital is now, not surprisingly, in financial distress.

These hospitals are now asking the Federal Government to bail them out, and it is completely a Democrat-caused failure to enforce the law at the southern border. Can you please explain why it is the responsibility of hardworking American taxpayers to foot the bill for all of this care for people, 9 million now from all across the world, who have flooded their way into the United States?

Secretary BECERRA. Senator, I appreciate the question. What I could tell you is that we have extended the resources and authorities that we have at HHS to try to be there to help any healthcare facility, when there is a way that we can go in to be sup-

portive. I do not know the particular case that you might want to mention, but I know that we are prepared to be supportive of any facility where the authorities that you have given us allow us to go in and support.

Senator BARRASSO. Well, in terms of—it is not hard to find stories about hospitals in one sanctuary city after another saying they are overwhelmed with the number of people that they are treating, and have no way to recover the costs other than to turn to the American taxpayers.

The Federal Government does not pay for the health care of every legal U.S. citizen. It seems like it is in the position now of having to do it for all these illegal immigrants. Why should the American citizens be forced to pay for illegal migrants to receive this same care for free, because that is what is happening?

Secretary BECERRA. Senator, as I said, I do not know how particular States operate their health-care systems with regard to the folks who are coming in. But what I can tell you is that when we are approached, whether it is through the Medicare program, the Medicaid program, or simply those who are seeking other types of authorities and funds that could help them, we are ready to try to be responsive.

Senator BARRASSO. You are aware that when a hospital is inundated with people who are not paying, they have to shift the cost to the people who are paying, and that is what is happening right now all across the country, and specifically in so many of the sanctuary cities.

I want to talk to you a little bit about something that Senators Lankford and Crapo asked about as well, and that is the nursing home staffing ratio requirements. Specifically, your department is proposing a rule on nursing home staffing ratios, requiring a registered nurse to be present 24 hours a day. Currently it is required for 8 hours.

CNA hours per patient per day are increasing. And the hardship exemption for rural communities that cannot find people to hire, even though they try very hard, it is requiring much more paperwork. Most of the Wyoming nursing homes that I talked to said they would have to actually hire additional staff, not in addition to taking care of the patients, but to just fill out the paperwork that your department is requiring.

We had concerns. We expressed them to the Director of Medicare and Medicaid, Brooks-LeSure. She shared that the Centers for Medicare and Medicaid have committed $75 million to support nursing staff in nursing homes. How do you plan for these funds to reach these rural communities that are really getting hammered by these additional rules? About four out of five nursing homes say they cannot comply with what the administration is now forcing upon them all across the country.

Secretary BECERRA. Senator, you packed a lot into that question. Let me respond first to the issue of the funding, how we can make sure that it gets into the rural communities. One of the things that we have done is make sure that we try to get those dollars into the communities that need it most, to be able to staff up.

But I must tell you, if you are going to call yourself a nursing home, you should have a nurse that is present to provide care to

the families that are leaving their loved ones there. It is embarrassing that, while not one of every five Americans lives in a nursing home—nowhere near 60 million people live in a nursing home—one of five people who died from COVID died in a nursing home.

We need to make sure that the standards that these homes have for the people that we love and leave in their custody will be the right care, and it will be with professional standards. All we are seeking is to make sure that all nursing homes—many of them already do this—but all nursing homes meet the standards that you or I would expect if we are going to leave our loved one there.

Senator BARRASSO. Well then, Mr. Chairman, let me just say—and my time has expired, so I will not go to additional questions. Only one in five nursing homes can meet the proposed requirements. Even those trying to hire people cannot find people to fulfill it. So four out of five nursing homes, they are going to be out of compliance with administration rules, and apparently what you are saying is that all of the nursing homes, these other nursing homes, are right now incompetent to provide care. But they are still providing pretty good care today.

Thank you, Mr. Chairman.

The CHAIRMAN. The time of the gentleman has expired.

Senator Bennet?

Senator BENNET. Thanks, Mr. Chairman. This is not the topic I was going to come to address today, but my dear neighbor from Wyoming raised Denver Health, and I feel like it is really important for me to respond. I want to make sure I do that before you leave.

First of all, Denver Health is a national treasure. I do not think the doctor would disagree with that. It is a critical public access hospital for the western United States, not just Denver. It serves the entire metro region. It has a massive problem because of the amount of uncompensated care it covers, even without the current immigration crisis that we are talking about, because we, unlike every other industrialized country in the world, do not have a system of health care where people know they have insurance, where people know they can get care.

And so, the doctors and nurses at Denver Health are left to cover the uncompensated care that no one else will cover, because no private insurance company will cover it or no other hospital will cover it. There is Denver Health sitting there in the middle of Denver, not just covering it but saying "send me the people that are uncompensated, because we have a moral obligation to cover."

By the way, the taxpayer covers that care too. It is not like the taxpayer is somehow off the hook. We are paying for that because of our broken health-care system. So what I would say to my colleague from Wyoming is, let's work together to fix our health-care system so we do not have the immoral crisis that we have because people are not covered in this society.

That is point number one. Point number two, it is not Denver Health's responsibility, or dare I say—I think the Secretary would agree with this—Denver's responsibility or even Colorado's responsibility to fix the immigration system in the United States of America.

The Founding Fathers of this country understood that Congress would have to fix the immigration system in this country and be responsible for it because, even in the 18th century, it would have made no sense to imagine that this was something we would leave to the States or the cities, or to a public hospital in the middle of Denver, CO to address.

We just had the opportunity to try to fix some of the chaos at the southern border of the United States, which I completely agree the American people are tired of, for good reason. I do not think that we should be allowing transnational gangs to set the immigration policy of the United States of America. I think that is a mistake.

Because we have failed to act, that is who is running the immigration policy for this country, in some respects. That is why so many people are showing up to the border. That is why the border is overwhelmed. And in the context of this Ukraine negotiation, we had the opportunity to try to address this in—in my opinion—a very incomplete way, but we were going to address it, and the other side walked away from their own negotiation, even though it was the quote-unquote "toughest border bill that ever had been agreed to." And now they are coming here and beating on Denver Health for the uncompensated care that they are providing, because that is what honorable nurses and doctors do. That is what an honorable community does.

It is the responsibility of the Federal Government to deal with this, and not just to point fingers at each other. And I will say it—you know, I wanted to ask you about mental health, Mr. Secretary, and the mental health epidemic that is raging among adolescents, young people in Colorado and across this country, something that we have to address as well.

But let me mention one last thing before my time is expired, and that is this. Two weeks ago, in *The Wall Street Journal,* okay—not the failing *New York Times,* not *Pravda,* but in *The Wall Street Journal*—they had a poll on immigration, and they asked about eight policies of the people who took that poll in *The Wall Street Journal* for the American people's support.

Number one, with 74 percent, was a pathway to citizenship for the 11 million people in this country who are undocumented, the people who spent 30 years in Oregon and in Colorado picking fruits and vegetables. The American people have too much common sense not to know that is a good idea. Second was the Dreamers. Third was dealing with the border.

My point—and I will stop, Mr. Chairman—is that we need a comprehensive solution to this problem. It is well understood we can come here and score political points. We have to fix the problem, and Denver Health deserves the support of this committee, not an attack on the work that they are doing.

The CHAIRMAN. As much as I agree with Senator Bennet's common sense, we have to move on to Senator Blackburn.

Senator BLACKBURN. Thank you, Mr. Chairman, and, Mr. Secretary, thank you for being with us today.

I know we have talked some about the unaccompanied minors who have traversed that southern border. A big part of the solution is to secure that southern border.

Now, these children who found themselves in the custody of HHS and the Office of Refugee Resettlement—and what we have seen during this surge is the administration's inadequate ability to actually handle the capacity of unaccompanied alien children that are coming into this country.

Instead of fixing the border, which is what we would have liked for the President to do, you pressured your staff to expedite the release of these children, prioritizing speed over due diligence. In fact, in a video and a Zoom call with your staff that I viewed, you actually said this, and I am going to quote you: "If Henry Ford had seen this in his plant, he would have never become famous and rich."

Now you made that comment, talking about how to assembly-line process children who were coming into the country. Over due diligence, over safety, you prioritized speed and moving them on out. Now the OIG, your HHS OIG, recently reported that your staff did not make timely safety and well-being calls, if they made them at all. Twenty-two percent were late, months past the time they were due, and 18 percent never went out at all—at all. And it also found that the staff skipped essential safety steps such as ensuring that the sponsors did not have a criminal record or that they were not sex offenders.

So it should be no surprise that we are continuing to hear reports suggesting the existence of trafficking schemes that are preying on these vulnerable individuals, allegations that we are hearing of coercion, of forced labor. And despite my persistent inquiries on this issue, your staff has stonewalled getting answers back to me.

Now, I have written you twice. I got responses that were non-answers from your Assistant Secretaries, one of them being over 6 months late, and I got it just last week before this hearing. Mr. Secretary, this leads me to believe that you do not give a ripping flip about what is happening to these vulnerable children.

Now you answered Senator Cornyn about knowing where the children are, and knowing who the sponsors are. But I have talked to caseworkers in some places, and they say they cannot ask if somebody is in the country legally or not. And OIG said they had concerns. They had 35 percent—35 percent of the case files had legibility concerns over images, scans of photo IDs, birth certificates, legal documents.

So let me ask you this. Can you sit here today in front of us and say with full certainty that your department knows the identity of these children's sponsors?

Secretary BECERRA. Senator, let me make sure I respond to the question, in terms of the identity of sponsors. No child in our custody is released to a sponsor without having gone through a full vetting. So, certainly we know——

Senator BLACKBURN. A full vetting where you said let's speed it up, because Henry Ford could never have been rich and famous if he worked at the slow process you are. Children are not widgets on an assembly line. They are human beings.

Secretary BECERRA. And that is exactly what I said.

Senator BLACKBURN. Well, sir, I would say OIG disagrees with you. He says that you do not know. Do you think you have a responsibility to follow up with these children when they are placed?

Secretary BECERRA. Senator, we not only believe it is our responsibility to take care of these children while they are in our custody; we make efforts, even though you and your colleagues did not give us the authority, to try to follow them after they leave our care.

Senator BLACKBURN. No sir, you have the authority, 6 U.S.C. 279(b).

Secretary BECERRA. To do what?

Senator BLACKBURN. "ORR, *shall* be responsible for coordinating and implementing the care and placement of unaccompanied alien children." That is a "shall."

Secretary BECERRA. That is correct.

Senator BLACKBURN. It means you have to do this.

Secretary BECERRA. That is the sponsorship and vetting process.

Senator BLACKBURN. And then section 2.8.4, "and care providers must conduct a safety and well-being follow-up call with an unaccompanied child and his or her sponsor 30 days after the release date." Mr. Secretary, Director Marcos is failing in this. There are 85,000 children that we know of that you all cannot find, and you are hesitant to move forward with giving us the information.

My time has expired.

Thank you, Mr. Chairman.

The CHAIRMAN. I thank my colleague.

Senator Whitehouse?

Secretary BECERRA. Mr. Chairman. Mr. Chairman, if I could just briefly——

The CHAIRMAN. Oh, just very briefly.

Secretary BECERRA. Very briefly. First, I take umbrage to the mischaracterization and in some cases misrepresentation of the facts by Senator Blackburn, and I also want to make it clear that we have people at ORR who are working as hard as they can with the resources that we have. Your misrepresentations on the authorities that we have at ORR are appalling. It is unfortunate that you wish to mischaracterize the work that we are doing, and we do everything we can with the authorities you give us to provide the care that these kids need. But——

The CHAIRMAN. Mr. Secretary, we have to move on with Senator Whitehouse.

Senator BLACKBURN. Mr. Chairman, I would ask to submit the letters and statute for the record.

The CHAIRMAN. Without objection, so ordered.

[The letters and statute appear in the appendix beginning on p. 173.]

The CHAIRMAN. Senator Whitehouse?

Senator WHITEHOUSE. Thanks very much, Mr. Chairman. Mr. Secretary, good to have you here. I want to move to a much more local issue, a Rhode Island issue.

As you know, from the very earliest beginnings of the value-based care effort, I have been very, very involved, helping to set up the Accountable Care Organizations that have been such a success in Rhode Island and elsewhere, in the Affordable Care Act, and establishing CMMI, which has largely been a success, in the Affordable Care Act. And I want to—actually, Senator Barrasso and I have just launched a bill today to improve and expand the ACO program.

I first want to thank you all for the AHEAD Model, which Rhode Island is applying to. The State total-cost-of-care model provides a very important potential avenue to get off the fee-for-service treadmill that has served us so badly. So, thank you for that, and any cooperation and support you can give to Rhode Island as we pursue that process and come to what I hope will be a very happy conclusion, I would be very appreciative of that.

So, CMMI; I have been trying to organize a—CMMI was designed to be able to try out pilots. That is its core function, and I have been trying to get a pilot in Rhode Island to deal with people who are approaching the end of life. And within that circumstance, the needs change.

So, there are a bunch of waivers—there are five of them that we have identified that are unhelpful and interfere with care and humaneness in that phase of life. They may make sense in the larger world, but at that point they really stop making sense, and they get in the way of families' ability to take care of their loved ones.

Today is the third time that I have raised this with you in hearings, when you have come before us. I do not just raise it in hearings. We have had repeated meetings with HHS staff. We have had multiple meetings with the CMS Administrator, and I have been meeting with CMMI Directors now through three different administrations. And every time that one leaves, it is Ground Hog Day, and I have to start all the hell over again to try to get this moving.

It has now been the better part of a decade, trying to get a very simple, very easy pilot launched in Rhode Island that allows from you five waivers that you have given over and over again in other circumstances. It is not that the waivers are for some reason unacceptable to CMS or to Medicare or to CMMI or to anybody else. The waivers have been granted in many circumstances. What you will not do, or what CMMI will not do, is to simply say "yes" to those five waivers in Rhode Island for a population that we are very willing to negotiate over.

I would propose that the population be those identified by ACOs, patients of Accountable Care Organizations who are nearing the end of life, for whom these waivers will be appropriate to help the doctors provide better care and save money. We can talk about others. Federally Qualified Health Centers could be another great population to work with.

I am open to working with you on what the population should be, so that CMMI and CMS and you can be comfortable that we have a manageable pilot that is not going to put the Federal health-care system at risk. I believe we will prove to you that you will be improving the humanity of care for people at the end of life if you let this go forward; that you will be saving money if you let this go forward; and that, to the extent that outcomes can be improved for a dying patient, that outcomes and experience will be better.

So, I am back to you again to say, "Please help me clear this logjam." This is not a difficult thing, and I do not want to hear that "not invented here" is the reason. I do not want to be told, "Well no, we have a different program. Why don't you go there?"

This is an easy thing that I have pursued for nearly a decade, asking only for waivers that have already been granted over and

over again, and narrowed to a very simple and negotiable population in the State of Rhode Island. We have been waiting for years to get this done, and I really need to get it done. Yes, you are invited to respond.

Secretary BECERRA. Senator, I know how committed you are——

Senator WHITEHOUSE. Really briefly would be "yes." That would be a great answer, one word; we are done, and we can get to work on fixing this after nearly a decade of obstruction.

Secretary BECERRA. Yes. I am rooting for you. Senator, I know how hard you have been working on this, and in my conversations with our team at CMMI, they understand the purpose. They understand all of the different elements of the proposal. They appreciate the fact that you are willing to be somewhat flexible on how it is developed.

They continue to raise concerns with the issue of having a State focus. We are trying to—CMMI is supposed to be an agency that comes up with models that can then be used nationwide. And I know that they are trying to move in a direction to make sure that anything that we do through CMMI—which has very limited resources, as you know; our authorities are somewhat limited—that it will be applicable broadly.

And so I am absolutely committed to getting back to you. I do not think it is as easy as you suggest it is, but I certainly believe that I owe you at least some conversation, to see if we can move this.

Senator WHITEHOUSE. Yes. We absolutely do need to move this.

The CHAIRMAN. The time of my colleague has expired.

Next is Senator Hassan.

Colleagues, here is what is going to happen. We have a number of Senators in the room who want to ask questions. Senator Cantwell will chair for a few minutes so I can go vote, but we are just going to keep this going. And at this point, it is Senator Hassan next, and Senator Cantwell will be chairing, and we will get everybody in.

Senator HASSAN. Well, thank you very much, Chair Wyden. I want to thank you and the ranking member for this hearing, and thank you, Mr. Secretary, for being here today. You and I spoke last week about the cyberattack on Change Healthcare, the payment processors for hospitals and doctors all across the country, and the impact that this hack is having in New Hampshire. And I raised the issue with the President on Monday.

As you and I discussed, this hack is having a really out-sized impact on small and rural hospitals, including four Critical Access Hospitals in New Hampshire, which have not received what amounts to 98 percent of their expected payments for the last 3 weeks.

After you and I spoke, at least one of our hospitals received approval for aid from the Medicare program, so thank you very much for your quick attention. While this has been some progress, our providers are facing a really long road ahead.

So this morning, I met with Andrew Witty, the CEO of UnitedHealth Group, which owns Change Healthcare, and this meeting followed my approach this week to urge United to step up and pro-

vide more urgent aid to providers. So Mr. Witty and I had what I would call a constructive conversation this morning.

UnitedHealth Group has made new commitments to provide cash aid today to the providers in my State who need it, without any unfair or risky terms. What will HHS's role be in the coming days to ensure that UnitedHealth Group is following up on these commitments?

Secretary BECERRA. Senator, first, thank you for the work that you are doing to make sure that not just in New Hampshire, but generally, that UnitedHealth and other payers step up. As you probably know, we had a meeting earlier this week with the payers, with UnitedHealth Group, and providers, and we are now having a follow-up meeting specifically with the payers on Friday.

What we are doing is essentially saying to the payers, many of whom actually have already received their payments from Medicare and Medicaid—they are holding money, and providers are not getting paid. We are saying to them, "You need to start making payments."

While you may not receive the actual bill, you have a general sense on a monthly basis what these providers bill you. So there is no reason to not work out an advance payment to these hospitals and other doctors and other providers.

Senator HASSAN. Okay. Well, I look forward to continuing to work with you and your team in making sure United Healthcare payers generally are doing what they need to do, especially with our Critical Access Hospitals.

Secretary BECERRA. I look forward to working with you.

Senator HASSAN. Yes. I want to turn to a different topic now. I was really pleased that the Department's proposed budget included $1.6 billion for State Opioid Response grants. These grants have helped New Hampshire improve its response to the fentanyl crisis. In the past, you and I have discussed the program's impact and the importance of continuity of funding here, so our providers can really plan and really work toward an overall comprehensive prevention, treatment, and recovery strategy.

The most recent appropriations language requires HHS to, and this is a quote, "avoid a significant cliff" for any State when allocating funds from year to year. States have to have clarity from the administration regarding how the new funding amounts will be calculated over the next 2 years.

Will you commit to having your staff work with mine to ensure that this information is clearly communicated to States as soon as possible?

Secretary BECERRA. You absolutely have that commitment.

Senator HASSAN. Thank you.

And finally, last week's set of government funding bills contained multiple provisions to support addiction treatment for those on Medicaid. One of these bipartisan measures—which I worked on with Senator Blackburn—permanently requires Medicaid programs to cover all medications used to treat opioid use disorder, a requirement that was set to expire next year.

The funding bill also included bipartisan legislation—which I worked on with Senators Thune and Blackburn—to expand access to short-term residential addiction treatment under Medicaid. Mr.

Secretary, can you discuss how these provisions, now signed into law, will be supported and expanded upon by the program in the President's budget?

Secretary BECERRA. Senator—and first, thank you very much for your commitment to this issue, and for being so dogged in pursuing real results for folks. We are going to try to make sure we are partnering with States and local communities to make sure that they are aware that Medicaid can actually now be more helpful.

We have to wait to see how they structure their programs, because they are the ones that operate them. But we want States to know that Medicaid wants to be in the game.

Senator HASSAN. Okay. Thank you very much, and I yield my time, Madam Chair.

Senator CANTWELL [presiding]. Thank you.

Senator Young?

Senator YOUNG. Thank you, Madam Chair. Mr. Becerra, welcome. It is good to see you again.

Mr. Secretary, HHS can and must play a critical role in advancing access to innovative medical technologies. I know you agree. But the reality today is that many medical technologies authorized by the FDA face significant barriers in securing Medicare coverage. This prevents patient access to key medical innovations.

I am encouraged by CMS's work last year on releasing the long-awaited proposal, Transitional Coverage for Emerging Technologies, or TCET. This would establish criteria for an expedited coverage pathway to provide Medicare beneficiaries with faster access to innovative and beneficial technologies. We are now waiting on a final TCET notice, which we thought would be finalized by the end of last year. I, along with a number of my Senate colleagues, sent a letter to CMS asking for TCET to be finalized as soon as possible, so that patients do not have to continue experiencing delays and barriers in accessing innovative and often lifesaving medical technologies.

Secretary Becerra, given that roughly 7 months has passed since the TCET comment period ended, can you assure us that CMS will issue the final TCET policy this spring or early summer?

Secretary BECERRA. Senator, thank you for the question, and for the work you have done on this particular issue. And by the way, I hope that we continue to work on this, because we are talking about the new frontier when it comes to medicine. So we are trying to make sure we do it the right way. Obviously, there are many eyes that are placed on these new proposals.

What I can commit to you is to make sure that we get this out as quickly as we can. We have to get it right, because we want to make sure people have access to the medicines.

Senator YOUNG. When do you estimate—surely you have an estimate of the time period, right? Would spring be realistic or early summer?

Secretary BECERRA. Senator, honestly, I wish I could say "yes," but I want to be honest with you that the process does not move always as quickly as one would expect. Again, this is not dealing with something we—you know, a movie. This is not a movie we have seen over and over again. This is new stuff. We have to get it right.

Senator YOUNG. What is—for those who are watching and care a lot about this issue, which is many of my constituents—what is the holdup, so to speak? Why is this taking longer than maybe they had expected, because business people and the innovators require certainty, and what are you doing to try and manage some of those dynamics?

Secretary BECERRA. First, we have to make sure that whatever we propose fits within the statutory prescriptions you gave us. So, we cannot go outside of it, and we do not want to be so narrow that it does not do everything you are asking us to do. And that, that takes a lot, because sometimes you all give us specificity in the legislation; sometimes it leaves it somewhat open, and we have to interpret.

Second, we have to make sure that everything we do at the end of the day will be done in the interest of the patients who will be receiving the medications and therapies.

Finally, we have to make sure that whatever we do, we have to be able to look around the corner, to make sure that what we are doing is not impacting something else, where we might end up in court and everything gets delayed because we are in court.

Senator YOUNG. Thank you. So, stepping back, how does HHS plan to address a broader, at least perceived disconnect between the pace of innovation and outdated pathways? I think that is always a dynamic that we are going to be dealing with to some extent, but closing that window will save lives and improve lives immeasurably. So what are your thoughts on that?

Secretary BECERRA. Yes, and remember—as you know, we are working with two different standards that really are at play here. FDA has a standard: before a drug can hit the market, FDA has to say it is safe and it is effective. Then you have a different standard with Medicare, and CMS has to make a determination, not of "safe and effective," but of "reasonable and necessary," two different standards.

And so, a drug gets out because FDA says it is safe and effective; that does not automatically mean Medicare covers it.

Senator YOUNG. So, you struck on sort of the inherent challenge that we are going to be dealing with probably on a going forward basis, unless we change the standard statutorily. But from a management perspective, how are you trying to minimize that delay?

Secretary BECERRA. And that is where we get into the rules and why have they not come out as quickly as you would like, because we have to make sure we are not overstepping our bounds.

Senator YOUNG. Okay.

Secretary BECERRA. And we could use your help, because the more you all direct us, the faster we can move.

Senator YOUNG. If you have thoughts on how we can do that—because you have an army of internal experts, surely they have some ideas about how we might consider optimizing the process. I would welcome this.

Secretary BECERRA. I will take up the invitation.

Senator YOUNG. Okay; fantastic. Well, I will look forward to working with you on that.

And as I come to the end of my time, I will just ask you. There are patient listening sessions—I could itemize some of the chal-

lenges—this is associated with the Inflation Reduction Act. CMS held a number of patient listening sessions.

It would not surprise me if you anticipated a question about this in your hearing. Suffice it to say that they were not perceived by participants to have been particularly helpful. In fact, they created the impression, because of their design, that they were not intended to really gather a lot of information.

So, what are your plans to improve the process so that patient concerns with the IRA changes are fully heard and addressed?

Secretary BECERRA. Senator, I will again offer to take your guidance. If you know of any particular concerns that are being raised, we would love to hear them.

Senator YOUNG. I will submit them to you. There is an itemization. Time does not permit me the ability to unpack about 10 concerns.

Secretary BECERRA. Okay. And we try to reach out, but our funds are limited on doing that type of outreach. Most of our money has to be spent on actually doing something. But we are always looking for ways to try to get feedback from patients.

Senator YOUNG. Thank you, Mr. Secretary.

Senator CANTWELL. Thank you, Senator.

Senator Tillis?

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

I want to get some housekeeping out of the way. I am going to resubmit some questions for the record in this hearing that I submitted back in November to Director Marcos, and I really would like to get a prompt response on today's questions. I am not going to go through them now.

They have to do largely with the facility down in Greensboro, that I do not think I will have time to talk about today. But I have a big concern with the timeliness of it. And I have been in and out because I have tried to get in the order here, but you can see how people come in and out.

But this is beautiful. Nobody's behind me, so I may even be able to ask——

Secretary BECERRA. I remember those days——

Senator TILLIS [continuing]. Extra questions. But yes. Actually, that is one thing I was going to mention. I have spoken with a number of people who have served with you, and they have great things to say about you. I know some of the bipartisan work that you have worked on.

But I do feel like there have been some partisan decisions that you are more or less responsible for implementing that I have a concern with, and I am going to point to drug pricing or price controls in the IRA as one of them.

No question that we can look at that and say that we saved—I think that you mentioned $100 billion. Is that what you mentioned in response?

Secretary BECERRA. That's true.

Senator TILLIS. But what have we lost? I know that shortly after the IRA was implemented, there was at least one call that was shared with us, that showed a double-digit drop in small molecule research, because it has to come from somewhere.

And so, I would be interested if you could maybe submit for the record—unless you have detailed information now—data that would refute the fact that if you take down—I worked in research and development; not in pharmaceuticals, in high-tech.

Margin has to come from somewhere. The money has to come from somewhere, and if you reduce the potential to get compensated for your product, then you just have less money to spend on R&D. It looks like there is a direct correlation to the IRA's price controls and a big dip in small molecule research. If you have any information to refute that, I would like to see it.

We have to get smarter with how we try and drive down drug pricing, because you mentioned in response to someone else that we want to bring manufacturing back home. If you squeeze the margins for a pharmaceutical manufacturer—and we have a lot in North Carolina—then you produce fewer resources to make the case to bring manufacturing home, when we know we are in a more expensive jurisdiction.

So all of these things are interrelated. You cannot, on the one hand, whack this industry and lower prices and then try to get this industry, which has a fiduciary responsibility to their shareholders, to come manufacture at home.

Now, maybe we can get them out of China, but we are not creating a hospitable environment in the United States for them to make these business decisions if we continue to whack them, not to mention that the President, through TRIPS waivers, is even making it more chilling on the pharmaceutical industry in terms of actually being able to defend their intellectual property rights over a period of time to recover the cost of an investment they made in a drug.

If we do not figure out a bipartisan way to deal with this, I will guarantee you, we can have people thrilled about winning the battle, but we are going to lose the war. And when we talk about drug pricing, the last time I checked, a therapy or a drug that was never brought to market costs zero, but so do the human consequences.

So I am going to give that soap box speech, because as you said to Senator Barrasso, there is a lot packed in there. We have to get to the right way to do it, and this is a very dangerous game that we are playing, of just making purely partisan progress on this issue, like arguably the IRA was. There was not a single Republican vote.

I also wanted to cover—one of the advantages of being this far down on the dais is, you get to hear a lot of other people talk. It is another thing that I think we will probably meet with you about separately.

Number one, we have got to get telehealth permanently authorized, period. Anybody who is just asking for another extension does not know how the free market works. The free market works this way. I know that this is the new operating standard from the perspective of the Federal Government, and I also know that there are State impediments that we need to work on. I am doing my part in North Carolina.

But you are not going to get, you are not going to stimulate investment and innovation in telehealth unless they know it is permanent. Businesses do not operate on 2-year horizons, and it has

been stress-tested. All of the naysayers about telehealth before COVID have been proven wrong.

It works. It works at scale. Its efficacy is indisputable. So we need to collectively work on the Federal layer, and then put pressure on the State layer. I have told my colleagues not to come to me in this State and tell me telehealth is good, except for a couple of professions, or except across certain territories. It is irrational, and I reject it before you even walk in my door.

But we need some leadership from the administration—I think from you—to get it done right. And I will submit other questions for the record. Thank you.

The CHAIRMAN. The time of my colleague has expired. We are going to go right to Senator Cantwell here in a minute. But just coming back, I heard my friend—and we have done a lot of work together—talking about manufacturing and bringing it back from overseas if we have bipartisan approaches in terms of issues like R&D.

I will tell you later if I can catch you, I know of such an example. It got 357 votes in the House of Representatives. And kidding aside, I want to work with my colleague.

Senator Cantwell?

Senator CANTWELL. Thank you, Mr. Chairman. Secretary Becerra, good to see you. Thank you so much for your leadership on many fronts.

I wanted to talk about the fentanyl crisis, which has claimed 1,000 people who died in King County, WA in 2023 from an overdose, and we have seen a 425-percent increase in fentanyl-related overdoses from 2020 to 2022, so we are very impacted.

One of the things that researchers—we have had lots of roundtables on this, and I know the President proposed $700 million in substance abuse disorder and mental health treatment, so thank you for that. One of the innovations that has been discussed by Dr. Caleb Banta-Green at the University of Washington is having, basically, health engagement hubs. You could either do this by building capacity at existing health clinics, or you could build hubs that would be available for treatment. Obviously, when we have held our roundtables around the State, the one thing that is really clear is, not enough beds.

And again, then you have all sorts of problems of when you can get people back into treatment. But if you had engagement hubs that were clinics based in big geographic locations, people could access daily the kind of treatments that they needed, and that would help us in addressing this issue.

We have also heard from law enforcement how mobile units could be used in rural areas in helping jurisdictions. So the long and the short of it is, I would assume that you think these are good ideas and innovations, and we want to get CMS's help in some technical assistance on this legislation.

We have had it over with your shop since January, and we want to get some technical assistance. Could you help us speed up this process?

Secretary BECERRA. We are on board.

Senator CANTWELL. Thank you; thank you. Critically, critically important.

I wanted to also ask about the basic health plan, which as you know, you and I have talked about many times. But I believe that it is a very successful program where it exists.

My understanding is that Oregon is rolling this out this summer, so they are finalizing the insurance providers. But are we not seeing how this is driving down the cost of premiums and out-of-pocket expenses, and helping the government, because it is driving more savings for us as well?

I think in the New York BHP program, enrollees are paying zero—well, they are paying a reduced premium, and I think they are up to a million beneficiaries in the program. So could you speak to why you think we should continue to expand from New York and Minnesota and Oregon?

Secretary BECERRA. Senator, I know this has been a program that has worked well in your State, and I know that other States are looking to adopt it. We are interested in having States innovate. We want to be supportive. We have been granting quite a few waiver authorities within the Medicaid program.

What we are interested in is seeing how States test these different operations. We would love to see any number of States take action to try to do what your State, Washington, is doing, what Oregon has done, because we think there are real cost savings that could be had, and we would love to be able to let the State keep some of those cost savings as we save some money at the Federal level, through the various Federal programs that we have: Medicare, Medicaid, and so forth.

Senator CANTWELL. Well, I think it is time. I think, Mr. Chairman—you know, we went through the pandemic, and I think the challenges of the exchange may have gotten buried in the capacity to just deal with the pandemic. But I think it is incumbent on us now to look back at where the exchange has been in driving down cost, and where bundling of lower-end above-the-Medicaid-rate customers to drive a bargain for them in premiums is winning the day, or at least allowing for those who are not insured to get better insurance at a cheaper rate.

And also, we obviously know here, we have our own financial challenges in doing—you know, why pay for an expensive silver plan? Why use Federal tax dollars to pay for an expensive silver plan, when you can bundle up a population above the Medicaid rate, just like when you buy in bulk at Costco and you get a discount.

So I think it is time, given all our financial priorities here, to pay more attention to those States that have implemented. And just to be clear, our State did, was the first BHP before the Affordable Care Act. So, we are not one of the States that have currently successfully moved forward on this, but I am hoping that we will in the near future.

Thank you, Mr. Chairman.

The CHAIRMAN. I thank my colleague from the Pacific Northwest. Whenever you hear Senator Cantwell talk about health care, you often come away saying, "This may be too logical for Washington, DC." But the fact is that dollar for dollar, the concepts that Senator Cantwell has been talking about for years in terms of the Washington basic health plan, the concepts and coordinating services

and the nuts and bolts of rewarding prevention and all this, I am very pleased that once again the Northwest, not just Washington State, is coming around and getting the message out. I look forward to working with her on this and many fronts.

Senator CANTWELL. Thank you.

The CHAIRMAN. Senator Warren?

Senator WARREN. Thank you, Mr. Chairman.

So, President Biden is working to lower drug prices for Americans, and now for the first time, look at the list. Medicare can negotiate the price of prescription drugs; drug companies face penalties when they hike prices above inflation; insulin copays are capped at $35 for seniors and people with disabilities; and all out-of-pocket costs for prescription drugs will be capped at $2,000 for Medicare beneficiaries beginning next year.

Now, President Biden wants to double down on this progress by ensuring that people who don't have Medicare feel the same relief, and I am all for it. There is no reason why Americans should have to pay more for prescription drugs than anywhere else in the world, especially when American taxpayers contribute billions of dollars to the research and development for those same drugs.

Secretary Becerra, do you know how much American taxpayers invest in medical research and development every year, drug research and development?

Secretary BECERRA. Senator, I hope you have that number. I know it's a big amount, but I can get it to you if you do not have it.

Senator WARREN. That's okay; I actually do have it. It's about $115 billion, of which $54 billion is for biomedical research. That's in a single year, and I think this money is well spent. I'm a big fan. It supports the scientific research that we need to develop new therapies and new cures.

But the problem is that big pharma takes these discoveries, turns them into drugs that they can market, and then charges Americans nearly triple what they charge other nations to access the very same drugs that American taxpayers helped develop.

So, Secretary Becerra, do you think that Americans should have to pay more for drugs that their tax dollars help develop than other people around the world?

Secretary BECERRA. Senator, first, in the spirit of competition, we should be able to get prices that everyone else gets. But second, if we put some skin in the game, we should probably be able to get far better pricing.

Senator WARREN. I like your approach on this. You know, charging Americans this much for drugs when we're the ones who help pay to develop those drugs is just greed, pure and simple, and the Biden administration wants to do something about it. So in December, it released a proposal that would allow more companies to produce a drug that taxpayers help develop, if the original drug manufacturer jacked up the price so much that people can't afford it. As you know, this is called "march-in rights," and it would inject some competition into the market and lower drug prices for families.

Now, this law has been on the books for over 40 years, but it has never, never been used, in large part because big pharma has spent

millions of dollars trying to convince policymakers that a drug's price has no impact on whether or not patients can access it. But I have to say, any person who is forced to make difficult decisions between affording their medication and paying rent or trying to put food on the table will tell you that argument is wrong, that if you can't afford to buy the drug, then you don't have access to it.

So, Secretary Becerra, if this draft framework that the Biden administration is working on right now is finalized, what impact would that have for American families?

Secretary BECERRA. Senator, our belief is that this would make the pharmaceutical industry far more competitive. It would also prevent the lockout of manufacturers who are willing to actually sell for competitive prices, and it would probably unlock access to some very crucial medications for more Americans.

And so, on the whole, I think what we're trying to do is fulfill the character of this Nation, to have competition drive what people get.

Senator WARREN. All right. I like this, and I very much appreciate your work on this. In February, I sent a letter with over 70 of my colleagues in the House and the Senate, urging the administration to strengthen and to quickly finalize this proposal that would have the benefits that you describe.

It would stop big pharma's price gouging and ensure that Americans can access the lifesaving drugs that their tax dollars help discover. So please, get this done as quickly and effectively as you can.

Secretary BECERRA. We will try.

Senator WARREN. Good. Thank you, Mr. Chairman.

The CHAIRMAN. I thank my colleague.

Mr. Secretary, it has been a long morning, but I have a couple of areas that I just need to clean up with you. One, as you know, our colleague from Oklahoma, Senator Lankford, was talking about women using dangerous chemicals for abortion. That was essentially the topic of his conversation, and I think he left most people kind of confused about what he was talking about.

I just want to ask you—and Senator Warren's been a great advocate for women in these areas as well—about what this is really all about. This topic is all about the safe, effective alternative to surgical abortion, and whether or not this medicine—which is now responsible for more than 50 percent of the abortions in this country—is going to be available.

That is what the court case is really all about. It stems from, of course, the overturning of *Roe v. Wade.* We are already seeing the consequences of that ruling playing out nationwide, with women being denied the health care they need and deserve.

And if, and I emphasize if the antiabortion activists get their way with mifepristone—which is, as I said, currently before the court—it would effectively be a nationwide abortion ban. Now, you and I served together in the other body, the House of Representatives, and quite some time I think before you came, I chaired the first congressional hearing on what came to be mifepristone. This was back in 1990.

The issue that we focused on then is still the issue of today, and that is, are these decisions going to be made on the basis of science, or are they going to be made on the basis of politics? And I started

arguing in that first hearing, I believe it was 1990, that we ought to make the decisions on the basis of science.

The Food and Drug Administration was activated. It has now been available for years and years, with evidence showing that it is as safe as Tylenol. I just wanted to kind of set the record straight, because what Senator Lankford was talking about with dangerous chemicals and the like, is contradicted by a lengthy set of data sets developed by the Food and Drug Administration.

And I wanted to ask you a question or two on this. If access to mifepristone is rolled back—which is what may happen with this court decision—what would that do to access to health care for women all over the country, in red and blue States?

You know, there was all this discussion about how the States would basically be able to proceed in their own kind of fashion. Now we have seen, with respect to mifepristone, if the antiabortion activists get their way, they could put restrictions or completely make it impossible to get access to the drug at all in every corner of the United States.

But I would like to have the Secretary of Health and Human Services—since we had Senator Lankford, my colleague, talking about it—give me your assessment about what a Federal ban via the courts would do to access to a safe, effective alternative to surgical abortion.

Secretary BECERRA. Mr. Chairman, well, first I think it is important that when you say "safe and effective," you are not just saying that because you believe it. It is because the science has shown that mifepristone, for more than 2 decades, has not only been safe but it has been effective.

If mifepristone were to be lost to Americans who need it as medication, it would further reduce access to care. My daughters, who today have fewer rights to access health care than their mother had, would lose even further access to the care that they need.

It would also mean that more women would probably place themselves in further danger, trying to access the care that they need, which would likely lead us to the scenarios that were very common pre-*Roe,* before 1973, where women would die, women would end up having life consequences, as a result of some of the surgeries or actions that were taken, medical actions that were taken, and it puts us in a place where we have regressed.

But I think, Mr. Chairman, the point that too often is missed is just not mifepristone. Mifepristone went through a process within the FDA to be found safe and effective. Many other drugs, many other medications that Americans rely on, went through essentially the same process of analysis.

If the analysis that was done with mifepristone were to be overturned, it would be very difficult for anyone to conceive that the only result is that mifepristone is taken off of the market. And access to consumers—because there are so many other drugs that went through the same process—that would then be subject perhaps to the same legal challenges on their accessibility throughout America for Americans.

The CHAIRMAN. It is an important point to make, and it is exactly the point that we made more than 30 years ago. I remember in a drafty House Small Business room, where I was chairing this

hearing, we said the second you decide to start making these decisions on the basis of politics rather than science—and we are talking about how the FDA spent literally decades working through the scientific issues with respect to the safety of mifepristone—we are going back to the Wild West.

I mean, you are going back to the days when basically politics and who has the political strength is going to drive decisions that I think the American people, by an overwhelming majority, want to have made through scientists and other policymakers who are not about Ds and Rs, but they are about good science.

I appreciate your bringing this up, and I am continually struck by how the issues we had to wrestle with more than 30 years ago, putting science above politics, are exactly what the challenge is now with respect to mifepristone.

Let me ask you about the Office of Refugee Resettlement, where we heard lots of back and forth and charges leveled against you, and you know, this is an office that works with unaccompanied children. That is their responsibility, and for years and years and years, these were the kids put in cages.

The Trump administration, as far as I can tell, even lost track of them, lost track of where they were. And my understanding is, the Office of Refugee Resettlement, under several statutes, is now working to improve the safeguards for these kids. And as we wrap up, that seems to be a mission that ought to get the support of Democrats and Republicans. Your thoughts?

Secretary BECERRA. It actually should, and as I tried to explain, when Congress passed the laws for placing children who did not have an adult with them who came from the border, our responsibility under the statutes that Congress passed was to provide the temporary care of these children until they were placed with a vetted sponsor.

Once we place that child with a vetted sponsor, our authorities over that child end. That child does not need to communicate with us. The sponsor does not need to communicate with us. So, we do everything we can, including after we discharge the child, to try to follow up, even though there is no requirement that the child or the sponsor get back to us.

We do try to do follow-up to make sure that everything is moving the right way with that sponsorship. And what we are doing is working with the Department of Labor, because they are the ones that track any labor violations that might occur, especially with child labor.

We are trying to work with them to make sure that we let them know what we know about any kids, in the event that some of these children who might be trafficked or used for exploitive child labor are among those who were at one point under our custody.

But we are trying to do everything we can, with the authorities and the resources Congress gives us, to provide the care that you would expect for any child to receive. We do not deal with the immigration circumstance of the child. That is done by the Department of Homeland Security.

We deal with the care under law, as we are required, to make sure that the children are receiving the care that any child in this country should receive.

The CHAIRMAN. So I guess, about 3 hours ago, what I did is tried to take the exact quotes from former President Trump, who claimed that he was going to do so much to lower medicine costs, and he was going to take on big pharma, and he was going to be for more competition.

And then I compared it to the record, which showed none of that. I contrasted it with President Biden and President Biden's conversation with me, and I am sure plenty of other people, shortly after the 2020 election. And we talked about getting rid of big pharma's holy grail, where they could just stop any negotiations, and we talked about price gouging, and we talked about out-of-pocket caps.

And I remember walking off the floor of the U.S. Senate in 2022, late in the summer, and I said, "We actually did it. This is not a debatable proposition. We passed this law. The President of the United States is going to sign it." And I just think it is important, as we wrap up, to make clear that there are differences as deep as Crater Lake, as I said 3 hours ago.

And what the differences are about is values, and the previous administration was sympathetic to the corporate interests, and those corporate interests were driving up health-care costs, particularly big pharma. And what President Biden said, and what I support as our North Star, is getting a fair shake for people without power and without clout, and all those seniors you know.

We now have been able—your people got it to us. Nine million Americans, one out of every seven seniors, are going to benefit in Medicare from the fact that we are negotiating, working to get a fair shake.

So you took a lot of hits this morning. I guess that goes with the turf, but I want you to know I think that what you are doing and the values that support these actions are what the American people want. I look forward to working with you closely in the days ahead.

And for Senators, questions for the record are due next Thursday the 21st, at 5 p.m.

Mr. Secretary, I look forward to talking to you soon.

With that, the Finance Committee is adjourned.

[Whereupon, at 12:52 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) 2025 budget for the Department of Health and Human Services (HHS). I am pleased to appear before you today, and I look forward to continuing to work with you to serve the American people.

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

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

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

In 3 years, the Biden-Harris administration has made the largest investment in behavioral health, which includes both substance use and mental health, in a generation. We are on the path to increasing the number of mental health counselors in schools, have improved support services for high-risk and underserved populations, and trained health-care providers, families, and school personnel on best practices for supporting young people with behavioral health needs, including those taking medications to treat opioid use disorder.

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

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

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

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

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

EXPANDING COVERAGE AND LOWERING HEALTH-CARE COSTS

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

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

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

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

TRANSFORMING BEHAVIORAL HEALTH

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

The budget seeks to expand access to high-quality mental health care, including through a $1 billion investment in the Community Mental Health Services Block Grant. The budget also improves behavioral health benefits for people with Medicare and Medicaid and in the private insurance market, with an emphasis on improving access, promoting equity, and fostering innovation. In addition, the budget invests $1 billion in health information technology adoption for inpatient psychiatric facilities, as well as certain outpatient and residential behavioral health facilities. If we are serious about integrating behavioral health providers into the rest of the health-care system, we must close the technology gap and advance better information exchange with other health-care, public health, and community partners.

The budget also addresses the sobering impact of the behavioral health crisis on our Nation's youth. National surveys of youth have shown significant increases in certain mental health symptoms, including depressive symptoms and suicidal ideation, compounded by the effects of the COVID–19 pandemic. The surveys underscore the urgency and importance of our commitment to equip our youth with the tools they desperately need to address these unique challenges. The budget expands mental health services in schools and bolsters youth mental health programs by investing an additional $50 million in Project AWARE (Advancing Wellness and Resiliency in Education) and an additional $50 million in children's mental health services. These programs provide services to States, Tribes, and communities to support children with serious emotional challenges and their families. The budget also includes $30 million for the Centers for Disease Control and Prevention's (CDC) Es-

sentials for Childhood: Preventing Adverse Childhood Experiences (ACEs) through Data to Action program, which will increase the number of States, territories, localities, and Tribes implementing ACEs prevention strategies and approaches in their communities.

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

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

IMPROVING THE WELL-BEING OF CHILDREN, FAMILIES, AND OLDER ADULTS

The FY 2025 budget invests in the future of our Nation's children through high-quality early childhood education. The budget proposes to guarantee affordable child care to low- and middle-income working families from birth until kindergarten and offer preschool to all 4-year-olds, making early care and education programs affordable and available where families live and work, and increasing wages for early childhood education workers. Under this proposal, preschool would be free and the average family would pay no more than $10 per day for child care until their child starts kindergarten, saving them over $600 per child, per month. This proposal will go a long way to support our most vulnerable children and their families.

The budget continues to bolster Head Start for children from birth to age 5 and provides an additional $544 million for the Head Start workforce, allowing wages to keep pace with inflation and for us to maintain a high-quality child-care workforce. As child care continues to be unaffordable or unavailable for millions of Americans, the budget provides funding to Americans that desperately need it to continue to work and support their families. It also provides an additional $500 million for the Child Care and Development Block Grant to continue our progress in stabilizing the child-care sector and helping more Americans afford child care.

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

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

ENHANCING LONG-TERM CARE IN ALL SETTINGS

HHS programs support the health and well-being of people with disabilities and older adults. The FY 2025 budget includes a 10-year, $150-billion proposal to expand Medicaid home and community-based services to allow more older adults and people with disabilities to receive care at home and in their communities. Recognizing that a strong, well-trained workforce is essential to delivering high-quality services, the budget initiative is designed to enhance the quality of these jobs. When older adults' support needs become so great that they must enter nursing homes, they deserve safe, high-quality long-term care. At the 2024 CR level, State survey

agencies would complete just 65 percent of statutorily required nursing home surveys in FY 2024, down from 100 percent in FY 2022 and 75 percent in FY 2023. To address the increasing workloads and align with the administration's commitments to improve the safety and quality of nursing home care, the budget requests an increase in funding to allow CMS to conduct 85 percent of the mandatory surveys, as well as legislative proposals that strengthen quality and care in long-term care facilities for FY 2025. In addition, the administration's proposal to shift survey and certification funding for nursing home facilities from discretionary to mandatory and increase that funding to conduct 100 percent of mandatory surveys, effective in FY 2026, would allow for sustained and reliable oversight and enforcement in the Nation's nursing homes and ensure that Americans receive high-quality, safe services within these facilities.

STRENGTHENING MATERNAL HEALTH OUTCOMES AND REPRODUCTIVE HEALTH-CARE ACCESS

The budget reflects the administration's commitment to address the U.S. maternal mortality rate, which is higher than all other developed nations and on the rise. The majority of these deaths are preventable, and Black and American Indian and Alaska Native women are disproportionately affected. Across HHS, the budget invests in tackling this maternal health crisis, including $376 million focused on addressing maternal mortality and maternal health equity. This includes targeted funding within the Indian Health Service (IHS) to provide culturally relevant maternal health care in Indian Country, additional funding for CDC to expand maternal mortality prevention, and continued support for the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative in the National Institutes of Health (NIH). It also includes $215 million in HRSA specifically for reducing maternal mortality and morbidity. This funding will improve access to pre- and postnatal care, including for behavioral health, provide access to emergency care services, expand maternal care in rural and underserved communities, and more.

To help improve maternal health coverage and prioritize person-centered care, the budget also includes an optional Medicaid benefit that expands coverage of maternal health support services across the prenatal, labor and delivery, and postpartum periods, with enhanced Federal funding available for the first 5 years in which States take up the State Medicaid option. This includes coverage for a range of maternal health support workers, including doulas. With this benefit, we aim to bolster maternal health supports throughout the entire continuum of care and to demonstrate our dedication to supporting women at every stage of pregnancy and beyond.

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

PREPARING FOR FUTURE PUBLIC HEALTH THREATS

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

This includes $8.9 billion in discretionary funding for preparedness across the Department. The budget invests an additional $38 million for CDC to manage the Response Ready Enterprise Data Integration platform, and an additional $20 million for the Biomedical Advanced Research and Development Authority to invest in medical countermeasures that combat drug-resistant microbes.

Our Nation continues to face emerging public health threats and it is important that we are well positioned to adequately respond. The budget continues to strengthen our domestic supply chain by investing $95 million to accelerate development and domestic production of medical countermeasures, and onshore production of active pharmaceutical ingredients and essential medicines through the Administration for Strategic Preparedness and Response. It also includes $12 million to sup-

port the Food and Drug Administration (FDA) in addressing medical and food shortages and $10 million for a new supply chain coordination office within HHS.

As a continuation of our work to treat and prevent infectious diseases, the budget also includes a new HHS-wide proposal to eliminate hepatitis C infections in the United States. This 5-year program focuses on high-risk populations and will increase access to curative medications, and expand implementation of complementary efforts such as screening, testing, and provider capacity.

ADVANCING HEALTH IN INDIAN COUNTRY

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

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

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

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

ADVANCING SCIENCE TO IMPROVE HEALTH

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

Additionally, ARPA–H will maintain its role as a catalyst for transformation in the health ecosystem—including through its recently announced Sprint for Women's Health. With its $1.5 billion budget, the agency will continue finding real-world solutions for real-world problems, driving biomedical innovation in a variety of arenas.

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

To keep our Nation at the forefront of scientific innovation, we must seize the promise of artificial intelligence—while also managing its risks. NIH is committed to harnessing the power of artificial intelligence to advance research, and has already launched ambitious initiatives to propel the fusion of biomedicine and artificial intelligence and machine learning. In addition, the FY 2025 budget provides re-

sources to oversee artificial intelligence within the Department to advance its responsible use in public health and health care.

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

SUPPORTING PROGRAM OPERATIONS AND MISSION-CRITICAL INFRASTRUCTURE

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

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

A fundamental component of HHS's infrastructure is its cybersecurity capabilities. We have seen a dramatic rise in large data breaches reported to HHS, and the health-care information HHS protects is a prime target for cybercriminals. Our plan sets the direction for cybersecurity in health care, both from a policy and operational lens, and commits HHS to pursuing new priorities to both strengthen and support the sector at this critical time. The FY 2025 budget prioritizes investments to address cybersecurity threats and invests $141 million in cybersecurity initiatives in the Office of the Chief Information Officer to address cybersecurity mandates and allow deployment of cybersecurity initiatives and tools that will keep the Department at the forefront in battling ever-evolving cyber threats. The investment in cybersecurity includes $11 million for the Department's Health Insurance Portability and Accountability Act modernization to increase compliance, enhance the privacy and security of health information, and to improve breach prevention and response efforts. The budget also includes an increase of $12 million above FY 2023 for ASPR as the agency designated to coordinate cybersecurity incident prevention and response in the health care and public health sector. The budget also establishes a Medicare incentive program to encourage hospitals to adopt essential and enhanced cybersecurity practices.

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

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

IMPROVING THE CUSTOMER EXPERIENCE FOR THE AMERICAN PUBLIC

Lastly, I wanted to talk about how we are making government and government programs easier for American people to access and use. HHS is improving customer

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

CONCLUSION

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

I want to thank the committee for inviting me to discuss the President's Fiscal Year 2025 budget for Health and Human Services. I look forward to working with you to fulfill that vision. Thank you for your partnership in advancing our shared goal to improve the health, safety, and well-being of our Nation.

QUESTIONS SUBMITTED FOR THE RECORD TO HON. XAVIER BECERRA

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. Artificial intelligence (AI) systems are currently being developed and deployed across the health-care system to address challenges including workforce shortages, rising costs, and persistent disparities in access to care. The Federal Government in general, and Health and Human Services (HHS) in particular, have a critical role to play in protecting patients and their privacy and, at the same time, fostering innovation.

To this end, the Biden administration has tasked HHS with numerous key responsibilities in AI governance over the last year. In October 2023, President Biden released Executive Order (EO) 14110 on Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence that required HHS to, among other responsibilities, establish an HHS AI Task Force, develop a strategy to assess AI quality, and establish an AI safety program.

However, the HHS FY 2025 budget includes only a single sentence describing investments in the Department's "role in promoting the use of artificial intelligence in health care and public health while protecting against its risks." I am concerned that HHS is not adequately preparing for what are likely to be significant changes across the healthcare system as a result of the widespread deployment of AI systems.

What activities is HHS planning to invest in over FY 2025 with respect to AI?

What steps will HHS be taking to protect patients across the health-care system from harmful AI systems, especially those enrolled in Federal health programs like Medicare and Medicaid?

What is HHS doing to address States and Medicaid managed care entities' use of AI when conducting eligibility and benefits determinations in the Medicaid/CHIP program?

How is CMS assessing and enforcing the requirement that MA organizations make medical necessity coverage decisions "based on the circumstances of the specific individual, as outlined at § 422.101(c), as opposed to using an algorithm or software that doesn't account for an individual's circumstances?"

Answer. On October 30, 2023, President Biden issued an EO [1] to help ensure the safe, responsible deployment and use of AI in the health-care, public-health, and human-services sectors. Among other items, the EO requires the Secretary of HHS, in consultation with the Secretary of Defense and the Secretary of Veterans Affairs, to establish an HHS AI Task Force that shall, within 365 days of its creation, develop a strategic plan that includes policies and frameworks—possibly including regulatory action, as appropriate—on responsible deployment and use of AI and AI-enabled technologies in the health and human services sector (including research and discovery, drug and device safety, health-care delivery and financing, and public health), and identify appropriate guidance and resources to promote deployment. CMS is actively participating in HHS's efforts and building our knowledge and capabilities in this space. We are reviewing the feedback we have received on this issue for potential future rulemaking. In this way, we are positioning ourselves to respond agilely to any developments which could negatively impact beneficiaries of CMS programs and provide guardrails that will enable our programs to safely reap the benefits of these technological innovations.

MEDICAID MANAGED CARE

CMS is committed to partnering with States to help strengthen the monitoring and oversight of Medicaid managed care programs. The increased prevalence of the use of managed care delivery systems over the past several years underscores the continued need for strong Federal and State oversight of Medicaid managed care. CMS has taken a number of steps to support States, including developing a series of technical assistance tools and toolkits that States are encouraged to use to improve the monitoring and oversight of their managed care programs.

The regulations at 42 CFR § 438.210 allow managed care plans to implement prior authorization processes, so long as certain requirements are met. Managed care plans must also comply with the grievance and appeal system requirements laid out in 42 CFR part 438, subpart F, including the requirement that they can only have one level of appeal at the plan level before a beneficiary has access to a State fair hearing under 42 CFR part 431, subpart F. The 2016 Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability Final Rule (CMS–2390–F) clarified that States could offer enrollees the option of an external medical review, as long as the review is provided at the enrollee's option, is not a requirement, and is not used as a deterrent to proceeding to the State fair hearing. Further, if States want to offer enrollees the option of an external medical review, it must be independent of both the State and managed care plan and must be offered without any cost to the enrollee. Some States have utilized this flexibility and chose to offer an external medical review to enrollees when the managed care plan upheld the initial prior authorization denial. In addition, CMS, in January, finalized the CMS Interoperability and Prior Authorization (CMS–0057–F) rule that requires managed care plans, beginning in 2026, to publicly report certain metrics about prior authorization, including the percent of prior authorization requests that were approved, denied, or approved after appeal. The rule also requires managed care plans to make detailed information about prior authorization requests and decisions for items and services (excluding drugs) available to providers electronically, significantly shortens response times for the managed care plan to respond to a prior authorization request and requires that the prior authorization status be made available to enrollees electronically within one business day. In the case of a prior authorization denial, the managed care plan must provide a specific reason for all denied requests. These policies and activities help address concerns about the use of AI in Medicaid managed care.

MEDICARE ADVANTAGE

An algorithm or software tool can be used to assist MA plans in making coverage determinations, but it is the responsibility of the MA organization to ensure that the algorithm or artificial intelligence complies with all applicable rules for how coverage determinations by MA organizations are made.

CMS will conduct both routine and focused program audits of organizations in 2024 to assess compliance with the coverage and utilization management (UM) re-

[1] Available at Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence | The White House, *https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/*.

quirements finalized in the CY 2024 final rule. For Medicare Advantage organizations (MAOs) that have routine program audits scheduled for 2024, these audits will follow our standard process similar to prior years, covering all applicable program areas, but will target the new UM requirements during the Part C Organization Determinations, Appeals, and Grievances (ODAG) review, as well as the Compliance Program Effectiveness (CPE) review. In addition, CMS is also adding new focused audits for plans that don't have routine scheduled audits, which are limited to ODAG and CPE, and are designed specifically to target compliance with the coverage and UM policies in the CY 2024 final rule. Through this combination of routine and focused audits in 2024, CMS expects to evaluate the UM-related performance of plans serving approximately 88 percent of people with MA. This expansion of our audit activity will help make sure that MA beneficiaries get the care they need without excessive burden or delays and have access to the benefits and services to which they are entitled. During both the routine and focused program audits, CMS will utilize physician reviewers to review denied requests to assess whether MAOs are meeting clinical coverage requirements, such as following coverage and benefit conditions included in Medicare laws, National Coverage Determinations (NCD), or Local Coverage Determinations (LCD), and when permissible, applying internal coverage criteria only when coverage criteria are not fully established in statute, regulation, NCDs, and LCDs.

CMS program audits will also ensure that internal coverage criteria are publicly available and otherwise meet regulatory requirements, MAOs are only using physicians (or other appropriate health care professionals) with appropriate expertise in the field of medicine for the service at issue when issuing adverse medical necessity decisions, and MAOs have established UM committees in accordance with regulatory requirements, including who the members of the committee are and the responsibilities they are required to complete.

We will be monitoring closely whether MA plans are utilizing and applying internal coverage criteria that are not found in Medicare laws, NCDs, or LCDs, and whether the internal coverage criteria are publicly accessible and coverage policies meet the regulatory requirements.

CMS has a number of tools it can use to address noncompliance with the new requirements, including issuing compliance and enforcement actions. Compliance actions include Notices of Non-Compliance, Warning Letters, and Requiring Corrective Action Plans.

These policies and activities help address concerns about the use of AI in Medicare Advantage.

Question. In December 2023, the Government Accountability Office (GAO) published a report recommending that HHS take action to achieve consistency with Executive Order 13960 on Promoting the Use of Trustworthy Artificial Intelligence in the Federal Government by retiring AI applications used in manners inconsistent with the EO and keeping up to date its public AI use case inventory. The report found that HHS's public AI use case inventory had data gaps or inaccuracy and incorrectly included research and development use cases.

By when will HHS update its public AI use case inventory to be in compliance with the latest Federal guidance on trustworthy and responsible AI, including the National Institute of Standards and Technology AI Risk Management Framework, EO 14110, and EO 13960?

Answer. On October 30, 2023, President Biden took action by signing EO 14110 on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. As of the date of the hearing, it is our understanding that OMB intends to issue a memorandum about detailed reporting requirements for forthcoming collections of agency AI use case inventories. The Department looks forward to receiving the formal memorandum and detailed reporting requirements (including dates) from OMB and will implement them as directed.

QUESTIONS SUBMITTED BY HON. MIKE CRAPO

UNITEDHEALTH GROUP AND CHANGE HEALTHCARE CYBERATTACK

Question. What tools are currently at your disposal to mitigate the ongoing damage due to the Change Healthcare cyberattack?

How are you ensuring that UHG is providing the needed support to its customers that are heavily reliant on the Change Healthcare IT platforms?

Do you know if any private personal information (PPI) was exposed during this attack?

Answer. We recognize the impact the attack on Change Healthcare has had on health-care operations across the country. HHS has acted with urgency in responding to this incident, and our first priority—as it is with any cyberattack on the Healthcare and Public Health (HPH) sector—has been to coordinate efforts to avoid disruptions to care and protect patient safety. Looking beyond this incident, the Administration for Strategic Preparedness and Response (ASPR) serves as the Sector Risk Management Agency for the HPH sector and HHS has recently established a cybersecurity "one-stop shop" within ASPR to manage collaboration and information sharing with other HHS divisions, the health-care industry, as well as the interagency. Efforts to bolster the sector's cybersecurity will be led from this new office. In December 2023, HHS released a concept paper that outlined the Department's holistic cybersecurity strategy for the health-care sector. In January 2024 the department published voluntary HPH Cybersecurity Performance Goals (HPH CPGs),[2] which are intended to help health-care institutions plan and prioritize implementation of high-impact cybersecurity practices. In the coming weeks and months as we emerge from this attack, we will be focused on developing additional tools, resources, and guidance to help with implementing these HPH CPGs and look forward to working with the sector to help improve its cyber posture.

Additionally, CMS has taken several key actions to support the provider community during this difficult situation, including making available accelerated and advance payments to ease cash flow disruptions experienced by some Medicare providers and suppliers, such as hospitals, physicians, and pharmacists, due to the unprecedented cyberattack that took health care electronic data interchange Change Healthcare offline in February. CMS has also provided flexibility for certain Medicare reporting deadlines. We encourage Medicare Advantage and Medicare Part D plans as well as Medicaid and CHIP managed care plans to offer advance funding to providers, and to remove or relax certain timely filing and prior authorization requirements.

Question. Historically, neither Congress nor CMS has mandated that skilled nursing facilities (SNFs) and nursing facilities (NFs) maintain a minimum nurse staffing level. Most private and public research has recognized the overall complexity of this issue, including how to calculate the so-called right minimum staffing number.

The administration's recently proposed minimum nurse staffing standards rule is a misguided attempt to force increased levels of direct resident care in SNFs and nursing homes. Because one-size-fits-all staffing mandates do not account for individual facility operational capabilities, capacity, and unique workforce conditions, the proposed rule is unlikely to achieve its desired result. Many long-term care facilities, particularly those in rural communities, will be forced to further limit access to care, or they will close altogether.

Do you think it is appropriate for CMS to impose a $40.6-billion unfunded mandate on long-term care providers over the next 10 years without including any Federal resources to assist facilities needing to come into compliance?

Why did the CMS proposed rule fail to include any discussion, relevant research, or economic impact analysis showing the number of long-term care facilities that will be forced to close due to the administration's proposal?

The proposed rule indicates that it will not increase Medicaid costs. The Congressional Budget Office (CBO), however, disagrees. CBO estimates the Medicaid budgetary effects of the proposed rule to be about $8.7 billion over the 2024–2034 period. How confident are you that the administration is not imposing sizeable compliance costs onto State Medicaid programs? Have you discussed this with the Governors?

Answer. Staffing in LTC facilities is a persistent concern, especially among low-performing facilities that are at most risk for providing unsafe care. Numerous studies have shown that staffing levels are closely correlated with the quality of care

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[2] *https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fhphcyber.hhs.gov%2F&data=05%7C02%7CAshley.Charest%40hhs.gov%7C04c2de177f6e4475cecd08dc543aeb76%7Cd58addea50534a808499ba4d944910df%7C0%7C0%7C638477859235644990%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=juRPtubsFn253Sv5dmYXhzVCbGatHFRS%2Fp6P6139jww%3D&reserved=0.*

that LTC facility residents receive.[3] CMS believes that national minimum nurse staffing standards in LTC facilities are necessary at this time to protect resident health and safety and ensure residents' needs are met. At the same time, CMS acknowledges the unique challenges that rural LTC facilities face, especially related to staffing, and recognizes the need to strike an appropriate balance that considers the current challenges some LTC facilities are experiencing.

With respect to the impact of this proposal on long-term care providers, CMS fully expects that LTC facilities will be able to meet the proposed minimum staffing standards. CMS crafted this proposed rule with careful consideration that many LTC facilities will need to recruit, hire, and train new staff. For example, CMS proposed that implementation of the final requirements will occur in three phases over a 3-year period for all nonrural facilities. Rural facilities will have 3 years to meet the proposed 24/7 R.N. requirement and 5 years to meet the proposed minimum staffing requirements. If finalized, the phased-in implementation will be helpful in that facilities may not have to hire nursing staff all at once. We recognize that in some instances, external circumstances may temporarily prevent a facility from achieving compliance despite the facility's demonstrated best efforts. To that end, we proposed to allow for a hardship exemption in limited circumstances. If finalized, LTC facilities could qualify for a temporary hardship exemption from the minimum.

Question. CMS implemented the Acute Care Hospital at Home initiative at the beginning of the COVID–19 pandemic. Hospital at Home allows participating hospitals and health systems to care for Medicare patients, who meet inpatient hospital admission criteria, in the comfort of their own home. Medicare pays the same rate as if the care was provided in the traditional brick and mortar inpatient hospital setting.

While patient satisfaction appears to be high, the Medicare claims data is incomplete. According to MedPAC, the most recent available data shows that 105 hospitals (37 percent of those participating) reported discharges under the Hospital at Home initiative. These hospitals reported 6,100 total patient discharges. Approximately 26 of the largest participating hospitals accounted for 71 percent of that total volume. MedPAC has said that this limited sample size makes evaluating the Hospital at Home initiative extremely challenging. MedPAC also reports that the Medicare claim forms only indicates the Hospital at Home start date and end date. The claim forms apparently do not show the type of practitioner providing medical care to the beneficiary. They do not list the actual medical services furnished to the beneficiary, and they do not indicate whether a caregiver lives in the beneficiary's home. This means that current claims data cannot answer key questions about patient selection, risk adjustment, quality improvement, and financial viability.

The 2023 omnibus extended the CMS initiative through the end of 2024 and required HHS to submit a report to Congress, by September 30th, assessing Hospital at Home utilization, quality, outcomes, and costs. Because MedPAC suggests that more time is needed in order to conduct randomized trials that provide more reliable data, it is unlikely that the HHS report will contain detailed recommendations to Congress.

Has CMS considered extending the Hospital at Home initiative for an additional 3- to 5-year period, under its Centers for Medicare and Medicaid Innovation (CMMI) demonstration authority? Do you believe that would help us understand more about its impact on hospital efficiency, selection bias, participation capabilities in rural and frontier areas, patient outcomes, and overall Medicare spending?

If you have no plans to use CMMI authority to extend the initiative, then what steps do you think HHS and Congress should take given the significant data gaps?

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

Section 4140 of the Consolidated Appropriations Act, 2023, extended this initiative through the end of 2024. This law also requires that additional data be col-

[3] Abt Associates. (2022). Nursing Home Staffing Study Comprehensive Report. Report prepared for the Centers for Medicare and Medicaid Services.

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

Question. The CMS proposed rule entitled, Ensuring Access to Medicaid Services, includes a number of proposals aimed at improving the quality of care for people receiving Medicaid home and community-based services (HCBS). While I share the administration's goal of improving transparency, quality, and access to HCBS, I am concerned that the proposed rule would have the unintended consequence of reducing access to these critical services.

In the proposed rule, CMS requires that at least 80 percent of Medicaid payments for personal care, homemaker, and home health aide services be spent on compensation for the direct-care workforce. Has CMS conducted an analysis of the impact of this requirement on overall Medicaid costs and beneficiary access to these services?

Answer. On April 27, 2023, CMS issued the Ensuring Access to Medicaid Services proposed rule. A substantive component of this proposed rule focuses on improving access to, and the quality of, HCBS. Over the past several decades, HCBS have become a critical component of the Medicaid program and are part of a larger framework of progress toward community integration of older adults and people of all ages with disabilities that spans efforts across the Federal Government. The changes proposed in this rule are intended to strengthen necessary safeguards to ensure health and welfare, promote health equity for people receiving Medicaid-covered HCBS, and achieve a more consistent and coordinated approach to the administration of policies and procedures across Medicaid HCBS programs. CMS presumes that references to the "80/20 proposal" are references to the HCBS payment adequacy policy CMS proposed in this rule, as further described below.

Access to most HCBS generally requires hands on and in-person services to be delivered by direct-care workers. However, direct-care worker shortages are impacting beneficiaries' access to services. In an effort to address direct-care workforce shortages, CMS proposed to require that States ensure that providers spend at least 80 percent of Medicaid payments for homemaker, home health aide, and personal care services on compensation for direct-care workers. We believe that this proposal would not only benefit direct-care workers but also individuals receiving Medicaid HCBS. We believe supporting and stabilizing the direct-care workforce will result in better qualified employees, lower turnover, and a higher quality of care.

This proposal was based on feedback from States that have implemented similar requirements for payments for certain HCBS. These States reported to us through various public engagement activities that similar requirements have had their intended effect of ensuring that a sufficient portion of the payment for Medicaid HCBS goes to compensation for the direct-care workforce. These States also indicated an 80-percent threshold is an appropriate threshold that takes into account the expected portion of payments that are necessary for provider administrative and other costs, aside from direct-care worker compensation. CMS proposed compensation to be defined as salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations; benefits (such as health and dental benefits, sick leave, and tuition reimbursement); and the employer share of payroll taxes for direct-care workers delivering HCBS.

Additionally, this proposed rule would require the establishment of an Interested Parties Advisory Group, to advise and consult with the State on payment rates for direct-care workers. This group would include, at a minimum, direct-care workers, beneficiaries and their authorized representatives, and other interested parties.

Input from stakeholders is an important contribution to CMS's policymaking process and CMS is carefully considering all comments received during the comment period on this proposed rule as we work to develop a final rule.

Question. The Medicaid Drug Rebate Program (MDRP) is critical to ensuring that millions of Americans enrolled in Medicaid have access to lifesaving medications. As intended by Congress, the MDRP both preserves incentives for medical breakthroughs and contains costs for State Medicaid programs.

Last May, CMS proposed a number of changes to the MDRP that threaten to upend patient access to lifesaving therapies and cures. While I agree with many of CMS's objectives in the proposed rule, I remain concerned by the agency's decision to make changes to the MDRP in ways that exceed its statutory authority. In October, I joined 10 of my Senate Finance Committee colleagues in sending a letter to CMS Administrator Brooks-LaSure expressing our concerns with several policies included in the proposed rule.

The proposed rule would require manufacturers to aggregate, or "stack," cumulative discounts, rebates, and other arrangements for purposes of determining a drug's "best price." There is currently no system in place for aggregating this information, and the President's budget request does not mention the need for such a system. How does CMS plan to operationalize and enforce this requirement?

A recent Avalere analysis [4] of the proposed rule noted that, if finalized, the proposed rule may lead to manufacturers restructuring discounts in other markets, including the commercial market. Has CMS considered the impact of this proposed rule on patient access across the prescription drug supply chain?

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

Question. The President's budget proposes to establish a State option to provide 36 months of continuous eligibility for children under the age of 19. The budget justifies this proposal by stating that it will "provide more stable coverage, decrease State administrative burden, and may avoid higher costs by addressing preventable care needs."

Has HHS received feedback from State Medicaid programs that the current requirement to provide 12 months of continuous eligibility to children in Medicaid and CHIP presents an administrative burden?

Answer. Disruptions in Medicaid and CHIP coverage often lead to delayed care, unfilled prescriptions, and less preventive care for beneficiaries. Stable coverage can help establish relationships between providers and families to better address each child's individual needs.

The Consolidated Appropriations Act, 2023 (CAA, 2023), requires that most children under the age of 19 who meet their State's Medicaid or CHIP eligibility requirements remain continuously eligible for coverage for a full 12-month period, effective January 1, 2024. Under this Federal continuous eligibility (CE) policy, children would remain eligible for coverage even if they experience an otherwise-disqualifying change in circumstance (*e.g.,* a change in household composition or income).

Prior to the CAA, 2023, States had the option to provide up to 12 months CE to children under age 19 and could determine both the duration of the CE period as well as the upper age limit for child eligibility. The intended effect of the new Federal CE requirement is to help reduce gaps in children's coverage due to fluctuations in family income or other temporary changes in eligibility status. In addition, CE has the potential to promote health equity by reducing coverage loss in groups disproportionately impacted by disenrollment, reduce administrative burden and costs, and promote uninterrupted access to health-care services for children and youth which is expected to improve their health outcomes.

The FY 2025 Biden-Harris budget builds on the requirement to provide 12 months of continuous eligibility to children in Medicaid and CHIP, enacted in the CAA, 2023, by establishing a State option to provide continuous eligibility from birth until the child turns 6. This will provide more stable coverage for young children enrolled in Medicaid or CHIP, decrease State administrative burden, and may avoid higher costs by addressing preventable care needs.

The budget further builds on the requirement to provide 12 months of continuous eligibility by establishing a State option to provide 36 months of continuous eligibility for children under the age of 19. This works in tandem with the proposal above to promote continuity of coverage for children in Medicaid and CHIP. States

[4] *https://avalere.com/wp-content/uploads/2023/12/Proposed-Changes-to-Best-Price-Could-Shift-Market-Dynamics-for-Stakeholders_1.pdf*

selecting to implement both State options would provide continuous eligibility to children until they turn 6, then continuous eligibility periods of 36 months until they turn 19. This will provide more stable coverage, decrease State administrative burden, and may avoid higher costs by addressing preventable care needs.

Question. The President's budget proposes to reduce reimbursement rates for placements in Qualified Residential Treatment Programs (QRTPs) to 5 percent below each State's Federal match rate. As you are aware, the bipartisan Family First Prevention Services Act, passed by Congress in 2018, established QRTPs as time-limited and trauma-informed care settings to be used only when clinically necessary, with the goal of preparing a child to return safely to their family and community.

Between 2019 and 2021, hospitals saw a nearly three-fold increase [5] in the number of pediatric patients who spent time boarding in emergency departments as they await psychiatric treatment.

How does limiting reimbursement rates for QRTPs help to ameliorate the pediatric boarding crisis currently experienced by hospital emergency departments across the country?

As a justification for this proposal, the President's budget cites "more than 20 studies published over 2 decades" that support that youth fare better in family foster care than in residential care. The Family First Prevention Services Act was enacted 6 years ago.

Do any of the studies cited consider the role of QRTPs in providing care to youth that may need clinically indicated, short-term residential treatment?

Answer. The proposal is one part of the administration's comprehensive child welfare budget proposals. Taken together, these proposals would reduce the number of children entering foster care, and for children who do need to enter care, would ensure more children are placed with kin and fewer are placed in congregate care facilities. This proposal aligns Federal financing with best practices, since most children do best in family settings. Across more than 20 studies published over 2 decades, researchers found that youth in family foster care consistently fared better than youth in residential care on outcomes relating to both internalizing behaviors (such as depression) and externalizing behaviors (acting out). In addition, studies have found that youth in family foster care have better educational outcomes and are much less likely to become delinquent than those who experience residential care.

Question. In its 2025 Medicare Advantage (MA) and Part D proposed rule, CMS seeks to implement certain changes to agent and broker compensation for enrollment. Stakeholders have raised concerns about how the proposed rule operates and what organizations would be subject to the new regulations. Agents and brokers play an important role in helping seniors select and enroll in the MA plan that best meets their needs, and it is important to avoid unintended consequences that could adversely impact beneficiaries.

Does CMS's proposed limit on fees for administrative services only apply to brokers and agents or would it also apply to field marketing organizations (FMOs) and third-party marketing organizations (TPMOs)?

Will you commit to working with relevant stakeholders before issuing any final or future rulemaking in order to ensure seniors continue to have the resources they need to navigate the enrollment process?

Answer. We agree that it is critical to ensure that as the MA and Part D programs continue to grow, they remain viable and that seniors and individuals with disabilities eligible for Medicare can make informed decisions about their health-care coverage, and, when appropriate, enroll in the plan that is best suited to their personal health-care needs. As discussed in the CY 2025 MA and Part D proposed rule, section 1851(j) of the Social Security Act requires that CMS develop guidelines to ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the MA plan that is intended to best meet their health-care needs. We have learned, however, that many MA and stand-alone Prescription Drug Plans (PDP), as well as third-party entities with which they contract (such as field marketing organizations (FMO)), have structured payments to agents and brokers that have the effect of circumventing existing CMS regulations that limit agent and

[5] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9822692/*

broker compensation to specified fair market value (FMV) levels. CMS has also received complaints from different organizations, including State partners, beneficiary advocacy organizations, and MA plans to this effect. A common thread to the complaints is that agents and brokers are being paid, typically through various purported administrative and other add-on payments, amounts that cumulatively exceed the maximum compensation allowed under the current regulations. Moreover, CMS has observed that such payments have created an environment, not dissimilar to what originally prompted us to set limits on agent and broker compensation in 2008, where the amounts being paid for activities that do not fall under the umbrella of "compensation," are rapidly increasing.

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

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

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

Question. Recent years have seen robust advances in radiopharmaceuticals, with respect to both diagnostic tools and therapeutics. In CMS's 2024 Medicare Outpatient Prospective Payment System (OPPS) proposed rule, the agency acknowledged the inadequacy of current OPPS packaging policies to account for diagnostic radiopharmaceuticals (DRPs) in particular, given the high fixed costs, limited radioisotope half-lives, raw material needs, and logistically complex production and distribution processes associated with many of these products.

As a range of medical providers noted in response to the comment solicitation on potential policy alternatives to CMS's current regulatory packing approach, advanced DRPs bear little resemblance to the older contrast and stress agents underlying the agency's initial decision to treat these technologies as supplies for imaging services, with no prospect for separate payment after transitional pass-through (TPT) status expiration. In the absence of a shift in reimbursement policy with respect to DRPs, many, if not most, hospital outpatient departments (HOPDs) will have no choice but to forgo these options, even when medically necessary and clinically appropriate, given the costs and complexities associated with DRP acquisition and administration. As a result, beneficiary access to groundbreaking, safe, and effective imaging services will continue to suffer.

Fortunately, movement away from the current categorical packaging policy would require no congressional action, as the agency first adopted the current methodology in the course of the Calendar Year (CY) 2008 rulemaking policy and presently maintains the tools and authorities needed to modernize reimbursement regulations regarding certain DRPs through the forthcoming CY 2025 OPPS rulemaking cycle, now informed by scores of constructive comments submitted by providers, clinicians, patient advocacy organizations, researchers, and innovators, among other experts and stakeholders, in response to last year's comment solicitation.

Moreover, as the agency rightly recognized in the course of the CY 2024 proposed rule, targeted action on this front could facilitate greater simplicity, streamlining, and consistency across the prospective payment system, particularly if implemented in alignment with existing separate payment policies applicable to other FDA-approved pharmaceutical products that exceed a stipulated cost threshold. This type of approach, as specified under the first option outlined in CMS's solicitation, would

simply extend existing regulatory provisions for other such products to DRPs, with no need for potentially costly or burdensome billing and payment system changes. The adoption of this approach would also trigger no outlay increases under Part B, given the OPPS's requisite statutory budget-neutrality adjustments.

For conditions like prostate cancer, Alzheimer's, and lung disease, along with numerous rare disorders, DRPs have become an indispensable component of the diagnostic imaging process, enabling better-targeted and more effective treatment. In the context of theranostics, for instance, DRPs play a central role in the delivery of therapeutic radiopharmaceuticals. Without access to the former, the latter cannot function.

With these and other considerations in mind, will you commit to leveraging this year's OPPS rulemaking cycle to take the steps needed to ensure meaningful and sustainable beneficiary access to FDA-approved DRPs, when reasonable and necessary for diagnostic and/or treatment purposes?

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

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

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

Question. While CMS understandably turned its attention, in the course of last year's OPPS rulemaking cycle, to DRPs, providers and patient advocates have also raised concerns around access to innovative FDA-approved therapeutic radiopharmaceuticals. To that end, one such product, Azedra, made news in recent years as the first and only FDA-approved radiopharmaceutical indicated to treat pheochromocytoma and paraganglioma, two families of rare and debilitating cancers. Unfortunately, per an announcement from last August, patients will no longer have access to this breakthrough orphan drug, constraining treatment options, due in part to inadequate uptake.

Inadequate reimbursement policies, coupled with the high fixed costs and complexities for therapeutics like Azedra, have made patient access increasingly untenable, with dire implications not just for approved radiopharmaceuticals, but also for the current and future pipelines of rare disease treatments and other cutting-edge therapies.

Will you commit to taking regulatory and subregulatory steps, in partnership with Congress and relevant stakeholders, to ensure that reimbursement policies provide adequate incentives to sustain the availability of breakthrough products like Azedra, as well as to improve access for rare disease treatments writ large?

Answer. We are committed to promoting higher-quality cancer care and improving outcomes for Medicare beneficiaries while reducing costs. The Hospital Outpatient Prospective Payment System (OPPS) pass-through and Inpatient Prospective Payment System (IPPS) New Technology Add-on Payment (NTAP) collectively incentivize hospitals to quickly adopt and promote beneficiary access to innovative technologies through additional payments. Section 1886(d)(5)(K) of the act requires the Secretary to establish a mechanism to recognize the costs of new medical services and technologies under the IPPS.

The OPPS transitional pass-through provisions appear in section 1833(t)(6) of the Social Security Act. Transitional pass-through payments provide additional payment

for new devices, drugs, and biologicals that met eligibility criteria for a period of at least 2 years but not more than 3 years while CMS gathers additional data on the cost of those items. The intent of pass-through payments is to help facilitate patient access to technologies that are too new to be well represented in the data that CMS uses to set OPPS payment rates. While new technology APCs are payments for complete services, pass-through payments are for specific drugs, biologicals, and devices that providers use in the delivery of services. After the pass-through payment period expires, drugs continue to receive separate payment if they exceed the packaging threshold of $135 per day and are not among the types of drugs, biologicals, or radiopharmaceuticals for which payment is packaged.

Question. As CMS continues to progress through the first price negotiation cycle under the central program established under the IRA, patient advocates and providers have raised a number of questions around potential systemic improvements for future cycles, especially with respect to data transparency.

In particular, uncertainty and unpredictability regarding the drugs likely slated for selection, with respect to any given round of the program's process, can complicate planning processes, along with negotiations and transactions across the supply chain, potentially imperiling patient access and triggering needless costs among providers, pharmacies, wholesalers, and other stakeholders. To that end, the publicly available Medicare Part D Drug Dashboard data accessible in advance of the agency's first selected drug announcement last year served as an outdated and poor proxy for the actual outlay window leveraged by the agency as the basis for its selections. Few, if any, analyses attempting to model the first 10 drug selections managed to do so with a high degree of accuracy, even allowing for inherent uncertainty at the margins.

More transparent and readily available data on the drug spending figures used to select medications for inclusion in the program would help to mitigate unpredictability and volatility across the prescription drug supply chain. Furthermore, greater clarity on the agency's approach to identifying which generic or biosimilar products meet CMS's "bona fide" marketing criteria could help to alleviate additional questions and uncertainties, which otherwise risk undermining investments in future candidate generic and biosimilar competitors.

With respect to biosimilars, for instance, pharmacy benefit managers and plan sponsors routinely exclude the lowest-cost biosimilars from their formularies, resulting in anemic utilization, as both the insulin market and the Humira biosimilar landscape have demonstrated. That said, if CMS opts not to treat biosimilars subject to broad formulary exclusions and aggressive utilization management protocols as "bona fide," then their branded reference products could end up with guaranteed formulary placement under the IRA's selected drug stipulations (once Secretary-set pricing applies), further constraining market share for these would-be competitors in favor of branded counterparts.

What steps does CMS, or HHS more broadly, plan to take in order to ensure timelier public access to the cost data underlying drug selection for the program? Does the agency plan to allocate a portion of the $3 billion directed toward implementation for the program to this effect?

Can you commit to providing a more clear and concrete definition for "bona fide" marketing in the context of generics and biosimilars, ideally accounting for the fact that even a marketed and commercialized biosimilar product may see extremely low uptake and utilization based on factors outside of the control of the relevant manufacturer, such as PBM and plan sponsor formulary exclusions or less favorable formulary placement?

Answer. Sections 1191(d)(3)(B) and 1192(d)(1)(A) of the Social Security Act require CMS to identify negotiation-eligible drugs for initial price applicability year 2026 using data on "total expenditures" under Part D during the period beginning on June 1, 2022, and ending on May 31, 2023. Currently, the Part D Drug Spending Dashboard allows for a longer claims run out to provide time for claims to be submitted, processed, and finalized than is possible for the data that CMS is statutorily required to use to identify and rank negotiation-eligible drugs. While CMS works to implement the new prescription drug law, we also plan to continue our annual updates to the Drug Spending Dashboards to provide the public with comprehensive data on trends related to drug spending for people with Medicare and Medicaid.

In the Medicare Drug Price Negotiation Program: Revised Guidance, issued June 30, 2023, CMS clarified the process it will use to determine if bona fide marketing of a generic drug or biosimilar competitor to a potential qualifying single source

drug is occurring for the purposes of drug selection. CMS will review both Prescription Drug Event (PDE) data and Average Manufacturer Price (AMP) data reported by manufacturers. The determination whether a generic drug or biosimilar is marketed on a bona fide basis will be based on a totality of the circumstances, including PDE and AMP data.

CMS clarified that, in addition to monitoring PDE data for a selected drug, CMS will use AMP data reported by manufacturers to determine whether bona fide marketing is occurring when the agency undertakes the process of deselecting a selected drug and monitoring for the continued bona fide marketing of a generic drug or biosimilar. CMS will consider an approved generic drug or licensed biosimilar biological product to be marketed when the totality of the circumstances, including these data, reveals that the manufacturer of the generic drug or biosimilar biological product is engaging in bona fide marketing of that drug or product.

Question. As CMS has acknowledged, certain shifts in the structure of the Part D program, as codified under the IRA, will likely accelerate trends toward more assertive applications of utilization management, as well as additional growth in formulary exclusions and hikes in beneficiary cost-sharing rates.

These mechanisms, if improperly executed, can result in inappropriate pharmacy-counter rejections, as HHS OIG has noted in a number of reports. Moreover, both formulary exclusions and high out-of-pocket costs can substantially depress medication adherence, hindering health outcomes for seniors and driving up medical costs elsewhere in the health-care system. Broad plan exclusions of low-wholesale acquisition cost (WAC) biosimilar alternatives to Humira present a case in point, as beneficiaries continue to incur inflated-list-price-based coinsurance for branded Humira or high-WAC biosimilars, sometimes abandoning their prescriptions altogether and suffering avoidable adverse reactions as a result.

What specific steps has CMS taken, and does the agency plan to take, to ensure a sufficiently robust formulary review process that requires clinically appropriate decision-making and meaningful P&T committee engagement in the development process, in accordance with existing statutory, regulatory, and subregulatory requirements?

Can you commit to issuing guidance or other forms of regulatory or subregulatory action to clarify the agency's consideration of factors like cost-sharing (*i.e.,* when evaluating plan selection of higher-cost versions of therapeutically equivalent products), utilization management protocols, and other formulary structures in reviewing formularies for compliance with general requirements, as well as with beneficiary protections against practices likely to discourage enrollment by certain groups of patients, such as those who utilize high-list-price/high-rebate products but face unduly high cost-sharing obligations that fail to account for rebating?

Does the agency plan to undertake any transparency efforts with respect to oversight and enforcement in terms of formulary design and utilization management regulatory and subregulatory compliance, given the implications of inappropriate or violative practices for beneficiary plan selection?

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

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

tity designing the formulary must base "clinical decisions on the strength of scientific evidence and standards of practice."

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

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

QUESTIONS SUBMITTED BY HON. DEBBIE STABENOW

Question. In a September 2023 Finance Health Care Subcommittee hearing on "Aging in Place: The Vital Role of Home Health in Access to Care," witnesses testified that the current Home Health Prospective Payment System, implemented in 2020, has led to cuts to home health that threaten access to these vital services for patients nationwide. These cuts particularly threaten access to care for patients in rural communities. The President's budget includes a proposal to convert the expanded Home Health Value-Based Purchasing Model into a permanent Medicare program.

How will this proposal help protect access to home health services for patients, and what other actions can Medicare take to support and expand home health services?

In addition to facing uncertainty due to the Medicare payment system, home health agencies face ongoing challenges due to the workforce shortages impacting the entire health-care sector. Home health agencies face increased difficulties recruiting and retaining staff due to the shortage of nurses and aides that provide care in the home.

What actions is the Centers for Medicare and Medicaid Services taking to increase certainty and stability for home health providers?

Answer. The Home Health Value-Based Purchasing Model, which the CMS Innovation Center launched in 2016 and expanded nationwide in 2022, successfully improved the quality of home health care at lower cost without evidence of adverse risks. The FY 2025 Biden-Harris budget proposal would convert the expanded model into a permanent Medicare program, similar to value-based purchasing programs already in place for other Medicare providers.

The original Home Health Value-Based Purchasing (HHVBP) Model provided financial incentives to home health agencies for quality improvement based on their performance relative to other agencies in their State. The HHVBP Model aimed to improve the quality and efficiency of home health services to Medicare beneficiaries. CMS first adjusted Medicare payments by up to ±3 percent in 2018. Payment adjustments increased each year, peaking at up to ±7 percent in 2021, the last year of the original HHVBP Model prior to the nationwide expansion of the model in January 2023.

With respect to Medicare payment rates, CMS updates the rates it pays to home health agencies (HHAs) for providing home health services annually as the statute requires. The Calendar Year (CY) 2024 final rule finalized routine, statutorily required, updates to the home health payment rates for CY 2024. CMS estimates that Medicare payments to HHAs in CY 2024 will increase in the aggregate by 0.8 percent, or $140 million, compared to CY 2023.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. I am a supporter of more transparency, and I am glad the Department of Health and Human Services (HHS) has continued Trump administration rules to require price transparency from hospitals and insurance companies. More needs to be done. We know that 47 percent to 65 percent of hospitals are not fully complying. I am working with Senators Braun and Sanders to ensure actual prices, not estimates, are listed and payers have access to their data.

Can you explain to me why 65 percent of hospitals are not complying, yet CMS has only fined 14 hospitals?

Please do not tell me you're robustly enforcing the law when you have only fined 14 hospitals.

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. The hospital price transparency regulation became effective January 1, 2021, and requires each hospital operating in the United States to make public its standard charges for the items and services it provides. After significant outreach and technical assistance to hospitals, hospitals have made substantial progress since the hospice price transparency regulation went into effect in January 2021.

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. Between September and November 2022, CMS conducted website assessments of 600 hospitals randomly sampled from Homeland Infrastructure Foundation-Level Data. Of the 600 acute-care hospitals sampled for the 2022 analysis, 493 (82 percent) posted a consumer-friendly display that met the consumer-friendly display website assessment criteria, 490 (82 percent) posted a machine-readable file that met the website assessment criteria, and 421 (70 percent) did both. The results of this website assessment suggest that there has been substantial progress in hospitals' implementation efforts since the Hospital Price Transparency regulation first went into effect, although approximately 30 percent of hospitals must still do more to achieve full compliance. 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.

In the CY 2024 Hospital Outpatient Prospective Payment System (OPPS), CMS finalized policies to strengthen compliance and improve the public's understanding and automated use of hospital information. CMS finalized a requirement for hospitals to display their standard charge information by conforming to a CMS template layout, data specifications, and data dictionary. These changes will increase standardization to help deliver on the promise of hospital price transparency, improve hospitals' ability to comply, enhance the public's ability to aggregate information (for example, for use in consumer-friendly displays), and streamline CMS's ability to enforce the requirements. Additionally, CMS finalized several regulatory additions and modifications to its enforcement provisions to improve CMS enforcement capabilities and increase transparency. These include submission of certification by an authorized hospital official as to the accuracy and completeness of the data in the machine-readable file and submission of additional documentation as needed to determine hospital compliance; submission of an acknowledgement of receipt of the warning notice in the form and manner and by the deadline specified; notification to health system leadership of compliance action; and publication on the CMS website CMS's assessment of a hospital's compliance, any compliance action taken and the status or outcome of such action, and notifications sent to health system leadership.

As of September 2023, CMS had issued approximately 989 warning notices and 631 requests for CAPs since the initial regulation went into effect in January 2021. Approximately 346 hospitals were determined by CMS after a comprehensive compliance review to not require any compliance action and approximately 738 hospitals received a closure notice from CMS after having addressed deficiencies indicated in a prior warning notice or a request for a CAP following an initial comprehensive compliance review. At the time of the publication of the CY 2024 OPPS/ASC proposed rule, we had imposed civil monetary penalties (CMPs) on four hospitals and publicized those CMP impositions on our website.

Question. I have been a consistent advocate for pharmacy benefit manager (PBM) transparency and accountability. While there is a lot Congress should do, changes to the Medicare Part D direct and indirect remuneration (DIR) fee clawback was a step in the right direction. These changes should not create cash flow challenges for rural pharmacies. At my urging, CMS used its bully pulpit last year and put PBMs on notice to protect rural pharmacy access during these changes.

Can you update me on the efforts CMS has taken since the beginning of the year to protect rural pharmacies? Have you put any PBMs on notice?

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

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

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

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

We are committed to ensuring beneficiaries have access to necessary health services. We value the critical role pharmacies play in health-care delivery and recognize that we must address the needs of pharmacies to serve our beneficiaries effectively. We will continue to engage with stakeholders and consider policies for inclusion in future rulemaking that would lower prescription drug costs for beneficiaries, address challenges that pharmacies face, and improve the quality of pharmacy care.

Question. I am glad CMS is implementing the 1,000 graduate medical education slots I helped add as then-chairman of the Finance Committee in 2020. However, I am concerned about the lack of slots going to rural communities. The law requires CMS to distribute 10 percent of slots to rural hospitals. CMS has told me in writing they intend to meet this threshold over a 5-year period. I realize CMS can only award slots based on applications submitted, but the agency can do a better job educating potential applicants. We know exposure to rural health care during a medical student's residency is associated with a greater likelihood of practicing in a rural area.

Can you have CMS follow-up with me between now and the end of the month on specific actions it's taken to educate rural applicants since July 2023?

The deadline to apply for the next 200 slots is March 30, 2024, so it's important I understand what actions the agency has taken since last summer.

Answer. The training and retention of physicians are both critical to ensuring access to health care in underserved and rural communities that historically have experienced workforce challenges.

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[6] *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-2-november-6-10.*

To support rural hospitals, CMS has worked in conjunction with the Health Resources and Services Administration's (HRSA's) Office of Rural Health Policy to educate potential applicants about the section 126 application process. On February 13, 2023, and January 17, 2024, CMS participated with HRSA and the Rural Residency Planning and Development—Technical Assistance Center in webinars aimed at educating potential rural applicants about the section 126 application process. CMS has also participated in the rural health and hospital open door forums and is committed to providing timely and accessible responses to anyone who submits a question through our section 126 email inbox at CAA126application@cms.hhs.gov. In addition, background information regarding the section 126 application process and frequently asked questions are posted on CMS's Direct Graduate Medical Education website.

Question. The President has announced a "strike force" to ease health-care costs.

Are you aware that HHS has finalized over 85 health-care regulations since 2021 that have imposed over $23 billion in costs to patients, providers, and taxpayers?

Answer. The Biden-Harris administration has delivered health care to millions more Americans while also lowering health-care costs. The administration continues to build on, strengthen, and protect Medicare, Medicaid, and the Affordable Care Act, including through the American Rescue Plan Act and the Inflation Reduction Act to lower prescription drug costs in Medicare and health insurance premiums for marketplace consumers. As a result of these efforts, more Americans have health insurance than under any other administration and are better protected against surprise medical bills and junk fees. Individuals with Medicare are already seeing lower prescription drug prices with insulin cost sharing capped at $35 per covered product per month's supply, no out-of-pocket costs for certain recommended vaccines under Medicare Part D, and annual Medicare Part D out-of-pocket costs for prescription drugs capped at $2,000 in 2025. The administration is well on its way to lowering the cost of drugs as Medicare negotiates the prices of certain high-expenditure prescription drugs for the first time ever. The Biden-Harris administration has also taken steps to make sure consumers aren't scammed by junk insurance and have better access to mental health care.

Question. In December 2022 and October 2023, I wrote to you about concerns that HHS had prioritized speed over the safe processing of Unaccompanied Alien Children (UAC), which includes serious failures in the sponsor vetting process.[7] Although your Assistant Secretary for Legislation provided a letter on March 13, 2024, supposedly in response to my letters, the responses were insufficient. It is important that HHS provide Congress with sufficiently detailed information and requested records so that we may conduct thorough and independent oversight of the Office of Refugee Resettlement, its vetting process, and the disastrous effect its failed processes have had on innocent children.[8] Accordingly, I ask that you respond to the requests below, and I once again reiterate the unanswered information requests from my previous letters.[9]

For sponsors who claim to be a relative or parent of the child, please provide data for what percentage of potential sponsors have been determined to have made a false claim of family relationship, and describe what steps were taken in those instances to punish these individuals for making a false claim or providing false documents.

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[7] Letter, Senator Charles E. Grassley, Ranking Member, Committee on the Judiciary, to the Hon. Xavier Becerra, Secretary, Department of Health and Human Services (December 12, 2022), *https://www.grassley.senate.gov/download/grassley-to-dept-of-health-and-human-services_-uac-placements;* letter, Senator Charles E. Grassley, Ranking Member, Senate Budget Committee, to the Hon. Xavier Becerra, Secretary, Department of Health and Human Services (October 12, 2023), *https://www.grassley.senate.gov/imo/media/doc/grassley_to_hhs_-_uac_sponsor_vetting.pdf.*

[8] Letter, Assistant Secretary for Legislation, Melanie Anne Egorin, Ph.D., to Senator Charles E. Grassley, Ranking Member, Committee on the Budget (March 13, 2024), on file with committee staff.

[9] Letter, Senator Charles E. Grassley, Ranking Member, Committee on the Judiciary, to the Hon. Xavier Becerra, Secretary, Department of Health and Human Services (December 12, 2022), *https://www.grassley.senate.gov/download/grassley-to-dept-of-health-and-human-services_-uac-placements;* letter, Senator Charles E. Grassley, Ranking Member, Senate Budget Committee, to the Hon. Xavier Becerra, Secretary, Department of Health and Human Services (October 12, 2023), *https://www.grassley.senate.gov/imo/media/doc/grassley_to_hhs_-_uac_sponsor_vetting.pdf.*

Answer. HHS's Office of Refugee Resettlement's (ORR) sponsor suitability assessment process includes verifying the sponsor's relationship to the child. This is accomplished by speaking with the child's parents when possible, conducting separate interviews with the child and sponsor, and collecting supporting documentation to verify the sponsor's information. For the child's safety, the process also administers background and address verification checks, which include public records and sex offender registry checks, as well as FBI fingerprint checks in certain cases. The potential sponsor must provide at least one form of evidence of the relationship they claim to have with an unaccompanied child, such as a birth certificate, marriage certificate, death certificate, court records, guardianship records, hospital records, schools records, or a written affirmation of relationship from a Consulate. Voluntary DNA testing is used for sponsors and unaccompanied children to establish biological relationships when other proof of relationship is unavailable or unverifiable.

During the period of January 21, 2021, through January 23, 2024, ORR received 401,288 sponsor applications for unaccompanied children. Within this time period, ORR denied 7,926 potential sponsor requests, and 7,966 potential sponsors withdrew from consideration.

Question. Your March 13, 2024, response letter states that on February 13, 2024, ORR published policy and procedure revisions to its sponsor vetting requirements. Those revisions appear to include the reintroduction of background check requirements for Category 2 potential sponsors, including immediate family relatives, potential sponsors' adult household members and adult caregivers. According to your response, these revisions supersede ORR issued Field Guidance #11, which ended background check requirements for most Category 2 sponsors for nearly 3 years.[10]

Please provide all records, including data and analysis compiled by HHS, on how Field Guidance 11 impacted the safety of unaccompanied alien children, and how this data was used to reinstate background check requirements for all category 2 sponsors.[11]

What processes does ORR have in place to ensure that these recently reintroduced background checks and requirements are followed during the vetting and placement process?

Why did HHS ORR decide to reinstate these background checks, and was any assessment conducted to determine the impact of the removal of background check requirements in the previous Field Guidance #11 on the safety and well-being of unaccompanied children?

Answer. ORR continuously reviews its sponsor vetting requirements and assessment processes and develops and refines policies, procedures and practices to further streamline and strengthen the screening of sponsors, without sacrificing child safety or unduly extending the time children remain in ORR's care. The latest changes reflect ORR's ongoing commitment to prioritize child welfare and safety while minimizing the time children spend in congregate care settings—consistent with child welfare best practices and ORR's legal obligation to place children without undue delay. The updated policies build upon longstanding vetting procedures as well as operational and technological improvements within the Unaccompanied Children (UC) Program. These changes improve the verification process, strengthen home study policies and guidance, incorporate child welfare outcomes and sponsorship history, expand background check requirements, and ensure third-party review for all cases.

This administration inherited a significantly underresourced UC Program with less than half of the needed shelter capacity in 2021. The prior administration imposed a months-long hiring freeze on ORR and its grant recipients, severely restricting the capacity to serve children referred to ORR care and address the needs of the UC Program in 2021. In FY 2020, ORR's bed capacity was insufficient to serve even 8,000 children in care. As of March 2024, ORR has updated its infrastructure

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[10] Department of Health and Human Services, Administration for Children and Families, Office of Refugee Resettlement, Field Guidance #11, Temporary Waivers of Background Check Requirements for Category 2 Adult Household Members and Adult Caregivers (March 31, 2021), *https://www.acf.hhs.gov/sites/default/files/documents/orr/FG-11%20Temporary%20Waiver%20of%20Background%20Check%20Requirements%202021%2003%2031.pdf*.

[11] "Records" include any written, recorded, or graphic material of any kind, including letters, memoranda, reports, notes, electronic data (emails, email attachments, and any other electronically created or stored information), calendar entries, interoffice communications, meeting minutes, phone/voice mail or recordings/records of verbal communications, and drafts (whether or not they resulted in final documents).

to have a standard network capacity with more than 12,000 beds and the ability to activate influx care facilities more quickly, so that ORR can care for all children referred to its custody. In addition to drastically expanding its capacity to serve unaccompanied children, ORR has made multiple improvements to its case management system, including: modernizing the UC Portal—the UC Program's data system—with child safety improvements, such as standardizing addresses and sponsor's names and making it easier to identify and flag potential child welfare concerns during sponsor suitability assessments and aid case managers in making informed decisions regarding home studies; now providing 7-day-a-week case management for family unification services; entering into Memoranda of Agreement with the Office of Trafficking in Persons (OTIP), National Center for Missing and Exploited Children (NCMEC), a nonprofit organization established by Congress, and the Department of Labor (DOL); and expanding access to post-release services (PRS) to children released from ORR care from just over 20 percent in FY 2021, to offering access to PRS to approximately 59 percent of children released from ORR care in FY 2023.

Question. Please provide in detail all policies HHS has in place to ensure the safe handling of children by government contractors and grantees, including temporary housing for UACs and transferring children to sponsors. In responding to this request, name what steps HHS takes to ensure children are able to report instances of abuse by Federal contractors and grantees and are informed of the processes in place to safely file those reports.

In responding to this request, please also provide data for reports of abuse at any UAC housing facility since January 1, 2022, broken down by facility and sorted by date;

Provide a copy of all contracts for UC care providers, and the costs for each Federal contract, including subcontracts.

Are there any instances in the past five years where contract employees have had access to children without or before completing criminal background checks? If so, which contractors, and why was this allowed?

Answer. HHS and ORR have a zero-tolerance policy for all forms of abuse and maltreatment and have implemented a number of safeguards designed to protect unaccompanied children in ORR facilities. ORR requires all care providers to report incidents affecting a child's health, well-being, and safety. Care providers must report on a wide range of incidents from behavioral incidents to allegations of sexual abuse, via Significant Incident Reports (SIRs) as described in UC Program Policy Guide Section 5.8. SIRs are filed for a variety of reasons in accordance with policy and procedure, including to document observations that may not necessarily affect immediate health and safety but that are valuable for enabling ORR care providers to meet children's individualized needs; to document allegations of sexual harassment or abuse, physical abuse, and child neglect; and to document threats to children from traffickers or criminal actors or other acts of fraud, and serious health or mental health issues. Following any report of abuse, ORR ensures that care provider facilities: (1) report the allegation to the appropriate investigative authorities, such as child protective services, the State licensing authority, local law enforcement, HHS's Office of Inspector General, and/or the Federal Bureau of Investigation (FBI); (2) cooperate with any investigation of the allegation; and (3) take immediate action to protect the victim and the safety of other children at the facility—such as separating the victim from the perpetrator, increasing supervision, housing changes, and/or transfers.

In accordance with UC Program Policy Guide Section 4.3.8, any care provider contractor or volunteer accused of sexual harassment or sexual abuse is immediately suspended until investigation of the incident is completed by the relevant authorities. Such incidents will result in termination if allegations are substantiated. Further, per UC Program Policy Guide Sections 4.7 and 4.10.1, ORR provides multiple, easily accessible methods for children and youth to report sexual abuse, sexual harassment, inappropriate sexual behavior, and staff Code of Conduct violations. Care providers must inform all children of policies for preventing, detecting, and responding to sexual abuse and sexual harassment, and the care provider's policies and procedures must include provisions for staff to accept and respond to such reports.

All staff, including contractors, grant recipients, and deployed Federal volunteers, are required to undergo thorough background checks, even during times of an increased number of children referred to ORR's custody. All personnel working with ORR must be compliant with all Federal child-care services background check re-

quirements and ORR's employee background investigation policy, and must pass public record criminal background, sex offender, and State Child Abuse and Neglect (CA/N) checks. Care providers must also meet State licensing requirements. In addition, ORR has new procedures in place to help care providers navigate circumstances in which CA/N check results are delayed or impossible to obtain. Given that some CA/N check results take longer than 30 days or the relevant State(s) do not provide CA/N check results, ORR care providers are permitted to onboard prospective personnel (staff, contractors, and volunteers) on a provisional basis and subsequently transition them off of their supervision plan during the pendency of CA/N checks only when certain conditions are met. Personnel must complete all requirements for working under supervision for 30 days and then ORR may approve the care provider's request to transition the individual off of the supervision plan. This is further outlined in UC Bureau Policy Guide, Section 4.3.3.2. ORR routinely monitors its care providers' policies and procedures to assess the documentation and adherence to required background checks, the frequency of checks, and the roles and responsibilities of individuals involved in the process.

The response to Question #31 below includes the ORR grant recipients and contract vendors from January 1, 2021, through March 14, 2023. Additional information regarding grants and contracts are available on *https://sam.gov/* and *https://grants.gov/*.

Question. Please describe in detail all processes ORR has in place to follow up with UACs after placement with sponsors, and provide data broken into the following categories for sponsors placed by ORR since January 1, 2022 (divided by month):

The total number and percentage of 30-day wellness check calls made;

The total number and percentage of wellness check calls answered and not answered, in absolute numbers and as a percentage of total unique calls attempted;

If the number of unique calls attempted is less than the total number UACs placed with sponsors in a given month, an explanation for the discrepancy;

Provide a copy of HHS's written policies and procedures detailing steps taken if wellness check calls are unanswered and contact cannot be made with sponsors after the first attempt; and

Provide all records related to all actions HHS has taken to reestablish contact with children whose sponsors failed to answer these wellness check calls.

Answer. While ORR's custodial responsibilities end when a child is discharged, ORR has policies in place to promote children's well-being as they transition into a new community, providing children with multiple ways to connect with ORR or community support services following their sponsor placement, such as through safety and well-being calls, post-release services, legal services, or the 24/7 ORR National Call Center (ORRNCC), which connects children and sponsors with community resources and is required to report all safety concerns identified by callers to ORR and other Federal, State, and/or local entities. While safety and well-being call data since FY 2023 shows that ORR has been able to make contact with a child, the sponsor, or both in 83 percent of these follow-up calls—which are voluntary for children or their sponsors to participate in—safety and well-being calls are just one of the variety of ways for children to be connected to additional community supports. In fact, ORR has expanded PRS to a historic level, and ORR is committed to expanding access to PRS even further to include all children by the end of FY 2024, as appropriations allow. Notably, ORR does not have the authority to remove a child from a home—that authority resides with law enforcement and State child welfare agencies. ORR recognizes the critical importance of its coordination and engagement with these agencies.

Per ORR's UC Program Policy Guide section 2.8.4, care providers must conduct a safety and well-being follow-up call with an unaccompanied child and their sponsor 30 days after the release date. The purpose of the follow-up call is to determine whether the child is still residing with the sponsor, is enrolled in or attending school, is aware of upcoming court dates, and is safe. The care provider must document the outcome of the follow-up call in the child's case file, including if the care provider is unable to contact the sponsor or child after reasonable efforts have been exhausted. If the follow up call indicates that the sponsor and/or child would benefit from additional support or services, the care provider must refer the sponsor or child to the ORRNCC and provide the sponsor or child the ORRNCC contact information. If the care provider believes that the child is unsafe, the care provider must

comply with mandatory reporting laws, State licensing requirements, and Federal laws and regulations for reporting to local child protective agencies and/or law enforcement. Additional information regarding required reporting of events related to an unaccompanied child's safety and well-being is available in UC Program Policy Guide section 5.8.

Question. In an October 6, 2023, "Fact Sheet" released by ORR it claimed that, "[a]s a part of the placement process, potential sponsors must undergo a criminal public records check, and in most cases, a sex offender registry check. When there is a safety concern for release to a related sponsor or when considering release to an unrelated sponsor, ORR also conducts background checks on adult household members and individuals identified in a potential sponsor's care plan."[12]

Please describe any exceptions to sponsors being required to undergo criminal public records checks, and the numbers of sponsors who have not undergone such background checks as a percentage of total sponsors by sponsorship category.

Please describe what cases do not require a sex offender registry check, and the reasons for this omission, as well as documentation of any changes in procedure made since 2021.

Please describe and provide all written policies for how ORR determines whether or not there is a "safety concern" about a related sponsor and the total number of identified household members who have not been subject to a background check, broken down by year since this policy was changed.

For background check results, provide a numerical breakdown of all hits within the criminal and sex offender category.

Does HHS take any steps to determine if a sponsor is connected to a cartel or other organization involved in transnational organized crime? If so, please describe those steps, to include interaction with other government agencies and database searches, as well as how that information is shared between agencies and whether HHS is notified by other agencies if they have information relevant to UAC sponsors.

How many potential sponsors have been identified as connected to cartels? Has HHS ever placed a UAC with a sponsor where available information showed the sponsor may be connected to a cartel? If so, when and how many times?

Please provide your written policies and any data you have collected concerning release of UACs to unrelated sponsors and the safety of those placements.

Provide all records documenting any instructions you have made to ORR or any other person or component within HHS requesting they expedite processing of UACs, and all records documenting any concerns expressed about those instructions by anyone, including contractors or HHS employees.

Answer. ORR has thorough sponsor screening and vetting processes in place for each category of sponsor. These categories are for parents or legal guardians (Category 1), or other specified family members (Category 2), as well as more distant relatives or unrelated sponsors (Category 3), often identified by the child's parent. ORR's process for the safe and timely release of a child from Federal custody includes several steps such as: separate interviews with the child and sponsor and with the child's parents, if available; a sponsor application; address checks, and requirements for supporting documentation; background checks including public records and sex offender registry checks; and in some cases, FBI fingerprint checks; as well as home studies as required in certain circumstances by the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA), or mandated by ORR policy. Additional details on this process are available in ORR's UC Program Policy Guide Section 2: Safe and Timely Release from ORR Care.

Per ORR policy, a public records check and sex offender registry check is required for potential sponsors in all categories. ORR also requires FBI fingerprinting for certain immediate relatives who were not previously the child's primary care giver and nonrelative sponsors. ORR may also require FBI fingerprinting for parents, legal guardians, immediate relatives who previously cared for the child, and nonsponsor adult household members and adult caregivers identified in a sponsor care plan in

[12] Department of Health and Human Services, Administration for Children and Families, Office of Refugee Resettlement, ORR Influx Care Facilities for Unaccompanied Children Fact Sheet (October 6, 2023), *https://www.acf.hhs.gov/sites/default/files/documents/orr/icf-uc-fact-sheet.pdf*.

certain cases, such as when the public records check reveals possible disqualifying factors; where there is a documented risk to the safety of the unaccompanied child; the child is especially vulnerable; and/or the case is being referred for a home study.

ORR requires a background check search of State CA/N registries maintained by individual States for certain cases, such as for potential sponsors in any category where a special concern is identified. In cases where a sponsor is required to undergo a CA/N check, all non-sponsor adult household members and adult caregivers identified in a sponsor care plan generally must receive the CA/N checks.

In accordance with UC Program Policy Guide section 2.5.1, Category 3 potential sponsors, which include distant relatives and unrelated sponsors, must undergo a public records background check of criminal history and sex offender registry databases, as well as a fingerprint background check processed through the FBI. Category 3 nonsponsor adult household members and adult caregivers identified in a sponsor care plan must also undergo a public records background check of criminal history and sex offender registry databases, as well as an FBI National Criminal History Check in certain cases. In cases that require a home study or where a special concern is identified, Category 3 potential sponsors must also undergo a CA/N check.

ORR continuously reviews its vetting policies and procedures for ways to improve its processes to promote the safety and well-being of children and to be more efficient and effective. For instance, on June 2, 2023, HHS released the results of its audit of the vetting process for potential sponsors who have previously sponsored an unaccompanied child, to ensure all necessary safeguards are in place without unnecessarily keeping children in government-funded, congregate care settings.

On February 13, 2024, ORR published policy and procedure revisions that enhance its sponsor vetting requirements. Among other enhancements, these revisions require parents and legal guardians (Category 1) sponsors to provide proof of address documentation (already a requirement for all other sponsors) and also requires, at minimum, sex offender registry checks for all adult household members and adult caregivers, including in Category 1 cases. The revisions also require, at minimum, proof of identity and criminal history public records background checks for all adult household members and adult caregivers, with a narrow exception for certain Category 1 cases such as where there are no safety concerns. These recent revisions also strengthen and expand home study policies and guidance to include mandatory home studies for potential sponsors of more than two children, regardless of the potential sponsor's relationship to the children. The February 2024 policy revisions supersede Field Guidance 10, 11, and 15. Additional information on sponsor vetting can be found in UC Program Policy Guide Section 2.

Question. According to a report by *The New York Times,* citing "five people familiar with the call," you told Ms. Cindy Huang, then ORR Director, that, "if she could not increase the number of discharges [of UACs], [you] would find someone who could," and that you "made a similar threat to her successor."[13] Are these reports true? If so, why did you issue these instructions, and what specific steps did you order to prevent the increased processing pace from endangering the safety of UACs? Please provide all records documenting those instructions.

Provide a list of all employees who were transferred, terminated, or threatened with any adverse action after expressing any feedback concerning the ORR vetting process or concerns about any aspect of ORRs placement of UACs.

Provide the name and personnel file for the employee referenced in the Florida grand jury report, who was "fired for reporting a case of suspected human trafficking (of over 100 UAC shipped off to a single house in Texas) to a government hotline because her ORR superiors refused to investigate the matter." When responding to this request, include all records related to the underlying matter, including the names of the HHS supervisors the employee reported the matter to, the entire file related to any internal investigation conducted, and all records related to their response to these reports.

Answer. HHS is committed to upholding the legal rights of and protecting whistleblowers, including by ensuring its policies abide by all applicable whistleblower protections statutes and reporting directives in annual Federal funding laws. Whistleblower protections are a key mechanism for ensuring the safety and well-being of

[13] *New York Times, supra* n. 13.

all children in ORR care and the staff providing such care. HHS and ORR do not tolerate any threats or retributory actions against whistleblowers.

Any time ORR becomes aware of information that could impact the safety of children, it conducts a review and puts additional safeguards in place if needed. In addition to HHS's mandatory supervisory whistleblower trainings, ACF has worked closely with HHS OIG to provide additional mandatory whistleblower trainings for all ACF staff, including ORR staff, and ORR has also worked with OIG to provide additional trainings for ORR grant recipients and contractors.

Questions regarding specific whistleblower complaints are best directed to HHS OIG as the division that handles such claims should a whistleblower choose to file a report.

Question. At the hearing, you were asked about a February 2024 HHS Office of Inspector General (OIG) report which found that "Gaps in Sponsor Screening and Follow-up Raise Safety Concerns for Unaccompanied Children."[14] In your response, you stated that, "I can assure you that most of the recommendations that were made by the Inspector General for incidents you are referring to, incidents that occurred back in Spring of 2021, a 2 or 3 month period, I can assure you that what was being observed by the Inspector General back then is not the case today. If you recall, at that point we had an infrastructure that had been virtually dismantled . . . and at that point we were dealing with an influx of children."[15] Documents in my possession show HHS even created a "UCMigration" email address in 2021 for employees to report potential trafficking flags to HHS's Administration for Children and Families (ACF), which further shows HHS was aware of potential trafficking in the program by at least July 2021.

When did HHS first become aware that required background checks or other safety steps had not been conducted, and did HHS take any steps to fix these problems and conduct the missing background checks after the problem was identified?

When in 2021 were you first alerted to trafficking concerns?

How many cases of potential human trafficking, abuse, or neglect, did HHS identify in 2021? When were those identified, and who did HHS notify with this information? Was law enforcement notified? If so, which agencies?

Did HHS instruct contractors to omit any required sponsor or household member background checks or other requirements of law or HHS policy due to the "influx" of migrant children, and if so, when was that instruction issued, to whom, and for what reason? If not, why did HHS officials overseeing contractors allow these steps to be omitted?

Why did you and others at HHS repeatedly place an emphasis on the speed of processing unaccompanied children if there was a major "influx" that made it difficult to accomplish the needed background and other safety checks?

Did HHS later conduct, or contract for, any data analysis of its placements in 2021 to determine which children were placed without background checks or to determine whether there were any signs of trafficking activity or other danger for those children who may have been missed during the "influx" period? If so, was information about potential trafficking or potential criminal activity referred to law enforcement? If it was, which agencies received that information, and what action was taken? If not, why didn't HHS take these basic steps when it was aware a problem existed?

Please describe any actions ORR took to reestablish contact with sponsors who UACs were released to and actions that ORR took to vet the sponsors to ensure children were not released into dangerous situations.

Were any of the incidents during this 2 or 3-month period covered by the OIG report, or at any time throughout 2021, referred to law enforcement? If so, please provide information on the number of cases and the reason for referrals to law enforcement.

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[14] Department of Health and Human Services, Office of the Inspector General, "Gaps in Sponsor Screening and Follow-up Raise Safety Concerns for Unaccompanied Children" (February 15, 2024), *https://oig.hhs.gov/oei/reports/OEI-07-21-00250.asp*.

[15] U.S. Senate Committee on Finance, full committee hearing, "The President's Fiscal Year 2025 Health and Human Services Budget" (March 14, 2024), *https://www.finance.senate.gov/hearings/the-presidents-fiscal-year-2025-health-and-human-services-budget*.

How many concerns were sent to the email address established by HHS in July 2021, and how were they acted upon? Were suspicious sponsors identified, and were any children removed from sponsors' homes as a result of that information? Please provide all records related to this email address and actions taken as a result of information obtained through it.

Please provide all data and analysis sufficient to establish your claim that any issues that existed in 2021 are no longer present in the UC sponsor vetting process. This data and analysis should cover all relevant categories related to safe placement of UACs, including sponsor background checks, address verification, authenticity of identity documents, sex offender registry checks, conducting of home studies, public records searches, etc.

Answer. When ORR receives a report of suspected labor exploitation or trafficking involving an unaccompanied child, ORR implements a range of actions as appropriate to the situation to both respond to the allegation and provide additional safeguards for other unaccompanied children if applicable. These actions can include immediately halting discharges to specific locations (utilizing street information) or individual sponsors; mandating home studies and/or supervisory reviews prior to case approval, which may already be required in certain cases; conducting welfare phone calls and/or in-person visits; and flagging for the State's child welfare agency, local law enforcement, Office on Trafficking In Persons (OTIP), and other relevant entities for certain locations and a geographically appropriate radius around those locations.

All trafficking reports are provided to the Department of Homeland Security (DHS) and OTIP. Specifically, ORR requires care providers to notify stakeholders like DHS and OTIP of all suspected trafficking or exploitation concerns within 24 hours. ORR and OTIP also work closely with DOL, which provides notice to OTIP when it detects indicators of trafficking affecting potential minors and can flag particular trends or cases related to labor exploitation more broadly. Further, the ORRNCC notifies local law enforcement and child welfare agencies—the entities with the authority to determine whether to remove the child from their current home.

HHS takes OIG recommendations very seriously and is committed to continuing to improve the UC Program, including through efforts to implement OIG's recommendations. Notably, ORR has already addressed many of the concerns raised by OIG as the report focused on a specific period, March through April 2021, during one of the most challenging periods in ORR's history amid a historic number of unaccompanied children placed in ORR care and at the height of the COVID–19 pandemic. ORR continuously reviews its intensive vetting policies and procedures for ways to improve its processes to be efficient, effective, and ultimately promote the safety and well-being of children.

Since April 2021, when OIG's review concluded, ORR has made substantial process improvements based on child-welfare principles to ensure the safety and well-being of unaccompanied children through comprehensive case management and enhanced technology, data gathering, and analytics. For instance, ORR provides 7-day-a-week case management, specifically for family unification services, and ORR has updated the UC Portal, the UC Program's data system, to enhance usability and search functionality. These updates and new features ensure that sponsors' records are accurately and comprehensively obtained and accessible across the entire network of care providers. The improvements build in safeguards and make it easier to identify and flag potential child welfare concerns during sponsor suitability assessments and aid case managers in making informed decisions, including regarding home studies.

In addition, in 2020, the prior administration imposed a months-long hiring freeze on ORR and its grant recipients, severely restricting the capacity to serve children referred to ORR care during the time of the OIG review. Since then, ORR has increased its staffing capacity to a level that can manage significant numbers of children in ORR's care. ORR appreciates the support from Congress to be able to increase staffing capacity and welcomes continued resources and flexibilities to hire additional staff in a timely manner in the event of another influx of unaccompanied children entering ORR care.

Question. The February 2024 OIG report found that in 35 percent of children's case files during the time period analyzed, sponsor-submitted IDs contained leg-

ibility concerns.[16] According to legally protected whistleblower disclosures to my office, HHS contractors often use third-party apps like WhatsApp to collect these identity documents from potential sponsors and lacked sufficient training to identify fraudulent documents. This raises serious concerns about the steps HHS is taking, or failing to take, to establish the identity of potential sponsors and their alleged family relationship to unaccompanied children. As you know, the category of the sponsor determines whether background checks are conducted, which means robust procedures to establish identity are critical to the safety of migrant children.

Has HHS permitted contractors to receive identity documents through third-party messaging apps? If so, do they still use such apps to collect identity documents and what steps are in place to assure the documents are authentic?

What steps has HHS taken, or will it take, to assure that all files where identity documents are partly or totally illegible are reviewed to ensure the identity documents provided are authentic and a clear copy is on file?

How have your policies and procedures for identifying fraudulent documents, receiving identity documents, and establishing family relationship based upon these documents changed since the time period examined by the HHS OIG in its February 2024 report?

Does HHS or its contractors and grantees ever place children in the custody of someone other than the sponsor, for example, when the child is transported to the sponsor's custody and another person is designated to pick up a child at an airport or bus station? If so, how is the identity of that person established and their connection to the sponsor?

Answer. ORR trains staff to use several robust tools to verify the identity of potential sponsors. All potential sponsors must submit original versions or legible copies of government-issued identification documents.

For verification of the relationship claimed with the child, the potential sponsor must also provide at least one form of evidence such as a birth certificate, marriage certificate, death certificate, court records, guardianship records, hospital records, school records, a written affirmation of relationship from a Consulate, or other similar documents.

If there are discrepancies or concerns that an unaccompanied child may be using fraudulent foreign identification documents, the ORR case manager may ask the respective consulate of the country of which the child is a national to verify the authenticity of the identification document and, in certain cases, to interview the child to inquire about family history (subject to restrictions on mandatory/non-mandatory notification contacts to countries as demonstrated in UC Program Policy Guide section 5.4.3). The respective consulate may also be able to provide a family tree that can be used by the ORR case manager and the consulate during assessments and interviews to determine any discrepancies.

Voluntary DNA testing is also used for sponsors and unaccompanied children to establish biological relationships when proof of relationship otherwise does not exist (*e.g.,* when documentation is unavailable or unverifiable). In these instances, the ORR case manager notifies the ORR Federal Field Specialist (FFS) and the Case Coordinator to recommend a DNA test be conducted.

If a sponsor, household member, or adult caregiver provides any false information in the application of release and/or accompanying documents or submits fraudulent documents for the purpose of obtaining sponsorship of the child, ORR reports the incident to the HHS OIG. ORR can deny release if it is determined that fraudulent documents were submitted during the application of release process.

ORR staff supervise and escort unaccompanied children until they are placed in the care of another ORR facility or a vetted family member or sponsor. This transportation is coordinated, and clearly communicated to all appropriate parties, from an ORR facility to a vetted family member or sponsor or to another ORR facility that is ready and awaiting the arrival of the child.

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[16] Department of Health and Human Services, Office of the Inspector General, "Gaps in Sponsor Screening and Follow-up Raise Safety Concerns for Unaccompanied Children" (February 15, 2024), *https://oig.hhs.gov/oei/reports/OEI-07-21-00250.asp*.

Question. At the hearing, I asked you whether HHS provides information to law enforcement without a subpoena being required.[17] You didn't answer my question. You instead said you work with law enforcement, while trying to protect the privacy of children and sponsors. Recent news reports state that reports of missing and runaway migrant children to HHS's national call center have spiked during the current administration from fewer than 500 in 2020 to over 2,700, more than five times as many, in 2022.[18] As these reports indicate, often local authorities know nothing about unaccompanied children placed in those communities, since they aren't notified before the placement. Yet, when children go missing, local law enforcement often turn to HHS for help, since HHS ORR has pictures of the children, as well as birth certificates, medical history, demographic information, and often contact information for family members living in the U.S. Nonetheless, as these reports indicate, HHS is not responsive to their requests and often fails to provide information needed to locate these children. This is beyond unacceptable.

What specific legal or regulatory provisions does HHS believe prevent it from sharing information that would assist law enforcement in locating a missing child?

What are HHS's policies for cooperating with law enforcement when they request information on a missing child?

Why would HHS refuse to provide information about missing unaccompanied children to local law enforcement in a timely manner?

Answer. If ORR care provider staff, such as a case manager or clinician, identifies or suspects any safety concerns at any point during their interaction with an unaccompanied child either while a child is in ORR care or post-release through a safety and well-being call, they are required to issue a Notification of Concern to ORR and notify appropriate investigative agencies, including local law enforcement and child protective services. This includes any suspicion that the child has run away, is at risk of or posing a danger to themselves or others, or is at risk of human trafficking, exploitation, or other abuse. ORR then conducts further review and determines what actions should be taken, which may include additional reporting and engagement with local law enforcement, State child welfare authorities, and/or referral for post-release services such as timely referrals and connection to community resources or intensive services, in cases where additional support is needed to address a child's specific needs or challenges. It is important to note that ORR, as a Federal agency, cannot remove a child from a home; that authority resides with State child welfare and law enforcement agencies. ORR recognizes the critical importance of its notification and coordination processes to ensure that local authorities can respond appropriately to any allegations of abuse or neglect.

If ORR care provider staff suspect that a child is a victim of trafficking or is at risk of trafficking at any point during their interaction with an unaccompanied child, per ORR policy, they must make a referral to the Department's ACF Office on Trafficking in Persons (OTIP) and to DHS's Homeland Security Investigations (HSI) Division and DHS's Center for Countering Human Trafficking for further investigation. OTIP provides further assessment assistance to ensure that victims can access appropriate care and services. Such care is then coordinated with ORR to provide direct referrals for grant-funded comprehensive case management services, medical services, food assistance, cash assistance, and health insurance tailored to the child's individual needs.

The ongoing partnership with DOL and third-party entities such as NCMEC, as well as HHS's collaboration with other Federal, State, and local government entities and national and community partners, are crucial to HHS's continuous commitment to protect and respond to the needs of unaccompanied children who may be at risk of or victims of exploitation, including child labor exploitation. These children face unique challenges that require a whole of government response—and HHS takes its part in this work seriously.

ORR shares information with investigative agencies, such as local law enforcement, in accordance with UC Program Policy Guide section 5.10, and in accordance

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[17] U.S. Senate Committee on Finance, full committee hearing, "The President's Fiscal Year 2025 Health and Human Services Budget" (March 14, 2024), *https://www.finance.senate.gov/hearings/the-presidents-fiscal-year-2025-health-and-human-services-budget*.

[18] Kristian Hernandez and Karen Rodriguez, *When migrant children disappear, many cases remain unsolved,* The Center for Public Integrity (February 23, 2024), *https://publicintegrity.org/inequality-poverty-opportunity/immigration/migrant-children-disappear-cases-unsolved/*.

with each respective agencies' mandate and authority, while not releasing information that is outside the scope of their investigation.

Question. A report from *The New York Times* noted that there is an "increasing share of migrant children [who] could not be reached by HHS after a month [from placement with a sponsor]."[19]

What are the FY 2023 numbers for how many children could not be reached by HHS after a month?

Answer. While ORR's custodial responsibilities end when a child is discharged, ORR has policies in place to promote children's well-being as they transition into a new community, providing children with multiple ways to connect following their sponsor placement, such as through safety and well-being calls, post-release services, legal services, or the 24/7 ORR National Call Center (ORRNCC), which connects children and sponsors with community resources and is required to report all safety concerns to ORR and other Federal, State, and/or local entities.

While safety and well-being call data for FY 2023 and since shows that ORR has been able to make contact with a child, the sponsor, or both in 83 percent of these follow-up calls—which rely upon voluntary participation of children or their sponsors. Safety and well-being calls are just one of the variety of ways for children to be connected to additional community supports. ORR has expanded PRS to a historic level, and ORR is committed to expanding access to PRS even further to all children by the end of FY 2024, as appropriations allow. Notably, ORR does not have the authority to remove a child from a home—that authority resides with law enforcement and State child welfare agencies. ORR recognizes the critical importance of its coordination and engagement with these agencies.

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

Question. That same report from the *The New York Times* noted a surge in monthly calls to HHS reporting trafficking, neglect, or abuse of minors placed with sponsors.[20]

How many children have called the hotline to report abuse, neglect, or trafficking, broken down by year?

What percentage of the calls to your hotline do you follow up with, and who conducts this follow up?

In what manner is the follow-up conducted (*e.g.,* by phone, in person, etc.)?

Have any children been removed from sponsors' homes as a result of calls to your hotline?

When is information received during hotline calls provided to local law enforcement? Please provide your policies and procedures for such referrals.

Answer. Upon their release, ORR provides unaccompanied children with information on the ORRNCC, a 24-hour, 7-day-a-week resource not only for released children, but their family members, sponsors, legal service providers, child advocates, and other members of the community who can request assistance or report concerns to the ORRNCC on a child's behalf. The ORRNCC reports matters of safety concern

[19] Hannah Dreier, "As Migrant Children Were Put to Work, U.S. Ignored Warnings," *The New York Times* (April 17, 2023), *https://www.nytimes.com/2023/04/17/us/politics/migrant-child-labor-biden.html*.
[20] *Ibid.*

to ORR and refers and reports to the appropriate local law enforcement or other authority, such as child protective services. Further, under ORR's UC Program Policy Guide, any grant recipient or contractor who works with or encounters unaccompanied children after their release from ORR care is required to report any concern about the child's safety and well-being to ORR and to the appropriate investigative agencies. Suspected trafficking concerns are reported to ACF OTIP, which provides further assessment assistance to ensure that victims can access appropriate care and services.

In February 2023, ORR finalized a data-sharing MOA with OTIP and NCMEC that will facilitate information sharing to protect unaccompanied children who are victims of exploitation or trafficking or at risk of being such victims. ORR also 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 will also connect children directly with the appropriate authority when possible, and place a follow-up call to the child to confirm if any further actions are needed.

If at any point during an interaction with an unaccompanied child, either while in ORR's care or post-release such as through a call to the ORRNCC, ORR care provider staff identifies or suspects any safety concerns, they are required to issue a Notification of Concern to ORR and notify appropriate investigative agencies, including local law enforcement and child protective services. This includes any suspicion that the child has run away, is at risk of or posing a danger to themselves or others, or is at risk of human trafficking, exploitation, or other abuse. ORR then conducts further review and determines what actions should be taken, which may include additional reporting and engagement with local law enforcement, State child welfare authorities, and/or referral to PRS.

While ORR does not have authority to remove a child from a home—that authority resides with State child welfare and law enforcement agencies—ORR recognizes the critical importance of its notification and coordination processes to ensure that local authorities can respond appropriately to any allegations of abuse or neglect. For this reason, ORR has engaged multiple child welfare agencies on the needs of unaccompanied children. However, State child welfare agencies vary in capabilities and these local and State entities also need robust resources to help ensure their ability to review or investigate such allegations.

With regard to the increase in the number of safety and abuse reports received by the ORRNCC in recent years, notably, there has been an unprecedented increase in the number of children referred to ORR's care and custody since FY 2021. Further, HHS has worked to build awareness and education around safety concerns, and improved outreach, training, and efforts to reduce stigma for victims of trafficking have resulted in an increase in individuals coming forward. Therefore, an increase in reports also reflects the fact that ORR's improved reporting policies are working.

Question. Please provide a step-by-step explanation of the process law enforcement must go through to obtain records from the Office of Refugee Resettlement (ORR) on the following: an unaccompanied alien child, the sponsor of an unaccompanied alien child, and adult household member(s) of an unaccompanied alien child.

How are law enforcement requests processed by ORR?

On average, how long does it take to provide a response?

On average, how long does it take to provide to an exigent request?

Under what circumstances does ORR require law enforcement to send a subpoena or court order to obtain records relating to an unaccompanied alien child, sponsor, and/or adult household member from an ORR database?

Please cite the specific statute and/or regulation that requires law enforcement to serve a subpoena or court order on ORR to receive this information.

Describe all steps taken to ensure ORR is providing law enforcement a complete return on its request.

Please provide an annual breakdown of the number of responses ORR has provided to law enforcement and include the following information for 2018, 2019, 2020, 2021, 2022, and 2023:

Number of times ORR was served with a subpoena or court order.

Number of times ORR responded to a law enforcement request without requiring a subpoena or court order.

Number of times ORR failed to respond to a law enforcement request.

Number of times ORR responded to a law enforcement request with a redacted production of records.

Number of times ORR responded to a law enforcement request with a complete return on the requested information.

Number of times ORR responded to a law enforcement request with a partial return on the requested information.

What law and/or regulation authorizes ORR to redact information provided in response to law enforcement requests?

Answer. If ORR care provider staff, such as a case manager or clinician, identifies or suspects any safety concerns at any point during their interaction with an unaccompanied child either while a child is in ORR care or post-release through a safety and well-being call, they are required to issue a Notification of Concern to ORR and notify appropriate investigative agencies, including local law enforcement and child protective services. This includes any suspicion that the child has run away, is at risk of or posing a danger to themselves or others, or is at risk of human trafficking, exploitation, or other abuse. ORR then conducts further review and determines what actions should be taken, which may include additional reporting and engagement with local law enforcement, State child welfare authorities, and/or referral to PRS. It is important to note that ORR, as a Federal agency, cannot remove a child from a home; that authority resides with State child welfare and law enforcement agencies. ORR recognizes the critical importance of its notification and coordination processes to ensure that local authorities can respond appropriately to any allegations of abuse or neglect.

If ORR care provider staff suspect that a child is a victim of trafficking or is at risk of trafficking at any point during their interaction with an unaccompanied child, per ORR policy, they must make a referral to the Department's ACF Office on Trafficking in Persons (OTIP) and to DHS's Homeland Security Investigations (HSI) Division and DHS's Center for Countering Human Trafficking for further investigation. OTIP provides further assessment assistance to ensure that victims can access appropriate care and services. Such care is then coordinated with ORR to provide direct referrals for grant-funded comprehensive case management services, medical services, food assistance, cash assistance, and health insurance tailored to the child's individual needs.

The ongoing partnership with DOL and third-party entities such as NCMEC, as well as our collaboration with other Federal, State, and local government entities and national and community partners, are crucial to our continuous commitment to protect and respond to the needs of unaccompanied children who may be at risk of or victims of exploitation, including child labor exploitation. These children face unique challenges that require a whole of government response—and ACF takes its part in this work seriously.

For incoming requests, ORR shares information with investigative agencies in accordance with its policy in section 5.10[21] of the UC Program Policy Guide and in accordance with each respective agencies' mandate and authority, while not releasing information that is outside the scope of their investigation. Investigative agencies may also use the case file records request process outlined in section 5.10.1[22] of the UC Program Policy Guide. Requests for case file records are eligible for expedited processing within seven (7) calendar days and may be further expedited at ORR's discretion due to the time-sensitive nature of the request. According to UC Program Policy Guide Section 5.10.1,[23] if the requesting party does not provide the signature of the sponsor, potential sponsor, or sponsor household member, ORR redacts all information pertaining to those individuals where information may be reflected in other types of unaccompanied children case file records.

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[21] *https://www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied-section-5#5.10*

[22] *https://www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied-section-5#5.10.1*

[23] *https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-section-5#5.10.1*

ORR UC Program Policy Guide section 10.1[24] outlines which case file information is restricted from release. ORR does not release certain information to the public or through case file requests that could present a potential safety risk or violate the privacy of children currently or formerly in care. In such cases (*i.e.,* release to the public or through case file requests), ORR does not release information in children's case files pertaining to sponsors, potential sponsors, or sponsor household members without their written consent. ORR may also redact law enforcement-sensitive information, as well as information protected by privacy considerations. ORR will not release the following categories of information through the case file request process unless this information is required to be provided in response to a lawfully issued court subpoena, court order, or other court litigation; or pursuant to federal investigation:

Internal communications, such as memoranda and emails by care provider staff or ORR, to the extent they are included in the case file (not all such emails and memoranda are considered case file information);

Internal care provider incident reports;

Sponsor Assessments;

Family Reunification Packets;

Background check results;

Foster parent information; and/or

Information pertaining to other unaccompanied children who are not the subject of the information requests, unless they are siblings of the child whose information is being requested.

Question. Please provide a complete list of grantees or contractors who have provided services related to Unaccompanied Alien Children since 2021. Please provide to Congress an un-redacted and complete copy of each contract or grant.

Answer. Provided below are lists of ORR grantees and contract vendors from January 1, 2021, through March 14, 2023. Additional information regarding grants and contracts are available on *SAM.gov* and *grants.gov*.

Grantees

A Greater Love Foster Family Agency, Inc.	A New Leaf, Inc.
A Tender Love and Care, Inc	Abbott House
Adore Children and Family Services, Inc.	Alba Care Services, Inc.
Applied Intellect LLC	Ark Homes Foster Family Agency
BCFS Health And Human Services	Berkshire Farm Center and Services for Youth
Bethany Christian Services of Michigan	Bethany Christian Services USA LLC
Bethany Home	Board of Child Care of the United Methodist Church
Bokencamp	Building Bridges Foster Family Agency
Catholic Charities of The Archdiocese of Miami Inc.	Catholic Charities of The Archdiocese of San Francisco
Catholic Charities of The Diocese of Galveston-Houston	Catholic Guardian Services
Cayuga Home for Children DBA Cayuga Centers	Center for Family Services, Inc.
Center for Juvenile Management Inc.	Chicanos Por La Causa, Inc.
Child Crisis Arizona	Children's Community Programs of Connecticut, Inc.
Children's First Residential Care	Children's Home of Kingston
Children's Home of Poughkeepsie	Children's Village

[24] *https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-section-5#5.10*

Church World Service, Inc.
Compass Connections
Comprehensive Health Services, LLC
Cplc Texas, Inc.
Crittenton
David and Margaret Youth and Family Services
Devereux Foundation
Dynamic Service Solutions LLC
Endeavors Eagle Lake Children's Center
Ettie Lee Homes Inc.
Family Endeavors, Inc.
Florence Crittenton Services of Orange County
Friends of Youth
Grace House Children's Shelter
Gulf Coast Jewish Family and Community Services
Gwen Mikeal Village
Hands of Healing Residential Treatment Center, Inc.
Hanna's House
Heartland Human Care Services, Inc.
Heartshare St. Vincent's Services
Hillsides
His House Inc.
HOH Casa Harlingen
HOH Case Sunshine
Holy Family Institute
House of Hope
Incarnation
Inspire Georgia
Inspiritus, Inc.
International Rescue Committee Inc.
JCCA
Jewish Child Care Association, New York
Juan Pirtle Center
Kids In Crisis, Inc.
Kidspeace National Centers, Inc.
La Salle School
Latin American Youth Center
Latino Family Institute
Leary Educational Foundation Inc.
Liberty Wilderness Crossroads Camp, Inc.
Lincoln Hall
LSSS Upbring
Lutheran Family Services Rocky Mountains Denver
Lutheran Family Services Rocky Mountains Fort Collins
Lutheran Immigration and Refugee Service
Lutheran Services Florida, Inc.
Lutheran Social Services of Metropolitan New York,
Lutheran Social Services of Michigan
Lutheran Social Services of The South, Inc.
Marsell Consulting and MHS
Maryville Academy
Mckinley Children's Center, Inc.
Mercy First
Michigan Department of Labor and Economic Opportunity
Morrison Child and Family Services
Nafi Connecticut, Inc.
National Youth Advocate Program, Inc.
Neighborhood Ministries, Inc.
New Life Foster Family Agency
Noank Community Support Services, Inc.
Nueva Esperanza—Neighborhood Ministries
Nuevo Amanecer Latino Children S Services
NYAP, Phoenix, AZ
Pioneer Human Services
Rancho San Antonio Boys Home, Inc.
Responsive Deployment LLC
Rising Ground, Inc.
Rite of Passage, Inc.
Ruby's Place
Samaritas
Seton Home
Sheltering Arms Children and Family Services, Inc.

Shenandoah Valley Juvenile Detention Home
Shiloh Treatment Center, Inc.
Southwest Key Programs, Inc.
St Christopher's, Inc.
St. Peter St. Joseph Children's Home
St. Vincent School for Boys
Sunny Glen Children's Home
The Baptiste Group, LLC
The Villages, Inc.
There Is Hope Foster Family Agency Inc.
Timber Ridge School
Trinity Youth Services
Twin Oaks Juvenile Development, Inc.
U.S. Committee for Refugees and Immigrants
U.S. Conference of Catholic Bishops
Urban Strategies LLC
U.S. Committee for Refugees and Immigrants Inc.
Village Family Services, The
Vision Quest National, Ltd.
Vista Del Mar
Vista Haven Program
Wayfinder Family Services
Welcoming Arms
Youth Care
Youth For Tomorrow

Contract Vendors

255 North San Houston Hotel LLC
Ace Parking Management, Inc.
Acacia Center for Justice
Acuity
Aecom Technical Services, Inc.
Allstate Security Services Inc.
Amentum Services, Inc.
American Canyon Solutions, Inc.
American Hebrew Academy Inc.
American Medical Response, Inc.
American National Red Cross
Applied Intellect
Asset Protection and Security Services Lp
Azzmeiah V Ward
BCFS Health and Human Services
Bexar, County of
Bravium Consulting
Bre SSP Property Owner LLC
Caduceus Healthcare Inc.
Carahsoft Technology Corp.
Cellco Partnership Dba Verizon Wireless
Cellco Partnership Dba Verizon Wireless
Centerplate, Inc.
Centro De Salud De La Comunidad De San Ysidro Inc.
Chenega Naswik International LLC
Cherokee Nation Management and Consulting, LLC
Chickasaw Health Consulting, LLC
Childrens Hospital—San Diego
Childrens Village Inc., The
City of Dallas
Cni Thl Ops LLC
Coforma LLC
Colliers International Valuation and Advisory Services
Community Action
Comprehensive Health Services LLC
Conclusive Solutions LLC
Corporate Lodging Consultants, Inc.
Cotton Commercial USA Inc.
Countertrade Products Inc.
Cross Match Technologies, Inc.
Culmen International LLC
Dallas Independent School District
Decorum Lackland LLC
Deloitte Consulting LLP
Deployed Resources LLC
Deployed Services LLC
Divine Family Care Pllc
DLT Solutions, LLC
DRC Emergency Services LLC
Duke University
Dulles systems Inc.
Dynamic Construction Group LLC

Dynamic Service Solutions LLC
Elite Medical Transport of Texas LLC
Emergent, LLC
Enterprise Technology Solutions, Inc.
Erie Hotel Ventures LLC
F2 Solutions, LLC
Family Endeavors Inc.
Fieldprint, Inc.
Freeman Decorating Company
General Dynamics Information Technology Inc.
Global Evaluation and Applied Research Solutions
Global Spectrum, LP
Gogo Charters LLC
Gray Matters Tech Services LLC
Guidehouse Inc.
Guidehouse LLP
Hhc Trs Portsmouth LLC
Houston Hold Em Inc.
ICF
Ideal System Solutions, Inc.
Ingenesis Inc.
Jackson Inn and Suites Inc.
J&J Maintenance Inc.
Joltec LLC
Kearney and Company Pc
Kind Inc.
Koniag Professional Services LLC
Los Angeles County Fair Association
MVM, Inc.
Mammoth Energy Services
Masterword Services Inc.
Metcor Ltd.
NACC Disaster Services
National Center for Appropriate Technology
National Conference of State Legislatures
National Council for Behavioral Health
Nugent Appraisal LLC
PAE Applied Technologies LLC
Palantir Technologies Inc.
Palm Laundry Inc.
Pennsylvania Academy Corp.
Platinum Business Services, LLC
Precision Receivable Services, LLC
Providencia Group LLC
Radiant Infotech LLC
Rady Children's Hospital—San Diego
Rapid Deployment Inc.
Resolve Soft
Rios Partners LLC
San Diego Convention Center Corporation, Inc.
SMG Holdings Inc.
South Bay Community Services Inc.
Southwest Key Programs, Inc.
SRE 4610 Opco Jv LLC
Starr Commonwealth
Stratton Securities Incorporated
Supreme Bright Dallas Subtenant LLC
TFC Consulting Inc.
The Mitre Corporation
The Urban Institute
The Young Center for Immigrant Children's Rights
T-Mobile USA, Inc.
Tsm Corporation
Unissant, Inc.
United Migrant Opportunity Services Inc.
United Site Services of California Inc.
Universal Building Maintenance LLC
Vera Institute of Justice Inc.
World Language Communications Inc.
WSP USA Solutions Inc.
Xator LLC
Young Center for Immigrant Children's Rights
Your Recruiting Company Inc.

Question. Please list by name any former government employees who have approached HHS or ORR within the last 5 years on the behalf of a nongovernment organization seeking a grant or contract from HHS or ORR related to Unaccompanied Alien Children.

Answer. The Federal Acquisition Regulation (FAR) gives government agencies the authority to award contracts. HHS deploys oversight to ensure accountability for contractual procedures. To help ensure compliance with legal, regulatory, and contractual requirements, ACF's contracting office, Government Contracting Services (GCS) currently appoints a certified Contracting Officer's Representative to work with the Contracting Officer to oversee required deliverables and responsibilities for the contracts under its authority. All contracts also include a Quality Assurance Surveillance Plan (QASP) requirement, which details several contractor responsibilities, such as recurring deliverables and data reporting requirements. The QASP ensures that contracts adhere to the established terms and conditions and applicable FAR clauses, including prohibitions and notification pertaining to waste, fraud, and abuse of Federal funds.

Since June 2021, ACF and ORR have identified and continue to implement a comprehensive range of actions to address the challenges posed by the historic increase in the number of referrals to ORR in 2021, including those related to contracting—such as increasing contracting staff capacity and moving toward competitive actions for all new ICF capacity and other UC Program needs.

Question. Since its inception decades ago, the Organ Procurement and Transplantation Network (OPTN) has exclusively contracted the United Network for Organ Sharing (UNOS) to oversee the U.S. transplantation network. The bipartisan Securing the U.S. Organ Procurement and Transplantation Network Act, which was signed into law on September 22, 2023, is intended to improve management of the U.S. organ donation system by breaking up the contract for the OPTN and encouraging participation from competent and transparent contractors. HHS recently issued draft requests for proposals relating to the act's implementation, a law intended to create competition.

Has HHS offered UNOS a contract extension for 6 months with an option to extend for 2 years? Yes or No.

If so, do you agree this 2.5-year contract extension would go against the very spirit of the law and allow UNOS to continue its monopoly over OPTN? Please explain.

Answer. HHS intends to pursue a short contract extension to allow time to award and onboard the new Board Support and Transitions Operations awardees while the current contractor is still under contract to sufficiently transfer knowledge and prevent disruption to the 24/7, lifesaving work of the OPTN and to patients.

At every step of the modernization process, HHS has been committed to robust competition for the first-ever multivendor solicitations for OPTN contracts, and we were pleased that Congress supported our vision for fundamental reform through passage of the bipartisan Securing the U.S. Organ Procurement and Transplantation Network Act.

Question. On November 10, 2023, the United Network for Organ Sharing (UNOS) alerted the Health Resources and Services Administration (HRSA) of a data breach that exposed up to 1.2 million patient records.[25] Further, on March 18, 2024, HRSA announced it would post a Request for Information (RFI) specifically focused on the Organ Procurement and Transplantation Network (OPTN) NextGen IT contract solicitation to modernize and develop organ matching technology. In light of the RFI and the recent UNOS data breach, please answer the following questions.

Will the OPTN NextGen IT contracts be open to both nonprofit and for-profit entities?

Which entity, HHS or UNOS, is the owner of the patient data and technology currently used to operate the OPTN?

If UNOS asserts ownership over OPTN patient data and the technology infrastructure in place, how does HHS plan to move forward operating the OPTN?

What steps has HHS taken to ensure data breaches do not occur with UNOS or future contractors?

Does HHS require UNOS to employ data privacy and cybersecurity protections for the information it is collecting? If so, provide those requirements in full detail. If not, why not? Will HHS require these protections for future contractors?

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[25] Bill Fitzgerald, *Data breach at Richmond-based UNOS exposed 1.2 million patient records,* CBS 6 News Richmond (December 19, 2023), *https://www.wtvr.com/news/local-news/unos-data-breach-dec-19-2023*.

Answer. HHS is committed to pursuing the widest possible competition in support of the OPTN Modernization. The OPTN NextGen IT contracts will be open to both nonprofit and for-profit entities. These OPTN NextGen IT awards and activities will be continuously informed by the ongoing engagement with stakeholders and leading government technologists, and the recently released RFI is one piece of that approach.

HRSA will utilize all applicable Federal procurement law, regulation, and policy to ensure accountability from new vendors, as we do with other vendors that currently implement IT or other technical functions through Federal contracts for other parts of the agency. HRSA will embed accountability requirements and performance expectations in the solicitation process for each OPTN vendor and actively monitor and evaluate contractor performance.

The OPTN IT system is currently a contractor-owned, contractor-operated system. HRSA ensures compliance with critical Federal IT security standards, including National Institute of Standards and Technology 800–171 and 800–53, the Federal Information Security Modernization Act, and the Federal Risk and Authorization Management Program. HRSA has unlimited rights and access to the OPTN data pursuant to Federal Acquisition Regulation 52.227–14. Having access to this data allowed HRSA to develop the OPTN dashboards that provides data at the transplant hospital level. The upcoming contract solicitations will provide further clarity on the data rights language per FAR regulations. HHS is committed to ensuring lifesaving transplantation continues without disruption as we advance our efforts to create a more equitable, transparent, and accountable OPTN and higher-performing transplant system.

Question. During the Senate Finance Committee's March 22, 2023, hearing on HHS's Fiscal Year 2024 budget request, I shared that I had received credible allegations regarding the United Network for Organ Sharing (UNOS) threatening whistleblowers, including patients and caregivers.[26] I asked you whether HHS would commit to fully investigating all instances of whistleblower retaliation and harassment. You responded: "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's going on."

Please provide an update on what actions HHS has taken to make sure allegations of wrongdoing by UNOS are investigated and addressed.

Has HHS referred any cases where UNOS allegedly retaliated against or threatened whistleblowers, including patients and caregivers, to the HHS OIG? If so, please explain.

Answer. HRSA's oversight of the OPTN board of directors and the OPTN contractor has included taking action to address key areas of concern, including member conduct and complaints. The February 2024 solicitation for the board of directors support contract includes supporting the establishment of a code of conduct and process for complaints, as well as supporting the new board of directors in executing other oversight and management responsibilities. This will include a process to escalate concerns to HRSA as needed. HRSA will work with the HHS Office of the Inspector General and other agencies in response to any allegations that warrant such action.

Question. On December 4, 2023, I wrote to you and the Centers for Medicare and Medicaid Services (CMS) expressing concern about your oversight of our Nations' nursing homes and the Care Compare Five-Star Rating System. Specifically, CMS has failed to take action to address findings and recommendations from U.S. Government Accountability Office (GAO) and HHS Office of Inspector General (OIG) reports, dating back to 2011. Significant work remains to safeguard vulnerable Americans who reside in these facilities and to ensure that Care Compare and the Five Star Quality Ratings System provide accurate, timely, and meaningful data about the quality of care in nursing homes. As of March 18, 2024, HHS and CMS have not responded to my questions.

Please provide an update to GAO's 2014 recommendation for CMS to include additional information on estimated out-of-pocket costs for Medicare beneficiaries in what is now referred to as the CMS Compare website.

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[26] U.S. Senate Committee on Finance, full committee hearing, "The President's Fiscal Year 2024 Health and Human Services Budget" (March 22, 2023), *https://www.finance.senate.gov/hearings/the-presidents-fiscal-year-2024-health-and-human-services-budget*.

Answer. With regard to estimating out-of-pocket costs for beneficiaries, it is important to note that Care Compare is not designed to serve as a compendium for the costs of a specific medical service. Care Compare for nursing homes is focused on a facility's overall performance, including the status of the facility's participation in the Medicare and Medicaid programs and the facility's quality and inspection results to enable a potential resident or their family member to find an appropriate facility. CMS has added some information to Care Compare relevant to cost. For example, Care Compare indicates which doctors and clinicians accept the Medicare-approved amount as payment in full, which results in lower out-of-pocket costs for patients. Care Compare also indicates whether nursing homes participate in Medicare or Medicaid. *Medicare.gov* also includes consumer-friendly information regarding what Medicare covers.[27]

Question. In 2016, GAO found that the Care Compare website lacked explanatory information about the Five-Star Rating System and recommended that CMS add information to the Five-Star Rating System that allows consumers to compare nursing homes nationally. HHS did not concur with the recommendation and indicated that State variations on the standard surveys make it difficult to compare nursing homes nationally and that the Five-Star System is one of many factors consumers can use when selecting a home. Please describe efforts that have been made to reduce State variation in standard surveys. For example, CMS regional offices tracking of State differences in deficiency citations. In addition, do HHS and CMS plan to take any additional actions to implement this recommendation? Please describe. If not, please describe why not.

Answer. With regard to comparing information about Medicare- and Medicaid-certified nursing homes nationally, two of the three components of the Nursing Home Five-Star Quality Rating System on Care Compare are already based on comparisons to national norms (quality and staffing measures). The third element, the health inspection rating is, by design, based upon the relative performance of facilities within each State. However, there are State-by-State variations in the surveys performed, making it difficult to compare nationally. For example, Medicaid nursing home payment policy or complaint intake processes vary by State, which can lead to differences in survey outcomes. CMS bases Five-Star quality ratings in the health inspection domain on the relative performance of facilities within a State to control for this variation among States. When someone is looking for a nursing home, they are typically looking for one in a particular State, not nationwide, so the in-State comparison provides a more accurate assessment of the local conditions for consumers. As State-level rating systems provide a valid measure of a nursing home's performance relative to other nursing homes in a particular location, CMS does not plan any additional action on this recommendation.

The Nursing Home Five-Star Quality Rating System is just one of many factors to be used when choosing a nursing home. Each individual's preferences or needs may differ, so it's important for patients and their families to consider a range of information to inform their decision. For example, we recommend that individuals contact the nursing home(s) they are considering and talk to the administrator, director of nursing, or medical director. These individuals can speak to the type of care they provide and answer questions that are important to individual families. Individuals can also reach out to their State long term care ombudsman's office; these individuals specialize in long-term care options.

Question. In 2021, GAO found that while CMS had taken steps to improve the staffing information on Care Compare, it still provided limited information about staffing in nursing homes. GAO recommended that CMS report minimum nurse staffing thresholds on Care Compare. Does CMS continue to non-concur with this recommendation, or did its position change? Please discuss and describe any steps that CMS has taken or plans to take to address this recommendation.

Answer. With regard to staffing information on Care Compare, over the last several years, CMS has made improvements to the information reported. Specifically, in 2022, CMS began posting new weekend staffing and staff turnover measures on Care Compare and added four new measures to the Nursing Home Five-Star Quality Rating System.[28] Care Compare also includes the national and State average for each of the staffing levels so consumers can compare a facility's performance to the average.

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[27] *https://www.medicare.gov/what-medicare-covers.*
[28] *https://www.cms.gov/newsroom/fact-sheets/updates-care-compare-website-july-2022.*

On September 6, 2023, CMS published the "Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting" proposed rule (88 FR 61352), which proposed to establish comprehensive nurse staffing requirements to hold nursing homes accountable for providing safe and high-quality care for the over 1.2 million residents receiving care in Medicare and Medicaid-certified LTC facilities each day.[29]

While CMS holds individual nursing homes accountable for compliance with the Federal requirements, CMS also holds State survey agencies accountable for their performance in surveying and certifying nursing homes. The State Performance Standards System (SPSS) is the process used to oversee State survey agency performance for ensuring Medicare/Medicaid-certified providers and suppliers are compliant with the Federal requirements to improve and protect the health and safety of Americans. The Fiscal Year 2024 SPSS Guidance includes measures in three domains—survey and intake process, survey and intake quality, and noncompliance resolution—to highlight these areas for State survey agencies to promote consistent monitoring of compliance of health care facilities.[30] CMS publishes each State's performance on the measures,[31] and States that do not meet the requirements are subject to corrective action. On September 1, 2023, the Biden-Harris administration announced that CMS will undertake new analyses of State inspection findings to ensure cited deficiencies receive the appropriate consequence, particularly in incidences involving resident harm. These analyses will ensure citations are applied more consistently and reflect the seriousness of the deficiency, permitting appropriate follow-through and enforcement.[32]

Question. Please provide updates with respect to HHS's implementation of the recommendations from the November 2022 HHS OIG report "Long-Term Trends of Psychotropic Drug Use in Nursing Homes."

Administrator Brooks La-Sure's March 15, 2023, letter to me states that "CMS is pursuing . . . ways to effectively monitor nursing home compliance regarding the prescription of psychotropic medications, including OIG's recommendations to use data to identify trends or characteristics associated with a higher use of psychotropic drugs and to continue evaluating whether additional action is needed." Please describe and provide an update regarding these efforts and an update to the implementation status of the HHS OIG recommendation.

Provide an update on the implementation status of CMS audits to identify facilities with patterns of erroneous MDS coding of residents with a diagnosis of schizophrenia. Please include a list of all facilities that have been selected for an audit and all records related to each audit.

For all audits, please provide details on whether the facilities' Nursing Home Care Compare Five Star Quality Measure Ratings were adjusted as a result of the findings.

Please describe and provide plans for CMS MDS audits in calendar year 2024.

For each facility that admitted misconduct after receiving a notification of an upcoming CMS audit, please provide the following: (a) a full list of facilities that admitted misconduct, (b) a description of the admitted misconduct, and (c) describe actions taken by CMS as a result. If a "lesser action related to their star ratings" was taken by CMS as a result of the disclosure, please describe and provide details on how this action differed from the originally planned action.

Please provide an update to CMS's plans to convene a Technical Expert Panel (TEP) to examine current and future quality measurements and the appropriateness of the exclusions for certain conditions, including whether schizophrenia should no longer be excluded. Specifically:

Has this TEP convened? If not, why not? If so, please provide an update on findings and any proposed changes to quality measurements that CMS is reviewing as a result along with timelines. Please include any considerations related to schizophrenia as a quality measure.

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[29] *https://www.govinfo.gov/content/pkg/FR-2023-09-06/pdf/2023-18781.pdf.*
[30] *https://www.cms.gov/files/document/admin-info-24-02-all.pdf.*
[31] *https://www.cms.gov/files/document/admin-info-23-10-all.pdf.*
[32] *https://www.whitehouse.gov/briefing-room/statements-releases/2023/09/01/fact-sheet-biden-harris-administration-takes-steps-to-crack-down-on-nursing-homes-that-endanger-resident-safety/.*

Has CMS taken any other actions to consider certain condition exclusions, such as schizophrenia, from calculations in future quality measures? If so, please discuss and provide details on the specific actions.

Answer. With regard to any inappropriate use of psychotropic drugs, CMS has long been concerned that some nursing homes have erroneously coded residents as having schizophrenia, which can mask facilities' true rates of antipsychotic medication use. CMS has worked diligently to optimize the quality of life for residents in nursing homes by taking actions to reduce antipsychotic overuse in nursing facilities and improve comprehensive care approaches to better address the psychosocial and behavioral health needs of all residents. For example, in 2016, CMS launched focused schizophrenia onsite surveys to specifically address the issue of erroneous coding of schizophrenia in nursing homes. CMS continues to look for opportunities to strengthen the survey process and enforcement efforts to ensure that nursing homes are focused on nonpharmacologic approaches and that residents are not receiving medications that do not have a clinical basis. CMS is currently evaluating the use of psychotropic drug use among residents in nursing homes by analyzing schizophrenia diagnosis history and prescribing trends, including inappropriate use of anticonvulsants. CMS has announced the collection of anticonvulsant information, including the indication, on the MDS effective October 2024.[33]

In addition, CMS has been conducting offsite audits of schizophrenia MDS coding and, based upon the results, will adjust the quality measure star ratings for facilities whose audit reveals inaccurate coding. Specifically, any facility with this finding on audit will have their quality measure star rating downgraded to one star, which would drop their overall star rating by a star. Facilities that have attested to errors have their quality measure rating suppressed while they correct their data. Facilities with an audit finding or an attestation to having coding errors are indicated on Care Compare with a footnote next to their quality measure rating stating that the facility's data could not be verified through an audit.

For all facilities where patterns of coding inaccuracies were identified, either through an audit or through a facility's admission, CMS will monitor each audited facility's data to identify if the information indicates they have addressed the identified issues, and if any downgrades or suppressions that are applied should be lifted at the time frames indicated above. Also, a follow-up audit may be conducted to confirm the issue is corrected. CMS is committed to conducting audits within the resources available.

CMS convened a Technical Expert Panel (TEP) to solicit feedback on options for respecification of the "Percent of Residents Who Newly Received an Antipsychotic Medication (Short-Stay)" and "Percent of Residents Who Received an Antipsychotic Medication (Long-Stay)" measures to accurately capture antipsychotic medication use in nursing homes. Feedback was solicited over the course of four topic-driven sessions during the TEP meeting on February 24, 2023, and a poll following the TEP. CMS is continuing to explore respecifying these measures to include drug claims data.

Question. To provide greater transparency and efficiency in tracking Federal grant spending, Congress passed the Grant Reporting Efficiency and Agreements Transparency Act ("GREAT Act") of 2019.[34] The GREAT Act requires the Office of Management and Budget (OMB) and the U.S. Department of Health and Human Services (HHS) to create "data standards to modernize grant reporting, reduce burden and compliance costs of grant recipients, and strengthen the management and oversight of Federal grants."[35] The Government Accountability Office published a report titled "Grants Management: Actions Needed to Ensure Consistency and Usefulness of New Data Standards" (January 2024), in which it reported OMB and HHS have not met their implementation requirements, beyond failing to meet the deadlines

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[33] *Please see* the Draft MDS 3.0 Item Sets version 1.19.1 at *https://www.cms.gov/medicare/quality/nursing-home-improvement/resident-assessment-instrument-manual*.

[34] Grant Reporting Efficiency and Agreements Transparency Act, Pub. L. No. 116–103, 133 Stat. 3266–3271.

[35] U.S. Government Accountability Office, GAO–24–106164, "Grants Management: Actions Needed to Ensure Consistency and Usefulness of New Data Standards" (January 2024), at 9, *https://www.gao.gov/assets/d24106164.pdf;* the GREAT Act requires OMB to designate the Federal agency that "administers the greatest number of programs under which Federal awards are issued in a calendar year as the standard-setting agency." 31 U.S.C. § 6402(a)(1). OMB designated HHS as the standard-setting agency in November 2020. GAO *supra* note 1, at 2.

mandated by the Act.[36] Additionally, GAO found that OMB and HHS failed to adequately involve stakeholders in the process of developing grant data elements and communicate on the implementation of the GREAT Act, including with Congress.[37] Accordingly, GAO made four recommendations in this report that remain open.[38]

Please explain what steps HHS has taken—or plans to take—to close the open recommendations the Government Accountability Office made in its report titled "Grants Management: Actions Needed to Ensure Consistency and Usefulness of New Data Standards" (January 2024).

Additionally, provide an updated compliance timeline for HHS's implementation of the GREAT Act of 2019.

Answer. HHS concurred with all four recommendations in the GAO report titled "Grants Management: Actions Needed to Ensure Consistency and Usefulness of New Data Standards" (GAO–24–106164), and are working with our joint implementation partners at OMB to make progress on addressing and closing each. HHS and OMB are developing a roadmap for overall GREAT Act implementation that will address the GREAT Act requirements and the GAO recommendations, including establishing points to appropriately consult stakeholders on the standards and keep congressional stakeholders informed and engaged on our progress. HHS and OMB are actively leveraging the Council on Federal Financial Assistance, which has identified grants data standards as a key priority, to collaboratively drive development of standard data elements on a tranche-by-tranche basis.

QUESTIONS SUBMITTED BY HON. MARIA CANTWELL

Question. One of the top concerns I hear from my constituents is access to affordable prescription medications. A 2023 poll found that one out of every three U.S. adults taking prescription drugs said they could not take their medication as prescribed because of the cost. Americans shouldn't be forced to choose between paying for rent, groceries, or life-saving medications. These are not the kind of health-care choices we want people to have to make.

We must address the impact that pharmacy benefit managers have on drug prices. PBMs are industry middlemen with powerful influence over the price and distribution of prescription medications. High drug costs are making Americans suffer, and we need more transparency.

That is why I'm leading the PBM Transparency Act with Senator Grassley. This bill would mandate transparency reporting requirements for PBMs and direct the Federal Trade Commission to ban unfair and deceptive practices like spread pricing and reimbursement clawbacks.

We must shine a light on the practices that PBMs engage in and increase their accountability. My bill would also examine how PBMs use anticompetitive practices to steer patients to their own mail-order and affiliate pharmacies, which is contributing to a series of pharmacy closures in my home State.

About 60 pharmacies closed in Washington State in 2023, including 20 Bartell Drugs locations. That's twice as many closures as reported from the previous year. More closures mean patients must travel farther to access necessary medications. For rural communities, this is devastating and dangerous. In the town of Darrington

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[36] *Id.*

[37] U.S. Government Accountability Office, GAO–24–106164, "Grants Management: Actions Needed to Ensure Consistency and Usefulness of New Data Standards" (January 2024), at 23–24, 29–31, *https://www.gao.gov/assets/d24106164.pdf*.

[38] U.S. Government Accountability Office, "Grants Management: Action Needed to Ensure Consistency and Usefulness of New Data Standards" (last accessed March 13, 2024), *https://www.gao.gov/products/gao-24-106164*. The four recommendations are as follows: Recommendation 1: The Secretary of HHS, in consultation with the Director of OMB, should ensure the grant data standards are consistent with the definition of machine-readable by appropriately incorporating technical specifications. Recommendation 2: The Secretary of HHS, in consultation with the Director of OMB, should review and revise as necessary the Version 2.0 grant data elements based on leading practices for the formulation of data definitions. Recommendation 3: The Secretary of HHS, in consultation with the Director of OMB, should develop a stakeholder outreach plan to help ensure timely consultation of all grant stakeholders identified in the GREAT Act during development and implementation of the GREAT Act data standards. Recommendation 4: The Director of OMB and Secretary of HHS should jointly develop a process to ensure and document clear, regular, and timely communication with congressional stakeholders regarding implementation of the GREAT Act.

in my home State, the town's only pharmacy closed last July. To get to the nearest pharmacy, Darrington residents now have to travel 56 miles. This is unacceptable. Pharmacies are often the face of health care for patients, and they should be open and accessible.

Do you agree that more transparency requirements, such as the ones mandated in my bill, would hold PBMs accountable for their actions and help reduce the cost of prescription medication?

What is the administration currently doing to prevent more pharmacy closures? Will you work with me to prevent PBMs from steering patients to their affiliate pharmacies and causing smaller and independent pharmacies to shutter?

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

Nonetheless, we continue to encourage Part D plan sponsors to work with pharmacies to address cash flow concerns. On November 6, 2023, we published a memo to all Part D plan sponsors via CMS' Health Plan Management System (HPMS) titled "Application of Pharmacy Price Concessions to the Negotiated Price at the Point of Sale Beginning January 1, 2024," which reiterates and emphasizes several key points related to this issue that CMS also stated in the Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs final rule. Within the memo, we strongly encouraged Part D plan sponsors to consider options such as payment plans or alternate payment arrangements in advance of the January 1, 2024, effective date. CMS additionally emphasized that Part D plan sponsors must meet the prompt payment requirements at 42 CFR § 423.520 and pharmacy access standards at § 423.120.

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

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

We are committed to ensuring beneficiaries have access to necessary health services. We value the critical role pharmacies play in health-care delivery and recognize that we must address the needs of pharmacies to serve our beneficiaries effectively. We will continue to engage with stakeholders and consider policies for inclusion in future rulemaking that would lower prescription drug costs for beneficiaries, address challenges that pharmacies face, and improve the quality of pharmacy care.

Question. Since the Supreme Court overturned *Roe v. Wade,* 21 States have banned or severely restricted abortion. Although Washington State is a leader in protecting abortion rights at the State level, our providers are overwhelmed by a surge in patients fleeing antichoice States to seek care in Washington. The number of abortions provided in Washington to out-of-State patients increased by 46 percent in 2022.

You have taken several actions to help protect access to abortion and other reproductive services—including fighting to ensure that people can access abortion in emergency situations, strengthening medical privacy through HIPAA, and expanding access to the abortion pill mifepristone by allowing pharmacies to dispense it. I was also pleased to see that your budget calls for using title X to deliver $390

million in funding to help 3.6 million patients access family planning services like contraception.

But we must do more. I've long said that the Washington-Idaho border is the epicenter of this crisis. In the wake of ongoing legal threats and harassment by anti-choice activists, our providers and patients are scared and they need as much support as we can give them.

Can you talk about what you've done so far to bolster HIPAA protections to protect providers and patients from harassment and prosecution?

Answer. The Department has taken numerous actions since the *Dobbs* [39] decision, including issuing several guidance documents in June 2022 for Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entities (most health-care providers, health plans, and health-care clearinghouses), their business associates, and the public. These materials describe existing Federal protections for individuals' health information related to reproductive health care, including abortion, and make clear that the HIPAA Privacy Rule [40] does not require providers to disclose protected health information to third parties. The materials also address the extent to which private medical information is protected on personal cell phones and tablets.

Within days of the *Dobbs* decision, the Department released Guidance on the HIPAA Privacy Rule and Disclosures of Information Relating to Reproductive Health Care,[41] based on questions and concerns we heard from patient advocacy groups and health-care providers. We additionally issued a resource for consumers, Protecting the Privacy and Security for Your Health Information When Using Your Personal Cell Phone or Tablet[42] to help provide best practices for consumers and patients in safeguarding their own data given HIPAA's limitations. Further, in response to Executive Order 14079, we held listening sessions and discussed privacy in health care with communities and stakeholders nationwide. In many of these conversations, we heard alarming accounts of interactions with law enforcement and providers, consistent with your reported investigation findings.

Subsequently, in April 2023, the Department published a Notice of Proposed Rulemaking (NPRM) on the HIPAA Privacy Rule to Support Reproductive Health Care Privacy.[43] The proposal would prohibit the use or disclosure of protected health information by covered entities and business associates for an investigation or proceeding against any person (including individuals, health-care providers, and others) for the mere act of seeking, obtaining, providing, or facilitating legal reproductive health care, including abortion care. The NPRM published in the Federal Register on April 17, 2023, with a 60-day comment period that closed on June 16, 2023 (88 FR 23506). HHS intends to finalize the rule in the near future.

Question. Last month, CVS and Walgreens announced that they will begin dispensing mifepristone through the new certification process that FDA established under your leadership.

What are you doing to ensure that as many pharmacies as possible apply for certification and start dispensing this essential medication?

Answer. Pharmacy certification is managed by the drug sponsors. We recommend contacting Danco Laboratories, LLC, the applicant for Mifeprex, or GenBioPro, Inc., the applicant for Mifepristone tablets, 200 mg for information.

Question. What would $390 million in family planning funding mean for patients on the ground? How would this increased funding be used?

Answer. With increased funding, HHS will continue its commitment to providing, through the title X family planning program, a broad range of services related to achieving pregnancy, preventing pregnancy, assisting clients with achieving their desired number and spacing of children, as well as its focus on increasing access to and quality of health-care services, especially in areas with low and limited access. The additional funding will continue to support organizations to provide even more family planning services to clients across the country; provide training and

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[39] 597 U.S. 215 (2022).
[40] 45 CFR part 160 and part 164, subparts A and E.
[41] *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/phi-reproductive-health/index.html.*
[42] *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/cell-phone-hipaa/index.html.*
[43] 88 FR 23506 (April 17, 2023).

technical assistance for title X providers and staff; support data collection on title X services and national trends related to reproductive health; and conduct research to identify innovative approaches to expand access, improve quality, and ensure equity to family planning services.

QUESTIONS SUBMITTED BY HON. JOHN CORNYN

Question. For years, Republicans and Democrats from the Texas congressional delegation have raised concerns with ongoing efforts by CMS to restrict the ways States can finance their share of the Medicaid program. CMS continues to challenge the legality of financing methods that are essential to Medicaid programs across the country and have been previously approved by the agency.

Last year, CMS released an informational bulletin and proposed rule that, if finalized, would threaten Texas's ability to care for millions of its most vulnerable citizens. Furthermore, these efforts by CMS have been found to run counter to statutory authority by a Federal judge in Texas.

Does CMS intend to move forward with these proposed restrictions on State financing through issuance of a final rule or by any other means?

How do you respond to criticisms that CMS's proposals are incompatible with the agency's stated goal of preserving equitable access to care for Medicaid managed care enrollees?

Answer. CMS has worked extensively with States across the country on payment arrangements that help improve access and quality and reduce health disparities. However, it's critical that we make sure these arrangements comply with Federal law and ensure Federal dollars are spent appropriately. That's why we've strengthened the accountability and transparency of these payment arrangements and taken steps to hold States accountable when necessary.

With respect to certain specific States, CMS is unable to comment due to pending litigation.

Question. The market for electronic nicotine delivery systems, commonly referred to as vapes or e-cigarettes, is in awful shape. It is estimated that as much as half of that market today are illicit products—primarily coming into the country from China. Some of this is due to confusion regarding current regulations.

We need clarity and more enforcement activity. FDA has a list of companies that have received marketing denial orders, but that list doesn't indicate which products are covered by the denial orders. The list also indicates at least 19 companies that have had the orders stayed or rescinded due to a court challenge or administrative review—and again most don't indicate the actual products covered.

FDA also has a list of actual products for which pre-market approval applications have been filed, but doesn't indicate which ones were and were not timely and does not say whether or not those products can be sold—due to the administrative review status, court proceedings, or otherwise.

It is clear from FDA's statements that some products that aren't on the marketing granted list can still be sold based on court or administrative proceedings, but the information about those products just isn't available. How is any business, especially a small business, supposed to follow all of this and guess which undisclosed products are the subject of court stays or administrative reviews by FDA?

Don't you agree with me that what makes the most sense is for FDA to provide everyone with clear lists of which actual products can and cannot be sold so that everyone has clarity and the law can be better enforced?

Answer. To date, FDA has authorized 27 tobacco-flavored e-cigarette products and devices. FDA provides a publicly available list of e-cigarette products and devices with marketing granted orders (MGOs) so that retailers, consumers, and others may know which products may be legally marketed. See *https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders*.

Question. For the past year a bipartisan group of Senators led by Senators Cassidy and Warner have been engaged in an effort to improve integrated care for the dual-eligible population. As you are aware, dually eligible beneficiaries account for a disproportionate share of spending in Medicare and Medicaid, and most are covered by two separate Medicare and Medicaid plans that do not coordinate or align

enrollment. The proposal we are working on seeks to deliver coordinated care for the duals population to provide higher quality and better outcomes.

Can you commit to helping in this effort by providing technical assistance on this important proposal in a timely manner?

Answer. Dually eligible individuals face a complex assortment of enrollment options. To improve the experiences and outcomes for dually eligible individuals, CMS issued the Contract Year 2025 Medicare Advantage and Part D proposed rule, which includes a proposal to increase the percentage of dually eligible Medicare Advantage plan enrollees who are in plans that also cover Medicaid by offering more opportunities for enrollment in plans that integrate Medicare and Medicaid and more opportunities to switch to traditional Medicare, as opposed to MA plans offered by organizations that are not related to the organization that offers the enrollee's Medicaid plan. The agency is committed to promoting beneficiary choice and facilitating improved access to an array of Medicare coverage options for low-income beneficiaries. CMS would be happy to provide technical assistance on any draft legislation.

Question. The recent cyber breach of Change Healthcare has shown us how vulnerable our Nation really is to bad actors. While you have put forth some short-term solutions to address fiscal concerns of providers whose payment claims are tied up, as well as urging payers to own the failures of the breach, what more can HHS do to ensure enhanced data safety moving forward so we don't face another cyber breach of this magnitude in our health system?

Answer. Sector (HPH) and ASPR is the designated lead within HHS for Sector Risk Management Agency (SRMA) activities. In this role, ASPR leads the incident response, coordinates across intra- and interagencies, assesses and reports impacts, and engages and informs the health-care sector. On February 27, 2024, HHS, along with the Cybersecurity and Infrastructure Security Agency (CISA) and the Federal Bureau of Investigation (FBI), released an updated joint cybersecurity advisory (CSA) on ALPHV Blackcat ransomware, which includes recently and historically observed tactics, techniques, and procedures (TTPs) and indicators of compromise (IOCs) to help organizations protect against ransomware. ASPR has led interagency coordination engagements, including regular, sometimes daily, calls in support of incident response. This allowed us to coordinate the response of the U.S. Government (USG), including the FBI, CISA, Department of Veterans Affairs (VA), DoD, and others.

In December 2023, HHS released a concept paper that outlined the Department's holistic cybersecurity strategy for the HPH. Towards the end of January, we released the voluntary HPH cybersecurity performance goals (CPGs), aligned with the first pillar of this strategy. We also rolled out a new gateway website as part of our efforts to establish the one-stop shop for HHS cyber and simplify how the sector can access our resources and tools across all HHS divisions. These HPH CPGs will help health-care organizations implement high-impact cybersecurity practices and ease access to the many cybersecurity resources HHS and other Federal partners offer. In the coming weeks and months as we emerge from this attack, we will be focused on developing additional tools, resources, and guidance to help with implementing these HPH CPGs and look forward to working with the sector to help improve its cybersecurity posture. We also launched the 2.0 version of our RISC Toolkit to the sector. It allows a system of systems risk assessment instead of focusing on a specific hospital.

It is important to note that this cyber-attack was of a private company, Change Healthcare, and not of HHS systems. We continue to engage regularly with the health-care sector and are urging UnitedHealth Group (UHG), clearinghouses, insurance companies, and other payers to do everything they can to maintain patients' access to care and support providers.

The HHS Healthcare Cybersecurity Coordination Center (HC3) was created by the Department to aid in the protection of vital, controlled, health-care related information, and to ensure that cybersecurity information sharing is coordinated across the health care and public health (HPH) sector. The HC3 developed and distributes briefs on relevant cybersecurity topics, provides high-level sector alerts to assist the sector with defense of large scale and high-level vulnerabilities, and develops white papers and other products all aimed to increase cybersecurity awareness and readiness in the HPH sector.

Question. The Centers for Medicare and Medicaid Services on March 9th issued a notice formally announcing terms for hospitals, physicians, and other providers impacted by the Change Healthcare cyberattack to apply for accelerated and ad-

vance payments (AAPs). We have heard concerns from providers that recoupment begins immediately, interest rates are high compared to where they were during the public health emergency (4 percent then and currently 12.375 percent), and the requirement for providers to have been unable to obtain sufficient funding from other available sources because it is unclear what criteria is being used to determine that.

Given these concerns, what steps are you taking to provide greater flexibility for providers?

I also understand that providers who are participating in the Medicare Periodic Interim Payment (PIP) program are not eligible for the HHS accelerated and advanced payment program that is being made available to health-care providers impacted by the cyberattack. As you know, the PIP program provides cash flow assistance for critical health providers, including long-term acute-care hospitals (LTACs) who require additional cash flow predictability in order to serve medically complex and often longer-stay patients.

As you know, Medicare PIP payments only help offset some of the costs for Medicare Part A fee-for-service claims and represent only a fraction of total Medicare payments received by a hospital. Medicare outlier, Part B and Medicare Advantage payments are not accounted for in the PIP program. For health-care providers in the Medicare PIP program, they are experiencing many of the same Medicare payment shortfalls and difficulties with billing as other health-care providers as a result of the cyberattack. In addition, these providers are also experiencing delays in checking patient eligibility and benefits, notification of admissions, billing, and payment collections in affiliated hospitals, physician offices, and with other providers.

Given that health-care providers in the PIP program are experiencing the same challenges as other Medicare providers, does CMS have any flexibility to allow these providers to apply and participate in HHS advanced and accelerated payment programs?

Providers who participate in the Medicare Periodic Interim Payment (PIP) program are required to submit 85 percent of their claims within 30 days after a patient is discharged, and 85 percent of those claims must be error free or "clean." Failure to meet these requirements places a provider at risk of being removed from the PIP program.

Since the Change Healthcare cyberattack on February 21, 2024, claims submission and processing stopped broadly for Medicare claims and has since been delayed while providers are establishing workarounds. This jeopardizes a provider's ability to meet timeliness requirements.

Establishing alternatives to submit claims requires new arrangements that take time to get up and running. And even once implemented, new processes may be slowed by the administrative procedures for eligibility and prior authorization (new arrangements will lack specific payer edits on claims) that if lacking these determinations, will cause claims to be denied and further delay paying for care that has been provided.

Would CMS be willing to use its authority to temporarily waive the timeliness requirements for filing Medicare claims by those providers in the PIP program impacted by the cyberattack?

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

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

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

Question. HHS has cleared a CMS rule that is waiting for White House approval that would overhaul the Medicare Advantage enrollment process. This committee has been engaged in this issue, and Chairman Wyden has led inquiries into marketing practices that cause headaches for seniors. But your proposal would limit fees in the enrollment market for everyone—not just the bad actors.

Would you commit to me to ensure that CMS will not limit the ability of agents and brokers to help beneficiaries find Medicare Advantage plans that best fit their needs?

Answer. We agree that it is critical to ensure that as the MA and Part D programs continue to grow, it remains viable and that seniors and individuals with disabilities eligible for Medicare can make informed decisions about their health-care coverage, and, when appropriate, enroll in the plan that is best suited to their personal health-care needs. As discussed in the CY 2025 MA and Part D proposed rule, (88 FR 78476), section 1851(j) of the Social Security Act requires that CMS develop guidelines to ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the MA plan that is intended to best meet their health-care needs. We have learned, however, that many MA and stand-alone Prescription Drug Plans (PDP), as well as third-party entities with which they contract (such as field marketing organizations (FMO)), have structured payments to agents and brokers that have the effect of circumventing existing CMS regulations that limit agent and broker compensation to specified fair market value (FMV) levels. CMS has also received complaints from different organizations, including State partners, beneficiary advocacy organizations, and MA plans to this effect. A common thread to the complaints is that agents and brokers are being paid, typically through various purported administrative and other add-on payments, amounts that cumulatively exceed the maximum compensation allowed under the current regulations. Moreover, CMS has observed that such payments have created an environment, not dissimilar to what originally prompted us to set limits on agent and broker compensation in 2008, where the amounts being paid for activities that do not fall under the umbrella of "compensation," are rapidly increasing.

We understand that FMOs help millions of Medicare beneficiaries to learn about and enroll in Medicare, Medigap, MA plans, and PDP plans by providing guidance on plan options, including comparisons of relative costs and coverage, as well as assisting beneficiaries with applying for financial assistance. However, financial incentives to agents and brokers, more readily paid by large plans, can result in beneficiaries being steered to some MA plans over others based on excessive broker and agent compensation rather than on the enrollee's best interest. Therefore, as part of the CY 2025 MA and Part D proposed rule, CMS proposed to redefine "compensation" to set a clear, fixed amount that agents and brokers can be paid regardless of the plan the beneficiary enrolls in.

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

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

Question. On August 30, 2023, the Department of Health and Human Services announced it recommended the reclassification of marijuana to Schedule III to the

Drug Enforcement Administration (DEA). Four months later, HHS released an unredacted version of its recommendation to reclassify the drug. FDA has used an established five-factor analysis in determining whether Schedule I drugs have "currently accepted medical use." In the report supporting the recommendation to reschedule marijuana, FDA used a new two-factor test to make that determination.

Why did HHS create a new two-factor test to determine currently accepted medical use when the five-factor test has been used for decades by Republican and Democratic administrations?

Answer. The scheduling review documents reflect HHS's evaluation of the scientific and medical evidence and its scheduling recommendation to DOJ.

Question. In the recommendation, FDA measured marijuana's potential for abuse by comparing it to a limited selection of Schedule I, II, and III drugs. For example, FDA compared marijuana to heroin, another Schedule I drug. The recommendation claims that because marijuana has a lower abuse potential than heroin, it shouldn't be in the same category. FDA failed to compare marijuana to other Schedule I drugs, such as LSD.

Why did FDA fail to do a more rigorous analysis and compare marijuana's abuse potential against all Schedule I drugs?

Answer. The scheduling review documents reflect HHS's evaluation of the scientific and medical evidence and its scheduling recommendation to DOJ.

Question. The Centers for Medicare and Medicaid Services have proposed significant changes to the Medicaid Drug Rebate Program. The savings from these changes have nothing to do with patient affordability; they are simply increases in the rebates realized by the Medicaid program at the Federal and State levels. Despite broad concerns being voiced about the concept, implementation, and legality of the proposals, the agency has indicated that it will move forward this June.

Will you commit that policies will not be finalized until stakeholders' concerns are addressed adequately? Specifically:

Manufacturers, distributors, and others in the supply chain have indicated that the operationalization of the stacking provision is not possible with current technology and within the current system and is not permitted under the Medicaid statute.

The survey proposed is intended to collect proprietary information from manufacturers with no clear government use articulated for the information gathered, but the implication is that the information may be shared publicly in some way.

The shift of inpatient drugs into the outpatient category is a violation of the statute and congressional intent.

The definition of vaccine that CMS included in the proposed rule is out of alignment with other agencies and could create barriers to access by the Medicaid population. The MDRP definition of a vaccine should be based on whether a product is either recommended by ACIP for adults and is included in the VFC program.

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

QUESTIONS SUBMITTED BY HON. JOHN THUNE

Question. I have been a long-time supporter of establishing permanent access to telehealth services.

And now that we're on the other side of the public health emergency, I hope that all of us can agree that the pandemic demonstrated the value of telehealth and the benefit it can afford to patients across the Nation, in particular those in rural areas that would otherwise be forced to travel hundreds of miles for doctor's appointments.

Congress extended many of the COVID-era flexibilities for Medicare telehealth services through 2024, and earlier this year, I joined some of my colleagues in sending a letter to you highlighting the critical role of telehealth in the delivery of health

care and the importance for these telehealth services to be made permanent before they expire at the end of this year.

Do you commit to working with Congress on this effort and advocating for permanent telehealth policies that would ensure Medicare beneficiaries maintain access to these vital services?

Furthermore, what measures is the department taking to minimize fraud as we seek to ensure telehealth services remain available?

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

CMS recognizes the importance of analyzing the impact of these changes, and, as such, immediately evaluated the waivers and flexibilities issued by the agency to determine the potential for fraud, waste, and abuse in the Medicare program. This process included identifying program integrity risks and vulnerabilities associated with the waivers and flexibilities; prioritizing those with the largest potential for financial loss, beneficiary harm and/or likelihood of occurrence; and creating mitigations that addressed these program integrity risks and vulnerabilities, including those related to telehealth.

One such mitigation strategy was the continued use of data analytics to identify potential program integrity risks. During and after the PHE, CMS has continued to analyze claims data to monitor, trend, and respond to existing telehealth fraud schemes and to detect and respond to potential new emerging fraud schemes. CMS uses a robust program integrity strategy to reduce and prevent Medicare improper payments, which includes the use of the Fraud Prevention System (FPS). The FPS is a predictive analytics technology that runs sophisticated algorithms against Medicare Fee-for-Service (FFS) claims nationwide. When FPS models identify aberrant activity or patterns, the system automatically generates and prioritizes leads for further review and investigation by Unified Program Integrity Contractors (UPICs). Based on the results of all information collected, the UPICs coordinate with CMS and the Medicare Administrative Contractors in taking appropriate administrative action to recover improper payments and prevent future loss of funds, or the UPICs refer the case to law enforcement.

Additionally, CMS has supported our Federal law enforcement partners during and after the PHE on various fraud schemes including those related to telehealth. CMS continues to meet regularly with law enforcement to discuss new cases, fraud referrals, active UPIC and law enforcement cases, and paths for various administrative actions.

CMS has also taken action to prevent improper Medicare payments by educating health-care providers and suppliers on proper billing. For example, CMS has undertaken a number of stakeholder calls including open door forums and Medicare Learning Network calls, as well as published numerous pieces of subregulatory guidance designed to educate practitioners on the additional telehealth flexibilities, including how to appropriately bill for these services.

Question. There are many features to this administration's disastrous handling of the border and their own created crisis. One of them is under your responsibilities to handle the care and placement of unaccompanied minors encountered at the border.

By your department's own data, there have been approximately 400,000 unaccompanied minors released into the country just in the past 3 years.

Can you tell this committee the number of individuals who have presented at the border over the past year who have posed as minors yet are adults?

Can you tell this committee the number of minors who have presented at the border over the past year with a known gang affiliation?

Answer. HHS defers to the Department of Homeland Security (DHS) on encounters with adults posing as minors who are identified before DHS makes a referral to HHS. HHS may make additional age determinations of individuals transferred to HHS's Office of Refugee Resettlement (ORR), if there is a reasonable suspicion that they are 18 years or older. The Homeland Security Act of 2002 and the Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA) instructs HHS to devise age determination procedures for individuals without lawful immigration status in consultation with DHS. The TVPRA requires that age determination procedures take into account multiple forms of evidence. If an individual's age is questioned at the time of admission to an HHS-funded care provider facility, the case manager must consult with the Federal Field Specialist (FFS) to make the age determination. In the event there is conflicting evidence, the FFS makes the age determination based on their review of multiple forms of available evidence, as set forth in section 1.6 of the UC Program Policy Guide.

DHS fingerprints all children 14 years old or older before making any referral to ORR, and if there is criminal history based on those biometrics, that history is reported to ORR, as required under the 2021 HHS and DHS Memorandum of Agreement (MOA). This MOA also creates an affirmative obligation for DHS to provide to ORR, the age of the unaccompanied child, along with any criminal history gang affiliation, or court documents, and any other related information. Per ORR policy, all children entering ORR custody undergo a variety of assessments, including the Initial Intakes Assessment, the Unaccompanied Child (UC) Assessment, Case Review, and clinical assessments, and children meet weekly with a trained clinician and case manager who are regularly assessing the children for issues that may impact their placement with a vetted sponsor. These assessments probe for human trafficking indicators and other vulnerabilities.

In accordance with section 3 of the ORR UC Program Policy Guide, various assessments determine, among other things, if unaccompanied children in ORR's custody and care may be a danger to themselves or others. In the event an unaccompanied child is assessed by ORR to be a danger to themselves or others, have a criminal history, or require close supervision, ORR may place the child in a restrictive facility. Restrictive facilities provide a heightened level of staff supervision, increased communication among staff, and services to prevent a child running away, among other measures and procedures to ensure safety and security.

Question. Last month's cyberattack against UnitedHealth Group has had wide-ranging repercussions on health systems in rural and urban areas across the Nation.

As the fallout from the cyberattack continues, can you please speak to what steps HHS is taking to support providers that were impacted by the cyberattack?

And specifically, what steps is your staff taking or planning to take to help health systems that are attempting to change clearinghouses for which their claims are processed but are facing frustrating delays in doing so? Is there any technical assistance that HHS is providing to health systems?

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

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

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

Question. Nursing homes across the Nation are facing a number of challenges that have forced many long-term care facilities to close or reduce the number of patients they can care for.

This is acutely problematic for rural States like South Dakota where the next available nursing home bed could be hundreds of miles away from home and away from friends and family.

The minimum staffing standards for long-term care facilities proposed rule from CMS that would slap onerous and unworkable staffing mandates on our Nation's nursing homes would exacerbate this problem and undoubtedly force more facilities to close their doors.

I am fearful that many nursing homes, including those in rural States like my State of South Dakota, would be forced to close as a result of this one-size-fits-all Federal staffing mandate.

Do you recognize the bipartisan concerns with this proposed rule and the reality that nursing homes would not be able to comply with an inflexible staffing mandate given the shortage of individuals in the nursing field today?

Answer. Staffing in LTC facilities is a persistent concern, especially among low-performing facilities that are at most risk for providing unsafe care. Numerous studies have shown that staffing levels are closely correlated with the quality of care that LTC facility residents receive.[44] CMS believes that national minimum nurse staffing standards in LTC facilities are necessary at this time to protect resident health and safety and ensure residents' needs are met. We intend to promote safe, high-quality care for all residents regardless of geographic location. At the same time, CMS acknowledges the unique challenges that rural LTC facilities face, especially related to staffing, and recognizes the need to strike an appropriate balance that considers the current challenges some LTC facilities are experiencing.

In developing the proposed staffing requirements for LTC facilities, CMS sought to identify minimum standards that, when applied across all LTC facilities, would significantly lower the risk of unsafe and low-quality care for residents, while being implementable. We believe we are proposing achievable goals that are informed by the totality of the evidence.

While we fully expect that LTC facilities will be able to meet our proposed minimum staffing standards, we recognize that in some instances, external circumstances may temporarily prevent a facility from achieving compliance despite the facility's demonstrated best efforts. Therefore, we proposed to allow for a hardship exemption. If finalized, LTC facilities could qualify for a hardship exemption from the minimum nurse staffing standards if they met several criteria, which are discussed in the proposed rule. The facility would have to be located either in an area where the supply of health-care personnel was insufficient, or at least 20 miles away from another LTC facility. Facilities also would have to meet other criteria including demonstrating good faith efforts to hire and retain staff and not be subject to disqualification.

Given the challenges rural communities face, CMS is proposing later implementation dates for rural facilities. Rural facilities will have 3 years to meet the proposed 24/7 Registered Nurse (R.N.) requirement and 5 years to meet the proposed minimum staffing standards. In addition, CMS is maintaining the current statutory waiver process for facilities for R.N. onsite requirements under qualifying circumstances. Facilities seeking relief from the proposed 24/7 R.N. requirement in the proposed rule would follow the applicable existing waiver process, as required by statute, and set out in the current regulations. As the LTC sector continues to recover from the COVID–19 pandemic, the proposed standards take into consideration local realities in rural and underserved communities.

Question. Improving the transparency, management, and hiring practices of the Indian Health Service has been a priority of mine for many years, and it's a big focus of the legislation I introduced with Senator Barrasso, the Restoring Accountability in the IHS Act.

Can you please update this committee on the actions HHS has taken or plans to take to improve IHS and bring more accountability to the agency, because clearly more needs to be done?

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[44] Abt Associates. (2022). Nursing Home Staffing Study Comprehensive Report. Report prepared for the Centers for Medicare and Medicaid Services.

Answer. IHS leadership is committed to providing improved transparency on initiatives that are being undertaken by the IHS, as well as in coordination with our partnering agencies, by enhancing dialogue with tribal and urban Indian organization partners to ensure our actions are sustainable and impactful. To keep everyone informed on IHS Work Plan priorities, IHS provides quarterly updates on our progress through the IHS Work Plan Status Report, which is posted to the IHS website.

The 2024 Agency Work Plan outlines steps the IHS is taking to address priorities as well as mitigate risks. The plan details critical actions that will ensure safe, quality, and patient-centered care, as well as improve IHS operations and communication. This plan builds internal capacity to design, implement, and evaluate actions and processes by applying principles of a learning organization that will lead to sustainable improvements in the management and oversight of our programs and services. The IHS will achieve these goals through rigorous management and oversight of resources to ensure the health-care needs of American Indians and Alaska Natives are met.

The IHS is currently reviewing its Human Resources procedures and moving from a segregated Area by Area approach to a one Human Resource "warehouse" approach. This will allow the IHS to streamline its processes resulting in a more efficient hiring process. The IHS also has several legislative proposals in the current FY 2025 President's budget request for IHS. For example, we have a legislative proposal aimed at addressing some of the time requirements for IHS scholarship and loan repayment recipients to entice such recipients to remain with the IHS. We also seek parity with certain Veteran's Affairs hiring authorities, such as the title 38 authorities, that will allow IHS to be competitive in offering higher salaries to potential health-care providers seeking to work for the IHS. The IHS is also prioritizing human resource information technology optimization and modernization. System optimization will streamline and more easily allow for efficient information flow. IHS, in concert with OASH, is also strategizing improvements in the placement and hiring of Public Health Service Officers.

QUESTIONS SUBMITTED BY HON. TIM SCOTT

Question. In February of this year, I joined Senator Blackburn in sending a letter to the Centers for Medicare and Medicaid Services on the proposed Ensuring Access to Medicaid Services rule. The rule mandates that at least 80 percent of reimbursements for home services must be directed toward front-line worker wages and benefits. States can determine their percentages for payments on direct-care workers but there are currently no States that have an 80-percent requirement. The letter expresses concerns regarding no official data analysis on how this proposal would impact the Medicaid system. States, such as my home State of South Carolina, have flagged that they expect it will harm provider networks and beneficiary access. The South Carolina Home Care and Hospice Association has weighed in on the rule and has said, "This blanket, one-size-fits-all approach will likely force agency closures, unfortunately reducing access to care." In the agency's response to this letter, CMS claims that this rule was based upon feedback from States.

Can you please tell me which States thought this rule would be a good idea and would not risk access to rural care for seniors during an already dire workforce shortage?

Answer. On April 27, 2023, CMS issued the Ensuring Access to Medicaid Services proposed rule. A substantive component of this proposed rule focuses on improving access to, and the quality of, home and community-based services (HCBS). Over the past several decades, HCBS have become a critical component of the Medicaid program and are part of a larger framework of progress toward community integration of older adults and people of all ages with disabilities that spans efforts across the Federal Government. The changes proposed in this rule are intended to strengthen necessary safeguards to ensure health and welfare, promote health equity for people receiving Medicaid-covered HCBS, and achieve a more consistent and coordinated approach to the administration of policies and procedures across Medicaid HCBS programs. CMS presumes that references to the "80/20 proposal" are references to the HCBS payment adequacy policy CMS proposed in this rule, as further described below.

Access to most HCBS generally requires hands on and in-person services to be delivered by direct care workers. However, direct care worker shortages are impacting beneficiaries' access to services. In an effort to address direct care workforce

shortages, CMS proposed to require that States ensure that providers spend at least 80 percent of Medicaid payments for homemaker, home health aide, and personal care services on compensation for direct care workers. We believe that this proposal would not only benefit direct care workers but also individuals receiving Medicaid HCBS. We believe supporting and stabilizing the direct care workforce will result in better qualified employees, lower turnover, and a higher quality of care.

This proposal was based on feedback from States that have implemented similar requirements for payments for certain HCBS, such as Minnesota and Illinois. These States reported to us through various public engagement activities that similar requirements have had their intended effect of ensuring that a sufficient portion of the payment for Medicaid HCBS goes to compensation for the direct care workforce. These States also indicated an 80-percent threshold is an appropriate threshold that takes into account the expected portion of payments that are necessary for provider administrative and other costs, aside from direct care worker compensation. CMS proposed compensation to be defined as salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations; benefits (such as health and dental benefits, sick leave, and tuition reimbursement); and the employer share of payroll taxes for direct care workers delivering HCBS.

Additionally, this proposed rule would require the establishment of an Interested Parties Advisory Group, to advise and consult with the State on payment rates for direct-care workers. This group would include, at a minimum, direct-care workers, beneficiaries and their authorized representatives, and other interested parties.

Input from stakeholders is an important contribution to CMS's policymaking process and CMS is carefully considering all comments received during the comment period on this proposed rule as we work to develop a final rule.

Question. In 2023, I, along with other members of the Senate Finance Committee, sent a letter to the Centers for Medicare and Medicaid Services expressing concerns with several policies included in the proposed rule "Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program" (NPRM). The NPRM fails to provide a patient-oriented justification for its proposed price verification survey. The NPRM seeks to establish a drug price verification survey process for certain "high-cost" covered outpatient drugs, including cell and gene therapies. In mid-February Senate Finance Committee members received a response that was simply an acknowledgement of our letter.

I still would like to know—what could be the unintended consequences of the proposed Medicaid Drug Rebate policy? CBO has said in past reports that changes in pricing regulations would likely change prices to other purchasers.

Do you see any instances where patients may be adversely affected? My concern is that manufacturers may pull back discounts from certain entities to mitigate the "stacking" effect. Won't that result in patients paying more out of pocket?

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

Question. Cell and gene therapies have the potential to transform health-care delivery, offering treatments and cures for previously incurable diseases, such as sickle cell disease. With the recent Food and Drug Administration approval of two gene therapies for sickle cell disease, the Medicaid Drug Rebate policy risks disclosing proprietary information without remedying the underlying statutory and regulatory barriers to value-based coverage arrangements for gene and cell therapies under Medicaid.

How are you ensuring that changes and requirements proposed in the "Misclassification of Drugs, Program Administration, and Program Integrity Updates Under the Medicaid Drug Rebate Program" will not limit Medicaid beneficiary access to gene therapies, especially those approved in December for sickle cell disease, and ensuring that changes do not undermine the operation or intent of the CMMI Gene and Cell Therapy Access Model?

How would the proposed rule impact Medicaid's ability to enter into value-based payment arrangements for novel, curative treatments that have recently been approved?

Answer. In the proposed rule, CMS proposed to use this authority now because of the introduction of higher-cost drugs and therapies to the market, such as cell and gene therapies, which have significantly impacted States' Medicaid budgets. Our proposal to survey manufacturers for certain information on specific covered outpatient drugs (CODs), and our proposal to make certain manufacturer information publicly available in a central location (unless it is proprietary), would make the manufacturer pricing process more understandable to CMS and to States as they establish and negotiate payment for Medicaid CODs consistent with section 1902(a)(30)(A) of the act. It also would give States another tool with which to help manage these extremely expensive drugs. This information should allow a State to understand the value of the drug as compared to its price, and better understand the impact of the drug on its budget. In addition, the use of this authority may help assure Medicaid beneficiary access to these important therapies.

We proposed to exclude those CODs that are subject to other CMS drug pricing initiatives in which participating manufacturers would negotiate directly with Medicare or Medicaid. Therefore, the CODs of manufacturers participating in the Center for Medicare and Medicaid Innovation's Cell and Gene Therapy Access Model (which is a result of the President's signed executive order) would not be subject to the price verification survey. In addition, when choosing the drugs subject to the survey, CMS will consider narrowing the list based on State-specific Medicaid program input regarding manufacturer efforts to lower drug prices (including through mechanisms such as subscription models, value-based purchasing arrangements under the multiple best price approach, or other purchasing arrangements favorable to the Medicaid program).

We note that CMS continues to review comments received on the proposed rule as we work toward issuing a final rule.

Question. Regarding drug shortages, the Finance Committee released a white paper in January in which we found that generic drugs typically make up two-thirds of all drug shortages in the U.S. And, in December of 2023, the committee held a hearing on drug shortages, during which we heard extensive testimony indicating that race-to-the-bottom pricing for generic drugs serves as the primary underlying driver of many of the ongoing drug shortages faced by patients in America today. Generic manufacturers seem to be facing intense pressure to reduce prices and often face contract terms from purchasers that render revenue unpredictable. As a result, generic prescription drug supply chains can experience manufacturer exits, low production, or stoppages required by regulators. This concern seems to be underscored by the recent Federal Trade Commission RFI that examines the market concentration of health-care group purchasing organizations (GPOs) and drug wholesalers and how they "impact the overall generic pharmaceutical market," including how both entities may influence the pricing and availability of pharmaceutical drugs.

What steps is the Department taking to address the issue of drug shortages and, more specifically, have you contemplated any payment or contracting changes in Medicare or Medicaid that would address the precarious economic position of generic drug manufacturers?

Answer. HHS recognizes the severe patient impact from the persistent problem of chronic drug shortages that have most frequently impacted inexpensive generic drugs, particularly sterile injectables. HHS is taking a coordinated approach to help address economic root causes of shortages.

In November 2023, HHS announced the establishment of a new Supply Chain Resilience and Shortage Coordinator role responsible for coordinating efforts across the Department that advance the resilience of medical product and food supply chains and accelerate the Department's response to related shortages. Institutionalizing this coordination across the Department will help HHS meet its long-term supply chain resilience and shortage mitigation goals. In addition, FDA on an ongoing basis works to identify shortage risks and determines actions that can prevent or mitigate patient impact, such as prioritizing review of manufacturer submissions or working with manufacturers to increase supply. ASPR also led the development of an Essential Medicines Supply Chain and Manufacturing Resilience Assessment to identify supply chain vulnerabilities in a critical medicines list and has invested, through the Industrial Base Management and Supply Chain (IBMSC) Office, targeted funds to bolster domestic manufacturing capabilities for essential medicines.

CMS is also taking steps to help align certain incentives to bolster supply chain resilience and further promote adoption of resilient supply chain practices. As discussed in the Calendar Year 2024 Outpatient Prospective Payment System (OPPS)

final rule, CMS solicited public comment on providing separate payment under the Medicare Inpatient Prospective Payment System (IPPS), and potentially the OPPS, for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply (88 FR 82127–30).

CMS also noted in the CY 2024 OPPS final rule that as part of the agency's initial efforts, CMS intends to propose new Conditions of Participation in forthcoming notice and comment rulemaking addressing hospital processes for pharmaceutical supply (88 FR 82130). CMS continues to review the comments received to consider ways the Medicare program can promote hospital resilient supply chain practices to help mitigate the impact of drug shortages on patients.

Question. Related to drug shortages, the committee found in its January white paper that Medicaid payment for prescription drugs may be putting unintended, downward pressure on generic medicines, including those that are prone to shortages. More specifically, there is some concern that the application of inflation penalties placed on generics under the Medicaid Drug Rebate Program (MDRP) presents challenges for manufacturers in addressing shortages given many of the broader economic issues they face, which have been raised by this committee and the Federal Trade Commission.

Has the Department explored the extent to which reforms of certain aspects of the MDRP can relieve drug shortages?

Answer. CMS administers the Medicaid Drug Rebate Program (MDRP) in accordance with Federal statute and regulations. With limited exceptions, if a drug manufacturer wants payment to be available under Medicaid for their covered outpatient drugs (CODs), the manufacturer must participate in the MDRP, and agree to pay rebates for CODs dispensed and paid for under the Medicaid State Plan. The amount of the rebate is determined by a formula set forth in section 1927(c) of the Social Security Act. Generally, the formula to calculate the rebate that applies to a particular drug depends on whether the drug is classified as (1) a single source drug or innovator multiple source drug (commonly referred to as a brand-name drug); or (2) other drugs, which include non-innovator multiple source drugs, commonly referred to as generic drugs, among others. In accordance with section 1927(c) of the act and Federal Regulations at 42 CFR 447.509, the rebate calculation for a particular COD may also include an additional inflationary component to account for increases in the drug's Average Manufacturer's Price.

Question. I'm very concerned about the proposed cuts to the Medicare Advantaged program in CMS Rate Notice for Plan Year 2025. According to a recent study by the Berkley Research Group, seniors who chose Medicare Advantage over Fee-for-Service will on average experience a $33 per month benefit cut. In January of this year, I coled a letter with Senator Cortez Masto with over 60 cosigners from both sides of the aisle supporting Medicare Advantage.

I strongly encourage HHS and CMS to reconsider cuts to this program, and to work with these groups to make the MA program stronger and more sustainable for the 51 percent of Medicare beneficiaries that have chosen MA for their health coverage.

CMS released proposed negative Medicare Advantage rates that do not keep up with inflation or rising medical costs. CMS proposed a −.16-percent overall payment environment for 2025. As part of the proposed negative payment environment, CMS incorporated a 2.44-percent growth rate into the payment methodology. Both external and government analyses show that medical costs are increasing and far above CMS's estimates, such as CMS's Office of the Actuary projects an average Medicare annual expenditure growth of 7.5 percent for the period 2022 through 2031 and specifically calls out that in 2025 Medicare spending growth will be 8.9 percent. Along with this, the Congressional Budget Office projects that Medicare spending is expected to grow by 8 percent in 2024.

It seems important to ensure the Medicare Advantage payment environment reflects these increased cost pressures, especially now that Medicare Advantage serves more than 50 percent of Medicare beneficiaries. Are you accounting for these increased cost pressures in the 2025 Medicare Advantage final notice?

For 2024, CMS finalized a negative payment environment and enacted the most significant changes to the program in a decade, including changes to Medicare Advantage payment through the implementation of a new risk adjustment model. CMS is phasing in the new Risk Adjustment Model over a 3-year period and the full im-

pact is yet to be realized. For 2025, CMS is proposing another year of negative rates.

Are you concerned these year-over-year cuts to the Medicare Advantage program will negatively impact seniors' benefits and premiums? What is being done to prevent negative impacts to seniors?

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

If finalized, CMS anticipates stable premiums and benefits for individuals for CY 2025, as was the case for offerings in CY 2024, which was the first year of the updated risk adjustment model implementation. For CY 2024, average premiums and benefits for MA remained stable. The MA average monthly plan premium remained stable with an increase of less than $1 on average, while plan choice and average supplemental benefit offerings across plans increased.

Question. The Inflation Reduction Act (IRA) made changes to Medicare Part D that will increase plan sponsors' liability for costs in the catastrophic phase beginning in 2025. As a result, plans have additional incentive to apply utilization management, including step therapy, in order to limit their expenditures and such actions could adversely impact patients access to timely and appropriate care. It is critical that CMS takes proactive steps to protect beneficiaries, including providing clear direction to health plans and pharmacy benefit managers, to ensure timely patient access to therapy. The magnitude of adverse impacts could be far reaching to millions of patients when you consider how many enrollees depend on medication to treat a range of conditions.

How is CMS monitoring changes in formulary design to ensure that beneficiaries maintain timely access to appropriate therapies?

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

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

Additionally, CMS requires Part D sponsors to submit utilization management requirements applied at point of sale, such as prior authorization, step therapy, and quantity limits not based upon the FDA's maximum daily dose limits, as part of their Health Plan Management System formulary submission. Sponsors must per-

form adequate oversight of their PBMs and other delegated entities to verify that they are complying with all CMS requirements and not causing beneficiary harm due to impermissible delayed or denied access to Part D drugs.

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

Question. For the first time since the enactment of the Bayh-Dole Act in 1980, the Biden administration has discovered an authority to use so-called "march-in rights" as a mechanism for government-imposed price controls. No previous administration, including the current one, has ever found a basis for doing this. In fact, Senators Bayh and Dole wrote "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."[45]

Where does the administration believe it gets the authority for this radical rewrite of existing law?

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 fully committed to implementing the law to uphold these aims and support the innovation needed to deliver new safe and effective drugs to patients. To that end, HHS has partnered with the Department of Commerce to review cases in which the use of march-in authority, as laid out in the Bayh-Dole Act, would be appropriate by clearly articulating the guiding criteria and processes for making determinations where different factors, including price, may be a consideration in the agencies' assessments.

Question. In 2020, you organized a letter signed by 36 Attorneys General urging the Secretary of Health and Human Services to exercise march-in rights on the drug Remdesivir even though the patents associated with that drug lacked the requisite Federal Interest Statement required under the Bayh-Dole Act. In fact, the Chief Patent Counsel for the U.S. Army Medical Research and Development Command, said "[a]lthough USAMRIID performed extensive and critical screening and testing for Gilead, testing a compound and finding that it is indeed an effective antiviral compound does not qualify USAMRIID as a joint inventor of the compound."[46] The Government Accountability Office reported "[f]ederally supported Remdesivir research conducted by CDC, DOD, NIH, and NIH-funded universities has not resulted in government patent rights, because, according to agency and university officials, Federal contributions to the research did not generate new inventions. In addition, Gilead entered research collaborations with Federal agencies and universities with a portfolio of existing patents and patent applications, including for the remdesivir compound, which would have left little room for the agencies to generate their own patents."[47]

It's a simple matter to look up a patent and determine whether it has a Federal interest statement making it subject to march-in. Did you or any member of your staff bother to check? If not, why not?

Do you now acknowledge that your demand that HHS march-in on Remdesivir was made without any basis in law or fact?

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

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[45] Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," *The Washington Post* (April 11, 2002) Available at: *https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/*.

[46] Christopher Rowland, "Taxpayers Paid to Develop Remdesivir but Will Have No Say When Gilead Sets the Price," *The Washington Post* (May 26,2020) Available at: *https://www.washingtonpost.com/business/2020/05/26/remdesivir-coronavirus-taxpayers/*.

[47] Government Accountability Office, "Biomedical Research: Information on Federal Contributions to Remdesivir," GAO–21–272 (March 31, 2021) Available at: *https://www.gao.gov/products/gao-21-272#:~:text=Remdesivir%20was%20the%20first%20drug,and%20related%20agency%20patent%20rights*.

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 the agencies' assessments.

Question. There are very few drugs where all the associated patents have a Federal interest statement enabling the government to march in and license another party to make a copy.

Has the Biden administration determined how many drugs would be subject to march-in if the law allowed it to be used in this manner? If so, could you share that information with the committee?

Answer. NIST is the agency with authority to interpret and promulgate implementation of the march-in authority. HHS is working with NIST, through the Department of Commerce, to finalize the implementation framework described above.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

Question. As you know, our oral health is closely tied to our physical health. Over the last 3 years, the Biden-Harris administration has taken significant steps to promote access to oral health care. While Medicare dental coverage remains considerably limited, in 2023, CMS clarified that in certain situations Medicare beneficiaries can access medically necessary treatments for oral health. This was a move Senator Stabenow and I long advocated for.

I was also pleased to see that CMS created a process to evaluate clinical evidence for additional dental services to determine whether they are medically necessary for beneficiaries, and I look forward to CMS continuing to examine the data to ensure coverage for all medically necessary oral health services.

Will you continue to use existing HHS authorities to ensure that oral health care is accessible to Medicaid and Medicare beneficiaries when it is medically necessary and work to reduce access disparities, including at-risk populations like communities of color, low-income individuals, and those living in rural communities?

What strategies is your agency implementing to ensure that children on Medicaid and CHIP are receiving the appropriate oral health screenings and treatment, particularly children with disabilities?

With all of this new activity, is CMS working to expand upon its dental expertise and resources within the agency to support implementation? What additional support is needed to help implement, oversee, and monitor CMS's dental efforts?

Answer. CMS believes that dental health is an important part of people's overall health. Medicare statute generally precludes payment under Medicare Parts A or B for any expenses incurred for coverage, items, and services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but there are some exceptions. Medicare has paid for dental services in some clinical circumstances when the dental services are inextricably linked to the clinical success of covered medical services. The Centers for Medicare and Medicaid Services codified that policy in the agency's regulations. CMS also adopted a set of examples of clinical scenarios under which Medicare payment under Parts A and B can be made for certain dental services furnished in either the inpatient or outpatient setting, including for dental exams and necessary treatments prior to the treatment for head and neck cancers, beginning in CY 2024.

In the CY 2024 Medicare Physician Fee Schedule final rule, CMS added more examples in regulations of clinical scenarios under which Medicare Part A and Part B payment can be made for dental services. Additionally, CMS finalized to make payment for certain dental services inextricably linked to covered services used to treat cancer, including chemotherapy services, Chimeric Antigen Receptor T- (CAR–T) Cell therapy, and the use of high-dose bone modifying agents (antiresorptive therapy). These policies increase access to important dental care that can improve the success of these cancer-related treatments. CMS will continue to explore whether there are additional clinical scenarios where dental services are inextricably linked to the clinical success of covered medical services.

Medicaid covers dental services for eligible child enrollees as part of a comprehensive set of benefits, referred to as the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit. Dental services covered as part of EPSDT must include relief of pain and infections, restoration of teeth, and maintenance of dental health. The EPSDT benefit requires that all services the State could cover under section 1905(a) of the Social Security Act (Act) must be covered for an EPSDT-eligible child if determined medically necessary. States determine medical necessity. If a condition requiring treatment is discovered during a screening, the State must cover any necessary services to treat that condition, whether or not such services are covered for adults or included in a State's Medicaid plan, as long as the services could be covered under section 1905(a) of the act. Each State is required to develop a dental periodicity schedule in consultation with recognized dental organizations involved in child health care. Dental services may not be limited to emergency services for children entitled to EPSDT.

States that provide CHIP coverage to children through a Medicaid expansion program are required to cover the EPSDT benefit. Dental coverage in separate CHIP programs is required to include coverage for dental services "necessary to prevent disease and promote oral health, restore oral structures to health and function, and treat emergency conditions." States are also required to post a listing of all participating Medicaid and CHIP dental providers and benefit packages on *InsureKidsNow.gov*.

Improving oral health outcomes for children and adolescents in Medicaid and CHIP is a priority for CMS. Tooth decay is one of the most common chronic conditions of childhood, can have long-lasting effects on healthy growth and development, and is more prevalent among children who are from low-income families. In recognition of this priority, CMS reports on quality improvement efforts and progress in this area each year. Furthermore, the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) includes three measures that focus on measuring access to high quality and appropriate dental and oral health services. These measures include comprehensive or periodic oral evaluation, receipt of dental sealants and receipt of topical fluoride. States began reporting this information on voluntary basis in 2022, and reporting becomes mandatory in 2024.

States also have flexibility to determine what dental benefits are covered for adult Medicaid enrollees. While most States cover at least emergency dental services for adults, less than half of the States currently cover comprehensive dental care. There are no minimum requirements for adult dental coverage in Medicaid. In order to help ensure that children on Medicaid and CHIP are receiving appropriate oral health screenings and treatment, CMS launched the Oral Health Initiative (OHI) in 2010 and set national and State-specific goals to improve Medicaid-enrolled children's use of preventive dental care, and invited State Medicaid agencies to develop State Oral Health Action Plans (SOHAPs) as a roadmap to achieving their goals. In 2020, CMS announced the next phase of the OHI to support continued progress and drive further quality improvement, and continued to offer technical assistance to States on refreshing or developing SOHAPs and identifying best practices to help States move toward their OHI goals. From 2020–2023, a CMS learning collaborative, Advancing Oral Health Prevention in Primary Care, supported State Medicaid and CHIP agencies' efforts to improve children's oral health. CMS looks forward to working with both States and Congress to continue improving access to important oral health-care services.

Question. According to HRSA, there are over 103,000 men, women, and children on the national waiting list, and around 17 people die each day while waiting for an organ transplant. This problem is even more acute for people of color and people in rural communities. For example, Black Americans are less likely to be given opportunities to consider donation, contributing to the shortage of available organs.

Over the last 2 years, Congress has worked with HHS, including CMS and HRSA to make historic reforms to the organ procurement transplant network (OPTN). I was pleased to hold a subcommittee hearing and colead legislation to modernize the transplant system, which President Biden signed into law last fall, titled the Securing the U.S. Organ Procurement and Transplantation Network Act. My colleagues, Chairman Wyden, Senators Grassley, Young, and Cassidy have been excellent partners in our effort to make our transplant system work for all Americans.

The President's budget takes steps in this direction by investing for a more fair, well-managed, and high functioning organ transplant system in this country, and highlighting priority issues in organ donation, including transparency.

Can you comment on what policies HHS and HRSA will support to require OPOs to be more transparent, including whether HRSA will require OPOs to publish data about donated organs, so we can tackle health disparities around organ donation?

Answer. HHS is taking transformational steps to modernize the critical organ matching technology while increasing transparency and accountability by issuing new data reporting requirements to better address pre-waitlist and organ procurement practices. In February, HRSA directed the current OPTN vendor to standardize and update data reporting on referral to transplant center, time-to-patient assessment, time-to-organ procurement, and other data to allow for greater accountability in organ procurement and transplant practices across geography and populations and facilitate improved system performance. Additional details on this data directive are provided on the OPTN website.

This important work on pre-waitlist practices will help address inequities in the transplant waitlist process by reducing racial and ethnic variation both in patient referrals and in organ procurement.

Question. In 2020, HHS finalized a new rule to hold organ procurement organizations (OPOs) accountable for their performance, meaning that failing OPOs will lose their contracts to higher performers who can better serve patients. Since HHS finalized this rule, OPOs have continued to lobby against enforcement of the rule, including through misinformation campaigns.

Will HHS commit today to enforcing the OPO rule, without any delay or weakening, at the end of the current OPO contract cycles, so that every part of the country can be served by a high-performing OPO?

Answer. The role of OPOs is critical to ensuring that the maximum number of transplantable organs are available to seriously ill people who are on a waiting list for an organ transplant. The 2020 OPO final rule was an important step forward in improving OPO performance and increasing accountability for these organizations to ensure lifesaving organs reach potential recipients.

CMS established and implemented two new outcome measures in the 2020 OPO final rule in accordance with the authorizing legislation to drive improved organ procurement that results in increased transplantation, reduces organ nonuse, and increases the number of lives saved. These outcome measures are based on objective and reliable data that compares each OPO's performance to the top-performing OPOs, and then stratifies OPOs into three different tiers based on their performance, with the lowest performers (those in tier 3) being decertified from the program. As specified in the final rule, CMS will conduct annual assessments of OPO performance. This will provide more frequent feedback to OPOs on their performance. The outcome assessments will be based on the most recent 12 months of data. For the first 3 years of the certification cycle, CMS will identify any low performing OPOs (those below the top performing rate) and these entities are required to revise their quality assessment and performance improvement program in order to improve their performance. CMS will also provide OPOs with feedback on their performance annually allowing time to make the needed changes to drive improvements. While the certification cycle is at least 4 years, we expect OPOs to continuously improve year over year in order to maximize the number of available organs for potential recipients. CMS provides data every year on the OPOs' tier status in order for them to continue to improve performance and address any barriers that they may have. However, the agency bases recertification on the most recent 1 year of performance data.

Additionally, CMS is offering technical assistance to chronically low-performing OPOs to help them in improving performance. CMS is currently providing OPOs the opportunity to participate in the End-Stage Renal Disease Treatment Choices Learning Collaborative, a joint quality improvement program from CMS in collaboration with the Health Resources and Services Administration. The learning collaborative is based on the success of the 2003 Organ Donation Breakthrough Collaborative and the 2016–2018 Organ Procurement and Transplantation Network Collaborative Innovation and Improvement Network project. The program provides technical assistance to several stakeholders, including OPOs, with three aims: to increase the number of deceased donor kidneys transplanted, to decrease the current national organ non-use rate of all procured kidneys, and to increase the percentage of change for kidneys recovered for transplant with a high kidney donor profile index.

While CMS is working closely with OPOs in an effort to boost their performance, we will take necessary action at the end of the current certification period if they

fail to meet established performance benchmarks. CMS will enforce requirements during the recertification process that will occur in 2026. While there is currently no formal appeals process for tier assignment, CMS provides OPOs the opportunity to preview their tier assignment and raise any concerns if they believe the information is incorrect. If an OPO were to be decertified for any reason, CMS provides the OPO an opportunity to appeal the decertification on substantive and procedural grounds. CMS continues to work to improve the overall organ donation and transplantation system to ensure that all lifesaving organs reach potential recipients.

As stated in the Fall 2023 Unified Agenda of Regulatory and Deregulatory Actions, we are developing a proposed rule regarding the standards used to evaluate and recertify OPOs. Since the OPO final rule, CMS has received feedback from stakeholder listening sessions and continued public comment on the rule, including comments received from a CMS Request for Information on OPO and transplant system concerns published in December 2021. As a result of the feedback, we are reviewing our OPO competition and decertification processes, and any changes would be made through future rulemaking. Any revisions will continue to hold OPOs responsible for improved performance.

Question. At the end of the second quarter of 2023, the American Society of Health-System Pharmacists identified 309 active, ongoing drug shortages—the highest number in nearly a decade.

In 2022, legislation I championed with Senator Collins was incorporated in the FY 2023 Omnibus, which requires FDA to update its guidance on stability testing tied to shelf-life expiration dates. One part of my proposal that was not included was the authority for FDA to levy civil money penalty if a manufacturer fails to comply. I look forward to continuing to work with you on that issue.

Can you talk about the broader efforts across HHS and partnerships across government you are implementing to mitigate and prevent drug shortages?

Answer. HHS recognizes the severe patient impact from the persistent problem of chronic drug shortages that have most frequently impacted inexpensive generic drugs, particularly sterile injectables. HHS is taking a coordinated approach to help address economic root causes of shortages.

In November 2023, HHS announced the establishment of a new Supply Chain Resilience and Shortage Coordinator role responsible for coordinating efforts across the Department that advance the resilience of medical product and food supply chains and accelerate the Department's response to related shortages. Institutionalizing this coordination across the Department will help HHS meet its long-term supply chain resilience and shortage mitigation goals. In addition, FDA on an ongoing basis works to identify shortage risks and determines actions that can prevent or mitigate patient impact, such as prioritizing review of manufacturer submissions or working with manufacturers to increase supply. ASPR also led the development of an Essential Medicines Supply Chain and Manufacturing Resilience Assessment to identify supply chain vulnerabilities in a critical medicines list and has invested, through the Industrial Base Management and Supply Chain (IBMSC) Office, targeted funds to bolster domestic manufacturing capabilities for essential medicines.

CMS is also taking steps to help align certain incentives to bolster supply chain resilience and further promote adoption of resilient supply chain practices. As discussed in the Calendar Year 2024 Outpatient Prospective Payment System (OPPS) final rule, CMS solicited public comment on providing separate payment under the Medicare Inpatient Prospective Payment System (IPPS), and potentially the OPPS, for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply (88 FR 82127–30).

CMS also noted in the CY 2024 OPPS final rule that as part of the agency's initial efforts, CMS intends to propose new Conditions of Participation in forthcoming notice and comment rulemaking addressing hospital processes for pharmaceutical supply (88 FR 82130). CMS continues to review the comments received to consider ways the Medicare program can promote hospital resilient supply chain practices to help mitigate the impact of drug shortages on patients.

Question. On President Biden's first day in office, he signed an executive order directing a whole-of-government approach to addressing racial equity and disparities among underserved communities. The President built on that through an additional executive order shortly after.

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 elevated 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.

How is the administration working to promote health equity and eliminate health disparities across HHS programs?

Answer. The National Institutes of Health (NIH) are advancing health equity by supporting research to improve minority health and reduce health disparities. These efforts are led by the National Institute on Minority Health and Health Disparities (NIMHD). Through an agency-wide plan, NIMHD coordinates research and activities on minority health and health disparities, supports training and capacity building, and fosters collaborations and partnerships. Research projects totaling approximately $5 billion across NIH support minority health and health disparities science.

NIH prioritizes minority health and health disparities research through collaborative initiatives and programs. For example, the Community Engagement Alliance (CEAL) initiative focuses on community-engaged research, which is a key component of the initiative's effectiveness in providing critical support on vaccination, therapeutics, and participation in clinical trials among those disproportionately affected by the COVID–19 pandemic. Moving forward, NIH is applying the CEAL research models, resources, lessons learned, and best practices to other important areas of population health such as prevention and management of chronic diseases.

The NIH Science collaborative for Health disparities and artificial intelligence bias Reduction (ScHARe) initiative, led by NIMHD in collaboration with the National Institute of Nursing Research, is an innovative cloud-based platform for population science, including social determinants of health (SDOH) and data sets designed to accelerate research on health disparities, health and health-care delivery outcomes, and artificial intelligence (AI) bias mitigation strategies. ScHARe aims to promote broad participation among data science researchers, including those from underrepresented racial and ethnic groups and women, provide opportunities for collaborations, trainings, and mentorship, and advance health disparities research by leveraging big data and ethical AI.

The NIH Common Fund Community Partnerships to Advance Science for Society (ComPASS) program is supporting multilevel structural interventions in community-driven research projects focused on SDOH and fostering collaborative partnerships between communities and researchers. In FY 2023, the ComPASS program made 25 awards directly to community organizations and funded a coordinating center, totaling approximately $171 million over 5 years, pending the availability of funds. Examples of ComPASS-supported research projects that focus on populations experiencing health disparities include: increasing access to healthy foods in underserved rural communities; improving telehealth models for preventative screening and disease management among agricultural workers; and investigating early childcare strategies to improve mental health for children and caregivers.

In addition to these select research activities and efforts, NIH remains committed to working with HHS partners to ensure that eliminating health disparities remains a priority for NIH and across HHS.

Question. The last 4 years have shown the benefits of telehealth for people across the United States. 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 the Senate Finance Committee Working Group on telemental 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 equal access to high quality care through telehealth?

As we look to make permanent telehealth policies, what additional tools do you need from Congress?

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

Question. Gun violence is an issue that plagues communities across the country, including many in my home State of Maryland. Aside from the obvious devastating human impact of this violence, according to Everytown for Gun Safety, gun deaths and injuries cost Maryland over $10 billion each year.

I am proud to be working on a bill that would provide guidance to States regarding Medicaid reimbursement for furnishing community violence prevention services and treatments that aim to ease the burden this traumatic violence places on communities. Hospitals in my State, including Shock Trauma and University of Maryland Capital Region Medical Center, are doing great work, partnering with the community to reduce gun violence.

Do you see gun violence as a threat to the health of our communities and how will the proposed budget support communities to reduce and prevent it?

Answer. Violence is a serious public health problem that impacts the health and safety of Americans. Firearm injury is among the 5 leading causes of death for people aged 1–44 in the United States and is the leading cause of death among children and teens ages 1–19.[48] In 2022 there were approximately 24,867 homicide-related deaths. Approximately 19,657 of these were firearm homicides.[49] In addition, more people suffer nonfatal than fatal firearm-related injuries. More than 7 out of every 10 medically treated firearm injuries are from firearm-related assaults.[50] The total cost of firearm related injuries and deaths in the U.S. was $493.2 billion in 2020.[51]

Community violence can cause mental health conditions such as depression, anxiety, and post-traumatic stress disorder (PTSD). Living in a community experiencing violence is also associated with increased risk of developing chronic diseases.

Community violence is preventable, and CDC is working with partners and communities to disseminate, implement, and scale-up strategies based on the best available evidence to create safer communities. CDC's Resources for Action help communities and States sharpen their focus on prevention activities with the greatest potential to prevent multiple forms of violence and their consequences.

The proposed FY 2025 budget provides a total of $2.5 billion over 10 years in mandatory and discretionary funds for Youth and Community Violence Prevention, including CDC's Community Violence Intervention initiative. Of this total, the budget assumes $100 million in discretionary funding per year and $150 million in mandatory funding per year to support scaling up existing community violence prevention efforts and implementing and evaluating programs, policies, and practices based on the best available evidence. With an annual investment of $250 million, CDC will fund up to 75 cities and communities in geographic areas with the highest

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[48] Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. WISQARS—Web-based Injury Statistics Query and Reporting System. *https://www.cdc.gov/injury/wisqars/index.html*.

[49] Centers for Disease Control and Prevention. WONDER—Wide-ranging Online Data for Epidemiologic Research. Provisional Mortality Statistics. *https://wonder.cdc.gov/mcd.html*

[50] Dahlberg LL, Haileyesus T. Victimization from gun violence. in: Schildkraut J, Carter GL, Guns in American Society: An Encyclopedia of History, Politics, Culture, and the Law. 3rd ed. ABC–CLIO Publishers, Santa Barbara, CA2022: 885–891.

[51] Miller GF, Barnett SBL, Florence CS, Harrison KM, Dahlberg LL, Mercy JA. Costs of Fatal and Nonfatal Firearm Injuries in the U.S., 2019 and 2020. *American Journal of Preventive Medicine,* 2024; 66(2): 195–204.

number of homicides or highest number of homicides per capita to (1) establish a collaborative, community-driven public health approach to reduce community violence, and (2) provide technical assistance and support to these communities. Increased funding for community and youth violence prevention will also allow CDC to fund additional National Centers of Excellence in Youth Violence beyond the five currently funded to develop, implement, and rigorously evaluate innovative strategies to prevent violence and create safer, healthier family and community environments for youth.

In addition, the $60 million proposed in the FY 2025 President's budget for firearm injury and mortality prevention research across NIH and CDC will be used to fund additional research and evaluation projects to better understand and prevent firearm-related injuries and deaths in the United States, and continue efforts to strengthen data at the local, State, and national level. CDC would also use this increased funding to expand the very successful near real-time data collection through the Firearm Injury Surveillance Through Emergency Rooms: Advancing Violence Epidemiology in Real-Time (FASTER: AVERT) program nationwide.

Question. I have long been a champion of our country's global health initiatives, and I am glad to see that this budget requests $10 billion to strengthen health systems globally. After the pandemic, it became clearer to many how interconnected all of the world's health systems are.

The U.S. Centers for Disease Control and Prevention play a key role in global health systems strengthening by exchanging scientific expertise and data with other nations, working alongside other agencies, such as the U.S. Agency for International Development and the State Department.

How will investments from the FY 2024 budget allow HHS to contribute to global health systems strengthening as a critical component of pandemic preparedness and global health security?

Answer. CDC is 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 advances the U.S. Government's newly released Global Health Security Strategy and National Biodefense Strategy by leading the U.S. Government response to public health emergencies. CDC experts work alongside local, regional, and global partners across our global health portfolio to provide unparalleled expertise in disease data and surveillance, laboratory systems, public health workforce and institutions, disease prevention and response, innovation and research, and policy, communication, and diplomacy.

The most effective and least expensive way to protect Americans from infectious diseases and other health threats that begin overseas is to prevent, detect, and respond to outbreaks before they spread to the United States. Due to CDC's global presence and decades of building peer-to-peer partnerships, collaboration, and public health networks, CDC staff are often the "first call" by partners abroad about signs of a potential disease outbreak event. The earlier a disease threat is identified, the sooner the response can begin to prevent further spread, including to the United States. In this way, CDC's global staff further CDC's mission by serving as the United States' first line of defense against infectious disease threats and their potential importation.

With the sustained funding, CDC will continue to:

Maintain its role in serving as the U.S. Government's lead agency for infectious disease outbreak response to keep Americans safe from the next emerging disease threat.

Prevent, detect, and respond to high consequence threats to the United States. This includes 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, et cetera), respiratory pathogens, and vector-borne diseases (diseases from pathogens spread by mosquitos, ticks, fleas, et cetera). CDC will also continue to help build and support laboratory and surveillance networks that can be leveraged to respond to new and emerging global threats to contain spread.

Work alongside countries and partners to strengthen global public health systems, including developing and enhancing disease surveillance systems that enable disease detection, tracking and reporting, as well as helping to build more effective public health laboratories. In addition, through CDC's focused efforts to modernize

and expand front-line disease detective training and emergency response capabilities, CDC will continue help building and supporting global public health systems to improve health security and protect the health and livelihoods of the American people.

Build strong cadres of international disease detectives through training in surveillance, leadership and management, and emergency response, through the Field Epidemiology Training Program (FETP), and assist countries in building sustainable public health emergency preparedness and response capacity through the International Career Epidemiology Field Officer (I–CEFO) program.

Help countries establish their own public health emergency management programs to prepare for, respond to, and recover from public health threats. CDC's programs train government leaders and a country's public health workforce on emergency management principles, helping to establish public health emergency operations centers from which responses are managed, and assisting in the development of plans and processes that guide response actions. CDC will scale and adapt its emergency management technical assistance to provide prioritized support across regions and to countries at their national and sub-national levels.

Support global and country-level outbreak readiness and response efforts to address emerging outbreaks and health threats. CDC global health security efforts, in-country presence, and global leadership are critical to prevent, detect, and respond to disease threats, including mpox, Ebola, Marburg, cholera, and more.

Help ensure the efficacy of vaccines for influenza and meningitis, maintain the primary global resource of respiratory laboratory reagents for outbreaks, and support global efforts to prevent, detect, and respond to respiratory disease threats. CDC continuously adapts to an evolving environment that includes persisting threats of COVID–19, influenza, respiratory viruses, and changing perspectives on global pandemic preparedness. Our global approach supports and advances CDC's global health goals to achieve health impact, health security, and public health science leadership.

Question. I was disappointed to learn last Friday about the failure of a promising ALS treatment in its final trials. My heart is heavy for all of the ALS patients and family members who were holding out hope for new therapies for this cruel and relentless disease. While we may be disappointed right now, we cannot let up on efforts to find new treatments for ALS. And the FDA's support in using its Accelerated Approval Program to achieve this is more important now than ever.

I have heard from companies across the country, including one in my home State of Maryland, about exciting therapies with promising results in clinical trials to address a range of neurodegenerative diseases. As you know, the Accelerated Approval Program is an important tool to get innovative treatments to patients facing the most serious health conditions.

Will you commit to ensuring that the Accelerated Approval Program remains a viable option for new ALS treatments?

Does your Department believe that any drug that demonstrates the "clinical benefit" of "survival" in a disease like ALS that is always fatal (where patients typically live 2 to 5 years after diagnosis) is by definition reasonably likely to predict an effect on mortality and should therefore be open for consideration under the Accelerated Approval Program?

Answer. I recognize the terrible impact of ALS on patients, their families, and caregivers, and I remain committed in all efforts to advance ALS drug development. I recognize the continued unmet need for treatments for patients living with ALS, and I am committed to engaging with companies and the patient community to facilitate the development of treatments for this disease. I can also assure you that FDA is exercising the regulatory flexibility described in FDA's 2019 guidance for industry titled Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment (ALS Guidance), and I continue to commit to doing so.

Despite years of research and the availability of some approved therapies, I know the lack of new treatments for ALS is deeply frustrating for patients and their families and caregivers. Gaps in disease characterization, the heterogeneity of the ALS patient population, and a lack of fit-for-purpose biomarkers, among other things, all create significant scientific challenges across all clinical phases of ALS drug development. It is critical that we work with all stakeholders to further advance the scientific understanding of ALS, encourage the development of treatments for ALS,

support patient involvement in clinical trials for ALS treatments, and facilitate patient access to investigational treatments when appropriate.

FDA and I are committed to facilitating product development for rare diseases, including ALS. We recognize that certain aspects of drug development used for common diseases may not be feasible for rare diseases, including ALS, and that development challenges are often greater in diseases with very small populations. FDA exercises regulatory flexibility in these situations to address unique challenges posed by each disease, such as in trial design, while applying statutory standards. A higher degree of uncertainty is common in drug development programs for ALS, where the prevalence of disease, and consequent limitations on study size, can limit the precision of safety and efficacy characterizations. We recognize that when a drug is developed to treat a serious disease for which there are few or no approved therapies, greater uncertainty or greater risks may be acceptable for a drug to be approved, provided that the approval standard has been met. Consequently, FDA often exercises regulatory flexibility in these cases. It is important to note that this flexibility applies to rare disease drug development programs that utilize both the traditional approval pathway and the accelerated approval pathway. FDA applies flexibility in these situations to address specific challenges posed by each disease and works with drug developers to consider the optimal development pathway.

I will note that Qalsody (tofersen) for ALS was approved via the Accelerated Approval pathway in April 2023. FDA approved Qalsody to treat individuals with ALS associated with a mutation in the superoxide dismutase 1 (SOD1) gene (SOD1–ALS). The approval was based on a reduction in plasma neurofilament light (NfL), a blood-based biomarker of axonal (nerve) injury and neurodegeneration.

To the question of whether we would consider a drug that has demonstrated the "clinical benefit" of "survival" in a disease like ALS under the accelerated approval pathway, I note accelerated approval is designed to provide an approval pathway for drugs based on surrogate endpoints or intermediate clinical endpoints that can be measured earlier than mortality and are reasonably likely to predict clinical benefit, such as improved survival. A drug that demonstrates this benefit may be eligible for traditional approval and would not need to leverage the accelerated approval pathway. Importantly, we have a number of programs that can speed the development and approval of promising drugs regardless of the regulatory approval pathway (*i.e.,* traditional versus accelerated approval), including breakthrough therapy designation, fast track, and priority review. If a drug meets the criteria for one or more of these expedited programs, we will work with the sponsor to expedite development of the drug, with the goal of approving the drug swiftly when evidence supports approval.

QUESTIONS SUBMITTED BY HON. BILL CASSIDY

Question. As I stated in the hearing, I am grateful to the National Association of ACOs for using VRDC data to find the $2 billion in Medicare catheter fraud. But I am disappointed this fraud was allowed to go on for so long and at such a high level without CMS discovering it.

How does CMS plan to improve their billing auditing to ensure this cannot happen again?

Does CMS use AI or similar tools to retrospectively review payment rates and trends?

What is HHS's total budget for technology and data modernization?

Can you please provide a list of technology vendors, contractors, and subcontractors performing work for HHS along with a list of work being performed by each broken out by project size, cost, and timeline. Does CMS require Quality Assurance Surveillance Plans (QASPs) for each contract?

How does HHS ensure that new technology systems are developed with a focus on end users, and an eye towards future upgrades? How are those who develop these systems held accountable for these goals?

Answer. CMS takes Medicare and Medicaid fraud and abuse seriously, and we are committed to taking swift and aggressive action to identify and investigate fraud, in support of law enforcement agencies. In early 2023, CMS identified a concerning rise in urinary catheter billings. CMS identified 11 Durable Medical Equipment (DME) suppliers responsible for 89 percent of all urinary catheter claims that ap-

peared to be allowable between January 1, 2023, and March 11, 2024. We quickly suspended Medicare payments to these suppliers. In most cases, CMS placed suspensions within days after learning about the billing spikes. From January 1, 2023, and March 11, 2024, $3.56 billion of catheter claims made it through most of our payment system checks and were considered "payable" for all suppliers. The 11 top suppliers represented $3.16 billion of this amount. CMS did not pay $3.16 billion to the 11 suppliers because we had them on payment suspensions. This amount would not be reflected on *data.cms.gov*. In addition, CMS revoked Medicare enrollments of these suppliers to prevent future improper billings. Revocations prevent the provider/supplier from reenrolling in Medicare for up to 10 years.

In general, Medicare regulations allow CMS to suspend payment to a provider when there is reliable information of an overpayment or when a credible allegation of fraud exists against a provider. According to federal Medicare regulations, a credible allegation of fraud is an allegation from any source, including fraud hotline tips verified by further evidence, claims data mining, patterns identified through provider audits, civil false claims cases, and law enforcement investigations. CMS is required by regulation to consult with law enforcement prior to suspending payment when we believe there is a credible allegation of fraud.

When CMS approves a payment suspension, we suspend payment for allowable claims submitted during the period of payment suspension. Providers can still submit Medicare payments while under suspension and these payments may be recorded as Medicare billings, although they have not actually been paid to a suspended provider. When a payment suspension is lifted, withheld funds are first applied to any Medicare overpayment assessed on the provider and second to other CMS or HHS obligations. If there is no legal financial obligation to another entity, any excess payments held in suspense are released to the provider.

Question. I am encouraged to hear you are willing to reconsider the VRDC transition in order to ensure data access for researchers and academic institutions. Medicare and Medicaid data are public goods which we must preserve access to.

Can you please provide additional details on how you intend to make the system affordable for researchers and students who use this CMS data, along with an analysis of how many researchers, academic institutions, and students you believe will be impacted by the change.

Additionally, it is my understanding the VRDC system is currently very cumbersome to use. Can you please provide a roadmap of how you intend to streamline and modernize the VRDC system to improve its utility in the future.

Answer. Due to growing data security concerns and an increase in data breaches across the health-care ecosystem, CMS is making changes to the policies around how CMS data is accessed for research. The agency updates the fees for research data requests periodically to account for changes in the costs CMS incurs supporting researcher access to CMS data. Costs associated with maintaining the RIF Data Use Agreement (DUA), conducting data privacy and security reviews, and providing Research Data Assistance Center (ResDAC) help desk support are built into a new Project Fee.

In March, CMS released an updated request for information (RFI) expanding the solicitation of researcher feedback to include two additional topics: data access fees and the timing for these changes to further aid CMS in planning for the implementation of these changes.[52] CMS also extended the due date for RFI feedback to May 15, 2024. CMS will be sending out additional guidance later this year and final guidance prior to requiring researchers to transition their ongoing research studies to the Chronic Conditions Warehouse Virtual Research Data Center.

Question. There is a pressing need to update the CMS 2014 National Coverage Determination (NCD) for screening of hepatitis C to reflect the USPSTF 2020 recommendations. The USPSTF covers a broader range of people who can get the test. In addition, an important update, should also include testing in non-primary care settings, where a large number of people of HCV get seen (opioid treatment programs, mobile clinics, emergency departments, et cetera). There is a precedent for CMS expanding to non-primary care settings in the CMS 2015 HIV NCD Screening for the Human Immunodeficiency Virus (HIV) Infection.

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[52] *https://www.cms.gov/files/document/request-information-research-data-request/access-policy-changes.pdf.*

When can CMS get the NCD reupdated to reflect the USPTF 2020 recommendations for screening of Hepatitis C and expand screening to non-primary care settings?

Answer. Under § 1861(ddd) of the Social Security Act, the CMS has the authority to add coverage of additional preventive services if certain statutory requirements are met. Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of "preventive services" under 42 CFR § 410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the act) that these services are all of the following: (1) reasonable and necessary for the prevention or early detection of illness or disability, (2) recommended with a grade of A or B by the United States Preventive Services Task Force, and (3) appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

While CMS has accepted a request to reconsider this NCD, we have not been able to act on it yet due to our internal capacity restraints. As CMS indicated in the August 2013 Federal Register notice, "In the event that we have a large volume of NCD requests for simultaneous review, we prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources." 78 Fed. Reg. 48168 (August 7, 2013). This is not meant to minimize the importance of this request; it only reflects the limitations of our available resources. This request will be considered in the future as we prioritize the requests for NCDs.

Question. According to a July 2023 Joint Economic Committee Report, "Obesity is one of the largest contributors to Medicare and Medicaid spending." Further, the report suggests that in light of such spending, identifying diseases [in Medicare and Medicaid] ". . . that impose the largest financial burden, or which offer the most practical means of cost reduction . . ." should be addressed. Obesity and obesity-related diseases fit both categories. The JEC economists project that the combined Medicare and Medicaid spending on obesity and obesity-related diseases will total $4.1 trillion.

What needs to be done to modernize comprehensive obesity care in Medicare and Medicaid?

Answer. 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.

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

Medicaid and the Children's Health Insurance Program (CHIP) can play a role in reducing the rate of obesity in the United States by improving access to health-care services that support healthy weight. For eligible children enrolled in Medicaid, the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit covers all medically necessary services described in section 1905(a) of the Social Security Act, which can include obesity-related services. For adults, the States can choose which services to provide, with most States choosing to cover at least one obesity treatment.

Question. We've heard concerns from providers that MACs have not been expediting provider Part B claims, despite not only CMS guidance but CMS having to go back to the MACs in response to provider complaints. For example, one MAC

posted a notice on their site that paper claims may take 29 days to process, could not be expedited, and that each claim had to be accompanied by written documentation demonstrating the need to file by paper.

What is CMS doing to require MACs to expedite Medicare Part B claims until Change Healthcare is fully operational and back on line?

Does this outage show that there is a MAC problem in not adhering to CMS guidance, especially in crisis situations like the current Change cyberattack?

Answer. Due to the unprecedented impact of the Optum Insight/Change Healthcare Cyber Incident, CMS is making Change Healthcare/Optum Payment Disruption CHOPD accelerated or advance payments for a limited time period to help alleviate financial strain attributed to the disruption in the claims submission to and payments from Medicare Administrative Contractors. The CHOPD payment is intended to cover up to 30 days of Medicare claims and providers/suppliers have 90 days to repay the payment. MACs are aiming to review requests and will notify most providers/suppliers of the outcome of their request within 5 business days of receipt.

At the time of this testimony, CMS does not have a projected end date for the CHOPD accelerated and advance payment program. CMS expects these payments will no longer be available upon resolution of the disruptions to Change Healthcare/Optum's Electronic Data Interchange (EDI). CMS is actively monitoring the Incident and will issue further guidance if it becomes necessary.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

Question. I appreciate this administration's continued support to fund this critical program, which trains the majority of our pediatric provider workforce.

The President's budget proposes $385 million for CHGME. Robust funding for this program is what is needed to ensure the longevity of the pediatric workforce and that children have access to the best care.

Will you continue to work with me and other CHGME champions to make sure that we continue to grow this essential program for our Nation's children's hospitals?

Answer. Yes. Thank you for your support of this critical program for ensuring children have access to the care they need. The FY 2025 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.

Question. As artificial intelligence (AI) technologies continue to integrate into the health-care system, I am concerned about patient protections that are in place. The FY 2025 budget includes funding to oversee HHS's use of AI and mitigate risks, as well as advancing the responsible use of AI in health care.

Does HHS have a strategy to educate patients on how AI might utilize their personal health information?

How is HHS ensuring that AI technologies used in health-care settings does not exacerbate existing disparities?

How is HHS working to ensure AI does not contribute to barriers to care or denials of services?

What metrics are being considered by HHS to track patient confidence when engaging with AI technology?

Answer. On October 30, 2023, President Biden issued an executive order[53] to help ensure the safe, responsible deployment and use of AI in the health-care, public-health, and human-services sectors. Among other items, the EO requires the Secretary of HHS, in consultation with the Secretary of Defense and the Secretary of Veterans Affairs, to establish an HHS AI Task Force that shall, within 365 days of its creation, develop a strategic plan that includes policies and frameworks—possibly including regulatory action, as appropriate—on responsible deployment and

[53] Available at *https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/*.

use of AI and AI-enabled technologies in the health and human services sector (including research and discovery, drug and device safety, health-care delivery and financing, and public health), and identify appropriate guidance and resources to promote deployment. CMS is actively participating in HHS's efforts and building our knowledge and capabilities in this space. We are reviewing the feedback we have received on this issue for potential future rulemaking. In this way, we are positioning ourselves to respond agilely to any developments which could negatively impact beneficiaries of CMS programs and provide guard rails that will enable our programs to safely reap the benefits of these technological innovations.

MEDICAID MANAGED CARE

CMS is committed to partnering with States to help strengthen the monitoring and oversight of Medicaid managed care programs. The increased prevalence of the use of managed care delivery systems over the past several years underscores the continued need for strong Federal and State oversight of Medicaid managed care. CMS has taken a number of steps to support States, including developing a series of technical assistance tools and toolkits that States are encouraged to use to improve the monitoring and oversight of their managed care programs.

The regulations at 42 CFR § 438.210 allow managed care plans to implement prior authorization processes, so long as certain requirements are met. Managed care plans must also comply with the grievance and appeal system requirements laid out in 42 CFR part 438, subpart F, including the requirement that they can only have one level of appeal at the plan level before a beneficiary has access to a State fair hearing under 42 CFR part 431, subpart F. The 2016 Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability Final Rule (CMS–2390–F) clarified that States could offer enrollees the option of an external medical review, as long as the review is provided at the enrollee's option, is not a requirement, and is not used as a deterrent to proceeding to the State fair hearing. Further, if States want to offer enrollees the option of an external medical review, it must be independent of both the State and managed care plan and must be offered without any cost to the enrollee. Some States have utilized this flexibility and chose to offer an external medical review to enrollees when the managed care plan upheld the initial prior authorization denial. In addition, CMS, in January, finalized the CMS Interoperability and Prior Authorization (CMS–0057–F) rule that requires managed care plans, beginning in 2026, to publicly report certain metrics about prior authorization, including the percent of prior authorization requests that were approved, denied, or approved after appeal. The rule also requires managed care plans to make detailed information about prior authorization requests and decisions for items and services (excluding drugs) available to providers electronically, significantly shortens response times for the managed care plan to respond to a prior authorization request and requires that the prior authorization status be made available to enrollees electronically within one business day. In the case of a prior authorization denial, the managed care plan must provide a specific reason for all denied requests.

MEDICARE ADVANTAGE

An algorithm or software tool can be used to assist MA plans in making coverage determinations, but it is the responsibility of the MA organization to ensure that the algorithm or artificial intelligence complies with all applicable rules for how coverage determinations by MA organizations are made.

CMS will conduct both routine and focused program audits of organizations in 2024 to assess compliance with the coverage and utilization management (UM) requirements finalized in the CY 2024 final rule. For Medicare Advantage organizations (MAOs) that have routine program audits scheduled for 2024, these audits will follow our standard process similar to prior years, covering all applicable program areas, but will target the new UM requirements during the Part C Organization Determinations, Appeals, and Grievances (ODAG) review, as well as the Compliance Program Effectiveness (CPE) review. In addition, CMS is also adding new focused audits for plans that don't have routine scheduled audits, which are limited to ODAG and CPE, and are designed specifically to target compliance with the coverage and UM policies in the CY 2024 final rule. Through this combination of routine and focused audits in 2024, CMS expects to evaluate the UM-related performance of plans serving approximately 88 percent of people with MA. This expansion of our audit activity will help make sure that MA beneficiaries get the care they need without excessive burden or delays and have access to the benefits and serv-

ices to which they are entitled. During both the routine and focused program audits, CMS will utilize physician reviewers to review denied requests to assess whether MAOs are meeting clinical coverage requirements, such as following coverage and benefit conditions included in Medicare laws, National Coverage Determinations (NCD), or Local Coverage Determinations (LCD), and when permissible, applying internal coverage criteria only when coverage criteria are not fully established in statute, regulation, NCDs, and LCDs.

CMS program audits will also ensure that internal coverage criteria are publicly available and otherwise meet regulatory requirements, MAOs are only using physicians (or other appropriate health-care professionals) with appropriate expertise in the field of medicine for the service at issue when issuing adverse medical necessity decisions, and MAOs have established UM committees in accordance with regulatory requirements, including who the members of the committee are and the responsibilities they are required to complete.

We will be monitoring closely whether MA plans are utilizing and applying internal coverage criteria that are not found in Medicare laws, NCDs, or LCDs, and whether the internal coverage criteria are publicly accessible and coverage policies meet the regulatory requirements.

CMS has a number of tools it can use to address non-compliance with the new requirements, including issuing compliance and enforcement actions. Compliance actions include Notices of Non-Compliance, Warning Letters, and Requiring Corrective Action Plans.

Question. COVID–19 pandemic-era legislation allowed for the continuous enrollment in Medicaid for beneficiaries, creating greater access to health-care coverage. Since these policies expired, over 106,000 Ohio children have lost Medicaid coverage (as of December 2023). I am deeply concerned about these coverage losses and want to ensure that this process goes smoothly, and that children and families are not inaccurately being disenrolled from Medicaid.

How is HHS working with States to provide guidance and oversight of this unwinding process?

What more can be done to help connect Ohio families to care and ensure children are reenrolled in affordable coverage, as soon as possible?

Answer. The Biden-Harris administration is committed to using every available lever to protect and expand coverage for children. As States undertake Medicaid unwinding, CMS has encouraged them to adopt a range of options to help ensure that otherwise eligible individuals do not lose coverage solely for procedural reasons. CMS has been actively working with States and urging them to adopt all options that we have offered to help eligible individuals and families maintain their health coverage during the unwinding process and to work with State partners to support individuals and families with the renewal process.

As outlined in the March 3, 2022 State Health Official (SHO) letter #22–001, CMS may approve time-limited authority under section 1902(e)(14)(A) of the Social Security Act to permit States to implement strategies that are necessary to ensure that States establish income and eligibility determination systems that protect beneficiaries. CMS has approved a number of section 1902(e)(14)(A) waivers in relation to unwinding-related challenges that States face. These include: Strategies to Increase Ex Parte Renewal Rates; Strategies to Support Enrollees with Renewal Form Submission or Completion to Reduce Procedural Terminations; Strategies to Update Contact Information, and Strategies to Facilitate Reinstatement of Eligible Individuals for Procedural Reasons. Additional information on section 1902(e)(14)(A) waivers and other strategies to prevent procedural terminations can be found here: *https://www.medicaid.gov/resources-for-states/coronavirus-disease-2019-covid-19/unwinding-and-returning-regular-operations-after-covid-19/covid-19-phe-unwinding-section-1902e14a-waiver-approvals/index.html*.

HHS continues to work to increase access to health-care services for children. Continuous coverage for children has been shown to reduce financial barriers to care for low-income families, promote health equity, and provide States with better tools to hold health plans accountable for quality care and improved health outcomes. Stable coverage also enables health-care professionals to develop relationships with children and their parents, track a child's health and development, and help a family avoid expensive emergency room visits. As of January this year, all States across the country are required to provide children in Medicaid and CHIP with uninterrupted eligibility over the course of a year. In addition, the budget includes pro-

posals that would expand continuous eligibility for Medicaid and CHIP, and HHS is working with States interested in providing multiple years of continuous coverage, such as up to age 6.

Question. Diagnostic tests are important for timely and effective health care. Laboratory tests are critical to early diagnosis of cancer, access to appropriate treatments, and genetic testing. Unfortunately, Medicare reimbursements to laboratories have not changed since 2016 and while Congress has continued to prevent devastating cuts to labs, we need a long-term solution to ensure continued access to laboratory services, especially those living in rural and underserved communities. I have bipartisan legislation with Senator Tillis to update Medicare's payment system for clinical diagnostic laboratory services to ensure beneficiaries continue to have access to vital lab services and innovative tests and treatments.

Do you agree that long-term stable payments for laboratory services is critical to maintaining access to these needed tests, especially in rural and underserved communities?

Answer. We share your goal of ensuring access to clinical laboratory services for Medicare beneficiaries. CMS follows the statute with respect to the Clinical Laboratory Fee Schedule (CLFS). Consistent with the law, for CYs 2025 through 2027, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

Question. The President's budget proposes an increase in funding for Federally Qualified Health Centers (FQHCs) to support their role in caring for the most vulnerable in communities across Ohio and the country.

Do you agree that community health center funding is essential in increasing access to care? Would you support an increase in funding for FQHCs in FY 2025?

Answer. Yes. Thank you for recognizing the important work the Health Center Program plays in ensuring health care to the most vulnerable communities. In 2022, health centers served more than 30 million patients. The FY 2025 President's budget requests $8.2 billion for the Health Center Program. The proposed mandatory investments continue progress on the President's plan to put the Health Center Program on a pathway to doubling. Health centers provide cost-effective, high-quality care. The health center model of care has been shown to reduce the use of costlier providers of care, such as emergency departments and hospitals. Investing in this program is essential to maintaining primary care services in underserved and rural communities.

QUESTIONS SUBMITTED BY HON. JAMES LANKFORD

Question. Because the CMS 2022 DIR rule is being implemented without full transparency and clear "reasonable and relevant" reimbursement requirements, pharmacies are currently being hit with a double whammy. They are still paying retroactive DIR fees from the last several months of 2023 while also being reimbursed significantly less on the front end for each prescription filled.

CMS has provided pharmacies facing financial troubles in light of this DIR transition with an email address to share complaints to CMS about their treatment from PBMs. Instead of offering appropriate oversight over PBM actions harming Medicare Part D beneficiaries' access to pharmacies, pharmacists receive a bounce back email from CMS telling them that they have no oversight authority nor are they able "to directly intervene in disputes related to Part D plans' reimbursement rates."

Why has CMS offered to receive information about pharmacy financial struggles if they are not fully willing to provide assistance to pharmacies?

What is CMS doing with the information submitted to them from pharmacies about the DIR transition?

Does CMS plan to act to further ensure Medicare beneficiaries' access to independent pharmacies?

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

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

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

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

We are committed to ensuring beneficiaries have access to necessary health services. We value the critical role pharmacies play in health-care delivery and recognize that we must address the needs of pharmacies to serve our beneficiaries effectively. We will continue to engage with stakeholders and consider policies for inclusion in future rule-making that would lower prescription drug costs for beneficiaries, address challenges that pharmacies face, and improve the quality of pharmacy care.

Question. In March 2022, the HHS OIG released a report titled "Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions with Increased Biosimilar Use." One of the findings of the report notes that if plans treated biosimilars like they do generics, beneficiaries could save 22 percent in out-of-pocket costs in a single year, and Medicare Part D could save nearly one-third in biologic product spending.

As you know, there are now a number of approved biosimilar products for the blockbuster drug Humira, most of which offer more than an 85 percent discount to the branded product. However, the branded Humira biologic maintains a 98-percent market share. Patients are not gaining cost-saving access to lower-priced biosimilars due to PBM formulary manipulation.

My bill, the Ensuring Access to Lower-Cost Medications for Seniors Act, would allow patients to have greater access to and lower cost sharing for lower priced generics and biosimilars.

How is HHS addressing this issue to ensure that lower cost alternatives are available on formularies and accessible to patients?

Will you commit to ensuring Medicare beneficiaries are able to gain access to low-cost biosimilars and generics by continuing to push PBMs to prioritize patient access and affordability over rebates?

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. CMS monitors submitted formularies for appropriate inclusion of all drug classes to ensure Part D sponsors' benefit structures meet statutory and regulatory requirements for the program. However, under current law, with some limited exceptions, CMS does not have statutory authority to require that biosimilar biological products be included on a Part D sponsor's formulary, placed on a particular tier, or offered at a particular cost-sharing amount.

CMS's regulatory requirements with respect to formulary changes take into consideration Part D sponsors' formulary flexibility, out-of-pocket savings for Part D plan enrollees, and maintaining formulary stability for Part D plan enrollees throughout a plan year. Part D sponsors may add biosimilars to their plan formularies at any time as a formulary enhancement. In a proposed rule issued on November 6, 2023 entitled "Contract Year (CY) 2025 Policy and Technical Changes to the Medicare Advantage Plan Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, and Health Information Technology Standards and Implementation Specifications Proposed Rule" (CMS–4205–P), CMS proposed to permit Part D sponsors to treat formulary substitutions of biosimilar biological products other than interchangeable biological products for their reference products as "maintenance changes" that would not require prior approval by CMS. Under our current guidance, plans must obtain explicit approval prior to substituting with biosimilar biological products other than interchangeable biological products, and these substitutions apply only to enrollees who begin therapy after the effective date of the change—delaying enrollees' access to cheaper options. Treating these substitutions as maintenance changes would also mean that any substitutions would apply to all enrollees (including those already taking the reference product prior to the effective date of the change) following a 30-day notice, so that enrollee access to equally effective, but potentially more affordable, options would be available sooner.

Additionally, within the December 2022 proposed rule entitled "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications" (CMS–4201–P), CMS proposed to permit Part D sponsors to immediately substitute: (i) a new interchangeable biological product for its corresponding reference product; (ii) a new unbranded biological product for its corresponding brand name biological product; and (iii) a new authorized generic for its corresponding brand name equivalent.

HHS will continue to use 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.

Question. In December of 2023, the Senate Finance Committee held a hearing on drug shortages, during which we heard extensive testimony indicating that the current prescription drug pricing structure that incentivizes patient access to high-cost drugs is a driver of many of the ongoing drug shortages faced by patients in America today. Generic manufacturers face intense pressure to reduce prices to a point below the cost of production. As a result, generic prescription drug supply chains can experience manufacturer exits, low production or stoppages required by regulators.

What steps is the Department taking to address the issue of drug shortages and, more specifically, have you contemplated any payment or contracting changes in Medicare or Medicaid that would address the precarious economic position of generic drug manufacturers?

Answer. HHS recognizes the severe patient impact from the persistent problem of chronic drug shortages that have most frequently impacted inexpensive generic drugs, particularly sterile injectables. HHS is taking a coordinated approach to help address economic root causes of shortages.

In November 2023, HHS announced the establishment of a new Supply Chain Resilience and Shortage Coordinator role responsible for coordinating efforts across the Department that advance the resilience of medical product and food supply chains and accelerate the Department's response to related shortages. Institutionalizing this coordination across the Department will help HHS meet its long-term supply chain resilience and shortage mitigation goals. In addition, FDA on an ongoing basis works to identify shortage risks and determines actions that can prevent or mitigate patient impact, such as prioritizing review of manufacturer submissions or working with manufacturers to increase supply. ASPR also led the development of an Essential Medicines Supply Chain and Manufacturing Resilience Assessment to identify supply chain vulnerabilities in a critical medicines list and has invested, through the Industrial Base Management and Supply Chain (IBMSC) Office, targeted funds to bolster domestic manufacturing capabilities for essential medicines.

CMS is also taking steps to help align certain incentives to bolster supply chain resilience and further promote adoption of resilient supply chain practices. As discussed in the Calendar Year 2024 Outpatient Prospective Payment System (OPPS) final rule, CMS solicited public comment on providing separate payment under the Medicare Inpatient Prospective Payment System (IPPS), and potentially the OPPS, for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply (88 FR 82127–30).

CMS also noted in the CY 2024 OPPS final rule that as part of the agency's initial efforts, CMS intends to propose new Conditions of Participation in forthcoming notice and comment rulemaking addressing hospital processes for pharmaceutical supply (88 FR 82130). CMS continues to review the comments received to consider ways the Medicare program can promote hospital resilient supply chain practices to help mitigate the impact of drug shortages on patients.

HHS looks forward to continuing to work with Congress on future steps, including potential changes to CMS programs, needed to comprehensively address economic root causes of shortages.

Question. A recent study published in *Psychological Medicine* found that 30 percent of young men who have schizophrenia could have prevented it by averting cannabis use disorder. Another recent study published in the *Journal of the American Heart Association* found that daily use of cannabis was associated with a 25-percent increased likelihood of heart attack and a 42-percent increased likelihood of stroke when compared to non-use of the drug. Marijuana has also been linked to depression, anxiety, and thoughts of suicide. Another recent study found that smoking cannabis during pregnancy is linked to lower birth weight. Both the CDC and NIDA have published that 30 percent of those who use marijuana have marijuana use disorder.

Was the HHS recommendation to DEA that marijuana be moved from Schedule I to Schedule III based on new science or public acceptance of the drug?

Answer. The scheduling review documents reflect HHS's evaluation of the scientific and medical evidence and its scheduling recommendation to DOJ.

Question. Why did HHS decide to use a new two-part test to determine whether marijuana has a currently accepted medical use instead of the well-established five-part test that was used in the 2016 evaluation of marijuana (that concluded that it had no accepted medical use).

Answer. The scheduling review documents reflect HHS's evaluation of the scientific and medical evidence and its scheduling recommendation to DOJ.

Question. Part 1 of the new test "considered whether there is widespread current experience with medical use of marijuana in the United States by licensed HCPs operating in accordance with implemented State-authorized programs, where such medical use is recognized by entities that regulate the practice of medicine under these State jurisdictions." Many of these States legalized medical marijuana through ballot measures and votes in State legislatures, not through a scientific and medical process.

Why does HHS consider the popularity of a drug as evidence for its medical use?

Answer. HHS did not consider popularity of a drug as evidence for determining if a drug has a "currently accepted medical use" under the Controlled Substances Act (CSA). The scheduling review documents reflect HHS's evaluation of the scientific and medical evidence and its scheduling recommendation to DOJ.

Question. Missing Data: HHS agreed to provide us with monthly data regarding safety and well-being calls for UACs and with monthly data regarding the Category 2 initiative. This agreement was made in December 2022 in exchange for Senator Lankford lifting his hold on Robert Gordon, the nominee for the Assistant Secretary for Financial Resources at HHS. HHS has failed to provide us with information since June, and what HHS provided in June was only partially responsive. The most recent Safety and Well-Being Call data we received was dated February 2023, and the most recent category 2 sponsor data we received was labeled November 2022, with the data within the document only going to September 10, 2022.

Can you advise why we have not received this information? This was an agreement made in exchange for confirmation. Does HHS not believe this is an agreement worth abiding by any longer?

When will Congress receive the data requested?

Answer. HHS is committed to working in good faith to address congressional oversight requests in a timely manner. Already this Congress, HHS has provided several briefings to both members and their staff, provided testimony to Congress on several occasions, and provided thousands of pages of documents detailing how ORR is working to promote the well-being and safety of unaccompanied children in our care. We regularly provide briefings to Congress on new developments and are committed to being responsive to letters that we receive. HHS looks forward to continuing our productive relationship with Congress—to ensure that unaccompanied children in our custody receive appropriate care.

Question. In February 2024, the HHS IG released an analysis of the sponsor screening and follow-up services HHS provides to UACs. Here is a summary of the report's findings:

In 16 percent of children's case files, one or more required sponsor safety checks lacked any documentation indicating that the checks were conducted.

For 19 percent of children who were released to sponsors with pending FBI fingerprint or State child abuse and neglect registry checks, children's case files were never updated with the results.

In 35 percent of children's case files, sponsor-submitted IDs contained legibility concerns.

ORR failed to conduct mandatory home studies in two cases and four other cases raise concerns about whether ORR guidance on discretionary home studies should offer more specificity.

In 5 percent of cases, sponsor records within ORR's case management system were not updated with child welfare outcomes or sponsorship history. In 22 percent of cases, ORR did not conduct timely Safety and Well-Being Follow Up Calls, and in 18 percent of cases, the follow-up calls were not documented in children's case files.

We know from public sources, like *The New York Times,* that at least some, if not the vast majority, of the 16 percent of children whose case files did not have sponsor safety checks were placed into labor trafficking situations or sex trafficking situations. What concrete steps, like changes in policy, has HHS taken to stop this trafficking and conduct background checks?

We know from these public sources that at least some, if not the vast majority, of the 19 percent of children who were released to sponsors with pending FBI fingerprint or State child abuse and neglect registry checks, children's case files were never updated with the results. What concrete steps, like changes in policy, has HHS taken to stop this trafficking and follow-up with sponsors whose pending FBI fingerprint and State Child Abuse and Neglect registry checks came back with negative results?

The HHS IG reported that ORR failed to conduct mandatory home studies in certain cases and that the guidance needed to have more specificity. Do you agree that HHS's guidance needs to prioritize more mandatory home studies? If so, when will we see new policies? If not, why not?

Answer. The HHS Office of the Inspector General (OIG) February 2024 report, reviewed March through April 2021, during one of the most challenging periods in ORR's history amid a historic number of unaccompanied children placed in ORR care, the largest and fastest expansion of emergency capacity, and in the midst of the COVID–19 pandemic. ORR agrees with the report's recommendations, which correspond with many of the improvements to processes and procedures, enhanced data systems, and new and updated policies we have put in place and developed over the last 3 years. These changes simultaneously prioritize child welfare and safety and minimize the time children spend in congregate care settings—in line with child welfare best practices and ORR's legal requirements to release children without undue delay.

Since April 2021, ORR has made substantial process improvements based on child-welfare principles to ensure the safety and well-being of unaccompanied children through comprehensive case management and enhanced technology, data gathering, and analytics. For instance, ORR provides 7-day-a-week case management, specifically for family unification services, and ORR has updated the UC Portal, the UC Program's data system, to enhance usability and search functionality. These updates and new features ensure that sponsors' records are accurately and comprehensively obtained and accessible across the entire network of care providers. The im-

provements build in safeguards and make it easier to identify and flag potential child welfare concerns during sponsor suitability assessments and aid case managers in making informed decisions, including regarding home studies.

ORR continuously reviews its vetting policies and procedures for ways to improve its processes to promote the safety and well-being of children and to be more efficient and effective. For instance, on June 2, 2023, HHS released the results of its audit of the vetting process for potential sponsors who have previously sponsored an unaccompanied child, to ensure all necessary safeguards are in place without unnecessarily keeping children in government-funded, congregate care settings. In October 2023, ORR awarded a contract to an outside entity to conduct future in-depth reviews of random samples of case files by sponsor category for all children released from ORR care from January 2021–December 2022. The external review is anticipated to be completed in the summer of 2024. Also, on June 2, 2023, HHS announced additional efforts to protect the safety and well-being of unaccompanied children, including a new ORR program and accountability team, now termed the Integrity and Accountability team, which will further enhance ORR's work to assess and address potential exploitation risks faced by unaccompanied children.

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

Question. The VAWA reauthorization in 2013 required ORR facilities to comply with PREA (Prison Rape Elimination Act) standards for juvenile facilities. ORR promulgated an IFR to begin implementation of this requirement in 2014; however, ORR has not taken the steps necessary to implement this requirement.

An October 2021 investigative report by Senators Grassley and Wyden found that ORR kept very little data regarding significant incident reports, which are what ORR uses to classify and monitor sexual assault and abuse incidents against children in its custody. Their report found that between 2016 and 2020, nearly 900 allegations of sexual abuse lodged against staff in its facilities. Based on the IFR above, ORR should have reached full compliance with PREA standards during this window.

A 2020 GAO examination had a recommendation that ORR develop a plan to comply with the IFR and with PREA standards; however, that recommendation is still listed as "open."

Can you share with me whether each ORR facility is now compliant with PREA standards for juvenile facilities? Has each ORR facility now completed its initial PREA inspection?

A bipartisan Senate Finance Committee report in October 2021 found that ORR keeps very little data regarding significant incident reports, which is how ORR classifies and monitors sexual assault and abuse against children in its custody. Has ORR updated policy since that report and, if so, how it has updated its policies? How many SIRs have been filed regarding sexual assault and abuse in ORR facilities since 2021? How has ORR investigated these reports?

Answer. ORR conducts monitoring to ensure that care provider facilities meet appropriate standards for the care and timely release of unaccompanied children and abide by Federal and State laws and regulations and ORR regulations and policies, including the Interim Final Rule (IFR), *Standards to Prevent, Detect, and Respond to Sexual Abuse and Sexual Harassment Involving Unaccompanied Children.* The compliance audit process required by the IFR applies to nonemergency care provider facilities. ORR's secure care provider facilities must comply with, and are subjected to audit process under the Department of Justice's (DOJ) National Standards to Prevent, Detect, and Respond to Prison Rape, 28 CFR part 115 (The Prison Rape Elimination Act). All other ORR facilities (not including traditional foster homes) must comply with the HHS Standards to Prevent, Detect, and Respond to Sexual Abuse and Sexual Harassment Involving Unaccompanied Children, 45 CFR part

411. This compliance auditing process does not apply to long-term foster care, secure facilities, and influx care facilities. ORR monitoring activities include routine site visits, monitoring visits, and site visits in response to Project Officer (PO), Federal Field Specialist (FFS), Prevention of Sexual Abuse Team, and other requests.

In compliance with ORR's IFR, in FY 2019, ORR initiated external audits of care providers. The audit process can typically take up to 9 months to conclude and encompasses a review of care provider files, staff member personnel records, trainings, and other documentation. The audit process also includes pre-audit activities, such as reviewing SIRs that are sexual in nature and having the program complete a pre-audit questionnaire, and on-site visit. Post-audit activities, include a report submission to ORR, report review by ORR, submission of a corrective action plan as applicable to care providers developed in conjunction with ORR, and final corrective action plan approval.

ORR has a zero-tolerance policy for all forms of sexual misconduct at all care provider facilities and makes every effort to prevent, detect, and respond to allegations of such conduct, taking every incident seriously to ensure every child in care is housed in a safe environment. In addition to providing required training for staff, contractors, and volunteers, ORR care provider facilities are required to provide an orientation to every unaccompanied child on topics related to preventing, detecting, reporting, and responding to sexual abuse and harassment. This is in coordination with an on-site Prevention of Sexual Abuse Coordinator who is able to support children at all times. Care provider facility staff, volunteers, and contractors must immediately report allegations to all appropriate investigating entities in accordance with ORR policy, mandatory reporting laws, State licensing requirements, and Federal laws and regulations. Since FY 2021, ORR has dedicated significant resources to improve policy and practices and strengthen collection of data regarding prevention of sexual abuse incidents such as hiring and reorganizing ORR's Prevention of Sexual Abuse Team; centralizing reviews, categorization, tracking, and reporting of Significant Incident Reports; implementing a new data visualization platform; and implementing new trainings, including in partnership with HHS OIG's Office of Investigations.

As part of HHS's continuing commitment to assess and improve the UC Program, since January 2022, ORR has reorganized, recategorized, and centralized of Significant Incident Reports (SIR) response and monitoring as part of ORR's effort to better track and trend incident report information. These improvements allow for more efficient and effective program oversight so that HHS's ORR and care providers can focus on incidents that effect immediate child safety and well-being, thereby strengthening program reporting and response efforts.

The SIR reorganization includes the addition of new categories and subcategories to improve reporting on incidents that occur in ORR care. SIR categories and subcategories have nearly doubled to capture a larger range of relevant incidents that occur in ORR care, and categories like "other" were removed to ensure the most serious incidents receive appropriate attention based on severity. The overhaul also streamlined incident notification and escalation through HHS ORR's new Significant Incident Report Triage Team, as well as referrals to legal service providers following incidents or disclosures that can affect a child's immigration case.

Question. As we discussed during the hearing, the Department of Health and Human Services has cut off access to vital health-care funds for Oklahoma over political disagreements over Oklahoma's desire to protect life. This is in direct violation of several laws including the law that authorizes the grants which prohibits funds from being "used in programs where abortion is a method of family planning." The same sentiment is reiterated each year as a condition of title X appropriations, which states that title X funds "shall not be expended for abortions." Additionally, the Weldon Amendment, an annual rider that has been included in every LHHS appropriations bill since 2004, that prohibits the government from discriminating against entities that refuse to provide, pay for, provide coverage of, or refer for abortion.

Compliance by the Oklahoma State Department of Health would have compelled the agency to violate Oklahoma State law. The administration's radical proabortion policies are disproportionately impacting rural communities that are already struggling with access to quality health care.

Oklahoma previously received $4.5 million in title X funds, which the State typically distributes to local county health departments. It is my understanding that despite ongoing court cases and administrative appeals, your agency has rerouted

Oklahoma's funding to two entities, one of which is in Missouri, not Oklahoma. The Missouri Family Health Council, Inc. received $3.25 million and Community Health Connection received $216,000, for a total $3.466 million, which is more than $1 million short of the $4.5 million that was supposed to provide health care for low-income Oklahomans.

Can you confirm for the record that HHS is denying public health funds to my State because they refuse to break State law and use Federal dollars to refer for abortions?

Does this administration prioritize abortion access over the provision of actual health-care services?

With the rescission of the funds to the Oklahoma State Department of Health, how does HHS plan to ensure that low-income individuals in rural communities can still access title X services? The previous award provided the State with more than $1 million than the additional grantees received. Further, those grantees are either in urban areas or in Missouri, and from what I can tell, they do not offer the breadth of services that OSDH provides. How is this meeting the needs of Oklahomans?

Is your belief that it would be better for the Oklahoma State Department of Health not to provide *any* health services if they refuse to also provide or refer for abortion, even if low-income and rural communities are disproportionately impacted?

Answer. In September 2023, HHS awarded nearly $3.5 million to two title X programs to provide services to residents of Oklahoma, ensuring that rural and low-income Oklahomans have access to title X services. Earlier in 2023, HHS notified the previous title X program, the Oklahoma State Department of Health, that they were out of compliance with Federal title X regulatory requirements and, therefore, the terms and conditions of its grant award. The title X program was given an opportunity to come into compliance but did not, and as a result it no longer receives title X funding. Oklahoma has since filed suit against HHS—litigation that is currently underway.

HHS has made great progress in restoring access to title X services nationwide. In 2022, with new regulations and services restored in all 50 States, Washington, DC, and eight U.S. Territories and Freely Associated States, the title X family planning network expanded and increased access to almost 1 million more clients compared to the year before. In 2022, the number of title X service sites increased by 26 percent and title X providers served 937,490 more family planning clients in 2022 (a 56-percent increase over the 1.6 million clients served in 2021).

The Biden-Harris administration is deeply committed to public health and will continue to champion access to affordable, high-quality, client-centered health services, including reproductive health information and care. The $390 million proposed for title X in the FY 2025 budget would expand services to additional clients and additional communities. We look forward to working with Congress to achieve the important vision that there are enough title X funds to support quality family planning, sexual health, and preventive care across our Nation.

Question. An internal workplace guidance document with your signature on it was brought to my attention regarding transgender participation in the HHS workforce. The guidance was accompanied by an unlisted YouTube video announcing the guidance with senior HHS officials talking about the contents in the leaked guidance I received. The guidance indicates that refusal to use preferred pronouns could lead to disciplinary actions, up to and including termination. The guidance also establishes a policy that anyone can use any bathroom, locker room, or lactation room that they desire—and no one is allowed to question their use of those facilities or require proof of any sort of transition.

Further, if any employees are made uncomfortable by having to share bathrooms, locker rooms, or lactation rooms with individuals using the wrong space, they will be directed to use other facilities because, "employees will not be barred from using the restroom consistent with their gender identity." This raises obvious concerns for the safety and privacy of women, protection of speech, religious freedom, and more.

This guidance also makes no attempt to address clear and longstanding court precedent about compelled speech. There is also no mention of the obligations placed on HHS by the first amendment, title VII of the Civil Rights Act, or RFRA.

When my office attempted to schedule a time for you and me to speak on the phone about these concerns, your office told my team it was not appropriate for us to connect on it.

Has this guidance or any substantively similar guidance gone into effect?

Do you intend to issue this guidance or any substantively similar guidance?

Is it the position of the Department that individuals who persist in refusing to used preferred pronouns will have their employment terminated?

What religious and conscience protections do you intend to put in place?

Has the guidance been modified to ensure it does not violate existing religious freedom laws and to protect speech and conscience?

Will you commit to working with me to address the serious concerns I have with the guidance?

Answer. HHS embraces diversity and strives to maintain an inclusive workplace where all employees have a sense of belonging and can work effectively to achieve the HHS mission. HHS is committed to an inclusive environment for all employees, including transgender and nonbinary employees, to address workplace changes (*e.g.,* changing official personnel records or staff directories) and to provide workplace procedures safeguarding gender expression. HHS has begun implementation of its Gender Identity Non-Discrimination and Inclusion Guidance (The guidance). The guidance is available on our website: *https://www.hhs.gov/sites/default/files/hhs-gender-identity-non-discrimination-inclusion-policy.pdf*

Question. Do you intend to issue this guidance or any substantively similar guidance?

Answer. See response above.

Question. Is it the position of the Department that individuals who persist in refusing to use preferred pronouns will have their employment terminated?

Answer. HHS believes that all of our employees, including our transgender and nonbinary employees, must be treated with dignity and respect when they come to work. To that end, the Department is committed to providing a workplace free of harassment and where everyone is safe to come to work.

Question. What religious and conscience protections do you intend to put in place?

Answer. HHS has preexisting protections for employees based on their religion. The guidance does not change any of those protections.

Question. Has the guidance been modified to ensure it does not violate existing religious freedom laws and to protect speech and conscience?

Answer. See response above.

Question. Will you commit to working with me to address the serious concerns I have with the guidance?

Answer. HHS is willing to engage with you as HHS works to ensure that all employees have a safe and productive working environment. These are important issues, and we are therefore of course willing to work with all stakeholders on these issues.

Question. Regarding the Change Healthcare February cyberattack, why did HHS take several weeks before making a public statement after being made aware of the attack? How does HHS plan to provide immediate flexibilities to providers, pharmacies, health plans, and State Medicaid agencies should a similar attack happen in the future?

Answer. CMS recognizes the impact the cyberattack on Change Healthcare, owned by UnitedHealth Group, has had on providers, particularly many small providers and those in rural areas. We are working expeditiously to do our part to ease the impact of the cyberattack. Specifically, CMS has taken several key actions to support the provider community during this difficult situation. CMS announced the availability of accelerated and advance payments for affected Medicare providers of services and suppliers. Providers and suppliers should reach out to their Medicare Administrative Contractors for more information or visit CMS's website for Frequently Asked Questions and Answers. CMS has also provided flexibility for certain Medicare reporting deadlines. We encourage Medicare Advantage and Medicare Part D plans to offer advance funding to providers, and to remove or relax certain timely

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

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

QUESTIONS SUBMITTED BY HON. MICHAEL F. BENNET

Question. In a white paper that I wrote with Senator Cornyn, we raised the importance of a unified strategy for Federal mental and behavioral health programs to reduce barriers and cut red tape. We need a clear strategy on how the Federal programs will collectively advance our Nation's mental and behavioral health. I know there are a lot of initiatives within your agency that address a wide array of issues like youth access, postpartum depression, workforce shortages, and mental health in schools.

What is the agency doing to coordinate these initiatives to maximize our resources and make sure that the programs are complementary to each other?

How do you plan to cut regulatory red tape so that schools, doctors, counselors, and families can better access these services and programs?

Answer. Addressing the country's behavioral health crisis is also a key priority for CMS. Medicaid and the Children's Health Insurance Program (CHIP) are the largest national payers for behavioral health services, financing more than a quarter of the country's behavioral health services. As a part of the agency's Cross Cutting Behavioral Health initiative, CMS has issued guidance to States on Medicaid and CHIP coverage and direct reimbursement for interprofessional consultations, making it easier to integrate behavioral health into a wider variety of settings and to more effectively involve current practitioners. CMS released a school-based services guide and fact sheet, which include guidance on how States can expand access to Medicaid-covered health services in schools. CMS is also awarding Medicaid grant awards to States and established a technical assistance center in coordination with the Department of Education to expand school-based health coverage and services. CMS has also issued guidance for States and examples on ways that Medicaid and CHIP payments, 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. This year, CMS has finalized policies related to changes in law allowing marriage and family therapists and mental health counselors to enroll in and bill Medicare. Medicare also now pays for clinical psychologists, licensed clinical social workers, marriage and family therapists, and mental health counselors to provide behavioral health integration services in primary care settings.

Question. I appreciate your commitment to make sure that insurance plans cover mental health visits, including through coordination with the Departments of Labor and the Treasury to increase enforcement of mental health parity laws.

Can you outline what gaps in statutory authority for enforcement may exist, which, if filled, would help address the barriers that children, adults, and seniors face when trying to access the full continuum of mental and behavioral health services?

Answer. Nearly a quarter of all adults experienced some form of mental illness in the last year. The FY 2025 President's budget strengthens and improves consumer protections by requiring all plans and issuers, including group health plans, to provide mental health and substance use disorder benefits in parity with medical and surgical benefits. The budget seeks to improve compliance with behavioral health parity standards by requiring plans and issuers to use medical necessity criteria for behavioral health services that are consistent with the criteria developed by nonprofit medical specialty associations, as well as putting medical necessity at the forefront of care decisions instead of profit. It also authorizes the Secretaries of HHS, the Department of Labor, and the Department of the Treasury to regulate behavioral health network adequacy, and to issue regulations on a standard for parity in reimbursement rates based on the results of comparative analyses submitted by plans and issuers.

The FY 2025 budget further strengthens consumer protections by closing various loopholes that have resulted in disparate coverage practices and providing additional funding for enforcement of mental health parity requirements. It also makes health care more affordable by requiring coverage of three behavioral health visits and three primary care visits without cost sharing. To support equitable treatment and increased access of covered mental health and substance use disorder services, the budget also supports a standardized definition of mental health and substance use disorders, as well as a permanent expansion of telehealth and other remote care services. In addition, the budget provides $125 million in mandatory funding over 5 years for grants to States to enforce mental health and substance use disorder parity requirements. Any funds States do not expend at the end of 5 fiscal years would remain available to the Secretary to make additional mental health parity grants.

Additionally, in July 2023, the Departments of HHS, Labor, and the Treasury proposed a rule that reinforces the Mental Health Parity and Addiction Equity Act's fundamental goal of ensuring that individuals have the same access to mental health and substance use disorder benefits as they do medical and surgical benefits. The proposed rules, if finalized, would make it easier to get in-network care for mental health and substance use disorders and eliminate barriers to access that keep people from getting the care for mental health and substance use disorders they need, when they need it.

DOL has advised that, with the loss of supplemental funding and without an increase in the Employee Benefits Security Administration's (EBSA) base appropriation, the agency faces a precipitous drop in resources that will require the reduction of its staff from approximately 850 to 720 and will sustain the loss of about a third of its enforcement budget by calendar 2025. EBSA is responsible for all the private employer-sponsored retirement, health, disability, and other welfare plans in this country, covering approximately 153 million people and 4.1 million plans. Without additional resources, DOL has informed us that it will not be able to sustain its MHPAEA and NSA implementation enforcement efforts without also dramatically reducing its focus on financial abuse in the retirement context and other categories of health violations (*e.g.,* fraudulent and mismanaged Multiple Employer Welfare Arrangements, and systemic claims process violations, among others).

In addition, the 2022 MHPAEA report to Congress states that EBSA believes that authority for DOL to assess civil monetary penalties for parity violations has the potential to greatly strengthen the protections of MHPAEA. In the absence of the authority to impose civil monetary penalties, DOL is limited in its ability to ensure appropriate corrective action in response to findings of noncompliance with MHPAEA. In 2016, a report issued by the Mental Health and Substance Use Disorder Parity Task Force concluded that authority to impose civil monetary penalties for MHPAEA violations, similar to the authority granted to DOL for enforcement of other laws relating to group health plans, would lead to more meaningful penalties for noncompliance and would incentivize compliance.

Question. The number of unaccompanied children arriving at the southwestern border continues to increase. This strains resources, which reduces quality of services for these children.

What specific steps is HHS taking to ensure that the infrastructure, personnel, and other resources are adequately scaled to manage this surge, especially in terms of providing care and finding suitable placements for unaccompanied children?

As of 2 weeks ago, 8,800 children are in government care or custody and the average referral rate is 316 children per day.

How is HHS addressing the challenges related to capacity, resources, and the overall well-being of these children to ensure they receive appropriate care?

Given the average length of stay for children in HHS care is 29 days, what strategies or programs is HHS implementing or considering to reduce this duration?

What strategies or programs are needed to minimize the potential negative effects on children's well-being and expedite their transition to more appropriate environments?

Answer. HHS's Office of Refugee Resettlement (ORR) applies child welfare best practices when placing children in its custody into care provider facilities, with a preference to place them within ORR's standard care provider facilities, including State-licensed shelters and shelters meeting State licensing standards in those States that refuse to license ORR facilities, group homes, and transitional and long-

term foster care, while sponsorship suitability determinations proceed and immigration cases are adjudicated. ORR has actively worked to build its network to ensure that ORR has sufficient standard shelter capacity that can adapt to the changing needs of the program and that influx care facilities are used only when needed to ensure ORR can quickly accept all referrals from Department of Homeland Security (DHS) in a timely manner.

ORR is focused on initiatives aimed at bringing more standard beds online, including adding beds to existing grants and funding new grants. For example, ORR has issued five standing notices of funding opportunities since December 2021 that will add thousands of additional standard beds to its network through licensed shelters, group homes, and/or transitional foster care. ORR continues to prioritize bringing online State-licensed beds for children placed in ORR care. ORR also continues to work closely with DHS partners to track migration trends and patterns and plan ORR capacity needs as far in advance as possible.

This administration inherited a significantly underresourced Unaccompanied Children (UC) Program with less than half of the needed shelter capacity in 2021. The prior administration imposed a months-long hiring freeze on ORR and its grant recipients, severely restricting the capacity to serve children referred to ORR care and to address the needs of the UC Program in 2021. In FY 2020, ORR's bed capacity was insufficient to serve even 8,000 children in care. ORR continues to enhance its ability to manage emergency response efforts by expanding standard network bed capacity and minimizing the amount of time children stay in congregate care settings. As of March 2024, ORR has updated its infrastructure to have a standard network capacity with more than 12,000 beds and the ability to activate influx care facilities more quickly, so that it can care for all children referred to ORR custody. In addition to drastically expanding its capacity to serve a historic increase in unaccompanied children, ORR has made multiple improvements to its case management system. These include modernizing the UC Portal—the UC Program's data system—with child safety improvements, such as standardizing addresses and sponsor's names; making it easier to identify and flag potential child welfare concerns during sponsor suitability assessments, aid case managers in making informed decisions regarding home studies; providing 7-day-a-week case management for family unification services; entering into a Memoranda of Agreement with the Office of Trafficking in Persons, National Center for Missing and Exploited Children, and Department of Labor; and expanding access to post-release services (PRS) to children released from ORR care from just over 20 percent in FY 2021, to offering access to PRS to approximately 59 percent of children released from ORR care in FY 2023.

ORR understands that the best place for a child is in a community setting and is committed to placing children with vetted sponsors without undue delay. To reduce the length of stay in ORR's care, ORR—in collaboration with interagency partners CBP and ICE—launched the Category 1 and 2 Sponsor Initiatives in August 2022 and May 2022, respectively. These two initiatives were designed to promote family unity and to safely streamline sponsor vetting where appropriate to do so. The Category 1 Sponsor Initiative aims to quickly unify unaccompanied children with their parent or legal guardian already in the U.S. The Category 2 Sponsor Initiative (also referred to by DHS as the Trusted Adult Relative Program) aims to improve processing for certain Category 2 family groups by allowing for more efficient sponsor vetting and reunification of children traveling with adult relatives, who are referred to ORR as unaccompanied.

Question. The budget includes "antimicrobial subscriptions" to encourage the development of innovative antimicrobial drugs—a proposal that aligns with the bipartisan, bicameral PASTEUR Act that I introduced with Senator Young.

What are HHS's plans to advance this critical new $9-billion AMR subscription proposal and realize the goals outlined in the budget?

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. 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 2025 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 spon-

sors of selected products and the U.S. Department of Health and Human Services (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 of 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.

This proposal complements other HHS and Federal activities under Goal 4 of the U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), which aims to accelerate basic and applied research and development for new antibiotics, other therapeutics, and vaccines. For example, NIH/NIAID is funding and conducting research on many aspects of AMR, including basic research on how microbes develop resistance, development of new and faster diagnostics, and clinical trials designed to find new vaccines and treatments effective against drug-resistant microbes, and ASPR/BARDA supports the end-to-end development of products (early research through licensure and commercialization) and providing capital and technical expertise to pharmaceutical companies with novel antimicrobial drug candidates. However, while these ongoing activities are essential to get new candidates for FDA review, they do not address the market challenges facing product sponsors after FDA approval. The FY 2025 President's budget proposal would protect these existing investments by the U.S. Government by helping to sustain product sponsors and keeping their products available for patients, while supporting stewardship and appropriate use.

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.

Question. Patients in Colorado are being harmed by insurers who refuse to correctly apply the No Surprises Act's clear coverage protections, including cases where insurers denied coverage for care related to newborns in NICUs in which the reason for the denial given by the insurers is that the clinician providing the care was out of network. Neonatal care provided by an out-of-network clinician at an in-network facility is explicitly named in the NSA as *always subject* to the law's coverage protections; any attempt to deny such care is unequivocally against the law. Enforcing compliance with the NSA is a massive undertaking with meaningful opportunities to protect patients and their access to care.

Does HHS have all of the necessary tools in its toolbox to compel strict adherence to the law?

Are there opportunities to improve the enforcement mechanisms within the NSA, especially with these types of insurer violations that can result in patient harm in mind?

Answer. CMS and States work closely to ensure compliance with the health insurance accountability and consumer protections in Federal law including those in the No Surprises Act (NSA). Many States, including Colorado, have established their own protections against surprise medical billing before the NSA was enacted. CMS is responsible for enforcement of provisions of the NSA and Transparency provisions applicable to providers, facilities, and providers of air ambulance services in a State, if CMS determines that the State is not substantially enforcing one or more of the applicable NSA requirements.

CMS operates the No Surprises Help Desk (NSHD) that allows consumers, and other interested parties to get answers about whether the NSA applies or to submit a complaint through a webform for electronic submission or by phone at 1–800–985–3059. After the NSHD receives a complaint, the complaint is reviewed in its entirety and is sent to the agency with the appropriate enforcement jurisdiction for further review. This could be CMS, the Department of Labor, the Department of the Treasury, or OPM, depending on the details of the complaint and which agency has jurisdiction over the plan or health insurance coverage. If the State has enforcement authority, the NSHD provides the appropriate contact information for that State so that the State may assist them with their specific situation. CMS is actively investigating and addressing complaints under our jurisdiction, and if a violation is found, CMS will not hesitate to enforce the requirement for payment and will ensure that future payments are made within the federally required time frame.

Through the CMS investigation process, CMS has directed plans, issuers, providers, health-care facilities, or providers of air ambulance services to take remedial and corrective actions to address instances of non-compliance, which has resulted in approximately $3,018,432 in monetary relief paid to consumers or providers, as of October 31, 2023.

Question. There are reports that insurers are refusing to pay or stalling payments to providers long past the 30-day statutory deadline after losing in the arbitration process.

Are you aware of long delays in IDR award payments, and what enforcement activity does HHS have available with respect to these violations?

I hear from providers that they have no choice but to go to the dispute resolution process—where I understand they are overwhelmingly winning—because they are being dramatically underpaid by payers.

What are you doing to ensure payers are paying appropriately up front?

Answer. The Departments of Health and Human Services, Labor, and the Treasury (the Departments) understand that the enforcement of the timeline for nonprevailing parties to make outstanding payments following a certified IDR entity's payment determination is an issue and we have received complaints regarding late payments after a payment determination has been made. We are actively investigating these complaints and we take the issue of late payments after IDR payment determinations very seriously. Additionally, based on our investigations, we have made operational changes to help mitigate issues we have identified. These changes include developing a new payment determination template for certified IDR entities to use which includes claim line-level details and developing a process for sending these templates through the Federal IDR portal. While we believe these operational enhancements should help mitigate some of the identified issues related to missing information, we continue to investigate complaints as they are received. In 2022, we provided guidance for certified IDR entities and, additionally, last fall the Departments proposed a rule to address specific issues critical to improving the functioning of the Federal IDR process in response to feedback and challenges noted by interested parties. In general, the Departments are seeing progress in payers making timely payments following a payment determination when we reach out to payers in response to complaints. As we continue to work with all parties to improve this process, we encourage parties who use the Federal IDR process and who are not receiving timely payments on closed determinations to submit complaints.

The Departments have also established a process for parties to an IDR dispute to submit complaints regarding the other party's non-compliance with the No Surprises Act's Qualifying Payment Amount requirements to the No Surprises Help Desk (NSHD). In general, after the NSHD receives a complaint, the complaint is reviewed in its entirety and is sent to the agency with the appropriate enforcement jurisdiction for further review. If the State has enforcement authority, the NSHD provides the appropriate contact information for that State so that the State may assist the provider with their specific situation. The Centers for Medicare and Medicaid Services (CMS) is actively investigating and addressing complaints under its jurisdiction, and if a violation is found, CMS will not hesitate to enforce the requirement.

Question. In August of 2023 HHS recommended to the DEA that cannabis be reclassified from Schedule I to Schedule III. Since that transmission we have heard little from your counterparts at the DEA. On March 9, 2024, a *Wall Street Journal* article[54] came out indicating some internal opposition to the rescheduling process within the DEA.

Would you describe your most recent conversations with the DEA and elaborate as to why HHS has asked the Office of Legal Counsel to weigh in on the issue of rescheduling?

What resources does HHS need to help get this process over the finish line?

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

[54] *https://www.wsj.com/politics/policy/biden-push-to-ease-marijuana-restrictions-sparks-tensions-051759f7.*

and its scheduling recommendation to DOJ. The scheduling review remains with DOJ.

Question. Do you feel that your local 988 systems have the capacity to meet current demand, and does the system overall have adequate resources to withhold a significant uptick in use as more people learn about this service, including for Spanish-speaking populations? If not, where do you lack the resources?

Answer. Since its launch in July 2022, the 988 Suicide and Crisis Lifeline has received about 9.1 million calls, texts, and chats, with total overall contacts trending upwards. Despite the increasing volume of contacts, the average response time across modalities remains below 1 minute and has decreased every year, with the most recent data showing an answer rate of 91 percent and an average response time of 42 seconds. For Spanish language response thus far in FY 2024, the Lifeline has received an average of just over 8,000 contacts per month, with an answer rate of 88 percent and an average response speed under 35 seconds.

The Lifeline's ability and capacity to handle and respond to increasing volume hinges on its network of national backup centers that answer contacts when local centers do not have capacity. In FY 2025, SAMHSA anticipates receiving approximately 7.5 million calls, texts, and chats to 988. SAMHSA will continue supporting States as they build local capacity to meet demand; however, if volume significantly exceeds the FY 2025 projected forecast, it could be challenging for the Network to maintain current performance levels without additional funding.

QUESTIONS SUBMITTED BY HON. STEVE DAINES

Question. Since Day One, the Biden administration's misguided policies and priorities at the southern border have led to the worst border crisis in our country's history. Now, rather than take steps to secure the border, the administration has proposed a rule that would use taxpayer dollars to fund abortions for minors at the border. Issued by the Office of Refugee Resettlement, the "Unaccompanied Children Program Foundational Rule" would continue the practice of directing ORR staff to submit requests to transfer pregnant minors to ORR facilities in other States in order to circumvent State laws to protect life while continuing the practice of distributing dangerous chemical abortion drugs without direct medical supervision to vulnerable children. Additionally, the proposed rule would now include abortion to the definition of "medical services requiring heightened ORR involvement," to prioritize the taking of unborn life rather than prioritizing the interests of the Unaccompanied Alien Child (UAC).

Does ORR's "Unaccompanied Children Program Foundational Rule" conform with the Hyde Amendment's restrictions on HHS funding elective abortions?

Will ORR's final rule explicitly explain how ORR staff will be able to avail themselves of protections under Federal conscience protection laws, such as the Weldon and Coats-Snowe amendments?

Will ORR's final rule explicitly acknowledge protections provided to employees by title VII of the Civil Rights Act of 1964 and explain the accommodation request process for employees?

Will ORR's final rule explicitly acknowledge that protections under the Religious Freedom Restoration Act would apply to individual employees, as well as organizations and contractors who serve UACs and object on religious grounds to the taking of unborn life via abortion?

Is ORR considering adding additional medical procedures, such as gender-affirming surgery, to the definition of "medical services requiring heightened ORR involvement?"

Please provide an estimate and cost analysis on how many abortions HHS would facilitate under this proposed rule, including whether such abortions would be chemical or surgical and where such abortions would take place, as well as each State and locality that HHS would transport UACs to in order to facilitate abortions.

Please provide a cost analysis for the funding that has been or would be spent on facilitating abortions for minors including staff time, transportation, and accommodation costs as a result of this proposed rule.

Answer. HHS's Office of Refugee Resettlement (ORR) has a moral and legal obligation to safely and humanely care for all youth referred to its care and works with its partners across the government to ensure that children and youth are safe and provided appropriate health care. HHS complies with Federal law and nothing in the *Unaccompanied Children Program Foundational Rule* undermines HHS's compliance with all applicable laws. In addition, ORR operates the UC Program in compliance with the requirements of Federal religious freedom and conscience laws. HHS may make accommodations, including for religious exercise, with respect to the application of a particular program requirement on a case-by-case basis in accordance with such laws.

ORR provides accommodations to care providers who maintain a sincerely held religious objection to abortion. If a care provider has a religious objection to abortion, and an unaccompanied child in the care of such a provider is discovered to be pregnant, ORR field staff will personally deliver any legally required notice to the youth verbally and in writing, along with other pregnancy-related information required by ORR policy. Faith-based providers are critical partners for ORR's mission and to the Unaccompanied Children (UC) Program. ORR operates in partnership with approximately 95 different faith-based providers in at least 19 States.

Question. President Biden claims that he supports putting America first, and that he prioritizes American jobs and American-made products. The manufacturing capacity for essential medical devices in the U.S. is at serious risk due to organized efforts by Chinese manufacturers entering the U.S. market and taking advantage of the inflationary pressures felt by American manufacturers, distributors, and providers. This current trend toward purchasing Chinese-made medical devices is significant and occurring at a pace that will likely leave U.S. hospitals dependent on Chinese-supplied devices.

During the COVID pandemic, CMS set new payment adjustments to hospitals for their share of additional cost incurred for domestically produced N95 respirators. Will CMS take similar action for American-made essential medical devices and ensure access to these products for Medicare beneficiaries?

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

Question. One of the hallmark health-care polices of this administration is the partisan Medicare "price negotiation" program, which effectively sets government-determined prices in Part D. It was interesting to have seen all 10 of the companies compelled to participate in this program reject the initial round of government-proposed prices last week. In the same week, you were quoted saying the "administration is committed to improving transparency and competition in health care." Government price-setting is the furthest thing from competition, and it is overly simplistic to think that price setting will bring down costs. On the contrary, in fact Medicare premiums are increasing despite the law's attempt to artificially cap them, with the average premium for a standalone Part D plan rising 21 percent.

Americans want more affordable coverage. What do you have to say about the expectations that seniors will have to pay higher premiums or risk losing their drug coverage?

Answer. CMS is committed to ensuring the Medicare Part D program works for people enrolled in Part D, that benefits remain strong and stable, and that payments to plans are accurate. Thanks to the Inflation Reduction Act (IRA), people with Medicare Part D prescription drug coverage will continue to have improved and more affordable benefits, including a $35 cost-sharing limit on a month's supply of each covered insulin product, recommended adult vaccines at no cost, and additional savings on their Medicare Part D drug coverage costs in 2024. These savings include the expansion of the Low-Income Subsidy (LIS) program, which helps eligible enrollees afford their premiums and cost sharing, as well as a cap on out-of-pocket (OOP) costs for millions of people with very high drug costs in the catastrophic phase of the Part D benefit. Notably, the IRA additionally provides for Part D premium stabilization. For CY 2024 through CY 2029, the annual increase in the base beneficiary premium, which is a component of the plan-specific basic Part D premiums, is capped at 6 percent.

Last year, CMS announced that the average total monthly premium for Medicare Part D coverage is projected to be approximately $55.50 in 2024. This expected amount is a decrease of 1.8 percent from $56.49 in 2023. Stable premiums for Medicare Part D prescription drug coverage in 2024 are accompanied by improvements to the Part D program made by the IRA that allows enrollees to benefit from reduced costs this year.

In CY 2025, the structure of the Part D benefit will be updated to reflect provisions of the IRA that become effective on January 1, 2025. The CY 2025 updates include a newly defined standard Part D benefit design consisting of three phases: annual deductible, initial coverage, and catastrophic coverage; the lower annual OOP threshold of $2,000; the sunset of the Coverage Gap Discount Program and establishment of the Manufacturer Discount Program; and changes to the liability of enrollees, sponsors, manufacturers, and CMS in the new standard Part D benefit design.

With regard to Part D premiums for 2025, Part D plans have yet to submit their bids for the 2025 plan year. The deadline for Part D plans to submit their bids for the 2025 plan year is June 3, 2024. As a result, until these bid submissions are received, CMS does not yet have information on Part D premiums for the 2025 plan year. CMS will be keeping a close watch on the 2025 Part D premiums.

QUESTIONS SUBMITTED BY HON. ROBERT P. CASEY, JR.

Question. The Fiscal Year 2025 President's budget request includes $150 billion in funding for home and community-based services. An investment in these services will improve the lives of our loved ones who need long-term services and supports, their families, and their caregivers, while filling gaping holes in our care economy. That is why I was proud to introduce a trio of bills—the Better Care Better Jobs Act, the HCBS Access Act, and the HCBS Relief Act—to make a generational investment in home care, enabling older adults and people with disabilities to receive care in their homes and communities, while also increasing pay and improving benefits for the caregivers who provide this life-sustaining care. We have a responsibility to our communities by investing in excellent HCBS and caregiving economy.

Why is securing the total $150 billion critical to improving and expanding HCBS for all families?

Answer. The FY 2025 budget proposal to invest $150 billion over 10 years in Medicaid home and community-based services would enable seniors and people with disabilities (including children) to remain in their homes and stay active in their communities. At the same time, the proposal would promote better quality jobs for direct care workers furnishing HCBS and enhance 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. This investment builds on the short-term HCBS funding that passed as part of the American Rescue Plan Act of 2021.

Question. The President's Fiscal Year 2025 budget proposes to provide $492 million for survey and certification activities conducted by State survey agencies to improve their oversight of nursing homes. State Survey Agencies are critical to holding nursing homes accountable in delivering safe and high-quality care. As Chairman of the Senate Aging Committee, I released a report last year showing how underinvestment and understaffing at State survey agencies has resulted in poorer quality of care for nursing home residents. We need to continue investing in our Nation's nursing homes and in good quality care for our loved ones.

How would increased investment in survey and certification activities for State survey agencies improve health and safety for nursing home residents?

Answer. Despite the tens of billions of federal taxpayer dollars flowing to nursing homes each year, too many facilities continue to provide poor, substandard care that leads to avoidable resident harm, abuse, and neglect. Since 2018, most nursing homes (approximately 13,000) were cited for an infection prevention and control noncompliance deficiency in 1 or more years. The overall number of nursing home complaints has sharply increased in recent years, creating a backlog of more than 30,000 complaint cases as of FY 2023. CMS expects that States would need to con-

duct over 90,000 nursing home complaint surveys in FY 2025, a 13-percent increase over FY 2022.[55]

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 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.

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 complaints against facilities. Complaint surveys, especially those alleging immediate jeopardy or actual harm to patient health and safety are the primary oversight provided, outside of statutory recertification surveys. In recent years, CMS has established priorities in light of flatlined budgets to support the inspection of complaint cases, which has limited the program's capacity to perform standard initial, recertification, and validation surveys. CMS remains committed to surveying every Medicare and Medicaid nursing home, every year to ensure these facilities fulfil their obligations to protect the health and safety of residents. CMS strongly supports this call for additional survey and certification activities.

Additionally, flat funding has made it difficult for many States to offer competitive wages to the health-care personnel who work as surveyors, leading to surveyor workforce shortages in some areas.[56] These factors make it challenging for States to complete all statutorily required nursing home surveys and complaint visits and can place nursing home residents at increased risk of abuse and neglect. That is why the FY 2025 Biden-Harris budget proposes to shift funds for nursing home surveys from a discretionary appropriation to a mandatory appropriation and increase the funding to a level necessary to achieve a 100 percent survey frequency, adjusted annually for inflation, effective in FY 2026. This proposal will guarantee sufficient funding to promote the health and safety of the Nation's nursing home residents.

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. As chair of the Senate Special Committee on Aging, I have used my position to examine compliance with this law. Following your March 22, 2023, testimony to the Finance Committee for the FY 2024 budget, I submitted a series of questions about section 508 at the Department of Health and Human Services. I appreciate your answers and have follow-up questions about the Department's section 508 compliance.

In your 2023 response, you reported that the scanning tools used by HHS scan about 8 percent of Internet webpages and 0.3 percent of intranet webpages for accessibility errors. Those numbers are troubling and unacceptably low, given that HHS websites include critical public health data and information for key health-care programs. However, I am pleased that, in your response, you related that the HHS Digital Accessibility Program was in the process of establishing a new services contract that was expected to allow for the scanning of all Operating Division homepages.

Please provide an update on the new services contract for automated website scanning. Is that contract in place? If so, how long has it been in place, how long is the contract for, and which company received the new contract?

Answer. The previous contract expired in December 2023, and the new contract is expected to be awarded by April 22, 2024. The new contract is s sole source to Level Access for the Amp Continuum enterprise tool. This tool has more capabilities then our previous Deque Axe Suite, is less expensive, and is FedRAMP-certified. The HHS section 508 operations board is scheduling a demonstration for all potential users tentatively scheduled for April 17th, to begin a transition.

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[55] FY 2025 Budget in Brief, *https://www.hhs.gov/sites/default/files/fy-2025-budget-in-brief.pdf*.

[56] FY 2025 Budget in Brief.

Question. Please detail what percentage of HHS internal websites and external websites are routinely scanned for accessibility errors as of March 14, 2024.

Answer. The previous HHS web crawler was not resourced to centralize the scans of HHS OpDiv websites. Therefore, licenses were provided but the full list of websites was not able to be aggregated. Since content is currently federated, there was no central list of HHS websites available for scanning. Furthermore, internal websites were not routinely scanned due to configuration challenges.

The HHS Digital Accessibility Program awarded a contract in September 2023 with a task to ensure all HHS OpDiv homepages are routinely scanned, and metrics are tracked for accurate reporting. Under this new task, the program will be better positioned to assist HHS OpDivs with routine measurement of website conformance. The HHS program continued to scan websites until December 2023 when the licenses expired. Scanning will resume when the new tool is implemented, expected delivery in April 2024.

However, we did routinely scan 19 websites, which included all OpDiv homepages and department-level websites. For details of the department-level websites, see the response to the next question.

Question. Although automated website scans are a useful tool, they do not catch all accessibility errors. The Office of Management and Budget, on pages 8 to 9 of its December 21, 2023 memorandum on digital accessibility,[57] recommended that Federal departments and agencies pair automated website scanning with manual testing for accessibility errors.

Does HHS currently engage in manual testing for website accessibility errors?

Answer. HHS has a federated website environment. So, reporting for each website's manual testing is not currently provided. However, under the new HHS Digital Accessibility services contract to be awarded by April 22, 2024, all OpDiv home pages will be routinely scanned and accompanied with manual testing. Furthermore, all HHS owned, and managed websites will be routinely scanned and manually tested. HHS has conducted several manual tests of high-profile websites such as:

1. The new simplified grants website.
2. Administration of Strategic Preparedness and Response's (ASPR) Technical Resources, Assistance Center, and Information Exchange (TRACIE).
3. *Youth.gov* and *engage.youth.gov*.
4. *Treatments.hhs.gov*.
5. *Health.gov*.
6. Geospatial Health Systems.
7. *Opa.hhs.gov*.
8. Inflation Reduction Act website.

These websites utilized tools and manual investigation to provide the site owners with a full accessibility conformance report indicating defects. After the defects are remediated, another full test will be conducted to determine the level of conformance.

Question. If so, please describe (a) the process for determining which HHS websites are subject to manual testing, (b) the number of HHS websites that were manually tested for accessibility errors from January 1, 2023, through December 31, 2023, and (c) how many FTEs or contractors are devoted to manual testing of HHS websites as of March 14, 2024.

Answer. All websites that go through the HHS Office of the Secretary IT governance process are automatically selected for manual testing. In addition, all HHS OpDiv homepages will receive automated scanning and manual inspection on a routine basis to ensure process on conformance defects. HHS OpDivs maintain the ability to establish their own processes for HHS OpDiv owned and managed websites.

Due to the federated environment for websites, the HHS OpDivs can manage their own manual tests and do not currently have a reporting requirement to provide that data. In addition, our previous web crawler did not provide an administra-

[57] *https://www.whitehouse.gov/wp-content/uploads/2023/12/M-24-08-Strengthening-Digital-Accessibility-and-the-Management-of-Section-508-of-the-Rehabilitation-Act.pdf.*

tive capability to gather this level of details. However, for HHS OS owned and managed websites, a total of 9 websites (going at least 4 levels down) were manually tested.

HHS Digital Accessibility Programs use a matrixed environment, so resources are dedicated across all program areas. Furthermore, HHS OpDivs can resource and manage their digital accessibility risk assessments as needed. However, the new task for web crawler administration and scanning calibration awarded in September 2023, for all HHS OpDiv homepages requires 1,900 contractor resource hours. This is a blended estimate that includes data analytics and a digital accessibility subject matter expert. The HHS Digital Accessibility Program Director monitors and directs the task as part of other duties.

Question. In December, the General Services Administration released a government-wide analysis of section 508 compliance.[58] I am pleased that HHS received a "high" section 508 conformance rating on page D–87 of the analysis. Nevertheless, the analysis also shows that important work remains to be done on section 508 conformance at HHS.

One area where HHS could improve is on its section 508 program maturity. HHS is rated as having a "moderate" section 508 program maturity level. It is also rated as having "low" maturity outcomes in four section 508 program dimensions: (a) communications; (b) human capital, culture, and leadership; (c) acquisition and procurement; and (d) training.

Please describe the steps that HHS will take to improve maturity in those areas.

Answer. *Communications:* The HHS Digital Accessibility Program is reevaluating and updating the program's communications strategy and plan. The strategy outlines the mission, vision, communication objectives, and stakeholders for the HHS Digital Accessibility Program. The plan provides a more technical approach for achieving the overarching communication objectives. In addition, the HHS Digital Accessibility Operations Board is drafting a communication strategy and plan to establish communication objectives and a plan to achieve those objectives.

Human Capital, Culture, and Leadership: The HHS Digital Accessibility Program and the HHS Office of Human Resources (OHR) have entered a partnership to provide OHR dedicated resources for ensuring content is conformant. The first initiative was to bring the time and attendance system (including associated training) into full section 508 conformance. The expected completion data is July 2024. Furthermore, the HHS Digital Accessibility Program Director is included as a critical partner in the development of the HHS IT Strategic Plan and included HHS OpDiv Digital Accessibility program metrics in the annual portfolio reviews.

Acquisition and Procurement: The HHS Digital Accessibility Operations Board is reviewing and updating the policy to include procurement language required in all contracts in which section 508 is applicable.

Training: The HHS Digital Accessibility Operations Board is exploring options to make section 508 awareness training mandatory. In addition, the tools contract referenced above has an optional task to procure a section 508 learning portal. This portal would provide extensive training opportunities to all HHS employees. Should funding become available to execute this optional task, the program stands ready to increase the learning opportunities for all HHS employees.

Question. Despite the "high" section 508 conformance rating at HHS as a whole, I am troubled that page D–88 of GSA's analysis reports "low" section 508 conformance for the Administration for Community Living. ACL's own mission statement, from its website, is to "maximize the independence, well-being, and health of older adults, people with disabilities across the lifespan, and their families and caregivers." That mission makes it particularly important for ACL's electronic resources to be accessible for people with disabilities.

How will HHS improve section 508 conformance at ACL?

The GSA analysis reported that resources were unavailable to test ACL's top internal and external webpages, public electronic documents, and videos.

How will HHS ensure that ACL is able to report on the accessibility of those electronic resources for GSA's next government-wide section 508 analysis in December 2024?

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[58] *https://assets.section508.gov/files/reports/cr-2023/FY%2023%20Governmentwide%20Section%20508%20Assessment%20Report.pdf*

Answer. HHS is committed to ensuring the accessibility of our online resources are consistent with Federal laws and regulations, including section 508 of the Rehabilitation Act. All of HHS is committed to making our online resources as accessible as possible to all users, with and without disabilities, and to complying with all laws and regulations, including section 508 of the Rehabilitation Act. All materials produced by ACL—including ACL authored reports, budget requests, and programmatic guidance—meet or exceed section 508's accessibility requirements, and ACL conforms to the U.S. Access Board's broader Revised 508 Standards. In addition, ACL requires its contractors and grantees to produce materials that comply with section 508 requirements, and ACL confirms compliance before posting these materials on its websites.

Despite ACL's ongoing success in ensuring its materials are accessible, ACL scored lower in GSA's government-wide section 508 assessment due to the relatively few resources, including staff, dedicated to the agency's 508 program. For example, ACL's two FTE fall short of the average number of FTE for an organization at a similar maturity level (6.05). Similarly, ACL's score reflected a lack of adequate scanning and testing of its public-facing and internal Information and Communications Technology (ICT) for compliance. Historically, ACL relied on the Department for this function, but this option was not available at the time of GSA's analysis, and ACL lacked resources to secure these services elsewhere. ACL's score reflected this change.

ACL is taking critical steps to strengthen its section 508 conformance program. First, ACL is working closely with the HHS 508 program as a member of the HHS Section 508 Operations Board. This ensures that ACL is engaged in all aspects of 508 and accessibility policy and planning at the HHS enterprise level. Further, ACL will be involved in testing and adopting new scanning and reporting tools and processes for the Department. ACL also will participate in the new HHS enterprise accessibility program; ACL's internet and intranet sites will again be included in the HHS enterprise scanning and reporting processes.

ACL has also backfilled a position with responsibilities for 508 compliance, and with the additional resources received in its FY 2023 appropriation, the agency has strengthened the statement of work for 508 compliance in its new IT services contract. The expected award for the new contract is late summer 2024. The new contract requires monthly deliverables specifically focused on 508 conformance and user experience. In addition, the contractor will use both automated and manual tools to test both 508 conformance and overall accessibility and user experience for ACL-managed systems on both computers and mobile devices, with tests including multiple browser types and versions.

In addition, ACL continues to provide training to staff and works with contractors and grantees to help them improve their ability to produce materials that are fully accessible to people with disabilities.

With these additional steps, ACL is confident that its score will improve in the next GSA 508 assessment.

Question. The Fiscal Year 2025 President's Budget includes a request for $10 million for the Countermeasures Injury Compensation Program. I am pleased to see both the request for additional funding and the progress that has been made to review more claims and speed up the pace of reviews, so that eligible claimants can be compensated faster. One step that would support faster reviews would be publication of an injury compensation table that identifies injuries associated with certain covered countermeasures. I understand, based on my staff's prior conversations with staff at the Health Resources and Services Administration, that the development of such an injury compensation table is underway.

Could you please provide an estimate for when this injury compensation table will be published in the Federal Register?

Answer. As reflected in the Office of Management and Budget Unified Agenda of Regulatory and Deregulatory Actions, HHS intends to issue a proposed rule to establish a COVID–19 Countermeasures Injury Table. By statute, the Secretary "may only identify such covered injuries, for purpose of inclusion on the table, where the Secretary determines, based on compelling, reliable, valid, medical and scientific evidence that administration or use of the covered countermeasure directly caused such covered injury," 42 U.S.C. § 247d–6e(b)(5)(A). The proposed table will be published in the Federal Register with an opportunity for public comment. The number and type of public comments received will affect the amount of time required to issue a final rule. If a Countermeasures Injury Table is published or amended and the

effect is that such a new Table or amendment may enable a requester who previously could not establish a Table injury to do so, the requester may file a new Request Form within 1 year after the effective date of the establishment of, or amendment to, the Table, 42 U.S.C. § 247d–6e(b)(5)(B) (incorporating 42 U.S.C. § 239b(a)(2)). While the COVID–19 Covered Countermeasures Injury Table is established through the Federal rulemaking process, requesters should still timely file COVID–19-related claims, and the CICP will make eligibility determinations as to whether a covered countermeasure directly caused a serious injury or death based on compelling, reliable, valid, medical and scientific evidence (42 U.S.C. 247d–6e(b)(4)).[59]

Question. I am grateful for the administration's commitment to addressing maternal mortality through the additional funding for research, prevention, and access to perinatal health services. Too many individuals are dying during pregnancy or in the postpartum period, and we must do everything that we can to prevent even a single maternal death.

Could you elaborate on how the funding in the President's budget will tackle this public health crisis affecting every community in the Nation?

Answer. The FY 2025 President's budget includes several investments to respond to this crisis and improve maternal health outcomes. For example, the FY 2025 budget dedicates $215 million across HRSA to support initiatives to address maternal mortality, a $51-million increase from FY 2024 levels. New investments include growing the nursing workforce to support maternal care, building an obstetric safety net in health-care settings that do not offer obstetric care, including in maternity care deserts, and growing the doula workforce to provide direct support before, during, and after childbirth. Other initiatives focus on social determinants of maternal health, including screening and connection to services, expanding the uptake of evidence-based models of maternity care, and investment in State data collection and innovation to improve local response strategies. Lastly, the budget includes grants aiming to improve access and continuity of maternal and obstetrics care in rural communities.

QUESTIONS SUBMITTED BY HON. TODD YOUNG

Question. Last Fall, CMS hosted what it called "patient listening sessions" to gain a patient perspective on the so-called drug negotiation program in the Inflation Reduction Act (IRA). My understanding is that CMS held these sessions virtually, did not show up on camera, and little direction was provided to the patients presenting their views. Speakers had a maximum of 3 minutes to present, but there was no time-keeping mechanism available, it was unclear how the speaker order was determined, and they did not know how CMS selected the speakers. There was also no way of knowing if more patient groups registered to share their views than the time allowed.

This lack of transparency and organization means that the true impacts of the IRA on the patients it was allegedly designed to serve are still unclear.

What are your plans to improve CMS's process so that patient concerns with the IRA changes are fully heard and addressed?

Answer. Public feedback has been instrumental in implementing the Inflation Reduction Act so far, and CMS will continue this engagement moving forward. CMS received more than 7,500 comment letters in response to the Medicare Drug Price Negotiation initial guidance, representing a wide range of views from academic experts and thought leaders, consumer and patient organizations, data vendors/software technology entities, health plans, health-care providers, health systems, individuals, labor unions, pharmaceutical and biotechnology manufacturers, pharmacies, pharmacy benefit managers (PBMs), State governments, trade associations, venture capital firms, and wholesalers.

Additionally, since enactment of the IRA in August 2022, CMS has engaged with interested parties through various platforms, including small and large group meetings and written materials and emails via the IRA mailbox (IRARebateandNegotiation@cms.hhs.gov). Between September 2022 and June 2023, CMS held over 140 meetings with interested parties representing the views of consumer and patient organizations, health-care providers, health plans, PBMs, pharmaceutical and bio-

[59] *https://www.govinfo.gov/link/uscode/42/247d-6e.*

technology manufacturers, pharmacies, researchers and academic experts, and wholesalers. CMS also received 161 written materials before publishing the initial guidance. CMS leadership participated in 31 speaking engagements on IRA implementation hosted by interested parties. In addition to meetings with interested parties on specific issues, CMS has held monthly calls open to all pharmaceutical and biotechnology manufacturers since December 2022. During these monthly calls, CMS staff provide an overview of recent IRA activities and take questions from manufacturer participants. Finally, in 2023 CMS also held quarterly strategic calls with trade associations, health plans, pharmacies, and patient groups; and strategic bi-annual calls with academia/think tanks, and providers/hospitals.

In the Medicare Drug Price Negotiation Program revised guidance, CMS outlined additional opportunities for engagement during the negotiation process. CMS established a web application through which patients and other interested parties were able to submit data by October 2, 2023, on each selected drug, such as data on therapeutic alternatives, and other relevant information. In addition, CMS hosted meetings with manufacturers of selected drugs in Fall 2023, and CMS hosted patient-focused listening sessions for the selected drugs. The patient-focused listening sessions brought together patients, beneficiaries, caregivers, and patient/public advocacy organizations as well as other interested parties to share their patient-focused feedback with CMS on the selected drugs and their therapeutic alternatives and other relevant information, such as unmet medical need and impacts on a wide variety of diverse populations, as CMS develops initial offers to the manufacturers for each of the selected drugs.

We believe that these sessions were important in helping to inform CMS as the negotiation process goes forward. On the website for the patient-focused listening sessions, CMS described the discussion topics for each selected drug. The sessions were live streamed, so that patient groups and other stakeholders could listen to the comments being made by the participants. Information about these patient-focused opportunities can be found at: *https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation-program-patient-focused-listening-sessions*.

Based on CMS's tracking of meeting agendas and materials provided, interested parties commonly provided feedback on key Negotiation Program topics including how to identify qualifying single source drugs for negotiation, how to apply the orphan drug exclusion to selected drugs, how to operationalize requests by a biosimilar sponsor to delay selection and negotiation of a biological product that is a reference product for biosimilar market entry, and how to effectuate the maximum fair price (MFP). CMS remains committed to ongoing engagement efforts with interested parties.

Question. The structure of the IRA drug price negotiations will change the landscape for the way drugs are developed, especially cancer drugs. New oncology drugs usually start in smaller populations, allowing innovators to bring medicines to the market quickly while they work on application for broader patient populations. The IRA starts the clock on negotiation with that first approval, which means that discovery could have a target on its back if it works really well.

How will you make sure that new oncology discoveries are encouraged and not discouraged by the law you supported?

Answer. CMS supports innovation and believes it is vitally important that beneficiaries have access to innovative new therapies. There's a serious issue now with millions of Americans being unable to afford the drugs that are currently on the market. If patients cannot afford the drugs they need, they cannot benefit from innovations. Through negotiations with participating drug manufacturers, CMS is striving to make drugs more affordable for people with Medicare. The drug manufacturing industry is strong and thriving. The U.S. market is the largest in the world—with a track record of fostering innovation. We pay more for prescription drugs than anywhere else. This will always be an environment to innovate. We also expect negotiation to encourage drug makers to create business models to stay competitive, fostering the development of new treatments and delivery methods.

This FY 2025 Biden-Harris budget builds on the success of the Inflation Reduction Act by significantly increasing the pace of negotiation, bringing more drugs into negotiation sooner after they launch, expanding inflation rebates and the $2,000 out-of-pocket prescription drug cap beyond Medicare and into the commercial market, and other steps to build on the Inflation Reduction Act drug provisions. Expanding the Medicare Drug Price Negotiation Program and inflation rebates would accel-

erate the gains in access for Medicare beneficiaries to innovative, lifesaving treatments enacted in the Inflation Reduction Act, generating lower costs for people with Medicare and savings to the Medicare program.

Question. The Inflation Reduction Act implemented a new government price-setting policy that includes an excise tax to compel participation by drug manufacturers. In the statute, the language describes the applicable tax percentage as between 65 and 95 percent, but tax experts have clarified that tax liability could be as high as 1,900 percent of a product's sales price. CMS is responsible for implementing the program, but has been unclear about how much such a tax penalty could be if levied.

Please provide an illustrative example of a scenario where a drug manufacturer has not agreed to the CMS-set price and is out of compliance for over 270 days. How much tax would they owe on each sale of a $100-dollar drug? Please consult relevant agencies (*e.g.,* the Internal Revenue Service) as needed to ensure a complete response.

Answer. A Primary manufacturer may be subject to excise tax liability under several circumstances, including: (1) the primary manufacturer decides not to enter into an agreement to participate in the negotiation program, (2) the primary manufacturer fails to provide certain required information, or (3) the primary manufacturer does not agree to a maximum fair price by the statutory deadline. To end a period of excise tax liability, the primary manufacturer can take the necessary steps to remedy the reason for the excise tax liability (enter into an agreement, provide certain required information, or agree to an MFP), or terminate all its applicable agreements under the Medicare and Medicaid programs.

The provisions enacted at 26 U.S.C. § 5000D give the primary manufacturer choices with regard to the negotiation program. The primary manufacturer may participate in the negotiation program. The primary manufacturer may opt out of the negotiation program and pay the excise tax on the sale of the selected drug during defined periods. Alternatively, the primary manufacturer may opt out of the negotiation program and avoid the excise tax on sales of the selected drug during the period for which the manufacturer does not have applicable agreements with the Medicare and Medicaid programs and none of its drugs are covered by an agreement under section 1860D14A or section 1860D–14C of the Act.

As described in section 90.1 of the revised guidance, during the negotiation period, CMS will track and monitor progress during all steps of the process and engage in direct communications with each primary manufacturer. To facilitate successful negotiation program operations and support manufacturer compliance with program requirements, CMS will issue reminder letters prior to manufacturer deadlines with warnings of potential applicability of excise taxes, written notification that a primary manufacturer is in an excise tax liability period, and written confirmation that a primary manufacturer has taken the necessary steps to end a period of excise tax liability.

The IRS will administer the excise tax.

Question. The world is facing an antimicrobial resistance crisis. Superbugs make us all more vulnerable and undermine treatment of everything from common ear infections to cancer treatments and routine surgeries. We see more resistant infection now than ever before.

In this budget, President Biden signaled an ongoing commitment to implementation of a subscription-style incentive program for the development of novel antimicrobial drugs. That aligns with legislation that Senator Bennet and I introduced, the PASTEUR Act, which would create a new payment model for antimicrobials that address an unmet need. As this issue continues to grow in severity, attention is needed from HHS to promote policies that will improve stewardship and promote innovation in drug development.

As Congress deliberates on the policy, what other administrative actions will the Department be implementing to address the public health crisis that faces us in antimicrobial resistance?

Answer. HHS cochairs, with USDA and DoD, the Federal interagency Task Force on Combating Antibiotic-Resistant Bacteria (CARB), which is charged with working toward the U.S. National Action Strategy for CARB. The CARB Strategy outlines five goals to combat antimicrobial resistance (AR) in bacteria and fungi through a One Health approach to (1) infection prevention and control and antibiotic stewardship; (2) surveillance; (3) diagnostic testing; (4) antibiotic, antifungal, and other

product development; and (5) global leadership. Since the launch of CARB in 2015, these coordinated efforts have included more than doubling the proportion of U.S. acute-care hospitals that have high-quality antibiotic stewardship programs, from 48 percent in 2015 to 97 percent in 2022;[60] phasing out the use of medically important antibiotics for growth promotion in food-producing animals and moving other uses of these drugs under veterinary oversight; providing support to move dozens of promising new diagnostics and treatments from the lab into clinical trials and into health care; and working with global partners to raise awareness of AR and support best practices across settings.

These coordinated efforts contributed to an overall 18-percent reduction in deaths from resistant infections and a 30-percent reduction in hospital-acquired resistant infections between 2012 and 2017.[61] Unfortunately, this work has been complicated by the COVID–19 pandemic, which caused disruptions and delays in actions to combat AR at the Federal, State, local, and health-care facility levels. CDC saw sustained high levels of inappropriate antibiotic use in many U.S. health-care facilities in 2020, as well as higher rates of some hospital-acquired resistant infections and resulting deaths.[62]

HHS is committed to getting back on course through evidence-based interventions that reduce the spread and impact of AMR, and that can also prevent other infections, including COVID–19. These efforts include:

HHS is collaborating with EPA and USDA in an interdisciplinary and One Health effort to improve assessments of potential risks to human and animal health where the use of certain pesticides could potentially result in antimicrobial resistance.

FDA is supporting antimicrobial stewardship in veterinary settings by drafting guidance for industry on a potential approach for defining durations of use for approved medically important antimicrobial drugs fed to food-producing animals where none currently exist.

CDC is building health equity into AR efforts by collecting more comprehensive patient demographic data through the AR Lab Network and the National Healthcare Safety Network, and by training health-care workers from diverse backgrounds through Project Firstline. CDC is also working to enhance public reporting and surveillance of antibiotic and antifungal use and antimicrobial-resistant infections, through an upcoming requirement for about 4,500 hospitals in the U.S. to report information into the National Healthcare Safety Network.[63]

CDC and FDA are exploring new developmental and regulatory approval pathways for novel pharmaceutical agents that can prevent antimicrobial-resistant infections.

NIH continues to support scholars through the Antibiotic Resistance Leadership Group, which recently published results showing that short course antibiotic treatment is superior to standard treatment for community acquired pneumonia in children (< 5 years old) and reduces the risk of developing bacterial resistance to antibiotics.

BARDA, within ASPR, recently recommitted CARB–X up to $300 million over the next 10 years. CARB–X has had a huge impact on the antimicrobial pipeline, with 92 innovative projects in 12 countries, and 12 of those products have progressed to clinical trials, since its launch in 2016.

These investments in support for the basic understanding of AR as well as the discovery, development, and regulatory review of innovative products, has been critical for addressing the inevitable evolution of resistance to currently effective treatments. However, these efforts have not been enough to substantially change the ongoing challenges to the antimicrobial product development pipeline. President Biden's FY 2025 budget includes a proposal to encourage the development of innovative antimicrobial drugs by creating a novel payment mechanism where product sponsors would enter into contracts with HHS that provide annual payments independent volume of sales. The contracts would help companies stay solvent and keep products that address critical needs available, without driving overuse and therefore resistance.

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[60] *https://arpsp.cdc.gov/profile/stewardship.*
[61] *https://www.cdc.gov/drugresistance/biggest-threats.html.*
[62] *https://www.cdc.gov/drugresistance/covid19.html.*
[63] *https://www.cdc.gov/nhsn/.*

HHS is leading the CARB Task Force in preparations for the UN General Assembly High-Level Meeting on Antimicrobial Resistance, to be held in September 2024. This meeting provides a powerful opportunity for the United States to demonstrate global leadership and express political commitment to combating AMR and underscore the urgency of addressing this global threat collaboratively at all levels and across sectors and regions.

HHS, USDA, and DoD will lead the CARB Task Force in developing a new National Action Plan for CARB, to be implemented between 2025 and 2030, and which will build on the foundational investments and progress of the past 10 years.

Question. As you know, I've been working with members of this committee on an investigation into organ donation and transplantation and have been advocating for HHS to take meaningful steps to provide transparency and accountability to the system.

Given HRSA's recent announcements with the Organ Procurement and Transplantation Network (OPTN) Modernization Initiative, does HRSA plan to implement any internal policy changes to play a more active role in OPTN oversight and performance improvement initiatives going forward?

Given expected changes with the OPTN contracts, HRSA will need to have the capacity and expertise to direct the contractors accordingly, particularly with the new IT contract. Understanding the funding requests included in the budget, how is HRSA creating sustainable staffing expertise and oversight *within the agency* for this OPTN contract shift?

Answer. HRSA is taking historic steps as part of its OPTN Modernization Initiative to improve transparency, performance, governance, and efficiency of the U.S. transplant system. HRSA has proactively taken action over the past 2 years to increase oversight and ensure the security of the OPTN system. This includes conducting site visits to review the current OPTN IT system management and processes; conducting penetration tests to identify and correct potential areas of concern; developing new OPTN security requirements for all OPTN member transplant programs and organ procurement organizations; and requiring the OPTN contractor to take corrective actions on identified security issues.

In addition, HRSA is working to improve oversight of the OPTN and OPTN contractor, dedicate staffing to increase HRSA's technical and contractual expertise, and establish a new project management office to coordinate efforts in this space.

The FY 2025 President's budget request of $67 million would ensure that resources are available to support all of this critical work. HRSA will utilize all applicable Federal procurement law, regulation, and policy to ensure accountability from new vendors, as we do with other vendors that currently implement IT or other technical functions through Federal contract for other parts of the agency. HRSA will embed accountability requirements and performance expectations in the solicitation process for each OPTN vendor and actively monitor and evaluate contractor performance. In addition, HRSA is pulling together a staff with informatics and data expertise, clinicians and organ experts to strengthen in-house expertise on patient safety and organ policies, and working with Federal partners to engage the technologists, project management office roles, and acquisition managers necessary to oversee a modern, multivendor environment.

HHS is committed to ensuring lifesaving transplantation continues without disruption as we advance our efforts to create a more equitable, transparent, and accountable OPTN and higher-performing transplant system.

Question. Funding for Long COVID research was appropriated by Congress in December 2020, followed by additional funding directed by the Biden administration in February 2024. Patient groups and industry publications have criticized the slow pace of clinical trial design and enrollment. As of March 2024, only three RECOVER-sponsored trials have started enrolling patients: RECOVER–VITAL began enrolling in July 2023; RECOVER–NEURO in September 2023; and RECOVER–AUTONOMIC in March 2024. The RECOVER trials have estimated completion dates ranging from the end of 2024 to March 2026. By comparison, Stanford University's STOP–PASC trial launched in November 2022 and completed in September 2023.

Please explain the multiyear delay between funding being appropriated to NIH and the clinical trials beginning enrollment?

Please describe the actions being taken to expedite RECOVER clinical trial enrollment and completion.

Please provide a timeline for when the remaining RECOVER trials, such as RECOVER–SLEEP, will begin enrollment.

Answer. The National Institutes of Health (NIH) has launched a comprehensive research program addressing Long COVID, which represents a new post-viral disorder which is highly complex and heterogenous, with over 200 potential symptoms that vary across the lifespan and demographic groups. NIH is supporting critical basic and clinical research to understand the fundamental aspects of Long COVID, such as its clinical spectrum, underlying biology, risk factors, and clinical subphenotypes. This provides the foundation to design scientifically and medically based clinical trials to determine which interventions to test, and who to test them in with the goal of generating meaningful results that would advance treatments for the millions of people experiencing these disorders. To understand the basics of Long COVID, NIH has taken a multifaceted and national-scale approach in order to understand and address the full range of conditions in all patient groups (adults, pregnant persons, and children) as well as communities severely impacted by the COVID–19 pandemic. It was critical that NIH first launch observational and pathobiology studies to identify the types and frequency of symptoms and their impact on patients' quality of life; elucidate the root causes and the biologic underpinnings of these symptoms; and identify biomarkers of disease and potential therapeutic targets. These studies are already informing diagnosis, appropriate monitoring and care, and importantly, have already informed the selection of the initial interventions targeted to specific symptom clusters and other key aspects of clinical trial design.

Within a year of receiving congressional funding for the study of Long COVID, NIH designed and implemented the world's most comprehensive and diverse patient-centered research program to understand, treat, and prevent Long COVID. Over the past 2 years, NIH has shared crucial information about Long COVID from RECOVER that is helping patients by informing diagnosis, monitoring, and preventive measures. This includes: findings about the spectrum of clinical symptoms in adults and children; risk factors for developing Long COVID; impact of viral variants on the risk for and severity of Long COVID; impact of vaccination on Long COVID; risk of developing new-onset conditions and/or worsening of preexisting conditions; and health disparities in Long COVID. Initial results from the RECOVER adult observational cohort published in the *Journal of the American Medical Association* describe clinical sub-phenotypes; provide a clinical research tool for identifying PASC patients according to the specific symptom-based criteria; further characterize the impact of different viral variants and of vaccinations; and define PASC prevalence in adults. Another 53 scientific papers have been published or accepted for publication in prestigious peer reviewed journals, 15 are under journal review, and another 80 reports are in preparation.

With a fundamental understanding of certain key aspects of Long COVID, NIH was able to design and launch evidence-based clinical trials that focus on the symptoms described as most burdensome by people experiencing Long COVID. To date, RECOVER has established 5 adaptive clinical trial platforms, designed 8 clinical trials, opened 4 trials to enrollment, and planned the launch of an additional 4 trials in the coming months, resulting in collectively testing 13 active interventions for Long COVID.

While the current RECOVER trials are Phase 2 clinical investigations, which typically have a limited number of participants, these trials are generally more comprehensive than many other clinical studies. For example, there are key differences in the design of the Stanford STOP–PASC trial compared to the RECOVER VITAL (Phase 2 trial), both of which are studying the effects of the antiviral Paxlovid on Long COVID symptoms. The RECOVER VITAL trial is designed to enroll 900 participants and test two different dosing regimens then following the participants for 6 months. The Stanford STOP–PASC trial enrolled 168 participants, tested a single dosing regimen, and followed patients for less than 4 months.

NIH is supporting an array of steps to optimize the design of RECOVER clinical trials, achieve diversity among trial participants and meet enrollment targets, and facilitate timely completion of clinical trials:

- Patients participate in the design of clinical trials and participate on trial governance committees. Their input has contributed significantly to the selec-

tion of interventions and trial design, which should aid with general patient acceptance of the trials and willingness to participate in the studies.

- Clinical trial sites are selected for their ability to provide broad and diverse reach, including enrollment in rural and underserved communities. Sites actively prescreen through reviews of medical records and medical history to identify potential participants for inclusion in the trials.
- RECOVER clinical trial study teams work to support rapid site start-up training and completion of mandated regulatory requirements. This helps to minimize delays in the launch and implementation of protocols and supports rapid enrollment in and completion of clinical trials.
- Clinical trial sites maintain contact with study participants, which is critical for retention and adherence to the interventions tested within each platform trial, as trials may engage patients for many months either on treatment or for follow-up.

Patient enrollment for RECOVER–SLEEP is scheduled to begin in Summer 2024. This study will test interventions for hypersomnolence (excessive sleepiness during major waking episodes) and for changes in sleep patterns or ability to sleep after having COVID–19.

Patient enrollment in RECOVER–ENERGIZE is scheduled to begin in Summer 2024. This protocol focuses on studying exercise intolerance and fatigue among patients with Long COVID.

Question. Patient groups, experts, and industry publications have raised concerns around existing Long COVID funding being spent on observational research. In particular, criticism was directed towards RECOVER funding being used to duplicate existing findings, instead of funding trials for treatments or diagnostics.

Will the administration provide assurances that, going forward, the remaining uncommitted RECOVER funding will be directed primarily towards trials or novel research directions, and not replicating existing observational research?

Answer. RECOVER funds have not been and are not being applied to replicate existing observational research. Long COVID is highly complex and heterogenous, with over 200 potential symptoms that vary across the lifespan and demographic groups. RECOVER observational studies are designed and conducted on a national scale and across the lifespan in diverse populations. This is essential to generate the necessary breadth of meaningful results about this heretofore unseen and highly diverse set of Long COVID conditions, as well as to provide the necessary robust evidence base for developing diagnostics, safe and effective treatments, and preventive strategies. While other observational studies have been conducted outside of RECOVER, they frequently lacked appropriate controls, were not conducted at a national scale, lacked the necessary diversity, and did not collect data in a standardized manner that enables robust conclusions about the range of heterogeneous conditions associated with Long COVID.

To bolster Long COVID research efforts, HHS invested an additional $515 million in February 2024, to build on and extend the scope of RECOVER's work over the next 4 years by:

- Testing additional interventions in clinical trials to find effective treatments to reduce the burden of Long COVID, in both adults and children;
- Increasing our understanding of how SARS–CoV–2 affects each part of the body as it triggers Long COVID and identifying potential biomarkers for diagnosis and therapeutic targets for treatment;
- Supporting additional Electronic Health Record (EHR)-based studies to answer specific questions about the course and effects of Long COVID and to understand patterns of patient care as well as clinical practice outcomes;
- Supporting critically important follow-up of observational study and clinical trial participants to assess the long-term health outcomes of SARS–CoV–2 infection, factors underlying recovery from Long COVID, and risk factors for long-term adverse sequelae; and
- Maintaining support for secure data management and research infrastructure to continue the collection, integration, analysis, storage, and sharing of many diverse types of clinical data and biospecimens necessary to further understand the long-term effects of COVID–19 and inform diagnosis, monitoring, and treatments.

These clinical studies will provide important insights into Long COVID and will improve our understanding of other infection-associated chronic conditions with similar symptoms to inform treatments.

Question. Artificial intelligence (AI) in medical imaging has proven to be an important modernization that is benefiting patients and will continue to provide valuable innovation in the future. However, Medicare policy needs to keep pace with appropriate use of AI. In addition to Congress, a range of Federal agencies are undertaking important steps to properly address and harness the use of AI and support continued innovation that benefits patients. Given the meaningful progress within the medical technology sector, patients, providers and innovators require updated clarity on CMS's coverage and reimbursement for AI in medical imaging. Specifically:

What plans are in place for appropriate reimbursement of AI in medical imaging devices?

Do existing Medicare payment pathways adequately support innovation, provider adoption, and beneficiary access to health-care services that are improved with AI?

Has CMS encountered or been made aware of barriers to innovation for developers and manufacturers of medical imaging devices that incorporate AI?

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

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

QUESTION SUBMITTED BY HON. MAGGIE HASSAN

Question. As we have discussed in this committee, hospitals have been buying physician practices and as a result patients can see prices double for the same service, at the same location—all because the hospitals have applied a so-called "facility fee." Patients should not be paying double what they used to pay for basic health-care services just because their doctor's office was bought by a hospital.

I have been working across the aisle to end unfair hospital facility fees in order to bring down health-care costs, save taxpayers and employers money, and make health care more accessible for more Americans.

The President's budget proposes to end unfair facility fees for routine care like office visits, mental health visits, and telehealth visits.

Can you speak to how this proposal would help patients and families afford their care?

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

QUESTIONS SUBMITTED BY HON. THOM TILLIS

Question. I want to thank you for the Frequently Asked Question CMS released last month which clarified that critically and chronically ill Medicare Advantage beneficiaries are entitled to the same access to Long-Term Care Hospital (LTCH) services as traditional Medicare beneficiaries. As Senator Murphy and I expressed to you in a letter last year, Medicare Advantage beneficiaries should have the same access to LTCH services as traditional Medicare beneficiaries, as required by law.

Can you describe the enforcement steps HHS/CMS will continue to take to ensure that bureaucratic red tape will not delay or prevent care which seniors are entitled to?

Answer. CMS is committed to ensuring that MA enrollees receive Medicare covered long-term health care. MA organizations must provide enrollees with access to all medically necessary Medicare Part A and Part B benefits available under traditional Medicare (with some limited exceptions), as provided in accordance with section 1852(a)(1) of the Social Security Act (the Act).

As part of the CY 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Final Rule (88 FR 22120), CMS clarified existing requirements and established new requirements affecting MA organizations' coverage criteria and the relation of such criteria to traditional Medicare coverage policies. We clarified the existing requirements that MA organizations must comply with National Coverage Determinations, Local Coverage Determinations, and general coverage and benefit conditions included in traditional Medicare statutes and regulations. CMS also established that when applicable Medicare coverage criteria are not fully established, MA organizations may create internal coverage criteria based on current evidence in widely used treatment guidelines or clinical literature made publicly available, consistent with § 422.101(b)(6). The CY 2024 final rule also finalized additional enrollee protection requirements to improve continuity of care and integration of health-care services and to increase MA organizations' compliance with regard to UM policies.

Furthermore, CMS regulations at § 422.101(b)(2) state that MA organizations must comply with coverage and benefit conditions included in traditional Medicare laws, which includes payment criteria for inpatient admissions at § 412.3. As described in the February 6, 2024, memorandum "Frequently Asked Questions Related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS–4201–F)," if a patient is being discharged from an acute-care hospital to a post-acute-care facility that would be covered under traditional Medicare and the patient's attending physician orders post-acute care in the specific type of facility (*i.e.,* Skilled Nursing Facility (SNF), Long-Term Care Hospital (LTCH)) and the patient meets all applicable Medicare coverage criteria for admission into that facility type, the MA organization cannot deny admission to that post-acute setting and/or redirect the care to a different setting.

Regarding enforcement of regulatory requirements, CMS has a well-established, robust, and successful process for ensuring organizations that offer MA and prescription drug plans are complying with applicable requirements. When an MA plan is not in compliance, CMS may require the plan to correct the non-compliance by submitting and completing a corrective action plan (CAP), hiring an independent auditor to test the corrections, and successfully completing a validation audit that

demonstrates correction of the issues identified in the CAP. CMS can issue an enforcement action when an MA plan is noncompliant with existing program requirements. This could also include situations where an MA plan improperly denies a service, including when a denial is based on UM criteria that does not comply with CMS's requirements, or the MA plan is out of compliance with either approving or covering required items and services.

Question. In the proposed rule on compensation rates, CMS said that the agency lacks the data to quantify the impact the proposed changes will have on the more than 30 million beneficiaries enrolled in Medicare Advantage. The information that CMS relied on to draft the proposed changes has not been publicly released for review.

Will CMS publish for public comment the sources that CMS relied on prior to making a final determination on the Medicare Advantage broker compensation proposal?

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

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

In our proposed rule, CMS is focused on current payment structures among MA organizations, agents, brokers, and third-party marketing organizations (TMPO), including FMOs, that may incentivize agents or brokers to emphasize or prioritize one plan over another, irrespective of the beneficiary's needs, leading to enrollment in a plan that does not best fit the beneficiary's needs and a distortion of the competitive process. In this rule, CMS has proposed to: (1) generally prohibit contract terms between MA organizations and agents, brokers, or other TMPOs that may interfere with the agent's or broker's ability to objectively assess and recommend the plan which best fits a beneficiary's health-care needs; (2) set a single agent and broker compensation rate for all plans, while revising the scope of what is considered "compensation;" and (3) eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services. The public comments received on the CY 2025 MA and Part D proposed rule, including those received on the proposals related to agent and broker compensation, are available for public reviewing on *Regulations.gov*.

Question. According to the Health and Human Services Office of the Inspector General, more than 50,000 Medicare Part D beneficiaries experienced an opioid overdose in 2021.

When it comes to treating acute pain with nonopioid alternatives, what direction are you giving as HHS agencies to ensure that patients will have access and incentives to move to alternative nonopioid medicines once approved by the FDA?

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

Do you believe that cost sharing requirements could be a disincentive and even a burden for patients who may benefit from nonopioid alternatives?

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

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

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

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

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

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

Combating the opioid epidemic is a top priority for CMS, and CMS remains committed to ongoing examination of its payment and coverage policies to ensure health-care providers are enabled to execute best practices with respect to pain management and treatment of OUDs.

CMS continues to support opioid alternatives offered by traditional Medicare, MA plans, and Part D plans, including the coverage of acupuncture to address lower back pain and educating providers on other non-opioid alternatives.

Question. You know how important a diagnostic test is for timely and effective health care. During COVID, we saw how critical access to diagnostic tests were and how quickly our laboratories stepped up to the plate for public health. But it's not just COVID when testing is needed, tests are critical to early diagnosis of cancer, patients finding the right treatment for their disease, and couples trying to start a family who need to know their genetics. Unfortunately, reimbursements to laboratories have not changed since 2016 and while Congress has prevented damaging cuts to labs annually, we need a long-term solution to ensure continued access to

laboratory services for Americans, especially those living in rural and underserved communities.

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

Answer. We share your goal of ensuring access to clinical laboratory services for Medicare beneficiaries. CMS follows the statute with respect to the Clinical Laboratory Fee Schedule (CLFS). Consistent with the law, for CYs 2025 through 2027, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

Question. I want to bring to your attention to an important initiative at the Department called the National Correct Coding Initiative (NCCI). It is an important program working to reduce fraud and abuse in the Medicare billing system. However, it is not always a transparent and collaborative process for stakeholders, which can lead to decisions that would restrict access to necessary decision-making tools for providers and patients. For example, last year, the NCCI proposed a coding policy edit critical to testing for substance use disorders. They made this decision without appropriately consulting relevant stakeholders and contradicting the American Medical Association (AMA) coding guidelines.

We are working to require more transparency in the NCCI program through legislation. Can you commit to assisting us in increasing transparency in the NCCI program?

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

Do you have the internal data and analysis systems to accurately evaluate access before and after implementation? Can you provide a list of all initiatives and the major actions taken or planned for each, including any improvements to data collection?

Answer. CMS's mission for program integrity is to prevent, detect, and combat fraud, waste, and abuse across its programs. CMS works with providers, plan sponsors, States, and other stakeholders to support proper provider enrollment and accurate billing practices. NCCI promotes national correct coding methodologies and reduces improper coding that may result in inappropriate payments in Medicare Part B claims. The coding decisions for these edits are based on coding conventions defined in the American Medical Association's Current Procedural Terminology (CPT) Manual, Medicare policies, coding guidelines developed by national societies, and the coding decisions for these edits are based on coding conventions defined in the American Medical Association's Current Procedural Terminology (CPT) Manual, Medicare policies, coding guidelines developed by national societies, and standards of medical and surgical practice. NCCI edit tables are refined and updated quarterly to address changes in coding guidelines and additions, deletions, and modifications of Healthcare Common Procedural Coding System (HCPCS)/CPT codes.

Question. The Institution for Mental Diseases (IMD) exclusion prohibits Medicaid funding for residential behavioral health treatment with more than 16 beds. This rule has been applied to Qualified Residential Treatment Programs (QRTPs), a trauma-informed placement for foster youth with assessed need, a CMS decision which has helped create the youth behavioral health bed shortage and workforce crisis we're in today.

Can you explain how youth placed in QRTPs with 17 beds fare worse than those in QRTPs with 15 beds?

The Biden administration has made clear that time-limited residential placements for children with assessed need should be phased out, despite the fact that Congress enshrined these settings in the Family First Prevention Services Act just 6 years ago. In your FY25 budget, you call for even further reductions in reimbursement rates for QRTPs—which would limit States' ability to provide qualified, accredited, and therapeutic care for foster youth with behavioral health needs.

Can you speak to where children should be placed instead of QRTPs, particularly if they have been unsuccessfully and disruptively shuffled between multiple foster family homes already?

Answer. Strengthening behavioral health care is a top priority for the Biden-Harris administration. CMS has worked within the confines of the law to provide

States with flexibility to increase access to services for certain individuals residing in institutions for mental disease (IMDs), including foster youth in Qualified Residential Treatment Programs (QRTPs) that are IMDs. CMS has approved Medicaid section 1115 demonstrations that allow State Medicaid programs to pay for services provided to certain individuals in QRTPs that are IMDs. Similarly, managed care plans are permitted to pay for up to 15 days per month of treatment in QRTPs that are IMDs as an in-lieu of service—that is, a service that is not included under the State plan, but is a clinically appropriate, cost-effective substitution for a similar covered service.

Children in foster care should receive the medical care that they need and to which they are entitled, without disruption, in a safe and nurturing setting that fosters their growth and development. CMS is committed to ensuring children with unique health needs receive high-quality care in the most appropriate setting permissible under the law, and CMS has worked within the confines of the law to provide States with flexibility to increase access to these services.

The FY 2025 budget proposes a set of comprehensive child welfare proposals that, combined, seeks to reduce the number of children entering foster care and, for those children who do need to enter care, expands the provision of kinship placements and discourages the use of congregate care. The budget seeks to align Federal financing with child welfare best practices and research that shows that most children do best with kin or in another foster family home and experience worse outcomes when in a group setting.

Question. With the Inflation Reduction Act's changes to Part D set to take effect in 2025, I am concerned that Part D plans will be incentivized to more broadly apply utilization management tools such as step therapy in ways that could restrict and delay seniors' access to care. It is important that the Centers for Medicare and Medicaid Services (CMS) get ahead of this issue before seniors are harmed.

What action is CMS taking now to protect seniors from adverse impacts, including by ensuring greater transparency of plans' utilization management policies? Will you ensure that adequate protections for beneficiaries are in place before 2025?

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

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

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

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

Question. A primary focus of the Department is to reduce longstanding disparities in health outcomes. The Centers for Medicare and Medicaid Services (CMS) have attempted to address some of these health equity issues through actions such as the Comprehensive Kidney Care Choices (CKCC) model. CMS' modified approach for 2024 and future years is through a retrospective trend adjustment (RTA), but the lack of an RTA for 2022 and 2023 spending benchmarks will result in financial losses for participating practices, jeopardizing the ongoing operations of the care model.

Will you commit to working with CMS to examine actions that the agency could take to ensure continued participation in the CKCC model?

Answer. One of CMS's top priorities is to expand access to quality, affordable health coverage and care. As of January 2024, the Kidney Care Choices (KCC) model includes 123 Kidney Contracting Entities (KCEs) and CMS Kidney Care First (KCF) practices, which are accountable for the quality of care of their aligned people with Medicare. The KCC model has more than 9,227 participating health care providers and organizations, a 10-percent increase from 2023, serving 282,335 people with Medicare who have chronic kidney disease and end-stage renal disease in 2024. The strong participation in our accountable care models in 2024 will help more people access high-quality coordinated health care that will improve their quality of life.

Question. In the FY 2025 the proposed budget, the administration has included additional offices, programs, and funding for industrial base expansion and strengthening our domestic supply chains. I have been closely tracking the work the Administration for Strategic Preparedness and Response has been doing regarding industrial base expansion (IBx), particularly as it relates to nitrile gloves and other PPE. Despite the administration purportedly prioritizing these efforts, it's come to our attention that ASPR recently canceled some of these IBx contracts, notwithstanding the significant Federal investment already made. This is concerning from both a public health and national security perspective. My staff recently asked the following questions of your staff. The answer was largely nonresponsive. Accordingly, I am now asking them of you.

With the $600-million Federal investment in domestic glove manufacturing, to date, how many gloves have been produced domestically? What is our current capacity for domestic production? What will our domestic production capacity be by the end of 2024?

Answer. Using COVID–19 supplemental appropriations, ASPR's Office of Industrial Base Management and Supply Chain (IBMSC) expanded the country's domestic manufacturing infrastructure, including domestic glove manufacturing infrastructure ASPR was grateful for the congressional funding provided for this work.

As of the date of the hearing, there are two active contracts supporting domestic glove manufacturing: U.S. Medical Glove Company and Showa.

U.S. Medical Glove Company has produced a total of 30 million gloves as of the date of this hearing and has a production capacity of 11 million gloves per month. Under the contract with Showa, manufacturing and production is anticipated to come online in March 2024 with total capacity of 16.6 million gloves per month.

Question. Have any of the funds originally allocated for the completion of these projects been repurposed? If so, for which specific projects or programs?

Answer. No funds originally allocated for the completion of these projects were repurposed. ASPR has utilized all funding provided to date for these efforts and has made significant investments to support and buildout domestic manufacturing capabilities. ASPR was appropriated $10 million in FY 2024 for continuation of these efforts.

ASPR requested $95 million in the FY 2025 President's budget to support sustained efforts in domestic manufacturing.

Question. Can you explain the contract modification process? Does ASPR allow for contract modifications when temporal milestones are missed as a result of governmental time constraints and delays?

Answer. ASPR adheres to and follows all contracting regulations and processes as outlined within the Federal Acquisition Regulation (FAR). Under required processes, any modification to existing contracts begins either when the Contracting Officer's Representative (COR) or the contractor initiates a written request to the Contracting Officer. If the modification is deemed appropriate by the Contracting Officer,

supporting documents are required to execute the modification. During this process, the Contracting Officer works closely with the COR to examine circumstances (who, what, when, where, why) that resulted in the need for the requested modification. In cases where a cost change is required, the Contracting Officer requires a full description of the work to be changed or modified and an independent cost estimate.

Question. Does ASPR allow for contract modification when temporal milestones are missed as a result of governmental time constraints and delays?

Answer. ASPR adheres to and follows contracting regulations and processes as outlined within the Federal Acquisition Regulation (FAR). Under these regulations, ASPR can allow for contract modification when temporal milestones are missed as a result of governmental time constraints and delays.

Question. What is ASPR's process for considering and subsequently determining contract termination? What factors does ASPR consider in process of terminating existing IBx contracts—those terminated for cause or for convenience?

Answer. It took the U.S. economy decades for industries to leave our shores and go overseas, and it will take time and continued investment to bring them back. ASPR continues to balance supporting domestic manufacturers and spending taxpayer dollars in a way that ensures appropriate management and oversight of existing contracts.

When deciding whether to terminate an IBx contract, ASPR adheres to and follows the contracting regulations and processes as outlined within the Federal Acquisition Regulation (FAR).

For contract terminations for cause, this process is initiated when the Contracting Officer becomes aware of a performance deficiency, *i.e.,* missed milestones/deliverables that constitute failure to perform or failure to make progress as to endanger performance of the contract. The Contracting Officer validates whether the contractor has failed to make delivery of the supplies or services or has failed to make progress as to endanger performance of the contract. Once the Contracting Officer validates the performance deficiency, the contracting officer may determine to send a written Letter of Concern to the contractor, or a Cure Notice in anticipation of a termination. A Letter of Concern describes the technical, cost, or schedule problem being experienced under the contract, and directs the contractor to respond to the letter with some type of "corrective action plan" by a certain date. In a situation where the contractor fails to deliver supplies or services, or some other of the provisions of the contract, or fails to make progress as to endanger performance of the contract, the Contracting Officer can instead send a written Cure Notice to the contractor stating specifically what deficiency exists and providing the contractor 10 days to "cure," or explain how it will "cure," the failure to deliver or failure to make progress. When making the termination decision, ASPR considers the contractor's cure response, whether the contractor has explained in sufficient detail how the contractor will meet the terms and conditions of the contract, and the likelihood of the contractor successfully completing the contract requirements.

QUESTIONS SUBMITTED BY HON. MARSHA BLACKBURN

Question. Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program. In the proposed rule, the Center for Medicare and Medicaid (CMS) redefines "best price" in Medicaid. For more than 30 years, "best price" has been defined statutorily as the single lowest price available from a manufacturer.

Please explain why your agency is looking to upend 30 years of legal and practical precedent in an attempt to rewrite the Medicaid law without Congress.

Stakeholders throughout the health care supply chain have raised operational questions about the agency's proposed rule and how it would be implemented. Specifically, there doesn't appear to be any system in place to capture—from the manufacturer all the way down to the pharmacy counter—all the data on rebates required to comply with the proposed rule. It also doesn't appear that all entities in the supply chain would be compelled to share the necessary data.

Please describe how your agency plans to set up such a system.

Do you plan to request additional congressional funding to build out such a platform?

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

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

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

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

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

As a reminder, under the NSA, providers are also prohibited from billing more than the amount of cost sharing (calculated using the recognized amount, or in the case of air ambulance services, the lesser of the billed amount or QPA). We have heard from stakeholders regarding this concern and are actively investigating the issue.

Question. The NSA established an independent dispute resolution (IDR) process to resolve disputed payment amounts between insurance companies and providers. Providers have repeatedly informed Congress that, even after the provider prevails in the IDR, health plans fail to actually pay the amounts owed in the time frames specified in law and regulation. In some instances, the insurers pay incorrect amounts; in others, they fail to pay at all. Although the agency has an online portal for complaints about these issues, providers consistently report never receiving a response or follow-up communication from the agency. This behavior by the plans poses a significant issue for cash flow for providers and eviscerates one of the most fundamental provisions in the law Congress passed.

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

Answer. Through the CMS investigation process, as of October 31, 2023, CMS has directed numerous plans, issuers, providers, health-care facilities, or providers of air ambulance services to take remedial and corrective actions to address instances of noncompliance, which has resulted in approximately $3,018,432 in monetary relief paid to consumers or providers. To provide transparency into our processes, CMS has begun to publish data on the resolution of certain consumer complaints, including complaints related to NSA (see: *https://www.cms.gov/files/document/enforcement-report-11-23.pdf*). CMS intends to update this chart regularly. Most consumer

submissions involve requests for basic information about the NSA, complaints related to potential balance billing in cases of nonemergency or emergency services, or complaints that a good faith estimate was not provided for scheduled care or upon request.

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

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

Question. In August of 2023, a Federal court in *Texas Medical Association, et al. v. U.S. Department of Health and Human Services, et al.,* Case No. 6:22–cv450–JDK (TMA III) invalidated the Department of Health and Human Services (HHS) regulations governing how insurers calculate Qualified Payment Amounts (QPAs) under the NSA. In response, the Department indicated it would appeal the court's ruling and exercise enforcement discretion to allow insurers to use invalidated QPAs during the appeal process. On January 12, 2024, the Department decided to withdraw its appeal regarding several important parts of the court's ruling which prohibited insurers from (1) using any out-of-specialty rates and (2) using the rates of other self-funded plans in calculating QPAs. It's been more than 2 months since that decision, yet the Department has failed to issue any guidance instructing insurers and IDRs to follow the law.

When will the Department be issuing that update?

Answer. On August 24, 2023, the United States District Court for the Eastern District of Texas (district court) issued an opinion and order in *TMA III* vacating certain provisions of the July 2021 interim final rules as well as certain portions of several No Surprises Act guidance documents issued by the Departments. The district court in *TMA III* held that several provisions of the regulations and guidance are unlawful and vacated and remanded them for further consideration. On October 6, 2023, the Departments released additional frequently asked questions (FAQs) regarding implementation of certain provisions of title I (the No Surprises Act) of Division BB of the Consolidated Appropriations Act, 2021 (FAQs part 62), in light of the August 24, 2023, decision in *TMA III*. The decision in *TMA III* requires certain changes to the methodology that is used to calculate a QPA. The Federal Government appealed parts of the *TMA III* decision to the Fifth Circuit and submitted a brief to the court in January 2024 (see: Brief of Appellant *Texas Medical Association v. U.S. Department of Health and Human Services,* No. 23–40605 (5th Cir. January 12, 2024), ECF No. 42). Regulatory text that was not vacated remains in effect and is key to operation of the Federal IDR process. Therefore, plans and issuers are required to calculate QPAs in a manner consistent with the statutes and regulations that remain in effect after the *TMA III* vacatur. Accordingly, plans and issuers are expected to calculate QPAs using a good faith, reasonable interpretation of the applicable statutes and regulations that remain in effect after the *TMA III* decision.

Question. In the Contract Year 2025 Medicare Advantage (MA) and Part D proposed rule, CMS proposes certain changes to agent and broker compensation for enrolling individuals in MA plans. The proposed rule has implications for Medicare beneficiaries, field marketing organizations (FMOs), and agents and brokers who all play important roles in helping seniors select and enroll in the MA plan that best

meets their needs, and it is important that there not be any unintended consequences that could adversely impact beneficiaries.

Will you affirm that the proposed limit on fees for administration services is intended to apply only to payments that agent and brokers receive from MA plans, and not to payments that FMOs receive separately from carriers?

Will you commit to making sure that this intent is clear in any final rule to ensure there are no unintended consequences for seniors in MA?

Will you commit to engaging FMOs and other relevant stakeholders prior to issuing any future rulemaking that could affect the FMO business model and FMOs' ability to enter into service contracts with carriers to ensure there are no adverse impacts to our Nation's seniors?

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

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

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

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

Question. The administration has estimated a change in the national per-capita MA growth percentage to 1.98 percent for 2025. This is a lower than expected and inadequate update from the 2024 proposed (1.81 percent) and finalized rates (1.60 percent), and considerably lower than the finalized rate for 2023 (4.75 percent). Similarly, the estimation does not appear to be aligned with recent figures in the 2023 Medicare trustees report from CMS's Office of the Actuary 2025 that shows average incurred costs per beneficiary at 5.8 percent. Additionally, recent projections from Berkeley Research Group also show that MA medical cost inflation will increase by 4 to 6 percent in 2025.

How specifically did the administration arrive at this figure for 2025?

What justification is there for such low estimates over the last 2 years?

What explains the discrepancy with estimates provided by the administration's own actuarial office?

Answer. As required by statute, the growth rates used in the calculation of the MA rates reflect growth in per capita costs for non-ESRD individuals enrolled in either Medicare FFS or Medicare health plans. The growth rates are based on the expected change in United States Per Capita Costs in Fee-for-Service (FFS USPCC) and in Medicare overall (both FFS and MA) and, as such, are largely driven by trends in per capita costs for individuals in Medicare FFS. The Effective Growth Rate of 2.44 percent reported by the CY 2025 MA and Part D advance notice is a national average of expected change in the per capita costs year over year. The main driver of the Effective Growth Rate is the FFS USPCC, with the total USPCC used to calculate the pre-ACA benchmark cap amount for each county. The growth percentages are based on CMS's best estimate of historical Medicare FFS program experience and projected trends in Medicare FFS program payments using the most up-to-date data available. CMS continues to consider it best practice to base the growth rates on the most recent data and assumptions available at the time those values are announced. Therefore, for each release of the growth rates, CMS updates historical experience, as well as projection factors, based on the most recent data.

Question. The Food and Drug Administration (FDA) has previously recognized the importance of patient access to medicines during the pandemic and granted enforcement discretion for compounded medications in shortage. The list of medicines in shortage continues to limit patient access to vital medications, but the agency has been slow to respond. In fact, as of March 12, 2024, there were 144 products listed on FDA's drug shortage database. There is widespread agreement among health-care providers that there are problems with the current process used by the FDA to establish the agency's drug shortage list. The FDA list does not consider direct input from health-care practitioners.

What is the Administration's short-term and long-term plan to alleviate drug shortages?

Answer. HHS recognizes the severe patient impact from the persistent problem of chronic drug shortages that have most frequently impacted inexpensive generic drugs, particularly sterile injectables. HHS is taking a coordinated approach to help address economic root causes of shortages.

In November 2023, HHS announced the establishment of a new Supply Chain Resilience and Shortage Coordinator role responsible for coordinating efforts across the Department that advance the resilience of medical product and food supply chains and accelerate the Department's response to related shortages. Institutionalizing this coordination across the Department will help HHS meet its long-term supply chain resilience and shortage mitigation goals. In addition, FDA on an ongoing basis works to identify shortage risks and determines actions that can prevent or mitigate patient impact, such as prioritizing review of manufacturer submissions or working with manufacturers to increase supply. ASPR also led the development of an Essential Medicines Supply Chain and Manufacturing Resilience Assessment to identify supply chain vulnerabilities in a critical medicines list and has invested, through the Industrial Base Management and Supply Chain (IBMSC) Office, targeted funds to bolster domestic manufacturing capabilities for essential medicines.

CMS is also taking steps to help align certain incentives to bolster supply chain resilience and further promote adoption of resilient supply chain practices. As discussed in the CY 2024 Outpatient Prospective Payment System (OPPS) final rule, CMS solicited public comment on providing separate payment under the Medicare Inpatient Prospective Payment System (IPPS), and potentially the OPPS, for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply (88 FR 82127–30).

CMS also noted in the CY 2024 OPPS final rule that as part of the agency's initial efforts, CMS intends to propose new Conditions of Participation in forthcoming notice and comment rulemaking addressing hospital processes for pharmaceutical supply (88 FR 82130). CMS continues to review the comments received to consider ways the Medicare program can promote hospital resilience practices and help mitigate the impact of drug shortages on patients.

Going forward, HHS is working to identify opportunities to reduce the risks of drug shortages. Examples of these include:

Gaining fuller insight into the supply chain. Interruptions or problems in the drug supply chain can create or worsen drug shortages. The Federal Food, Drug, and Cosmetic Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act, requires manufacturers to notify FDA of active pharmaceutical ingredient (API) manufacturing discontinuances or interruptions of certain drugs under certain circumstances and includes a requirement for firms to report annually the amount of listed drugs they manufacture for commercial distribution, but it does not require reporting of shortages due to increased demand. Expressly including this requirement would greatly assist FDA's work to prevent and mitigate drug shortages.

Increasing the resilience of the drug supply chain. Drug manufacturing in more than one facility and more than one geographic region can provide agility that reduces the risk of drug shortages and helps with resolution of shortages when they occur. For example, if a manufacturing facility needs to temporarily close, or its operations are curtailed by factors such as travel restrictions, quarantines, or natural disasters, it is important to have alternative facilities available to manufacture the drug or its API. FDA is ready to work with manufacturers to address these needs. Furthermore, an express statutory requirement that drug manufacturers provide data identifying the suppliers they relied on to manufacture a listed drug, in reporting on the annual amount of the drug manufactured for commercial distribution, and the extent of such reliance, would help FDA identify vulnerabilities in the supply chain that may be hidden.

Overall, important progress has been made in preventing drug shortages from occurring, and FDA continues to work to ensure that patients in the United States have access to the medicines they need. FDA has put forth legislative proposals in its fiscal year 2025 proposed budget that address the example above *(https://www.fda.gov/media/176924/download?attachment)*. If enacted, these proposals would greatly enhance the FDA's ongoing work to address potential drug shortages.

Question. Would the FDA consider amending its definition of "drug shortage" to include input from health-care practitioners to better align the process used by the FDA to establish the shortage list, which could expedite and improve the process at FDA?

Answer. FDA continues to welcome input from health-care practitioners regarding drug shortages. In fact, March 2024 marks FDA's launch of a new portal[64] for patients, consumers, and health-care practitioners to report potential drug shortages.[65] The new public portal allows anyone, including health-care practitioners, to submit shortage information through an online form directly into FDA's Center for Drug Evaluation and Research's NextGen system.

Since 2017, NextGen has been a way for regulated industry to communicate with FDA, including by submitting information on shortages, discontinuations, and anticipated supply disruptions. Prior to the new portal, nonindustry stakeholders have had to report information about potential shortages to FDA's Drug Shortages Staff by email.

Expanding access to NextGen's shortage reporting beyond regulated industry will allow for greater consistency and ease of reporting by outside stakeholders, and greater efficiency in tracking and responding to these reports. Early notification from health-care practitioners and others about drug shortages or potential supply challenges can help FDA staff take action to quickly resolve or reduce the duration of the shortage. FDA staff investigate every notification submitted through NextGen to determine if the nationwide demand for the drug exceeds available supply. If the Drug Shortages team determines a shortage exists, they will add that product to FDA's Drug Shortages Database.

Question. Ensuring that Medicare beneficiaries can obtain accurate and timely diagnoses is critical to improved outcomes and quality of life for seniors. From a Medicare spending perspective, accurate and timely diagnoses are essential to avoid more expensive treatment courses resulting from delayed diagnoses and repeat scans. To that end, the HHS should ensure that Medicare's payment system for hospital outpatient services does not create disincentives for hospitals to use cutting-edge diagnostic radiopharmaceuticals, such as those used in PET scans, to detect diseases in early stages, including prostate cancers and other cancers. Last year, the Centers for Medicare and Medicaid Services (CMS) sought information from stakeholders on Medicare payment approaches that could avoid payment disincentives for these in-

[64] *https://cdernextgenportal.fda.gov/publicportal/s/dsm-submission.*
[65] *https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages.*

novative diagnostic radiopharmaceuticals, but the agency has not yet proposed a policy path forward.

Will you commit to working with me and my office to help ensure that Medicare payments provide the appropriate incentive for hospitals to utilize innovative diagnostic radiopharmaceuticals for imaging scans?

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

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

CMS agrees this is a complex and important issue, and given the wide array of information presented through the public comment process, we intend to further consider these points and take them into consideration for future notice and comment rulemaking. CMS welcomes ongoing dialogue and engagement from stakeholders regarding suggestions for potential future payment changes and would be happy to provide technical assistance on any draft legislation.

Question. Despite the advancements in prevention, treatments, and therapies, challenges to access and disparities in care persist in the U.S. health system. Factors such as geographic inaccessibility, economics, insurance, workforce shortages, and many other factors contribute to this growing trend. In addition, for many conditions, access to evidence-based first-line therapy is limited at best, reducing care quality, negatively impacting population health, and increasing total health-care costs. Many prescription digital therapeutics offer clinically validated interventions for a variety of mental health and substance use disorder conditions and can help fill the gap for many beneficiaries. The very nature of prescription digital therapeutics also provides opportunities to achieve access to evidence-based care at scale, especially for underserved populations. However, the lack of Medicare coverage has hindered the uptake of these much-needed products and prevented Medicare beneficiaries from accessing them. In the CY 2024 Physician Fee Schedule proposed rule, CMS took an important step by including a request for information regarding coverage for prescription digital therapeutics. Medicare's leadership in covering and paying for these new medical technologies is key to expanding access to care and helping to address provider shortages across a wide range of professionals, including mental health provider shortages that have driven the ongoing mental health crisis in the United States and globally.

What is CMS doing to ensure beneficiary access to prescription digital therapeutics?

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

In the CY 2023 PFS final rule, CMS noted that we accepted the Relative Value Scale Update Committee's (RUC's) recommendation to contractor price CPT code 98978, a PE-only code that describes provision of a monitoring device for cognitive behavioral therapy (CBT) and that we would work with our Medicare Administrative Contractors (MACs) to better understand the kinds of devices and device costs they are encountering as they review claims for payment for the services described by this code. Additionally, in the CY 2024 Physician Fee Schedule final rule, we noted that the existing codes described by CPT codes 98978, 98980, and 98981 allow for the billing of remote therapeutic monitoring services, including monitoring pa-

tient adherence and therapy response for use with cognitive behavioral therapy. CMS continues to be interested in any feedback from interested parties on this topic, including feedback from interested parties about any potential codes that we would review under those processes and considerations we might need to take into account for future rulemaking to improve the accuracy of coding and payment under the Medicare PFS (88 Fed Reg 79103).

Question. I want to thank CMS for finalizing a National Coverage Determination (NCD) for coverage of power seat elevation systems in 2023. As you know, I've long advocated for access to these important systems for people with disabilities like paralysis, muscular dystrophy, ALS, and spina bifida. Additionally, I've been asking CMS to consider power-standing systems for these consumers as well. There is a significant body of clinical evidence suggesting these systems can be incredibly valuable to the medical and health outcomes of patients with significant mobility impairments.

When do you plan to open the NCD for coverage of power standing systems?

Answer. Millions of people with Medicare rely on medically necessary assistive devices to perform daily tasks that directly impact their quality of life. CMS remains committed to ensuring persons with disabilities are receiving available benefits that improve their health. CMS follows a longstanding process established by Congress to determine whether a medical item or service can be covered nationally by Medicare, including when an item or service is reasonable and necessary for the diagnosis of and/or treatment of an illness or injury.

Although CMS has accepted a request for a national coverage determination for power standing systems, we have not been able to act on it yet due to our internal capacity restraints. As CMS indicated in the August 2013 Federal Register notice, "In the event that we have a large volume of NCD requests for simultaneous review, we prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources," 78 Fed. Reg. 48168 (August 7, 2013). This is not meant to minimize the importance of this request; it only reflects the limitations of our available resources. This request will be considered in the future as we prioritize the requests for NCDs.

QUESTIONS SUBMITTED BY HON. ELIZABETH WARREN

Question. Maximus contracts with the Federal Government to provide call center operations for Medicare, Medicaid, and the Affordable Care Act (ACA). Maximus's 9-year Contact Center Operations (CCO) contract is valued at $6.6 billion and represents the company's single largest contract. About 10,000 customer service agents are employed under this contract at 10 call centers in 8 States. Employees at these call centers are mostly women of color.

In response to reports of low wages, unacceptable working conditions, and racial inequity at Maximus's Federal call centers, and following some of the largest Federal call center worker strikes in history, the Department of Health and Human Services (HHS) announced in December 2023 that it would rebid Maximus's contract to include a labor harmony provision. Yet according to the Communication Workers of America (CWA), the union representing Maximus's Federal call center workers, HHS, and the Centers for Medicare and Medicaid Services (CMS) have claimed that the process of recompeting the call center contract could take as long as 30 months. This is an unusually long timeline for such a contract: for comparison, Maximus won the most recent CMS call center contract in September 2022, roughly 15 months after proposals were due to CMS in July 2021.

What are the steps HHS, CMS, or other agencies must take in the rebidding process? What is the specific timeline for each step? At what step of the process is HHS currently?

Why is the process for rebidding the CMS call center contract expected to take 30 months?

What actions can HHS and CMS take to streamline the rebidding process so as not to prolong call center workers' hardship? Has HHS or CMS taken any such action to date?

Answer. Offering best-in-class customer service is a top priority for HHS, and that includes service provided to American families through 1–800–MEDICARE and the ACA marketplace call centers. In June 2023, CMS issued a Request for Information

on the call center contract requesting input in major areas, including a labor harmony requirement (available at: *https://sam.gov/opp/7c4e9a33081d44049ded7360ae9ec7c9/view*). In the interest of customer service and continuity of operations, CMS will, under the legally required process, recompete its contract for the Medicare and ACA marketplace call centers. CMS anticipates issuing a "Sources Sought" notice to determine the potential bidder pool in March 2024.

Question. The Department of Health and Human Services aims to "achiev[e] universal legal representation for unaccompanied children by 2027." Without legal counsel, it is virtually impossible for unaccompanied children to navigate the complex and adversarial U.S. immigration system and to understand and defend their legal rights. Legal representation of children also prevents waste of judicial and other government resources, given that attorneys can help screen out inapplicable forms of protection, minimize unneeded court time, and avert hearing postponements that would otherwise be necessary to afford children an opportunity to obtain counsel. Furthermore, attorneys help combat labor exploitation, sometimes serving as the only authority figure in whom children feel safe confiding information about workplace abuses.

Can you share in more detail the actions the Office of Refugee Resettlement (ORR) will take in FY 2024 and beyond to expand legal services for unaccompanied children?

How can Congress support ORR in its expansion of legal services for unaccompanied children?

Answer. By statute, HHS's ORR is responsible for the care and placement of unaccompanied children who are in Federal custody by reason of their immigration status, from the moment they enter ORR custody from the Department of Homeland Security (DHS) or other Federal entity, to when they are safely placed with a vetted sponsor who has undergone a robust screening process. See 6 U.S.C. 279; 8 U.S.C. 1232(b)–(c). As part of this mission, consistent with legal requirements, ORR arranges legal services for some unaccompanied children to assist them in their immigration proceedings and provides legal information to each child upon entering ORR care. See 8 U.S.C. § 1232(c)(5).

ORR's Unaccompanied Children (UC) Program Policy Guide Section 3.7, states that when in ORR custody, unaccompanied children should receive "Know Your Rights" (KYR) presentations on immigration law and the children's rights and responsibilities and legal screenings within 10 business days of admission. ORR contracts with a legal service provider to administer the KYR presentation and legal screenings. The contractor also provides direct representation for a limited number of children in ORR care and upon release from ORR. Direct representation means attorneys enter into a representation agreement with unaccompanied children to represent them before the immigration court, U.S. Citizenship and Immigration Services and/or State court in the child's defense against removal and application for affirmative petitions, such as applications for asylum or adjustment of status through Special Immigrant Juvenile Status.

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 CY 2027. Congress can support this effort with additional funding and resources. Due to shortages of appropriate legal service providers, ORR anticipates that it will take several years to scale up to the capacity in the legal service field necessary to serve all unaccompanied children, which will require investments in attorney recruitment and training, mentoring programs and opportunities, and technical support for the pro bono network. More funding from Congress would help address issues identifying and retaining legal service providers and build up contract capacity so that more children have legal representation.

Currently, direct representation is prioritized for the most vulnerable cases, including children who are expected to have a longer stay in ORR care, such as those in long-term foster care or those who do not have an identified sponsor, and children for whom courtroom assistance does not satisfy the legal needs of the individual child, such as those who are seeking voluntary departure or who otherwise have complex legal needs.

In response to these needs, ORR awarded a 5-year legal services contract in March 2022 and expanded that contract to invest in legal service provider capacity building, by expanding to new, previously unserved or underserved areas and bringing on new attorneys. ORR also plans to award one or more new contracts for addi-

tional direct legal representation capacity in FY 2024, which will also expand representation for unaccompanied children who have been released from ORR care, as current appropriations from Congress allow.

Question. In August 2023, the Department of Health and Human Services recommended that the Drug Enforcement Administration (DEA) reschedule marijuana from Schedule I of the Controlled Substances Act to Schedule III. The recommendation explained that marijuana "does not produce serious outcomes compared to drugs in Schedules I or II," and "the vast majority of individuals who use marijuana are doing so in a manner that does not lead to dangerous outcomes to themselves or others." Though HHS recommended placing marijuana in Schedule III, its recommendation also explained that marijuana's rate of adverse outcomes is *lower* than that of alcohol, which is not scheduled in the Controlled Substances Act, and that the "risks to the public health posed by marijuana are low compared to other drugs of abuse," such as benzodiazepines (a Schedule IV drug). The DEA is currently reviewing HHS's recommendation. Additionally, according to a recent report, HHS has asked the Justice Department's Office of Legal Counsel (OLC) to provide input on legal issues related to rescheduling marijuana.

Relatedly, in 2022 the Medical Marijuana and Cannabidiol Research Expansion Act directed HHS to report to Congress "the potential therapeutic effects of cannabidiol or marijuana on serious medical conditions" by December 2023.

Please describe how marijuana's abuse potential and risk to public health compares to that of alcohol, which is not scheduled in the Controlled Substances Act.

If HHS has sought OLC's input on the topic of rescheduling or de-scheduling marijuana, what question(s) did HHS raise for OLC? Has HHS received a response from OLC?

What is the status of the HHS report mandated by the Medical Marijuana and Cannabidiol Research Expansion Act, and when should members anticipate its release?

Answer. All drug use comes with risk, though different drugs pose different potential health effects and associated harms. While many of the health effects of alcohol have been well established through decades of research, we do not have the same evidence base for cannabis at present. Rigorous research on the potential risks, benefits, and health effects of cannabis use is urgently needed.

Cannabis use among adults has increased in recent years, alongside an increase in doses and regular patterns of consumption. At the same time, there are well-documented adverse health effects associated with cannabis use including addiction, respiratory problems, accidents, psychosis, and cardiovascular events. Using cannabis every day, or almost every day, is associated with developing cannabis use disorder, cannabis-induced psychosis, and other adverse mental health effects—especially if a person starts using cannabis at a young age.

The U.S. Food and Drug Administration (FDA) has not approved a product containing whole cannabis or marijuana plant material for any purpose. However, the FDA has approved synthetic THC-based medications (dronabinol and nabilone), to treat nausea and vomiting associated with cancer chemotherapy and to treat anorexia and weight loss associated with HIV/AIDS. The FDA has also approved a plant derived CBD-based medication (cannabidiol) to treat seizures associated with rare forms of epilepsy.

There is evidence that cannabis can be effective in treating some forms of pain, and there is emerging evidence that it may have additional therapeutic uses. Research will continue to explore potential therapeutic effects of cannabis to help inform individual and public health decisions, including strategies to minimize potential harms associated with cannabis use.

HHS did not request that the Office of Legal Counsel conduct an analysis of legal issues related to rescheduling marijuana.

The landscape of cannabis research and policy is complex. As with any deliverable to Congress, the agency works as hard as possible to meet the appropriate deadlines. The report will be submitted to Congress as soon as it is completed.

Question. Medical neglect is rampant in jails, prisons, and immigration detention facilities. The quality of medical, mental, and dental care in these facilities routinely falls far below the community standard of care. It is estimated that a person loses 2 years in life expectancy for every 1 year spent behind bars. Meanwhile, individuals in custody often have greater health needs than the general population. An es-

timated 50 percent of individuals in State and Federal prisons have had a chronic health condition and around 37 percent of individuals in prisons have a mental illness—roughly double the share in the general population. COVID–19 helped reveal the lack of health infrastructure in custodial facilities, yet given the lack of health data reporting, these facilities largely remain a black box.

What steps is HHS taking to help address the crisis of poor health and substandard health care in jails, prisons, and immigration detention facilities?

For prisons and jails that receive Medicaid funds pursuant to 1115 waivers of the Medicaid Inmate Exclusion Policy, what data on the health status of individuals in custody or data on the provision of health services will the Centers for Medicare and Medicaid Services (CMS) ask facilities to report (if any)?

What additional health data is CMS considering collecting from jails and prisons that receive Medicaid funds?

What health-related technical assistance does the Centers for Disease Control and Prevention (CDC) currently provide in jails, prisons, and/or immigration detention facilities?

What health-related data does CDC collect from such facilities?

What additional technical assistance or data collection is CDC considering providing or performing in such facilities?

Answer. CMS understands data related to carceral status, release and reentry details, Medicaid eligibility, and the health-care needs of individuals who are incarcerated and returning to the community may reside in fragmented systems, including nonelectronic systems. This may present some challenges in data sharing for purposes of case management and collection of data for the Reentry Section 1115 Demonstration Opportunity.

To support monitoring activities, a State with an approved Reentry Section 1115 Demonstration will be expected to include information in its demonstration quarterly and annual monitoring reports that, among other things, details performance measures representing key indicators of progress toward meeting the milestones for the demonstration. CMS expects such metrics to include, but not be limited to: administration of screenings to identify individuals eligible for pre-release services, participating pre-release services providers, utilization of applicable pre-release and post-release services (*e.g.,* primary, behavioral, medications for opioid use disorder, case management), provision of health or social service referral pre-release, participants with established care plans at release, and takeup of data system enhancements among participating carceral settings. Additionally, the State will be expected to report quality of care and health outcomes metrics known to be important for closing key quality and health equity gaps in Medicaid/CHIP (*e.g.,* the National Quality Forum "disparities-sensitive" measures) and prioritizing key outcome measures and their clinical and non-clinical (*i.e.,* social) drivers of health. Not all measures on the list will be applicable based on a State's demonstration design. The State and CMS will collaborate to determine the appropriate measures the State will report. The monitoring reports will also be expected to include qualitative information that will align with the milestones outlined above, including but not limited to the State's progress on data development and exchange. A State will also be expected to conduct independent and robust interim and summative evaluations. Outcomes of interest could include, but are not limited to, measurement of cross-system communication and collaboration, connections between carceral settings and community services, provision of preventive and routine physical and behavioral health care, and avoidable emergency department visits and inpatient hospitalizations, as well as all-cause deaths. To the extent feasible, the State will be expected to collect data to support analyses stratified by key subpopulations of interest (*e.g.,* by sex, age, race/ethnicity, primary language, disability status, geography, and sexual orientation and gender identity).

SUBMITTED BY HON. MARSHA BLACKBURN,
A U.S. SENATOR FROM TENNESSEE

United States Senate

WASHINGTON, DC 20510

April 27, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
Washington, DC 20528

Dear Secretary Becerra:

As I expressed when you appeared before the Senate Finance Committee last month, I am deeply concerned regarding the recent reports that the Department of Health and Human Services (HHS) has mishandled unaccompanied migrant children by placing them with unvetted sponsors, leading to their exploitation and forced labor.

President Biden's border crisis has placed illegal immigrants in dangerous—and often deadly—situations, and the over 250,000 unaccompanied minors who have crossed our southern border over the last 2 years are no exception.[1] As you know, many of these children who have been placed with sponsors have been forced to work dangerous jobs across the country in violation of child labor laws. By losing contact with over 85,000 children, your Department has failed to uphold its basic obligation to ensure that these children are placed with sponsors who will protect them. Even more troubling, initial reporting indicated that case management officers were aware of children in exploitative situations, yet the Department did not act.[2] Democrats have spent years telling the American people that their immigration policies are compassionate and humane, but there is nothing compassionate about turning a blind eye to the victimization of children.

When questioned at the hearing, you indicated that you were not aware that children were being forced to work in dangerous jobs for long hours, nor were you familiar with the fact that 85,000 children had gone missing under your watch. While you claimed you were uninformed about this situation, reporting following your testimony indicates a grave dereliction of duty. According to *The New York Times,* staffers and outside contractors informed HHS multiple times that migrant children appeared to be at risk of exploitation, and they even presented evidence that allegedly reached your desk. Not only were these individuals ignored, but they were punished for daring to challenge you.[3] This reporting directly contradicts your previous testimony.

These allegations of the Department ignoring these concerns are deeply troubling, but even if they are untrue, the Department is clearly guilty of gross incompetence. I am requesting answers regarding the abuse and exploitation of these children that were entrusted to your Department, and I am committed to holding accountable every individual responsible for this dereliction of duty.

Please respond to the following questions by May 4, 2023.

1. When did you learn of the mishandling and exploitation of migrant children who were released by HHS to unvetted sponsors?
2. Are you aware that, under Federal law, it is a crime to "knowingly and willfully" make a "materially false" statement to Congress?[4]
3. Please provide any reports, correspondence, or other documentation that you received regarding the potential exploitation of these migrant children.

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[1] Hannah Dreier, *Alone and Exploited, Migrant Children Work Brutal Jobs Across the U.S.,* N.Y. TIMES (February 28, 2023), *https://www.nytimes.com/2023/02/25/us/unaccompanied-migrant-child-workers-exploitation.html.*

[2] *Id.*

[3] Hannah Dreier, *As Migrant Children Were Put to Work, U.S. Ignored Warnings,* N.Y. TIMES (April 17, 2023), *https://www.nytimes.com/2023/04/17/us/politics/migrant-child-labor-biden.html.*

[4] 18 U.S.C. § 1001(a)(2).

4. The Department's Office of the Inspector General released a report indicating that several demotions and dismissals of individuals who raised concerns about migrant child safety "may have risen to the level of whistleblower chilling."[5] Did you personally approve these demotions and dismissals?
5. An employee of the office of Homeland Security Investigations, an investigative arm of the U.S. Department of Homeland Security, stated, "As the government, we've turned a blind eye to [the] trafficking [of migrant children]."[6] Have you turned a blind eye to your Department's role in child trafficking?

I look forward to your prompt and honest response.

Sincerely,

Marsha Blackburn
United States Senator

United States Senate

WASHINGTON, DC 20510

September 20, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
Washington, DC 20528

Dear Secretary Becerra:

As I expressed when you appeared before the Senate Finance Committee in March and again in my letter to you in April, I am appalled by reports that the Department of Health and Human Services (HHS) has mishandled unaccompanied minors by placing them with unvetted sponsors, leading to their exploitation and forced labor.

Your agency's written response to my inquiry, which you did not even take the time to write yourself, was completely inadequate and an insult to the duty of oversight entrusted to the United States Senate. I asked you specifically about your knowledge of this crisis and your involvement in the alleged whistleblower retaliation that has taken place under your watch, yet your Assistant Secretary declined to answer a single question. Additionally, I asked you to provide the documents you received regarding the potential exploitation of these migrant children, but Assistant Secretary Hild failed to produce a single document. Instead, over 5 months later, my inquiry was met with general information about your failed policies. Your Department's lack of urgency on this matter, and your continued refusal to provide information about the amount of time you spent in California instead of fulfilling your duties in-person, speaks volumes regarding your mishandling of this crisis.

Democrats on the Senate Judiciary Committee, who refused to call any government witnesses at a hearing entitled "Ensuring the Safety and Well-Being of Unaccompanied Children," seem content distracting and deflecting from this administration's border crisis. In fact, they are doing anything but ensuring the safety and well-being of these children, and I will not join them in turning a blind eye to your negligence. The American people, and the families of the 85,000 migrant children that this administration lost, deserve answers about your role in this grave dereliction of duty. I will allow you the opportunity to respond to the questions I posed in April, and I expect to see you before the Senate Judiciary Committee as soon as possible.

Please respond to the following questions by September 27, 2023.

1. When did you learn of the mishandling and exploitation of migrant children who were released by HHS to unvetted sponsors?

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[5] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, OPERATIONAL CHALLENGES WITHIN ORR AND THE ORR EMERGENCY INTAKE SITE AT FORT BLISS HINDERED CASE MANAGEMENT FOR CHILDREN (2023), *https://oig.hhs.gov/oei/reports/OEI-07-21-00251.pdf.*

[6] Hannah Dreier, *Alone and Exploited, Migrant Children Work Brutal Jobs Across the U.S.,* N.Y. TIMES (February 28, 2023), *https://www.nytimes.com/2023/02/25/us/unaccompanied-migrant-child-workers-exploitation.html.*

2. Are you aware that, under Federal law, it is a crime to "knowingly and willfully" make a "materially false" statement to Congress? [1]
3. Please provide any reports, correspondence, or other documentation that you received regarding the potential exploitation of these migrant children.
4. The Department's Office of the Inspector General released a report indicating that several demotions and dismissals of individuals who raised concerns about migrant child safety "may have risen to the level of whistleblower chilling." [2] Did you personally approve these demotions and dismissals?
5. An employee of the office of Homeland Security Investigations, an investigative arm of the U.S. Department of Homeland Security, stated, "As the government, we've turned a blind eye to [the] trafficking [of migrant children]." [3] Have you turned a blind eye to your department's role in child trafficking?
6. Please provide copies of your schedule, travel expense reports, and any other relevant documents since the beginning of your tenure as Secretary that you committed to sharing with Senate Finance Committee members.

I look forward to your personal, prompt, and honest response.

Sincerely,

Marsha Blackburn
United States Senator

United States Senate
WASHINGTON, DC 20510

May 3, 2024

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Dear Secretary Becerra:

I am writing you today to follow-up on the false statements that you made in your March 14th testimony before the Senate Finance Committee and to set the record straight. Between fiscal years 2021 and 2023, over 360,000 unaccompanied children at the southern border were referred to the custody of the Department of Health and Human Services (HHS) Office of Refugee Resettlement (ORR).[1] Disturbingly, your Department has lost track of over 85,000 of these unaccompanied migrant children, many of whom have found themselves in dangerous trafficking rings and forced labor networks.[2]

At your March 14th appearance before the Senate Finance Committee, I asked you whether your Department has a responsibility to follow-up with these unaccompanied children once they have been placed with a sponsor. To my astonishment, you responded though you and your colleagues did not give us the authority to follow them after they leave our care." But, to put it mildly, the facts indicate otherwise.

Federal law explicitly grants ORR with broad authority to ensure the well-being and safety of these migrant children, specifically by "coordinating and implementing"

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[1] 18 U.S.C. § 1001(a)(2).
[2] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, OPERATIONAL CHALLENGES WITHIN ORR AND THE ORR EMERGENCY INTAKE SITE AT FORT BLISS HINDERED CASE MANAGEMENT FOR CHILDREN (2023), *https://oig.hhs.gov/oei/reports/OEI-07-21-00251.pdf.*
[3] Hannah Dreier, *Alone and Exploited, Migrant Children Work Brutal Jobs Across the U.S.,* N.Y. TIMES (February 28, 2023), *https://www.nytimes.com/2023/02/25/us/unaccompanied-migrant-child-workers-exploitation.html.*
[1] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF THE INSPECTOR GENERAL, GAPS IN SPONSOR SCREENING AND FOLLOWUP RAISE SAFETY CONCERNS FOR UNACCOMPANIED CHILDREN (2024), *https://oig.hhs.gov/oei/reports/OEI-07-21-00250.pdf.*
[2] Hannah Dreier, *Alone and Exploited, Migrant Children Work Brutal Jobs Across the U.S.,* N.Y. TIMES (February 28, 2023), *https://www.nytimes.com/2023/02/25/us/unaccompanied-migrant-child-workers-exploitation.html.*

their care and placement.[3] ORR is also tasked with "implementing policies with respect to care and placement of unaccompanied alien children."[4] Building off of that broad authority, the reality is that *your very own Department* has issued guidance stating that "care providers ***must*** conduct a Safety and Well Being Follow-up Call with an unaccompanied child and his or her sponsor 30 days after the release date."[5] That guidance also makes clear that "the purpose of the follow-up call is to determine whether the child ***is still residing with the sponsor.***" "If the care provider believes that the child is unsafe, the care provider must comply with mandatory reporting laws."[6] Put simply, your Department has failed to follow its own guidance for the sake of expediency, and you have tried to shift the blame to Congress.

Your efforts to ensure that these children are safe with their sponsors have been insufficient, so much so that the HHS Office of the Inspector General (OIG) released a 62-page report in February 2024 titled "Gaps in Sponsor Screening and Followup Raise Safety Concerns for Unaccompanied Children."[7] In its findings, the OIG report notes that in 22 percent of cases, ORR did not conduct timely Safety and Well Being Calls, and in 18 percent of cases, the follow up calls were not documented in children's case files.[8] Given these shortcomings, it is no surprise that the Biden administration has lost track of tens of thousands of these migrant children.

With President Biden's border crisis continuing to spiral out of control, I urge you to recognize your direct role in ensuring the well-being of unaccompanied children entrusted to your care and correct ORR's failures in doing so thus far.

Thank you for your attention to this urgent matter.

Sincerely,

Marsha Blackburn
United States Senator

U.S.C. TITLE 6—DOMESTIC SECURITY

§ 279. Children's affairs

. . .

(b) Functions

(1) In general

Pursuant to the transfer made by subsection (a), the Director of the Office of Refugee Resettlement shall be responsible for—

(A) coordinating and implementing the care and placement of unaccompanied alien children who are in Federal custody by reason of their immigration status, including developing a plan to be submitted to Congress on how to ensure that qualified and independent legal counsel is timely appointed to represent the interests of each such child, consistent with the law regarding appointment of counsel that is in effect on November 25, 2002;

. . .

(E) implementing policies with respect to the care and placement of unaccompanied alien children;

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[3] 6 U.S.C. § 279(b)(1)(A).
[4] 6 U.S.C. § 279(b)(1)(E).
[5] ORR UNACCOMPANIED CHILDREN PROGRAM POLICY GUIDE: SECTION 2, OFFICE OF REFUGEE RESETTLEMENT, *https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-section-2* (emphasis added).
[6] *Id.* (emphasis added).
[7] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF THE INSPECTOR GENERAL, GAPS IN SPONSOR SCREENING AND FOLLOWUP RAISE SAFETY CONCERNS FOR UNACCOMPANIED CHILDREN (2024), *https://oig.hhs.gov/oei/reports/OEI-07-21-00250.pdf.*
[8] *Id.*

ORR Unaccompanied Children Program Policy Guide: Section 2

Safe and Timely Release from ORR Care
Current as of: April 1, 2024

2.1 Summary of the Safe and Timely Release Process

The Office of Refugee Resettlement (ORR) has policies and procedures in place to ensure unaccompanied children in ORR care are released in a safe, efficient, and timely manner. ORR's policies require the release of unaccompanied children to parents, guardians, relatives, or individuals designated by the child's parents, referred to as "sponsors." Safe and timely release (also known as "family reunification") must promote public safety and ensure that sponsors are able to provide for the physical and mental well-being of children.

ORR evaluates potential sponsors' ability to provide for the child's physical and mental well-being, as required by law. ORR also protects children from smugglers, traffickers, or others who might seek to victimize or otherwise engage the child in criminal, harmful or exploitative activity. The process for the safe and timely release of an unaccompanied child from ORR custody involves several steps, including: the identification of sponsors; sponsor application; interviews; the assessment (evaluation) of sponsor suitability, including verification of the sponsor's identity and relationship to the child (if any), background checks, and in some cases home studies; and post-release planning.

In certain cases, ORR may begin vetting the potential sponsors of unaccompanied children likely to enter ORR care prior to their physical transfer to further diminish the time a child would remain in ORR care (see **UC Policy Guide Section 2.2 Sponsor Application Process**).

Revised 2/22/24

2.2 Sponsor Application Process

As soon as a child is physically transferred to ORR custody, ORR begins to assess potential sponsors, which may include interviewing the child, their parent(s), legal guardian(s), or other primary caregiver(s), in order to identify family members and others who may be qualify as sponsors to care for the child. Sponsors may include parents, relatives, close family friends, or other individuals, and any of these individuals may apply to have the child released to their care (see **UC Policy Guide Section 2.2.1 Identification of Qualified Sponsors**).

In addition, ORR may begin vetting potential sponsors of children likely to be referred to ORR prior to their physical transfer, where the Federal agency communicates they will likely be determined to be unaccompanied children, in response to specific humanitarian missions and other special operations. In these cases, ORR will not wait for children to placed in an ORR care provider facility to begin its reunification process, but will instead follow discrete guidance, published as **Field Guidance** *(https://www.acf.hhs.gov/orr/policy-guidance/uc-program-field-guidance)*, tailored to the requirements and legal authorities of the specific circumstance.

Revised 2/22/24

2.2.1 Identification of Qualified Sponsors

The ORR **care provider** *(https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-guide-terms#Care%20Provider)*, the ORR funded facility that cares for the child, interviews the child as well as parents, legal guardians, and/or family members to identify qualified custodians ("sponsors") (see the section below on how ORR confirms relationship with child). If a child is either too young or there are other factors that prohibit the care provider from obtaining potential sponsor information from the unaccompanied child, the care provider may seek assistance from the child's consulate in collaboration with the **ORR Federal Field Specialist (ORR/FFS)** or from a reputable family tracing organization. Finding a sponsor for the child is an ongoing process that continues during the unaccompanied child's stay in ORR care and custody in the event that the primary potential sponsor or primary release plan is not approved.

ORR releases children to a sponsor in the following order of preference:[1] parent; legal guardian; an adult relative (brother, sister, aunt, uncle, grandparent or first cousin); an adult individual or entity designated by the parent or legal guardian (through a signed declaration or other document that ORR determines is sufficient to establish the signatory's parental/guardian relationship); a licensed program willing to accept legal custody; or an adult individual or entity seeking custody when it appears that there is no other likely alternative to long term ORR care and custody. ORR has grouped UC cases into the following categories.[2]

- **Category 1:** Parent or legal guardian. This includes qualifying step-parents that have legal or joint custody of the child or teen.
- **Category 2A:** A brother; sister; grandparent **or** other immediate relatives (*e.g.,* aunt, uncle, first cousin) who previously served as the UC's primary caregiver. This includes biological relatives, relatives through legal marriage, and half-siblings.
- **Category 2B:** An immediate relative (*e.g.,* aunt, uncle, first cousin) who was not previously the UC's primary caregiver. This includes biological relatives, relatives through legal marriage.
- **Category 3:** Other sponsor, such as distant relatives and unrelated adult individuals.
- **Category 4:** No sponsor identified.

Although ORR gives preference to a parent or legal guardian when determining release plans, there are instances when ORR does not release an unaccompanied child to a parent or legal guardian. These include:

- There has been a court ordered termination of parental rights over the child.
- There is substantial evidence that the child would be at risk of harm if released to the parent or legal guardian.

In some cases, a UC enters the United States with their biological child. In those cases, ORR identifies a sponsor for the UC as well as for the infant or toddler. In most instances, it is in the best interest of the UC and the biological child to be released to the same sponsor. In cases where the relationship between the UC parent and the sponsor and the infant and the sponsor fall under different sponsor categories, ORR assigns the sponsor category representing the closer relationship in the infant's case. For example, if the relationship between the UC parent and the sponsor falls under Category 2A and the relationship between the sponsor and infant falls under Category 3, then category assigned in the infant's case would be Category 2A.

Revised 03/8/2022

2.2.2 Contacting Potential Sponsors

The child's **care provider** is responsible for implementing safe screening methods when contacting and communicating with potential sponsors. These methods are to ensure that a potential sponsor does not pose a risk to the unaccompanied child, to other children in the care provider facility or to care provider staff.

Safe screening methods include:

- Use of appropriate interpreters
- Proof of sponsor's identity is obtained
- Verification of family relationships
- Coordination with the unaccompanied child's parents, legal guardians, or closest relatives prior to contacting non-relative adult potential sponsors
- Screening for exploitation, abuse, trafficking, or other safety concerns
- Engaging the child to communicate openly with care provider staff about their own sense of safety

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[1] As per the release order preference outlined in *Flores v. Reno* Stipulated Settlement Agreement, No. 85–4544–RJK (Px) (C.D. Cal., January 17, 1997).

[2] These categories were created for program use, to help identify potential sponsors. They are not intended to replace the legal order of preference established in *Flores.*

Effective 02/13/24

2.2.3 The Family Reunification Application

All potential sponsors must complete an application in order for a child to be released to them from ORR custody (the "Family Reunification Application").

Within 24 hours of identification of a potential sponsor for a child or youth, the care provider or the ORR National Call Center sends the sponsor a package with the application and related documents (called the Family Reunification Packet or FRP).

The application package includes the following documents:

- Family Reunification Packet Cover Letter
- Authorization for Release of Information
- Family Reunification Application (FRA)
- Sponsor Care Agreement
- A flyer with contact information on organizations offering a Legal Orientation Program for Custodians (LOPC)
- A flyer with contact information for the UC Sexual Abuse Hotline
- Fingerprint instructions
- Sponsor Handbook
- Letter of Designation for Care of a Minor (If parent or legal guardian wishes to specify)
- A flyer warning sponsors of potential fraud schemes

The care provider is available to help the potential sponsor complete the application. ORR may require certain sponsors to fill out the FRA and other documents based on concerns related to safety, including sponsor motivation. ORR may in its discretion require the sponsor to submit their own FRA if there has been a safety concern identified that indicates that the sponsor should file the FRA without the case manager's assistance OR if the sponsor indicates that they prefer to submit the FRA by themselves.

The care provider case manager or other care provider staff or volunteer may assist the sponsor by filling out the FRA with a sponsor over the phone.

The case manager or other care provider staff or volunteer must read the attestation of perjury that is found in the FRA to the sponsor. The completed FRA is sent to the sponsor for verification. Sponsors must verify and sign the FRA and submit back to the case manager with any corrections. Copies, including photographs, and/or electronic signatures are accepted.

Revised 03/8/22

2.2.4 Required Documents for Submission with the Application for Release

In addition to completing and signing the Family Reunification Application (FRA) and the Authorization for Release of Information (ARI), potential sponsors must provide documentation of identity, address, and relationship to the child they seek to sponsor.[3] Potential sponsors must also submit documentation verifying the identity of the children they seek to sponsor, and evidence verifying the identity of all adults residing with the sponsor and all adult caregivers identified in a sponsor care plan. In addition to their use as evidence of the foregoing, all documentation submitted under this section is used as part of the overall sponsor assessment process. See **Section 2.4 Sponsor Assessment Criteria and Home Studies.** As a result, ORR may in its discretion require potential sponsors to submit additional documentation beyond the minimums specified below.

Proof of Sponsor Identity

To verify their identity, all potential sponsors must submit original versions or legible copies of government-issued identification documents. They may present either one selection from List A or two or more documents from List B. If a potential sponsor presents selections from list B, at least one selection must contain a legible photograph. Expired documents are acceptable for the purpose of establishing identity.

[3] The care provider may offer assistance to potential sponsors in securing necessary documentation, but it is ultimately the potential sponsor's responsibility to find and submit them.

LIST OF ACCEPTABLE DOCUMENTS

LIST A

U.S. Passport or U.S. Passport Card

Permanent Resident Card or Alien Registration Receipt Card (Form I–551)

Foreign Passport that contains a photograph

Employment Authorization Document that contains a photograph (Form I–766)

U.S. Driver's License or Identification Card

OR

LIST B

U.S. Certificate of Naturalization

U.S. Military Identification Card

Birth Certificate

Marriage Certificate

Court order for name change

Foreign national identification card

Consular passport renewal receipt that contains a photograph

Mexican consular identification card

Foreign driver's license that contains a photograph

Foreign voter registration card that contains a photograph

Canadian border crossing card that contains a photograph

Mexican border crossing card that contains a photograph with valid Form I–94

Refugee travel document that contains a photograph

Foreign driver's license that contains a photograph

Other similar documents (includes ORR Verification of Release form with a photograph for individuals under the age of 21[4]

Proof of identify of adult household members and adult caregivers identified in a sponsor care plan

As a general matter, ORR prioritizes the placement of unaccompanied children with parents and legal guardians available to provide care and custody in the United States (*i.e.,* Category 1 sponsors). Where there are no safety concerns, ORR does not require proof of identify for household members and adult caregivers of Category 1 sponsors, so long as:

- The child is not determined to be especially vulnerable through ORR's screening and assessment process;
- The child is not subject to a mandatory Trafficking Victims Reauthorization Act (TVPRA) home study (See **Section 2.4.2 Home Study Requirement**); and
- There are no other safety concerns present in the case, including relating to abuse or neglect.

When an individual is simultaneously sponsoring multiple closely related children for whom they would be a Category 1 and Category 2A or Category 2B sponsor, the proof of identity for HHM and adult caregiver is not required so long as there are no safety concerns as described above. All other potential sponsors that do not meet the criteria above must submit documentation verifying the identity of non-sponsor adults in their household and adult caregivers named in the sponsor care plan. Po-

[4] Potential sponsors, adult household members, and adult caregivers identified in a sponsor care plan may submit an original version or legible copy of an ORR Verification of Release form, but only to verify the identity of adults under the age of 21, and only if the form contains a photograph. ORR will not accept a Verification of Release as proof of identity if it does not contain a photograph and/or is for anyone 21 and older.

tential sponsors must submit at least one identification document that contains a photograph for all such adults. The document may be from either List A or List B above and may be an original version or a legible copy of the document. Expired documents are acceptable for the purpose of establishing identity.

Proof of Address

All potential sponsors must submit at least one form of documentation verifying their current address. Acceptable forms of documentation include original versions or legible copies of:

- A current lease or mortgage statement dated within the last 2 months before submission of the FRA;
- A valid, unexpired State ID with current address and photo;
- A utility bill, addressed in the sponsor's name and dated within the last 2 months before submission of the FRA;
- A bank statement dated within the last 2 months before submission of the FRA;
- A payroll check stub issued by an employer, dated within the last 2 months before submission of the FRA;
- A piece of mail from a county, State, or Federal agency (with the exception of ORR) with the sponsor's name and residential address and dated within the last 2 months before submission of the FRA;
- A notarized letter from a landlord on the business stationary of the real property owner confirming the sponsor's address; and
- Other similar documents reliably indicating that the sponsor resides at the claimed address, dated within the last 2 months before submission of the FRA.

ORR may use alternative methods to verify address. For example, ORR may send a letter containing specific instructions to the address given by the sponsor and provide a timeline by which the sponsor must comply with the instructions.

Proof of Child's Identity

The potential sponsor or child's family must provide the unaccompanied child's birth certificate or a legible copy of the child's birth certificate.

Proof of Sponsor-Child Relationship

The potential sponsor must provide at least one form of evidence verifying the relationship claimed with the child.[5] Acceptable documents include original versions or legible copies of:

- Birth certificates;
- Marriage certificates;
- Death certificates;
- Court records;
- Guardianship records;
- Hospital records;
- School records;
- Written affirmation of relationship from Consulate; and/or
- Other similar documents.

Category 2A potential sponsors providing evidence of "primary caregiver"

Category 2A sponsors who are not grandparents or adult siblings must prove they are or were the child's primary caregiver. A primary caregiver is defined as any person who is primarily entrusted with the child's care and who lives with the child.

If the potential sponsor has any guardianship documents or other documents from a state or foreign government, they must submit this with the Family Reunification Application. ORR also accepts sworn affidavits from potential sponsors in addition to corroborating interviews the case manager has with the child, potential sponsor,

[5] Verification of the potential sponsor's relationship to the child is a minimum step required by the TVPRA to determine a potential sponsor's suitability and capability of providing for the child's physical and mental well-being. See 8 U.S.C. § 1232. As a result, as stated above, ORR may in its discretion require the submission of multiple forms of evidence.

and other family members to establish whether the potential sponsor was a primary caregiver to the child.

Category 3 potential sponsors without a bona fide pre-existing relationship

Category 3 potential sponsors who are unable to provide verifiable documentation of a familial relationship with the unaccompanied child must submit evidence that reliably and sufficiently demonstrates a bona fide social relationship with the child and/or the child's family that existed before the child migrated to the United States. Care providers must attain sufficient corroboration to be confident that they have received needed verification of the relationship between the potential sponsor and the child or child's family.

If a Category 3 potential sponsor does not submit evidence that reliably and sufficiently demonstrates a bona fide preexisting social relationship between the potential Category 3 sponsor and the child and/or the child's family, ORR may take this into account when determining the suitability of the case for release. In such cases ORR may require that the potential Category 3 sponsor, the child, and the child's family, establish ongoing regular contact while the child is in ORR care, prior to a release recommendation.

Criminal History

If a potential sponsor has been charged with or convicted of any crime or investigated for the physical abuse, sexual abuse, neglect, or abandonment of a child, they must provide related court records and police records, as well as governmental social service records or proof of rehabilitation related to the incident where there has been a substantiated finding or a conviction.

Fraud

If a sponsor, household member, or adult caregiver provides any false information in the application of release and/or accompanying documents or submits fraudulent documents for the purposes of obtaining sponsorship of the child, ORR will report the incident to HHS/Office of the Inspector General (OIG). Fraudulent documents include documents on which the address, identity, or other relevant information is false or documents that have been manufactured or altered without lawful authorization. ORR may deny release if it is determined that fraudulent documents were submitted during the application of release process.

Effective 02/13/24

2.2.5 Legal Orientation Program for Custodians

All potential sponsors of children and youth under the care of ORR should attend a presentation provided by the Legal Orientation Program for Custodians (LOPC). The purpose of this program is to inform potential sponsors of their responsibilities in ensuring the child's appearance at all immigration proceedings, as well as protecting the child from mistreatment, exploitation, and trafficking, as provided under the Trafficking Victims Protection Reauthorization Act of 2008. The program also provides information about possible free legal counsel (pro bono legal services) for the youth or child during the immigration court process.

The Office of Legal Access Programs (OLAP), within the Executive Office for Immigration Review (EOIR) at the U.S. Department of Justice, manages the LOPC and contracts with legal service organizations around the country to provide LOPC services to potential sponsors in their local communities or in metropolitan areas served by the program. EOIR is the entity in the Federal Government that is also responsible for adjudicating immigration cases by fairly, expeditiously, and uniformly interpreting and administering the nation's immigration laws.

The unaccompanied child's **case manager** is responsible for informing potential sponsors about all procedures related to the child's case—including attendance at an LOPC presentation. The Family Reunification Packet (FRP) that goes to each potential sponsor includes an *Authorization for Release of Information* that the sponsor must sign before the case manager may schedule an appointment for LOPC services. All potential sponsors should submit the *Authorization for Release of Information* immediately and prior to submitting the complete FRP to ensure timely scheduling of their LOPC session.

Upon receipt of the *Authorization,* the case manager schedules an appointment for a potential sponsor to attend a presentation with one of the LOPC providers around the country. Alternatively, the case manager contacts the **LOPC National Call Center at (888) 996–3848** and arranges for the Call Center to schedule an LOPC

appointment for the potential sponsor or mail an LOPC Information Packet to the sponsor.

When evaluating family members and other potential sponsors, ORR considers whether they have attended an LOPC presentation. Attendance at an LOPC presentation is a factor in the release assessment.

Revised 12/4/17

2.2.6 Additional Questions and Answers about this Topic

Q: Will sponsors receive the Family Reunification Packet through the mail or electronically?

A: Case managers will work with sponsors to identify the best way to get the packets to them, whether electronically or by fax transmission or postage paid overnight mail.

Q: Do sponsors need assistance from an attorney or a paid representative to complete the packet?

A: No. The unaccompanied child's case manager will be able to help the potential sponsor complete the form and explain the process.

Q: Is it possible for an unaccompanied child's spouse to be a sponsor?

A: ORR considers release to an unaccompanied child's adult spouse on a case by case basis.

Q: Is it possible for family members in the United States to proactively contact ORR about children who may have entered the country unaccompanied?

A: Yes. Family members may call the ORR National Call Center, at (800) 203–7001.

Posted 01/27/15

2.3 Key Participants in the Release Process

ORR's sponsor assessment and release decision process requires coordination among care provider staff, nongovernmental third-party reviewers (Case Coordinators), ORR staff, other Federal agencies, stakeholders, and Child Advocates, where applicable.

Case Managers communicate with potential sponsors, gather necessary information and documentation, talk to any relevant stakeholders, and assess sponsors to formulate a recommendation to the Case Coordinator. **Case Coordinators** concurrently review all assessment information on an unaccompanied child and sponsor to also make a recommendation. Once Case Managers and Case Coordinators agree on a particular recommendation for release, the **ORR/FFS** makes a final release decision. If the Case Manager and Case Coordinator cannot agree on a recommendation, the case is elevated to the ORR/FFS for further guidance.

Revised 06/18/19

2.3.1 ORR/Federal Field Specialists (ORR/FFS)

ORR/FFS are ORR's field staff located regionally throughout the country and are assigned to a group of care providers within a particular geographic region. ORR has final authority on transfer and release decisions. ORR/FFS act as agents of HHS/ORR to approve all unaccompanied children transfer and release requests. In addition, ORR/FFS have authority to oversee care providers to ensure all services are properly provided and implemented and serve as a local liaison to community stakeholders, including other Federal agencies, local legal service providers, communities, Child Advocates, etc. ORR/FFS also provide guidance, direction, and technical assistance to care providers.

Acting as agents of HHS/ORR, ORR/FFS also make final decisions as to whether home studies are conducted and/or post-release services are provided.[6] ORR/FFS coordinate all aspects of a child's case with care provider staff, Case Coordinators, stakeholders, and other Federal agencies.

[6] The ORR Director delegates final authority for approving discretionary home studies to ORR/FFS Supervisors who act as agents of HHS/ORR. (See Section 2.4.2).

Revised 03/28/23

2.3.2 Case Managers

Care provider case managers perform a variety of duties, including coordinating the completion of assessments of unaccompanied children, completing individual service plans, assessing potential sponsors, making transfer and release recommendations, and coordinating the release of a child or youth from ORR care and custody. Care providers are required to provide case management services, at minimum, during normal business hours. ORR may also require care providers to extend service hours to evenings and weekends (*e.g.,* requiring availability of case management services 7 days a week, including holidays, 8 am through 10 pm local time). The care provider also provides a range of services through other trained staff that are described in **Section 3: Services** *(https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-section-3)*.

The role of the case manager within the release process is to initiate and maintain ongoing communication with the potential sponsor, gather sponsor information, and assess whether the potential sponsor is a suitable sponsor who can safely provide for the physical and mental well-being of the child or youth. When communicating with the potential sponsor, the case manager:

- Provides direct assistance on completing the sponsor application packet and ensuring provision of supporting documentation;
- Involves the sponsor in making a plan for individualized services for the child, as appropriate;
- Keeps the sponsor informed of the child's progress and current functioning;
- Provides the sponsor with detailed information about the child's needs in order to fully assess the sponsor's ability to provide care and services, including completing a sponsor care plan, when necessary;
- Discusses services that are available in the sponsor's community for the child; and
- Shares relevant information on the UC in accordance with applicable privacy and information-sharing policies, including policy related to a child's pregnancy or abortion decision as found in **Policy Memorandum: Medical Services Requiring Heightened ORR Involvement** *(https://www.acf.hhs.gov/sites/default/files/documents/orr/garza_policy_memorandum.pdf)*, and in collaboration with the UC and the child's clinician in a way that best serves the child's safety and well-being.

The case manager's role is also to ensure that information is gathered or shared with the appropriate staff and stakeholders during the sponsor assessment process. The case manager participates in weekly case management staffings with the child's assigned case coordinator and ORR/FFS on the progress in achieving a safe and timely release with family members as well as potential challenges that may delay a release. The Child Advocate may attend case staffings, at the request of the FFS. Case management staffings may occur monthly for children in LTFC if they are not being considered for reunification to a sponsor.

The case manager provides weekly status updates (monthly for children in LTFC if they are not being considered for reunification to a sponsor) to the child on the child's case and provision of services, preferably in person. The child may have their attorney of record and Child Advocate present for these case management updates, if applicable.

The case manager provides legal service providers (LSPs), attorneys of record, and Child Advocates, if applicable, of the progress of a child's case on a weekly basis on case management decisions, which includes the following:

- Notification that a child may not have a potential sponsor,
- Change in sponsor categories,
- Any final release decisions, and
- When a child has been recommended for, has initiated, or is pending transfer to a different level of care (specifically long-term foster care), and when a child's transfer request has been approved.

LSP and attorneys of record information requests for a child's case file information beyond these updates must go through the established case file request process in

Section 5.10.1 UC Case File Request Process *(https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-section-5#5.10.1).*

Case managers may share case information with ORR post-release and home study providers and Unaccompanied Refugee Minors (URM) providers if a child is being referred for those services.

Revised 08/07/2023

2.3.3 Case Coordinators

Case Coordinators are non-governmental contractor field staff assigned to one or more care providers primarily to review unaccompanied children cases and provide transfer and release recommendations to ORR staff. The Case Coordinator is responsible for integrating all areas of assessment from the Case Manager, Child Advocates, where applicable, and other stakeholders into a release plan that will provide for the unaccompanied child's physical and mental well-being. After staffing and reviewing a case, Case Coordinators and Case Managers must agree on a release recommendation. If there is a disagreement or a particularly complex case, then the case will be elevated to the ORR/FFS for further guidance.

- Providing timely review and assessment of potential sponsors and unaccompanied children to make recommendations for release to ORR in conjunction with the Case Manager;
- Assisting ORR in ensuring that children are placed in the least restrictive setting while receiving all appropriate services;
- Meeting with individual unaccompanied children and care provider staff at designated ORR-funded care provider sites;
- Providing targeted child welfare-based assistance to care provider staff, as directed by ORR staff;
- Making recommendations for home study and post-release services for at-risk children;
- Making placement recommendations for children who require more specialized levels of care, such as long-term foster care and residential treatment centers;
- Participating in collaborative meetings with local stakeholders; and
- Participating in staffing of cases with care providers and designated ORR staff.

Revised 08/1/16

2.3.4 Child Advocates

ORR may appoint **Child Advocates** for victims of trafficking and other vulnerable children. Child Advocates are third parties who make independent recommendations regarding the best interests of a child. Their recommendations are based on information that is obtained from the child and other sources (*e.g.,* the child's parents, potential sponsors, government agencies, and other stakeholders). Child Advocates formally submit their recommendations to ORR and/or the immigration court in the form of Best Interest Determinations (BIDs). ORR considers BIDs when making decisions regarding the care, placement, and release of unaccompanied children, but it is not bound to follow BID recommendations.

As required by the TVPRA, ORR provides Child Advocates with access to information necessary to effectively advocate for the best interests of children with whom they are working. After providing proof of appointment, Child Advocates have access both to their clients and to their clients' records. Child Advocates may access their clients' entire original case files at care provider facilities, or request copies from care providers. Child advocates must keep the information in the case file, and information about the child's case, confidential from non-ORR grantees, contractors, and Federal staff. Further, they may participate in case staffings.[7]

Child Advocates and ORR maintain regular communication, informing each other of considerations or updates that impact service provision and release planning.

Child Advocates' duties include:

- Client Visits: The Child Advocate meets with the unaccompanied child regularly and speaks with the child's care provider staff in order to understand the child's background and current situation.

[7] Child advocates must keep the information in the case file, and information about the child's case, confidential from non-ORR grantees, contractors, and Federal staff.

- Decision Making: The Child Advocate helps the unaccompanied child understand legal and care-related issues, explains the consequences of decisions made in response to those issues, and assists the child in making decisions when the child requests such help.
- Best Interests Advocacy: The Child Advocate develops a service plan containing best-interest recommendations with respect to the care, placement, and release options; and keeps the care provider, ORR, and the legal service provider or attorney of record apprised of the plan and advocacy efforts.
- Case updates: The Child Advocate collaborates and regularly communicates with the care provider, ORR, and other stakeholders in the planning and performance of advocacy efforts. For children who have been released from ORR care, Child Advocates provide timely updates as appropriate or as requested by ORR.

In most cases, ORR appoints Child Advocates while children are in its custody. However, in its discretion, ORR may appoint Child Advocates for unaccompanied children after their release from ORR care.

Revised 08/07/2023

2.4 Sponsor Assessment Criteria and Home Studies

As noted in the **Section 2.2 Application for Safe and Timely Release of an Unaccompanied Child from ORR Care,** the application process for release of an unaccompanied child involves a number of steps, including background checks (see **Section 2.5 ORR Policies on Requesting Background Checks**) and submission of the application by the sponsor. This section describes the criteria ORR uses to assess each potential sponsor's ability to provide for the physical and mental well-being of the unaccompanied child, and the role of home studies in the process.

The sponsor assessment reviews a sponsor's strengths, resources, risk factors and special concerns within the context of the unaccompanied child's needs, strengths, risk factors, and relationship to the sponsor.

ORR also determines whether to conduct a home study, as required by the law or as necessary to ensure the welfare of the child.

Revised 03/15/16

2.4.1 Assessment Criteria

ORR considers the following factors when evaluating family members and other potential sponsors:

- The nature and extent of the sponsor's previous and current relationship with the child or youth and the unaccompanied child's family, if a relationship exists.
- The sponsor's motivation for wanting to sponsor the child or youth.
- The unaccompanied child's parent or legal guardian's perspective on the release to the identified potential sponsor (for cases in which the parent or legal guardian has designated a sponsor).
- The child or youth's views on the release and whether he or she wants to be released to the individual.
- The sponsor's understanding of the unaccompanied child's needs, as identified by ORR and the care provider.
- The sponsor's plan to provide adequate care, supervision, access to community resources, and housing.
- The sponsor's ability to provide the child with a stable home environment and a sense of permanency, to include whether the sponsor has an outstanding order of removal.
- The sponsor's understanding of the importance of ensuring the unaccompanied child's presence at all future hearings or proceedings, including immigration court proceedings, and the sponsor's attendance at a Legal Orientation Program for Custodians (LOPC) presentation. See **Section 2.2.5 Legal Orientation Program for Custodians**.

- The linguistic and cultural background of the child or youth and the sponsor, including cultural, social, and communal norms and practices for the care of children.
- The sponsor's strengths, resources, and mitigating factors in relation to any risks or special concerns of the child or sponsor, such as a criminal background, history of substance abuse, mental health issues, or domestic violence and child welfare concerns.
- The unaccompanied child's current functioning and strengths in relation to any risk factors or special concerns, such as children or youth who are victims of human trafficking; are a parent or are pregnant; have special needs, disabilities or medical or mental health issues; have a history of criminal, juvenile justice, or gang involvement; or a history of behavioral issues.

Revised 01/30/23

2.4.2 Home Study Requirement

The care provider screens each case to determine whether to recommend a home study of the potential sponsor as required under the **Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA)** *(https://www.govinfo.gov/content/pkg/BILLS-110hr7311enr/pdf/BILLS-110hr7311enr.pdf)* (as codified at 8 U.S.C. § 1232(c)(3)(B)) or ORR's policy. Information about the child is collected during initial placement into an ORR facility and throughout their stay. The care provider then uses the information collected about and from the child and sponsor to determine whether to conduct a home study.

TVPRA Mandatory Home Studies

The TVPRA requires home studies in the following circumstances:

1. The child is a victim of a severe form of trafficking in persons;
2. The child is a special needs child with a disability as defined by the Americans with Disabilities Act of 1990, as amended (42 U.S.C. § 12102);
3. The child has been a victim of physical or sexual abuse under circumstances that indicate that the child's health or welfare has been significantly harmed or threatened; or
4. The child's sponsor clearly presents a risk of abuse, maltreatment, exploitation, or trafficking, to the child based on all available objective evidence.

ORR Mandated Home Studies

ORR requires a home study before releasing any child to a sponsor in the following circumstances:

1. The potential sponsor is seeking to concurrently sponsor two or more children (regardless of whether the potential sponsor has previously sponsored or sought to sponsor a child) **and at least one of the children is unrelated to the potential sponsor;**
2. The potential sponsor has previously been the sponsor of two or more children and is now seeking to sponsor one or more additional children **(regardless of whether the previous or current children are related to the potential sponsor)**; or
3. The potential sponsor is seeking to sponsor an unrelated child who is 12 years or under.

DISCRETIONARY HOME STUDIES

In circumstances in which a home study is not required by the TVPRA or ORR policy, the case manager, and case coordinator may recommend that a home study be conducted if they agree that the home study may provide additional information to determine that the sponsor is able to care for the health, safety and well-being of the child. See **Footnote 6.**

The care provider must inform the potential sponsor whenever a home study is conducted, explain the scope and purpose of the study and answer the potential sponsor's questions about the process. In addition, the care provider must provide the home study report to the potential sponsor if the release request is denied. See also **UC Policy Guide Section 2.7.7, Notification of Denial.**

Home Study Report and Final Recommendation

The purpose of a home study is to:

1. Assess the potential sponsor's ability to meet the child's needs,
2. Educate and prepare the potential sponsor for the child's release; and
3. Corroborate information gathered on the sponsor assessment.

A home study consists of interviews, a home visit, and a written report containing the home study case worker's findings.

The final recommendation must present a comprehensive and detailed assessment of the sponsor's ability to care for the needs of the child and identify any information that emerges regarding the sponsor, the sponsor's household or the child. This may include information that raises child welfare concerns. The home study report may identify areas where additional services, resources, or information are needed to support a successful sponsorship. The home study provider makes a recommendation to ORR about release to the sponsor. The ORR/FFS takes the home study provider's recommendation into consideration when making a release decision. ORR has final authority on release decisions. ORR/FFS acts as agents of HHS/ORR to approve all unaccompanied children release requests.

The home study provider must accept the home study referral from ORR and staff the case with a case manager within three (3) calendar days of ORR's referral. The home study provider must contact the care provider within 24 hours of home study referral acceptance and contact the sponsor to schedule the home visit within 48 hours of referral acceptance.

The home study provider conducts the home visit in person. In exceptional circumstances, where conducting the visit virtually would be in the best interest of the child, the home study provider may request ORR's case-by-case approval to conduct a virtual visit. The home study provider submits the written report within 10 calendar days of receipt of the referral. Any requests by the home study provider to extend beyond 10 calendar days or to cancel a home study must be submitted in writing to the ORR/FFS for consideration.

All releases following home studies require post-release services.

If the case manager learns new information that raises child welfare concerns after the home study provider has submitted their final report, the ORR/FFS has the authority to request a home study addendum from the original home study provider to gather more information for an informed release decision. The FFS may request an addendum any time after the final home study report has been submitted, but in some circumstances, it may be necessary to request a new home study if the sponsor's circumstances have significantly changed or if the home study was completed over a year prior to the current date. Home studies are only valid for 1 year.

Must a child receive a Trafficking Eligibility or Interim Assistance Letter from HHS prior to being referred for a TVPRA-mandated home study under #1 above?

No, a child does not need to receive a Trafficking Eligibility Letter from HHS prior to being referred for a home study. A care provider may refer a child for a home study under #1 above if, during the assessment for trafficking, the care provider determines the child is a victim of a severe form of trafficking in persons.

In determining whether a TVPRA-mandated home study is required under #3 above, care providers consider the following questions:

What is physical abuse?

Physical abuse is an act that results in physical injury, such as red marks, cuts, welts, bruises, broken bones, missing or broken teeth or muscle strains. Acts of physical abuse include but are not limited to punching, beating, kicking, biting, hitting (with a hand, stick, strap, or other object), burning, strangling, whipping, or the unnecessary use of physical restraint.

Is physical abuse intentional?

Generally, physical abuse is intentional; however, physical abuse can occur when physical punishment goes too far. In other words, an accidental injury of a child may be considered physical abuse if the act that injured the child was done intentionally as a form of punishment.

Must a child have physical injuries to meet the standard for physical abuse under #3?

No, in some cases, a child may not have physical injuries at the time the care provider makes an assessment. Children may be in various stages of the healing proc-

ess or thoroughly healed from the physical abuse by the time they arrive in ORR care.

For the purposes of #3, who can physically or sexually abuse a child?

A parent, legal guardian, caregiver or other adult with a special relationship to the child can physically or sexually abuse a child.

Who is considered to be a caregiver or adult with a special relationship?

A caregiver is defined as any person who is entrusted with the child's care and who lives with the child. Other adults with a special relationship to the child could include a teacher, priest, or health-care provider.

What is sexual abuse?

Sexual abuse of a child by a parent, legal guardian, caregiver or other adult with a special relationship to the child includes any of the following acts, with or without the consent of the child or youth:

- Contact between the penis and the vulva or the penis and the anus, including penetration, however slight;
- Contact between the mouth and the penis, vulva, or anus;
- Contact between the mouth and any body part where the adult has the intent to abuse, arouse, or gratify sexual desire;
- Penetration of the anal or genital opening, however slight, by a hand, finger, object, or other instrument where the adult has the intent to abuse, arouse, or gratify sexual desire;
- Any other intentional contact, either directly or through the clothing, of or with the genitalia, anus, groin, breast, inner thigh, or the buttocks where the intent is to abuse, arouse, or gratify sexual desire;
- Any attempt, threat, or request by the adult to engage in the activities described above;
- Any display by the adult of his or her uncovered genitalia, buttocks, or breast in the presence of the child; and
- Voyeurism.

State laws on statutory rape are not the standard in assessing whether a youth has been sexually abused for the purposes of #3. Care providers use the definition from the ORR rule concerning sexual abuse and harassment; however, for the purposes of determining when a home study is required, the perpetrator is limited to a parent, legal guardian, caregiver, or other adult with a special relationship to the child.

Under what circumstances is a child's health or welfare considered to have been significantly harmed or threatened?

Care providers assess the totality of the circumstances in determining whether a child's health or welfare has been significantly harmed or threatened. In evaluating a specific case, care providers take into consideration not only the definitions of physical and sexual abuse listed above, but also the circumstances surrounding the incident and any behaviors that the child or youth exhibits as a result of the abuse. Circumstances to consider include but are not limited to: the amount of time that has passed since the abuse, the period of time in which the abuse occurred, the cultural context in which the abuse occurred, the age of the child or youth at the time of the abuse, and the relationship between the youth and the perpetrator.

Care providers take into consideration the situations and behaviors listed below, but do not make a determination based solely on the presence or absence of one of them.

- The child experiences on-going medical issues from physical injuries.
- The child exhibits negative or harmful behaviors, thoughts or emotions, such as, but not limited to, excessive hostility or aggression towards others, fire setting, cutting, depression, eating disorders suicidal ideation or substance abuse.

In evaluating difficult cases, the care provider should consult with their ORR/FFS.

Effective 02/13/24

2.4.3 Additional Questions and Answers on This Topic

Q: What happens if a new sponsor is identified during the sponsor assessment process?

A: If there are multiple potential sponsors, the ORR-funded care provider will exhaust all efforts to facilitate a release to a parent or legal guardian while also contacting and evaluating other potential sponsors concurrently. ORR has release order preferences and will evaluate sponsors concurrently in accordance with the preference orders to determine the best placement for the child.

Q: Must a child receive a Trafficking Eligibility or Interim Assistance Letter from HHS prior to being referred for a TVPRA-mandated home study under #1 above?

A: No, a child does not need to receive a Trafficking Eligibility Letter from HHS prior to being referred for a home study. A care provider may refer a child for a home study under #1 above if, during the assessment for trafficking, the care provider determines the child is a victim of a severe form of trafficking in persons.

In determining whether a TVPRA-mandated home study is required under #3 above, care providers consider the following questions:

Q: What is physical abuse?

A: Physical abuse is an act that results in physical injury, such as red marks, cuts, welts, bruises, broken bones, missing or broken teeth or muscle strains. Acts of physical abuse include but are not limited to punching, beating, kicking, biting, hitting (with a hand, stick, strap or other object), burning, strangling, whipping, or the unnecessary use of physical restraint.

Q: Is physical abuse intentional?

A: Generally, physical abuse is intentional; however, physical abuse can occur when physical punishment goes too far. In other words, an accidental injury of a child may be considered physical abuse if the act that injured the child was done intentionally as a form of punishment.

Q: Must a child have physical injuries to meet the standard for physical abuse under #3?

A: No, in some cases, a child may not have physical injuries at the time the care provider makes an assessment. Children may be in various stages of the healing process or thoroughly healed from the physical abuse by the time they arrive in ORR care.

Q: For the purposes of #3, who can physically or sexually abuse a child?

A: A parent, legal guardian, caregiver or other adult with a special relationship to the child can physically or sexually abuse a child.

Q: Who is considered to be a caregiver or adult with a special relationship?

A: A caregiver is defined as any person who is entrusted with the child's care and who lives with the child. Other adults with a special relationship to the child could include a teacher, priest, or health care provider.

Q: What is sexual abuse?

A: Sexual abuse of a child by a parent, legal guardian, caregiver, or other adult with a special relationship to the child includes any of the following acts, with or without the consent of the child or youth:

- Contact between the penis and the vulva or the penis and the anus, including penetration, however slight;
- Contact between the mouth and the penis, vulva, or anus;
- Contact between the mouth and any body part where the adult has the intent to abuse, arouse, or gratify sexual desire;
- Penetration of the anal or genital opening, however slight, by a hand, finger, object, or other instrument where the adult has the intent to abuse, arouse, or gratify sexual desire;
- Any other intentional contact, either directly or through the clothing, of or with the genitalia, anus, groin, breast, inner thigh, or the buttocks where the intent is to abuse, arouse, or gratify sexual desire;
- Any attempt, threat, or request by the adult to engage in the activities described above;
- Any display by the adult of his or her uncovered genitalia, buttocks, or breast in the presence of the child; and

- Voyeurism.

State laws on statutory rape are not the standard in assessing whether a youth has been sexually abused for the purposes of #3. Care providers use the definition from the ORR rule concerning sexual abuse and harassment; however, for the purposes of determining when a home study is required, the perpetrator is limited to a parent, legal guardian, caregiver, or other adult with a special relationship to the child.

Q: Under what circumstances is a child's health or welfare considered to have been significantly harmed or threatened?

A: Care providers assess the totality of the circumstances in determining whether a child's health or welfare has been significantly harmed or threatened. In evaluating a specific case, care providers take into consideration not only the definitions of physical and sexual abuse listed above, but also the circumstances surrounding the incident and any behaviors that the child or youth exhibits as a result of the abuse. Circumstances to consider include but are not limited to: the amount of time that has passed since the abuse, the period of time in which the abuse occurred, the cultural context in which the abuse occurred, the age of the child or youth at the time of the abuse, and the relationship between the youth and the perpetrator.

Care providers take into consideration the situations and behaviors listed below, but do not make a determination based solely on the presence or absence of one of them.

- The child experiences on-going medical issues from physical injuries.
- The child exhibits negative or harmful behaviors, thoughts or emotions, such as, but not limited to, excessive hostility or aggression towards others, fire setting, cutting, depression, eating disorders suicidal ideation, or substance abuse.

In evaluating difficult cases, the care provider should consult with their ORR/FFS.

Revised 03/28/23

2.5 Sponsorship Assessment Background Check Investigations

One of ORR's priorities is ensuring the safe release of unaccompanied children to an appropriate sponsor. Consistent with ORR's mission and in compliance with requirements found at 8 U.S.C. 1232(c)(3)(A) to perform an independent finding that a potential sponsor has not engaged in any activity that would indicate a potential risk to the child, ORR generally requires a background check of all potential sponsors and for any of their adult household members, except where indicated below.

As a general matter, ORR prioritizes the placement of unaccompanied children with parents and legal guardians available to provide care and custody in the United States. Where there are no safety concerns, ORR does not require background checks or proof of identify for household members and adult care givers when the sponsor is a parent or legal guardian, so long as:

- the child is not determined to be especially vulnerable through ORR's screening and assessment process;
- the child is not subject to a mandatory TVPRA home study; and
- there are no other safety concerns present in the case, including relating to abuse or neglect.

A Category 2A or 2B sponsor who is simultaneously sponsoring multiple children related to them undergo the background check requirements of the child most closely related to them. For example, a sponsor who is the parent to one child and an uncle to another child, undergo the unification requirements as a Category 1 sponsor for both children.

All potential sponsors undergo a public records background check of criminal history and sex offender registry databases. Adult household members of potential sponsors in Categories 2A, 2B, 3, and in some cases Category 1, must also undergo public records background check of criminal history and sex offender registry databases. Sponsors in Categories 2B and 3, as well as some Category 1 and 2A sponsors, adult household members, and adult caregivers identified in a sponsor care plan require fingerprint background checks that are processed through the U.S. Department of Justice's (DOJ) Federal Bureau of Investigation (FBI).

ORR transmits fingerprint submissions (if required) to the U.S. Department of Justice's (DOJ) Federal Bureau of Investigation (FBI) to perform criminal history checks.[8] The FBI submits the results to the U.S. Department of Health and Human Services/Program Support Center (HHS/PSC). HHS/PSC provides the results and notifies ORR that the biometric and biographic checks conducted by the FBI are complete. HHS/PSC also provides copies of the results to ORR.

In some cases, ORR requires sponsors, adult household members, and adult caregivers to undergo a background check search of State child abuse and neglect (CA/N) registries maintained by individual States. In these cases, HHS/PSC works with the relevant State agency or directs the subject of the check to request results from the relevant State agency in compliance with State law and regulation.

Effective 02/13/24

2.5.1 Background Check Requirements

To begin the background check process, the potential sponsor and adult household members must first complete the Authorization for Release of Information form (if applicable),[9] and submit fingerprints and provide a copy of a valid government issued photo identification (if required). Adult caregivers identified in a sponsor care plan also require background checks, as outlined in the chart below. The type of background checks performed on a sponsor, adult household members, and adult caregivers is dependent in part on the sponsor's relationship, if any, with the child. See Section 2.2.1 Identification of Qualified Sponsors for a description of sponsor categories.

The following table lists the types of background checks performed, and explains when they are performed, based on the potential sponsor's relationship to the unaccompanied child and other release considerations. The table only indicates the minimum requirements for the background check process for sponsors and others. ORR may require additional checks, verifications, or procedures for sponsors and others in any category if there are any unresolved issues or questions related to the well-being of the child.

TYPE OF BACKGROUND CHECK	PURPOSE	PERSONS CHECKED	WHEN PERFORMED
Public Records Check	Identifies arrests or convictions of sponsors, adult household members, or others. If a check reveals a criminal record or safety issue, it is used to evaluate the sponsor's ability to provide for a child's physical and mental well-being	Potential Sponsors in Categories 1–3 Non-sponsor adult household members and adult caregivers identified in a sponsor care plan	For all sponsors, regardless of category In all cases for household members and adult caregivers identified in a sponsor care plan for category 2A, 2B, and 3 For category 1 household members, only where there is a documented risk to the safety of the unaccompanied child, the child is especially vulnerable, and/or the case is being referred for a home study

[8] An *Authorization for Release of Information* is not required for sponsors, adult household members, or adult care givers identified in a sponsor care plan undergoing a sex offender registry check. An *Authorization for Request of Information* also is not required for sponsors, adult household members and adult caregivers identified in a sponsor care plan undergoing a public records check. However, sponsors will receive notice that public records and sex offender registry checks will be performed, and will have an opportunity to explain the results of these checks to ORR. ORR will also provide a method for disputing the results of checks. (See **Section 2.5.3, Q4**)

[9] As part of the FBI background check process, DHS databases are searched. The FBI also forwards biographic information to ICE's Law Enforcement Support Center (LESC). Neither HHS/PSC or ORR verify any records produced by DHS for background check purposes.

TYPE OF BACKGROUND CHECK	PURPOSE	PERSONS CHECKED	WHEN PERFORMED
Sex Offender Registry Check, conducted through the U.S. Department of Justice National Sex Offender Public Website	Identifies sponsors and others that have been adjudicated as sex offenders through a national search and, if available, a local public registry search	Potential Sponsors in Categories 1–3 Non-sponsor adult household members and adult caregivers identified in a sponsor care plan	In all cases
FBI National Criminal History Check, based on digital fingerprints or digitized paper prints	Determines whether a sponsor or adult household member (as applicable) has a criminal history, has a profile in DHS IDENT, has been convicted of a sex crime, or has been convicted of other crimes that compromise the sponsor's ability to care for a child	Potential Sponsors in Category 1 and Category 2A	Where a public records or sex offender check reveals possible disqualifying factors under 2.7.4; or where there is a documented risk to the safety of the unaccompanied child, the child is especially vulnerable, and/or the case is being referred for a home study
		Potential Sponsors in Categories 2B and 3	In all cases
		Non-sponsor adult household members and adult caregivers identified in a sponsor care plan	Where a public records or sex offender check reveals possible disqualifying factors under 2.7.4; or where there is a documented risk to the safety of the unaccompanied child, the child is especially vulnerable, and/or the case is being referred for a home study
Child Abuse and Neglect (CA/N) Check, obtained on a State by State basis as no national CA/N check repository exists	Checks all localities in which the sponsor or household member has resided in the past 5 years	Potential Sponsors in Categories 1–3	In cases that require a home study, and cases where a special concern is identified
		Non-sponsor adult household members and adult caregivers identified in a sponsor care plan	In any case where a sponsor is required to undergo a CA/N check
State Criminal History Repository Check and/or Local Police Check	Assists in locating police or arrest records, or other criminal offense details, as needed	Potential Sponsors in Categories 1–3 Non-sponsor adult household members and adult caregivers identified in a sponsor care plan	Used on a case-by-case basis when there is an unresolved criminal arrest or issue that is still in process

Fingerprint Exception for Category 2B Cases with Qualifying Category 1 or 2A Sponsors

Fingerprints for a Category 2B sponsor of a case related to a Category 1 or Category 2A case may not be required, provided that all of the following conditions apply:

1. The children are screened and determined to not be especially vulnerable;
2. The children are not otherwise subject to a mandatory TVPRA home study; and
3. There are no other red flags present in the case, including red flags relating to abuse or neglect.

If one of the cases falls under one of these categories and the other(s) does not, the case manager and case coordinator will make a recommendation to the FFS whether to separate the cases for purposes of processing. Case managers will document the exception in all children in the family units? Release Request documents.

Effective 02/13/24

2.5.2 Results of Background Checks on Release Decisions

ORR uses the results from background checks to determine whether release to a potential sponsor is safe. A potential sponsor may be denied based on the results of a background check, and a release decision may remain undecided until ORR obtains the results of a potential sponsor's criminal history or child abuse and neglect reports.

The biometric and biographical information, including fingerprints, are shared with FBI to investigate criminal history through the National Criminal Information Center and may be used consistent with their authorities. Biometric and biographical information may be shared with Federal, State or local law enforcement or State child welfare agencies, as necessary, to conduct criminal history searches or search for adverse child welfare findings.

Criminal History and Adverse Child Welfare Finding Results

In the event that a background check of a potential sponsor or, if applicable, adult household member, reveals criminal history or a safety risk, the care provider and ORR evaluate this information and request the potential sponsor to provide any additional information that may demonstrate the potential sponsor's ability to provide for the child's physical and mental well-being.

If release is not barred by **Section 2.7.4,** the decision to release a child or youth to a sponsor in these circumstances is based on all the following considerations:

- The severity of the criminal and/or child abuse/neglect history;
- The length of time that has passed since the criminal act or child abuse/neglect allegation occurred;
- The relationship of the potential sponsor and other adult household members to the child or youth; and
- The evidence, if any, of rehabilitation since the criminal act or child abuse/neglect allegation occurred.

In cases where the proposed sponsor or an adult household member has been charged with, but not convicted of, a crime, ORR may postpone a final release decision until the legal issue is resolved.

In cases where ORR has released a child and later obtains derogatory information on a sponsor or sponsor household member, ORR determines whether the information if known prior to release would have led to a denial of sponsorship or presents some other high risk child welfare concern. In these instances ORR contacts State CPS and/or local law enforcement (as necessary) with jurisdiction over the sponsor's home and provides them with ORR's findings. ORR may contact the sponsor in certain situations to inform them of child welfare concerns post release in these instances, especially where it concerns an individual in the sponsor's home.

Summary Table of Results of Background Checks and Next Steps

The following table shows procedures following the results of background checks.

BACKGROUND CHECK RESULTS	NEXT STEPS
No arrest record; check completed	Proceed with release decision-making process. See Section **2.7 Recommendations and Decisions on Release.**
Criminal arrest record and/or substantiated adverse child welfare findings; check completed	Determine whether release is barred. See Section 2.7.4 Deny Release Request. If release is not barred, elevate safety issues for third party review. For any findings that could affect safe release, care provider and/or ORR will obtain additional documents to determine current situation (*e.g.,* sponsor is on probation, criminal charges are resolved, etc.). Final release decision shall take into account the criminal records and all other relevant information that is available.
Criminal history pending results; check not complete	ORR/FFS will provide instructions to care provider.
CA/N pending results	ORR may choose to release a child pending CA/N results if there are no significant child welfare concerns associated with the sponsor or an adult in the sponsor's home, with the UC or other children.

Revised 06/18/19

2.5.3 Commonly Asked Questions on the ORR Background Check Process

Q1: Where can a sponsor get his or her fingerprints taken?

A1: ORR funds a network of digital fingerprint providers at locations that are not affiliated with law enforcement entities. Sponsors may also go to any local police department for paper fingerprinting services in the event a digital fingerprint provider is not conveniently located near a sponsor's location. Fingerprinting services are not available at ORR headquarters or at HHS/PSC offices.

Q2: Are potential sponsors required to disclose to the care provider that they have a record of a criminal charge or child abuse?

A2: Yes. The sponsor must immediately advise the care provider of this situation and gather detailed documentation of the charges, dispositions, police reports, and evidence of rehabilitation.

Q3: What happens if a public records or sex offender registry check returns disqualifying findings for a sponsor, adult household member, or adult caregiver identified in the sponsor care plan?

A3: The Case Manager informs the sponsor, and provides the sponsor with a copy of the results. The sponsor and household member/adult caregiver may dispute the results, and provide further evidence or information that a check was not performed correctly (*e.g.,* the wrong date of birth was used, the individual's name was spelled incorrectly, etc.). The Case Manager reruns the check using the corrected information. If further information is required, such as additional background checks, the Case Manager contacts the sponsor and household member/adult caregiver to obtain the information, or make other arrangements so that the safety risk to the unaccompanied child is mitigated (*e.g.,* taking steps so that the household member no longer resides in the sponsor's home, identifying a new adult caregiver, etc.).

Q4: What happens if an adult household member refuses to cooperate with a background check?

A4: ORR may deny release when an adult household member refuses to cooperate with a background check. In such cases, ORR considers the totality of the circumstances, including the adult household member's refusal and all other relevant and available information to determine whether the release process may continue. ORR determines the best interests of a child and does not release any child to a sponsor until ORR has determined that it is safe to do so.

Q5: Do background checks expire?

A5: Yes. The FBI National Criminal History Check, Child Abuse and Neglect (CA/N) Check, and State Criminal History Repository Check and/or Local Police Check all expire 270 days from the day results are received. The Public Records Check and Sex Offender Registry Check expire 90 days from the day ORR receives results.

ORR requires new background checks if the previous results have expired prior to ORR approving the child's release; this includes obtaining a new set of fingerprints (re-fingerprinting) when applicable.

Q6: Does ORR share the results of the FBI fingerprint checks with other parties?

A6: ORR does not release the results of the FBI fingerprints to outside organizations or individuals, or to ORR care providers. The FBI searches DHS databases that may contain overlapping records. The FBI system automatically initiates a notification to the DHS system if a particular record has been searched.

Q7: Can DHS use information gathered from the ORR background check process to enforce immigration policies against potential sponsors or others?

A7: Until September 30, 2021, DHS is restricted from using a background check subject's information for immigration enforcement actions such as placing a subject in detention, removal, referring the individual for a decision on removal, or starting removal proceedings. Generally stated, they include: certain felonies; an association with a business that employs minors and does not pay a legal wage or prevents the minor from going to school; or an association with prostitution. The felonies include: (A) an aggravated felony as defined in 8 U.S.C. 1101(a)(43); (B) child abuse; (C) sexual violence or abuse; or (D) child pornography. An aggravated felony, is defined at 8 U.S.C. § 1101(a)(43), and includes a listing of 21 different kinds of crimes.

If the subject of a background check is concerned about having been charged or convicted of a crime, Case Managers make a request that the subject talk to an attorney about whether their criminal history would fit the definition.

Revised 06/4/21

2.6 Sponsor Immigration Status and Release of Unaccompanied Children

ORR does not disqualify potential sponsors based solely on their immigration status or for law enforcement purposes.

ORR does not collect information on immigration status directly from the sponsor. However, the Federal Bureau of Investigation (FBI) searches Department of Homeland Security (DHS) databases as part of the FBI national criminal background check (see **Section 2.5 Sponsorship Assessment Background Check Investigations,** *https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-section-2#2.5*) and ORR may obtain immigration status information through background check results. ORR does not share FBI background check results, or any immigration status information contained therein, with outside individuals or with ORR care providers (see **Section 2.5.3 Commonly Asked Questions on the ORR Background Check Process**). In addition, ORR does not use or share any information for immigration enforcement purposes (see **Section 5.10 Information Sharing**).

If ORR learns through background check results that the sponsor has an outstanding or pending order of removal that is related to an underlying criminal act, the decision to release a child to a sponsor in these circumstances is based on the considerations described in **Section 2.5.2 Results of Background Checks on Release Decisions.**

Revised 01/30/23

2.7 Recommendations and Decisions on Release

ORR care providers must make a recommendation to release a child to a potential sponsor after the care provider has completed the full assessment of the sponsor, including completed background checks, and collected necessary documentation to prove the sponsor's identity and relationship to the child. The recommendation must take into consideration all relevant information, including the report from a home study, if conducted; the child advocate's recommendation, if appointed; DHUC's recommendation, if the child has a complex medical or mental health related issue which implicates whether a child may be released safely to a sponsor with available community supports; laws governing the process; and other factors in the case. The

ORR care provider makes a recommendation for release if the care provider concludes that the release is safe, and the sponsor is capable of providing for the physical and mental well-being of the child.

- The **Case Manager** and the **Case Coordinator** must make a recommendation tothe **ORR/FFS** on the release of the unaccompanied child to a particular sponsor. If the case manager and case coordinator cannot agree on a particular recommendation, or if the case is particularly complicated, they may refer the case directly to an ORR/FFS for guidance on how to proceed.
- After receiving the recommendation, the **ORR/FFS** and/or other **ORR/Headquarters staff** reviews the recommendation.
- Acting as an agent of HHS/ORR, the FFS makes a release decision in consideration of the recommendations from the care provider, the case coordinator, DHUC, and other stakeholders, including the home study provider and the child advocate, where applicable.

Only ORR (or ACF) has the authority to make the final decision on a release. FFS act as agents of HHS/ORR to approve unaccompanied children release requests. The case manager, case coordinator, and other stakeholders have an important role in making recommendations. In some cases, the FFS may remand a case back to the case coordinator and case manager to obtain additional information before they make a final release decision.

The ORR/FFS must make one of the following release decisions:

- Approve release to sponsor
- Approve release with post-release services
- Conduct a home study before a final release decision
- Deny release
- Remand for further information

Effective 02/13/24

2.7.1 Approve Release Decisions

A recommendation for a release without a home study or post-release services is made after a thorough assessment of the sponsor, the sponsor's family unit, and the needs of the child or youth are taken into consideration. The ORR/FFS, acting as an agent of HHS/ORR, makes this release decision when they determine that the release is a safe release, the sponsor can care for the health and well-being of the child, and the sponsor understands that the child is to appear for all immigration proceedings.

Posted 03/28/23

2.7.2 Approve Release with Post-Release Services

The ORR/FFS, acting as an agent of HHS/ORR, may approve a release with post-release services when the release is determined to be safe and appropriate, but the unaccompanied child and sponsor need additional assistance to connect them to appropriate resources in the community or to address other concerns, such as mental health or other needs that could benefit from ongoing assistance from a social welfare agency. The sponsor must consent before services may be provided and may withdraw his or her consent at any time after services have begun, since post-release services are a voluntary service. See **Section 6.2 Post Release Services** *(https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-section-6#6.2)*.

Revised 03/28/23

2.7.3 Conduct a Home Study Before a Final Release Decision Can Be Made

The Case Manager and Case Coordinator will recommend to the ORR/FFS that a home study be conducted prior to making a release recommendation. If the ORR/FFS agrees then, acting as an agent of HHS/ORR, they will approve that a home study be conducted before a final release decision can be made. The home study provider uses a standardized template to complete the review; however, the provider may include any additional supporting documentation regarding the sponsor or the child or youth, as applicable.

Once the Case Manager and Case Coordinator receive the home study results, they will review the case in light of the home study and make a release recommendation

to the ORR/FFS. (See **Section 2.4.2 Home Study Requirements,** *https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-section-2#2.4.2*)

Posted 03/28/23

2.7.4 Deny Release Request

ORR *will* deny release to a potential sponsor if any one of the following conditions exists:

- The potential sponsor is not willing or able to provide for the child's physical or mental well-being;
- The physical environment of the home presents risks to the child's safety and well-being;
- Release of the unaccompanied child would present a risk to him or herself, the sponsor, household, or the community; or,

ORR may deny release to a Category 1 potential sponsor, and will deny release to a Category 2A/2B or Category 3 potential sponsor, if any one of the following conditions exists:[10]

The potential sponsor or a member of the potential sponsor's household:

- Has been convicted of (including plea of no contest to) a felony involving child abuse or neglect, spousal abuse; a crime against a child or children (including child pornography); or a crime involving violence, including rape, sexual assault or homicide;
- Has been convicted within the last 5 years of a felony involving physical assault, battery, or drug-related offenses;
- Has been convicted of a misdemeanor for a sex crime, an offense involving a child victim, or a drug offense that compromises the sponsor's ability to ensure the safety and well-being of the child;
- Has been convicted of alien smuggling or a crime related to trafficking in persons; or
- Has other criminal history or pending criminal charges or child welfare adverse findings from which one could reasonably infer that the sponsor's ability to ensure the safety and well-being of the child is compromised;

or

- A potential sponsor or a member of the potential sponsor's household has one of the following substantiated adverse child welfare findings:[11]
  - Severe or chronic abuse or neglect;
  - Sexual Abuse or other sexual offenses;
  - Abuse or neglect of other children in the household;
  - Long-term mental illness or deficiency;
  - Long-term alcohol or drug induced incapacity; or
  - Involuntary termination of the parental rights to another child.

Revised 06/18/19

2.7.5 Remand Release Request—Decision Pending

The ORR/FFS may remand the release request, which means that the ORR/FFS is sending the recommendation back to the Case Manager for additional information or additional actions before a final release decision can be made. ORR records the date of the remand and the decision will be pending further review until the documentation is provided or actions are taken.

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[10] ORR will also reject any sponsor care plans that identify an adult care giver who has any of the disqualifying criteria.

[11] See U.S. Department of Health and Human Services, Children's Bureau. Grounds for involuntary termination of parental rights, at 2. Washington, DC: Child Welfare Information Gateway, January 2013.

Posted 01/27/15

2.7.6 Issues Related to Recommendations and Decisions

Safety Plan

Case managers, in consultation with Case Coordinators, prepare a safety plan, as needed, to address any outstanding needs the child may have after they are released and to ensure the child's safe and successful integration into the sponsor family unit and community. The goal of the safety plan is to ensure the child's safety. The safety plan also has guidance for sponsors on participating in post-release services and on other areas of care critical to the child's adjustment in the family and the community, such as maintaining mental health services for the unaccompanied child, accessing any needed special education, helping the child avoid drugs and alcohol, and using appropriate parenting techniques.

Sponsor Care Plan

A sponsor care plan identifies an adult caregiver who will assume care of an unaccompanied child if the sponsor becomes unable to care for the child. ORR requires a sponsor care plan for all potential sponsors. The goal is to ensure an unaccompanied child has a caregiver, despite any complications that may arise after release to their sponsor.

The plan:

- Identifies an adult caregiver, and their relationship to the UC and sponsor, if any;
- Includes copies of the adult caregiver's vetting information (background check results, identifying documentation, etc.);
- Includes the adult caregiver's contact information;
- Discusses how the adult caregiver is notified that a transfer of care is required, if required;
- Provides that the adult caregiver will abide by the terms of the Sponsor Care Agreement;
- Includes the date the UC's Case Manager discusses the plan with the child's sponsor and the adult caregiver identified in the plan; and,
- Includes additional information and materials (*e.g.,* a Safety Plan), as appropriate or when required by ORR.

A copy of the sponsor care plan is maintained in the UC's case file, provided to the sponsor, and to the adult caregiver identified in the plan.

Revised 01/30/23

2.7.7 Notification of Denial

If ORR denies the reunification application of a potential Category 1, 2A, or 2B sponsor, the ORR Director or their neutral and detached designee sends that potential sponsor a Notification of Denial Letter after receiving all the required information and documentation in a specific case. If the sole reason for denial of release is related to a concern that the unaccompanied child is a danger to themselves or the community, the ORR Director sends to the child and their attorney of record a copy of the Notification of Denial Letter that was sent to the potential Category 1, 2A, or 2B sponsor.

The Notification of Denial Letter includes:

- An explanation of the reason(s) for the denial;
- Evidence and information supporting ORR's denial decision, with instructions for obtaining a copy of the child's case file;
- Instructions for requesting an appeal of the denial (see **Section 2.7.8 Appeal of Release Denial,** *https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-section-2#2.7.8*);
- Notice that the potential sponsor may submit additional evidence, in writing before a Hearing occurs, or orally during a hearing;
- Notice that the potential sponsor may present witnesses and cross-examine ORR's witnesses, if such witnesses are willing to voluntarily testify; and

- Notice that the potential sponsor may be represented by counsel in proceedings related to the release denial at no cost to the Federal Government.

If ORR denies sponsorship to a potential Category 3 sponsor, the care provider notifies the potential sponsor, providing the reasons for the denial verbally. If the sole reason for denial of release is a concern that the unaccompanied child is a danger to themselves or the community, the ORR Director sends a Notification of Denial Letter to the child as described above.

Revised 07/21/23

2.7.8 Appeal of Release Denial

Category 1, 2A, or 2B sponsor applicants may seek an appeal of ORR's denial decision by submitting a written request to the Assistant Secretary, Administration for Children and Families, or their neutral and detached designee within 30 business days of receipt of the final decision from ORR. The appeal request must follow the instructions that accompanied the Notification of Denial Letter that was sent to the potential sponsor by the ORR Director or the ORR Director's designee. The Notification of Denial Letter includes information as set forth in **Section 2.7.7 Notification of Denial.**

The requestor may seek an appeal with a hearing or without a hearing. The Assistant Secretary or their neutral and detached designee will acknowledge the request for appeal within five (5) business days of receipt. The appeal process shall be completed within 30 calendar days of receipt of the appeal request unless an extension of time is warranted to accommodate the schedule of either the potential sponsor or the Assistant Secretary or their neutral and detached designee.

Without a Hearing:

If the requester seeks an appeal without a hearing, the Assistant Secretary or their neutral and detached designee will consider only:

- The Notification of Denial Letter and any information referenced therein;
- The appeal request; and
- Any additional supporting materials or information submitted by the requester.

The Assistant Secretary or their neutral and detached designee will notify the requester of a decision within 30 calendar days of receiving the request unless an extension was warranted to accommodate the schedule of either the potential sponsor or the Assistant Secretary or their neutral and detached designee. If more information is needed to make a decision, or for good cause, the Assistant Secretary or their neutral and detached designee may stay the request until they have the information needed. In these cases, the Assistant Secretary or their neutral and detached designee will send a written explanation to the potential sponsor, communicating a reasonable process and timeframe for addressing the situation and making a determination.

With a Hearing:

If the requester seeks a hearing, the Assistant Secretary or their neutral and detached designee will schedule a teleconference or video conference, per the potential sponsor's preference, at which time the potential sponsor (or the potential sponsor's representative) may explain the reasons why they believe the denial was erroneous. In addition, the potential sponsor may offer evidence or additional material in support of the request to reverse the release denial.

The Assistant Secretary or their neutral and detached designee will consider the testimony and evidence presented at the hearing, in addition to the original denial letter and information referenced therein, to make a determination. The Assistant Secretary or their neutral and detached designee will notify the requester of the decision in writing within 30 calendar days of receiving the request for the hearing unless an extension was warranted to accommodate the schedule of either the potential sponsor or the Assistant Secretary or their neutral and detached designee.

The Assistant Secretary or their neutral and detached designee makes a determination based on the relevant law, regulations, and policies concerning release decisions (see **Section 2.7.4 Deny Release Request** for the basis of a release denial). Any evidence submitted to the Assistant Secretary or their neutral and detached designee by ORR is shared with the requester in compliance with privacy protections. The Assistant Secretary or their neutral and detached designee conducts a *de novo* review and may affirm or overturn the ORR Director's or their designee's decision

or send the case back to ORR for further action. Appeal hearings are recorded, and the requester may request a copy of the recording.

The Assistant Secretary's or their neutral and detached designee's decision to affirm or overrule the ORR Director's or their designee's decision to deny release to a potential sponsor is the final administrative decision of the agency on the application that had been under consideration. However, if there is new information or a change in circumstances regarding the reunification application, or regarding the unaccompanied child's circumstances, a new reunification application may be submitted that highlights the change(s) and explains why such changes should alter the initial decision. Similarly, if ORR discovers new information or becomes aware of a change in the circumstances of the potential sponsor and/or the unaccompanied child, ORR may assess the case anew.

Denial for sole reason that the unaccompanied child is a danger to themselves or the community

If the sole reason for denial of release is concern that the unaccompanied child is a danger to themselves or the community, the unaccompanied child may seek an appeal of the denial as described above, provided the Category 1, 2A, or 2B potential sponsor is not seeking an appeal (see **Section 2.7.7 for Notification of Denial**). If the child expresses a desire to seek an appeal, ORR encourages the child to consult with their attorney of record or a legal service provider for assistance with the appeal. The unaccompanied child may seek such appeal at any time after denial of release while the child is in ORR custody.

Revised 10/27/22

2.7.9 90-Day Review of Pending Family Reunification Applications

ORR reviews the cases of all pending sponsor applications for unaccompanied children (UC) in ORR custody for 90 days. The purpose of this review is to identify and resolve the reasons that a family reunification application remains pending in a timely manner. Upon completion of the review, Case Managers will update the sponsor and UC on the status of the case, highlighting the reasons that the family reunification process is incomplete. In addition, the Case Manager will work with the sponsor, relevant stakeholders, and the ORR/FFS on a plan to address the portions of the application that remain incomplete in accordance with **Section 2.2.3 The Family Reunification Application.**

For cases that are not resolved after the initial 90-Day Review, ORR will conduct additional reviews every 90 days until the pending sponsor application is resolved in accordance with **Section 2.7 Recommendations and Decisions on Release.**

Posted 10/27/22

2.8 Release from Office of Refugee Resettlement (ORR) Custody

Release from the ORR custody is a three-step process:

- After care planning, which occurs during the entire safe and timely release process.
- Transfer of physical custody of the child, which occurs as soon as possible once an unaccompanied child is approved for release.
- Closing the case file, which occurs within 24 hours of the unaccompanied child's discharge.

Posted 01/27/15

2.8.1 After Care Planning

Throughout the release process, care providers work with the child and sponsor so that they can plan for the child's after care needs. This involves working with the sponsor and the child to:

- Prepare them for post-ORR custody
- Assess the sponsor's ability to access community resources
- Provide guidance regarding safety planning, sponsor care plans, and accessing services for the child

Once the sponsor assessment is complete and a sponsor has been approved, the sponsor enters into an agreement with the Federal Government in which he or she agrees to comply with the following provisions (see ***Sponsor Care Agreement,*** *https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program#Family%20Reunification%20Packet%20for%20Sponsors*):

- Provide for the physical and mental well-being of the child, including but not limited to, food, shelter, clothing, education, medical care and other services as needed.
- Enroll the child in school and ensure their attendance, following the requirements of the State in which you live, and otherwise support their academic success. For example, the child may benefit from supplemental classes or services, such as English as a Second Language (ESL), tutoring, or summer school.
- For those who are not the child's parent or legal guardian, make best efforts to establish legal guardianship with the local court within a reasonable time.
- Attend a legal orientation program provided under the Department of Justice/Executive Office for Immigration Review's (EOIR) Legal Orientation Program for Custodians (Sponsors), if available where they reside.[12]
- Depending on where the child's immigration case is pending, notify the local Immigration Court or the Board of Immigration Appeals within five (5) days of any change of address or phone number of the child by using DOJ's Change of Address form (Form EOIR–33). In addition, if necessary, file a Change of Venue motion on the child's behalf.[13]
- Notify the Department of Homeland Security (DHS)/U.S. Citizenship and Immigration Services within 10 days of any change of address by filing DHS's Change of Address Card (AR–11) or electronically at *www.uscis.gov/ar-11.* Sponsors in need of assistance may call or text the ORR National Call Center at 1–800–203–7001 or email **information@ORRNCC.com.**
- Notify ORR immediately if the child permanently leaves the sponsor's custody and provide updated contact information for the child by calling or texting the ORR National Call Center at 1–800–203–7001, or emailing **information@ORRNCC.com.**
- Notify ORR within 30 days of any change of address and provide updated contact information by calling or texting the ORR National Call Center at 1–800–203–7001, or emailing **information@ORRNCC.com.** The sponsor must continue to notify ORR of any change of address for a period of three (3) years after the child is released into their custody or while the sponsor is receiving post-release services, whichever come later. However, if the child if the child turns 18, their immigration case is resolved, or they permanently leave the sponsor's custody before three (3) years, the sponsor does not need to continue notifying ORR of address changes.
- Ensure the child's presence at all future proceedings before the DHS/Immigration and Customs Enforcement (ICE) and the DOJ/EOIR.
- Ensure the child reports to ICE for removal from the United States if an immigration judge issues a removal order or voluntary departure order. The child is assigned to a Deportation Officer for removal proceedings.
- Notify the U.S. Department of Labor, Wage and Hour Division if the sponsor or the child are being forced to work against their will, to repay a debt, or in unsafe conditions by calling 1–866–4–USWAGE (1–866–487–9243) or visiting *https://webapps.dol.gov/contactwhd.*
- Notify local law enforcement or State or local Child Protective Services if the child has been or is at risk of being subjected to abuse, abandonment, neglect or maltreatment or if the sponsor learns that the child has been threatened, has

[12] Sponsors are provided a Legal Orientation Program for Custodians Overview flyer as part of the Family Reunification Package that contains further information.

[13] "Change of venue" is a legal term for moving an immigration hearing to a new immigration court location. The Change of Venue motion must contain information specified by the Immigration Court. A Change of Venue motion may require the assistance of an attorney. For guidance on the "motion to change venue," see the Immigration Court Practice Manual at *www.justice.gov/eoir/reference-materials/ic.* For immigration case information please contact EOIR's immigration case information system at 1–800–898–7180. Visit EOIR's website for additional information at: *www.justice.gov/eoir.*

been sexually or physically abused or assaulted, or has disappeared. Notice should be given as soon as it is practicable or no later than 24 hours after the event or after becoming aware of the risk or threat.

- Notify the National Center for Missing and Exploited Children at 1–800–843–5678 and the ORR National Call Center at 1–800–203–7001 or **information @ORRNCC.com** if the child disappears, has been kidnapped, or runs away. Notice should be given as soon as it becomes practicable or no later than 24 hours after learning of the child's disappearance.
- Notify ICE at 1–866–347–2423 if the child is contacted in any way by an individual(s) believed to represent a smuggling syndicate, organized crime, or a human trafficking organization. Notice should be provided as soon as possible or no later than 24 hours after becoming aware of the information.
- In case of an emergency (serious illness, destruction of home, etc.), temporarily transfer physical custody of the child to another person who will comply with the terms of the Sponsor Care Agreement.
- In the event that a sponsor who is not the child's parent or legal guardian is no longer able and willing to care for the child and is unable to temporarily transfer physical custody to an alternative caregiver, and the child meets the definition of an unaccompanied child, notify the ORR National Call Center at 1–800–203–7001 or **information@ORRNCC.com.**

The agreement includes the notice that the release of the child to the sponsor's care does not grant the child any legal immigration status and that the child must present himself or herself for immigration court proceedings.

The care provider also provides the sponsor with a Sponsor Handbook that outlines the responsibilities in caring for the child's needs for education, health, obtaining legal guardianship, finding support to address traumatic stress, keeping children safe from child abuse and neglect and from trafficking and exploitation. The handbook reiterates the importance of continuing with immigration proceedings and includes links to EOIR's website and forms. The handbook discusses laws related to employment, such as the Federal law prohibiting minors under the age of 18 from working in hazardous occupations.

After care planning includes the care provider explaining the following to the child and the sponsor:

- The U.S. child abuse and neglect standards and child protective services that are explained on the Administration for Children and Families **Child Welfare Information Gateway** *(https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program#Family%20Reunification%20Packet%20for%20 Sponsors)* website.
- Human trafficking indicators and resources.
- Basic safety and how to use the 911 number in emergency situations.

The care provider notifies all stakeholders of the child's discharge date and change of address and venue, as applicable. Where applicable, ORR also provides child advocates with access to their clients' documents and forms, and helps child advocates to remain informed about their clients' after-care plans and legal proceedings. The care provider coordinates with the legal service provider or attorney of record to help complete the necessary legal forms. Stakeholders notified of the change of address and, if applicable, request for change of venue for the immigration case include the U.S. Immigration and Customs Enforcement (ICE) Office of Chief Counsel and the U.S. Executive Office for Immigration Review (EOIR) Immigration Court Administrator.

Revised 03/25/24

2.8.2 Transfer of Physical Custody

Once ORR approves an unaccompanied child for release, the care provider collaborates with the sponsor to ensure physical discharge happens as quickly as possible (within 3 calendar days after ORR approves the release). The care provider notifies DHS prior to the physical release to allow DHS an opportunity to comment on the imminent release as well as time to prepare any DHS paperwork for the ICE Chief Counsel's office.

The care provider ensures that all the child's belongings—including those he or she had at the time they entered ORR custody and any they acquired during their stay—are given to the child and sponsor at time of release. The care provider also

makes sure that the child and sponsor have copies of files or papers needed for the child to obtain medical, educational, legal or other services following release.

Whenever possible, sponsors are expected to come to the care provider or to an off-site location designated by the care provider for the transfer of physical custody of the child.

Escorting Children to a Sponsor

Under extenuating circumstances (*e.g.,* a sponsor cannot travel due to a medical condition), ORR may approve an unaccompanied child to be escorted to a sponsor. Similarly, if a sponsor pick-up would result in delay of a timely release of the child, ORR may approve an escort for an unaccompanied child.

If an unaccompanied child's final destination involves air travel and the sponsor will not be traveling with the child, the care provider must follow the procedures in the table below concerning care provider escorts and airline escorts.

Unaccompanied children who are under the age of 14 years old traveling via air may only be escorted by care provider staff, unless an ORR/FFS Supervisor has approved the use of an airline escort in advance.

Sponsors are not required to use a travel agent proposed or used by a care provider if they are able to find lower airfare using another agent or airline, provided escort conditions are met.

The following table summarizes procedures for each method of transfer.

METHOD OF TRANSFER	PRE-TRANSFER STEPS	AT POINT OF TRANSFER
Sponsor pick-up at care provider facility	• Case manager collaborates with the sponsor on selecting a date and time for the sponsor to pick-up the child	• Care provider checks the sponsor's identification upon arrival by comparing it to the identification previously submitted by the sponsor in the FRP (see **Section 2.2.4**)
	• Case manager notifies the sponsor that he/she is required to bring the same valid government issued photo identification previously submitted by the sponsor in the FRP (see **Section 2.2.4**)	• If the sponsor's identification matches the identification previously submitted, care provider gives the sponsor the unaccompanied child's release documents and personal possessions • Care provider advises the sponsor, if traveling by airplane, to check in the child at the ticket counter with a copy of the child's DHS form I–862, Notice to Appear • Care provider may not release the child unless the sponsor presents the same valid government issued photo identification he or she submitted in the FRP
	• Case manager collaborates with the sponsor in selecting a time and location for transfer, and flights for the child and care provider escort	• If traveling by air, at the departure airport, care provider escort checks in the child at the ticket counter with a copy of the child's DHS form I–862, Notice to Appear
	• Case manager notifies the sponsor that he/she is required to bring the same valid government issued photo identification previously submitted by the sponsor in the FRP to the transfer location	• At the transfer location, care provider escort compares the sponsor's identification with the copy previously submitted by the sponsor in the FRP. If the identification documents correspond, care provider escort releases the child to the sponsor and provides the sponsor with the release documents and the child's personal effects and papers

METHOD OF TRANSFER	PRE-TRANSFER STEPS	AT POINT OF TRANSFER
Care provider escort to offsite transfer location	• Case manager arranges or assists in arranging the child and care provider escort's transportation, including airline tickets where applicable • Case manager prepares a copy of the sponsor's identification that was submitted in the FRP, for the care provider escort to take to the transfer location	• Care provider escort may not release the child unless the sponsor presents the same valid government issued photo identification he or she submitted in the FRP. If the sponsor does not produce valid identification, if the care provider escort has concerns regarding the sponsor's identity, or if the care provider escort has concerns regarding the safety of the situation upon meeting the sponsor, the care provider escort will return with the child to the care provider facility
Travel via airline's unaccompanied minor escort policy (only for youth 14 years of age and older)	• Case manager contacts the airline to obtain information on airline escort requirements, in order to ensure that they are adequate to protect the safety of the child, and to ensure that both the sponsor and the care provider can meet the requirements	• At the departure airport, care provider checks in the unaccompanied child at the ticket counter with a copy of the DHS form I–862, Notice to Appear, and a copy of the approved identification of the sponsor picking up the child
	• Case manager arranges or assists in arranging the child and care provider escort's transportation, including airline tickets where applicable	• At the departure airport, care provider gives the child their personal possessions and documents and a copy of the sponsor's approved identification, and mails an additional copy of the release documents to the sponsor
	• Case manager ensures that the government issued photo identification submitted by the sponsor in the FRP will be acceptable to the airline to complete custody transfer	• At the destination airport, the sponsor arrives 2 hours before the child's arrival time, and contacts the care provider immediately to check in
	• The care provider instructs the sponsor to meet the unaccompanied child and escort at the airport with the identification they submitted in the FRP, and to follow the requirements of the airline's unaccompanied minors escort policy	• The airline follows its standard procedures for escorting a child traveling alone to the designated parent or guardian • The care provider contacts the sponsor shortly after the child's scheduled arrival time to confirm the child's transfer from the airline representative to the sponsor • If the sponsor fails to arrive at the airport or fails to contact the care provider upon arrival at the airport, the care provider will notify the ORR/FFS and the Project Officer, and the child will either be returned to the care provider or taken to another nearby care provider facility

When arranging for children to travel with airline escorts, care providers should also refer to the U.S. Department of Transportation recommendations for unaccompanied minors traveling by air (**"When Kids Fly Alone,"** *https://www.transportation.gov/airconsumer/when-kids-fly-alone*).

Revised 01/10/22

2.8.3 Closing the Case File

The care provider completes a Discharge Notification form within 24 hours of the physical discharge of a youth, and then emails the form to DHS and other stakeholders. Once a child is released to a sponsor, ORR's custodial relationship with the child terminates.

Although the custodial relationship ends, the care provider keeps the case file open for 30 days after the release date in order to conduct the Safety and Well Being Follow Up Call (see **Section 2.8.4**) and document the results of the call in the case file. The care provider closes the case file record after completing the Safety and Well Being Follow Up Call.

Revised 03/14/16

Section 2.8.4 Safety and Well Being Follow Up Call

Care providers must conduct a Safety and Well Being Follow Up Call with an unaccompanied child and his or her sponsor 30 days after the release date. The purpose of the follow up call is to determine whether the child is still residing with the sponsor, is enrolled in or attending school, is aware of upcoming court dates, and is safe. The care provider must document the outcome of the follow up call in the child's case file, including if the care provider is unable to contact the sponsor or child after reasonable efforts have been exhausted. If the follow up call indicates that the sponsor and/or child would benefit from additional support or services, the care provider must refer the sponsor or child to the ORR National Call Center and provide the sponsor or child the Call Center contact information. If the care provider believes that the child is unsafe, the care provider must comply with mandatory reporting laws, State licensing requirements, and Federal laws and regulations for reporting to local child protective agencies and/or law enforcement.

Revised 03/14/16

2.8.5 Post-Release Services for UC with Zika Virus Disease or Infection [REPEALED]

2.8.6 Release for Children with Legal Immigration Status

Some unaccompanied children may obtain legal immigration status while in ORR care. ORR may also discover during the process of placing and providing services to a child that he or she already has legal immigration status or is a U.S. citizen. By law, ORR is not authorized to have custody of children with legal immigration status or U.S. citizenship. Therefore, these children cannot remain in ORR's care, and ORR must promptly release them from ORR-funded care provider facilities.

As soon as ORR determines that an unaccompanied child may be eligible for legal status, ORR begins development of a Post Legal Status Plan. The case manager develops the plan, and ORR approves it, tailoring it to the needs and pending immigration status of the child.

As is the case for all UC, ORR continually makes efforts to reunify children who have promising immigration cases with family members. However, if no parent, legal guardian, relative, or other suitable adult is available, ORR and the care provider, as part of the development of the Post Legal Status Plan, identify alternative placements for the child, including specialized programs, State or county entities or licensed nonprofit organizations that will take custody of the child. In limited circumstances, children with certain types of immigration status may be eligible for release into ORR's Unaccompanied Refugee Minors (URM) Program. Placement in the URM Program is limited by type of immigration status and the availability of appropriate placement options. ORR will not release children on their own recognizance under any circumstances.

Posted 05/8/17

2.8.7 Release of Saravia Class Members

Generally, ORR must release a UC to the previous sponsor within 3 calendar days of a successful Saravia hearing unless one of the following exceptions applies:

- The sponsor is physically unavailable (*e.g.,* has been removed from the United States, imprisoned, cannot be located, or is unwilling to take the minor back);
- There has been abuse or neglect (*e.g.,* ORR has evidence that the prior sponsor, or individuals in the sponsor's household, have abused or neglected the UC or other children in the sponsor's home); or

- The UC was previously released to a Category 2B or Category 3 sponsor but the child was not living with that sponsor immediately prior to arrest. (For UC who are arrested by ICE after serving time in a local jail, ORR releases to the previous Category 2B or Category 3 sponsor within 3 calendar days if the UC was living with that sponsor immediately prior to their arrest by local authorities.)

Where release is not possible for one of the reasons above, ORR follows the standard safe and timely release process (see **Section 2 Safe and Timely Release from ORR Care,** *https://www.acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide-section-2*). However, this process shall not take into account any prior allegations of gang affiliation that existed at the time of a Saravia class membership determination.

If a Saravia class member returns to ORR custody after not having prevailed at his or her Saravia hearing, ORR follows its normal policies and procedures for release of the UC.

Posted 02/12/21

2.9 Bond Hearings for Unaccompanied Children

Consistent with the Ninth Circuit Court of Appeals decision in *Flores v. Sessions,* unaccompanied children have the opportunity to seek a bond hearing with an immigration judge.

In a bond hearing, an immigration judge decides whether the child poses a danger to the community.[14] For the majority of children in ORR custody, ORR has determined they are not a danger and therefore has placed them in shelters, group homes, and in some cases, staff secure facilities. For these children, a bond hearing is not beneficial.

The burden is on the requestor to demonstrate that the child can be released because he or she is not a danger to the community. An immigration judge's decision that the unaccompanied child is not a danger to the community supersedes an ORR determination on that question, unless the immigration judge's decision is overturned by the Board of Immigration Appeals (BIA). However, even if an immigration judge decides the child is eligible for bond (meaning the child does not pose a danger to the community and need not remain in an ORR facility for that reason), in all cases release from ORR custody cannot occur until ORR has identified, evaluated and approved an appropriate sponsor in accordance with **Section 2** of this policy guide. An immigration judge does not rule on any of the following:

- release to a sponsor;
- the unaccompanied child's placement or conditions of placement while in ORR custody; or,
- releasing the child on his or her own recognizance.

ORR also takes into consideration the immigration judge's decision in the bond hearing about the youth's level of danger when assessing the youth's placement and conditions of placement.[15]

Although these hearings are known as "bond hearings," ORR does not require payment of any money in the event a court grants bond.

Requesting a Bond Hearing

A request for a bond hearing may be made by the child in ORR care, by a legal representative of the child, or by parents/legal guardians on their children's behalf. These parties may submit a written request for a bond hearing to the care provider using the ORR form, *Notice of Right to Request a Bond Hearing,* or through a separate written request that provides the information requested in the form. ORR provides the *Notice of Right to Request a Bond Hearing* to UC in secure and staff secure facilities.

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[14] Immigration judges also consider risk of flight. However, ORR does not make a determination of flight risk for the purpose of deciding whether a child is released. If an immigration judge offers an opinion about a youth's risk of flight, ORR takes the judge's opinion into consideration when assessing the child's placement and conditions of placement, but the decision does not affect release.

[15] Please see footnote above concerning risk of flight.

A request for a bond hearing must minimally include:

- The full name and alien registration number ("A number") of the child;
- If a parent or legal guardian, or an appointed legal representative, is making the request, the parent/legal guardian's or legal representative's name;
- The location of the care provider facility;
- The date of the request; and
- The signature(s) of the requesting child, the parent/legal guardian, and/or legal representative.

There is no filing fee to submit a request for a bond hearing to the care provider.

A child (or his or her legal representative) may also request a bond hearing by making an oral request in immigration court.

Bond Hearings Proceedings

Bond hearings are usually held at the immigration court where the request for a bond hearing is filed.

If the immigration judge finds an unaccompanied child eligible for bond, and ORR does not appeal, then ORR follows its sponsor assessment and release procedures as described in **Section 2** of this policy guide.

Appeals

Either party may appeal the immigration judge's decision to the BIA. Because ORR cannot release a child until it identifies a suitable sponsor, an immigration judge's finding that the unaccompanied child is not a danger to the community does not necessarily result in a release of the child while an appeal is pending.

Age Outs

If an unaccompanied child becomes 18 years old during the pendency of a bond hearing or bond hearing appeal, ORR forwards the request for a bond hearing and any relevant information to the local DHS/ICE Office of Chief Counsel's office.

Further Requests for Bond Hearing

If an immigration judge (or BIA, when appealed) determines that an unaccompanied child is ineligible for bond, such decision is final unless the child can demonstrate a material change in circumstance to support a second request for a bond hearing.

Revised 07/19/17

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.

Over the course of the past year, the Finance Committee has taken bipartisan action to tackle a range of health-care challenges, leveraging collaboration and consensus to advance common-sense solutions for seniors and working families. Our pharmacy benefit manager reforms would modernize Medicare's prescription drug benefits, driving down costs at the pharmacy counter and netting billions in savings for taxpayers. Moreover, the committee's mental health proposals would build on previous efforts to shore up patient access to critical services, especially in rural communities.

These policies received nearly unanimous support from across this dais, all through regular order. Your department and its subagencies, Mr. Secretary, have offered essential technical assistance throughout these processes. That support has ensured alignment between our legislation and its intended goals, and I thank you for that.

As we move forward, further action on these overdue, patient-focused proposals must become an urgent priority not just for our committee, but also for the administration. We have a responsibility to patients, community pharmacies, and front-line health-care providers to deliver on these commitments, regardless of policy differences on other fronts.

The President's budget request, unfortunately, falls severely short of that aim. On prescription drug affordability, for instance, the document makes virtually no men-

tion of the robust bipartisan, bicameral efforts to reform PBM practices, instead opting to double down on price control policies that polarize members in both chambers.

Bipartisan bills in the Senate and House would address unintended consequences spurred by the Inflation Reduction Act's pricing provisions, particularly for patients with rare diseases, who will likely see fewer treatment options under the law. Rather than embrace these avenues for viable reform, however, the budget seeks to expand the program's scope, with no attempt at improved transparency, certainty, or mitigation. Further, the President's budget request affirms an overreaching mandate that will force more nursing homes to close their doors and result in less access to home and community-based services for Medicaid beneficiaries.

This document highlights divisions and misses vital opportunities for productive, patient-driven partnerships with Congress.

We will continue engaging with your department on a host of health-care hurdles that demand policymakers' attention. You have rightly raised concerns, for instance, around the ongoing surge in medication shortages, including for lifesaving therapies. The chairman and I recently released a white paper outlining potential solutions to prevent and mitigate this crisis, and we look forward to working with HHS and CMS to develop legislation designed to achieve these goals.

We also stand ready to partner on proposals aligned with the President's Cancer Moonshot, including by ensuring that seniors can access innovations like multicancer early detection screening tests. Earlier this Congress, I joined Senator Bennet in reintroducing our bill to grant Medicare coverage for these technologies, and bipartisan majorities in both chambers have joined as cosponsors.

More broadly, while the administration erred in rescinding regulations aimed at expediting access to medical breakthroughs, your department could take a range of steps to restore patients' trust in reliable coverage for medical devices, including by expanding and enhancing the proposed pathway that CMS published last year.

Before closing, let me emphasize the importance of timely communication with respect to the cyberattack on Change Healthcare. While your department has recently taken steps to issue guidance and flexibilities to insurers, providers, and contractors to mitigate the effects of the hack, the over 2-week delay resulted in avoidable uncertainty.

Already financially vulnerable rural hospitals and providers, with little to no cash reserves, required immediate action by the administration to ensure payrolls could be met and services could continue without interruption.

In the coming days and weeks, HHS should continue to update members and stakeholders on efforts to limit further disruption.

We have an obligation to build on longstanding legacies of bipartisanship to bolster the clinician workforce, drive value-based care, improve broken payment systems, and ensure long-term access to telehealth.

With these joint goals in mind, thank you again for being here today, Mr. Secretary, and thank you, Mr. Chairman.

PREPARED STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON

Today, the Finance Committee meets to discuss the year ahead for health care in our country. Thank you, Secretary Becerra, for joining us.

I'm going to start us off today with a little history lesson. Topic one: drug prices. In July of 2020, Donald Trump said, and I quote: "Since the day I took office, I have made reducing drug prices one of my highest priorities." For 4 straight years Donald Trump complained about high drug prices, did lots of finger pointing about the problem, and repeatedly talked about how he was a great friend to seniors who depend on Medicare. What did he accomplish over his 4 years? Exactly nothing.

Fast forward to the Biden administration. From the time he took office, President Biden made it clear from Day One that he was committed to lowering drug prices and health-care costs for families. Two years later, he was signing the Inflation Reduction Act into law.

For the first time, under that law, Democrats and President Biden gave Medicare the authority to negotiate better drug prices. Now, most Americans have access to free vaccines. We capped insulin costs for seniors at $35 a month. The commercial market caught on.

We created price-gouging penalties to hold big pharma accountable for high drug costs. They're already benefiting patients and taxpayers. And there's more for us to do. For example, it's essential that we get pharmacy benefit manager, or PBM, reforms across the finish line this Congress to lower drug costs for patients and protect community pharmacies.

Topic two: health insurance. In March of 2019, Donald Trump tweeted: "The Republican Party will become 'The Party of Health Care!'" With the help of Senate Republicans, his number one health-care goal was repealing the Affordable Care Act. Thankfully, he failed.

Under President Biden's leadership, Democrats boosted tax credits for health insurance, saving millions of Americans an average of $800 per year on their coverage and expanding access to care. When you look at President Biden's health-care budget for the upcoming year, it's clear Democrats are committed to building on the progress we've already made. There's a lot more work to do for the American people.

So, with all these health-care challenges in mind, the next question is, what do Donald Trump and Republicans have planned for health care? The American people are wondering, because not once during their ACA "repeal and replace" crusades did they offer up a serious replacement.

Seven years after his efforts to repeal the ACA crashed and burned, nothing has changed. Trump is still saying he wants to repeal it, and he still lacks a plan to take care of all the people whose health coverage he'd rip away. And now he's even talking about gutting Americans' hard-earned Social Security and Medicare benefits. No plan for how to keep seniors out of poverty and illness either. That, folks, in a nutshell is the Republican health-care plan: shred the health-care programs countless Americans rely on, and pretend there won't be disastrous consequences.

So in my view, there's a clear contrast for the American people to observe on health care. Since the day President Biden took office, he's been laser-focused on bringing down costs and improving care. But for all Donald Trump's bluster on various health-care issues, the gap between his promises on health care and his actual record is as deep as Crater Lake.

Democrats made promises to the American people, and we delivered.

Finally, here's another reason to get my bipartisan tax deal with Congressman Smith passed in the Senate, and immediately lift 400,000 kids out of poverty. Dr. Ben Hoffman—a doctor at Oregon's very own OHSU and president of the American Academy of Pediatrics—has said that there's an "inextricable link between poverty and child health," and that passing my bipartisan Child Tax Credit expansion is essential to lift kids out of poverty and improve their health. I'm all in to get that done.

When I say that 16 million kids from low-income families—particularly families with more than one kid—will be better off if the Senate passes this bill, the health and well-being of those children is a core part of what I'm talking about. If you don't want to take my word for it, listen to the American Academy of Pediatrics.

I look forward to hearing from Secretary Becerra about how President Biden will continue to lower costs and improve care for more American families.

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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 2025 Budget Request.

General Approach

For obvious reasons, this year will be more hectic than the last. The budget and appropriations process need to be simple. To do this, pass a consensus caretaker budget with two draft partisan supplemental bills, one of which can be enacted during the Lame Duck Session or at the beginning of the next Congress for the President-Elect to sign upon taking office, depending on who wins.

If such a budget is enacted, use it as the basis for spending caps for a new Budget Control Act. Make the targets realistic and self-enforcing for purposes of Appropriations Committee allocations.

Contingencies

In the event the majority in the House shifts due to early retirements or insurrection indictments, the Senate majority and the House minority should have legislation ready to enact a Public Option, including reconciliation instructions for the FY24 budget year. Please see the attachment for details.

As any such change in control will only last through the special election cycle, this should be the second priority. The first must be amending the Electoral Count Act and the jurisdiction of the Ethics Committees to provide for the enforcement of the Fourteenth and Twentieth Amendments, including provisions for removing and related disability for members and the President-elect.

The **President's Budget** addresses the following two top line points:

Lowers Health Care Costs, making permanent the expanded premium tax credits that the Inflation Reduction Act extended, providing Medicaid-like coverage to individuals in States that have not adopted Medicaid expansion, paired with financial incentives to ensure States maintain their existing expansions.

Protects and Strengthens Medicare, extending the solvency of the Medicare Hospital Insurance (HI) trust fund indefinitely by modestly increasing the Medicare tax rate on incomes above $400,000, closing loopholes in existing Medicare taxes, and directing revenue from the Net Investment Income Tax into the HI trust fund as was originally intended.

Regarding lowering health-care costs, the President is forgetting his promise to create a Public Option.

We disagree with the President on how to shore up the HI trust fund and expand the *Affordable Care Act.* ACA subsidies are too low and are funded by taxing the wrong people (investors). Families in the Silver Plan still have problems meeting copays and paying premiums. The funding is also unfortunate. Rather than expanding Medicaid, replace it for the non-elderly with the Public Option proposed in 2009.

The public option should be extended to individuals who are denied coverage under pre-existing condition rules. Such rules must be revoked as the price of passing the

bill. Such a trade-off is necessary for enactment of such a proposal on a bipartisan basis.

Developing the Public Option needs to be funded in this budget. Particularly, it should explore the impacts on coverage and cost of automatically enrolling individuals who are denied coverage under pre-existing condition rules.

The way to fully fund health care is through an employer-paid subtraction value-added tax.

Taxes to support Medicare should be broad based, funded either by an employer paid subtraction VAT or a border adjustable goods and services tax (credit invoice VAT). **This would allow for the repeal of the ACA–SM surtax on higher-income individuals enacted as part of the Affordable Care Act.** Tax increases on higher income individuals should be dedicated toward fully funding net interest, eventually reducing the national debt, funding veteran's health care and overseas military and ocean deployments.

The President's budget cites PHARMA profits as a rationale for increasing business income tax rates. He proposes **raising Tax Rates for Large Corporations.**

Instead, we suggest eliminating Corporate Profits taxes and taxation of business income on Form 1040 with a Subtraction VAT (with offsets for employee and retiree health care) and a credit invoice tax on both labor and profit. The combined rates of these taxes will burden both profits and labor costs, raising much more money.

This tax will be levied for all income earned in the country of production (for subtraction VAT) and of sale (Credit Invoice VAT). A new agreement on rate uniformity for our proposed Asset VAT will prevent rate shopping for stock trading (see the second attachment).

From Tax Reform Attachment: Subtraction Value-Added Taxes

Subtraction Value-Added Tax (S–VAT). Corporate income taxes and collection of business and farm income taxes will be replaced by this tax, which is an employer paid Net Business Receipts Tax. S–VAT is a vehicle for tax benefits, including:

- Health insurance or direct care, including veterans' health care for non-battlefield injuries and long-term care.
- Employer-paid educational costs in lieu of taxes are provided as either employee-directed contributions to the public or private unionized school of their choice or direct tuition payments for employee children or for workers (including ESL and remedial skills). Wages will be paid to students to meet opportunity costs.
- Most importantly, a refundable child tax credit at median income levels (with inflation adjustments) distributed with pay.

Subsistence-level benefits force the poor into servile labor. Wages and benefits must be high enough to provide justice and human dignity. This allows the ending of State administered subsidy programs and discourages abortions, and as such enactment must be scored as a must pass in voting rankings by pro-life organizations (and feminist organizations as well). To assure child subsidies are distributed, S–VAT will not be border adjustable.

As above, S–VAT surtaxes are collected on all income distributed over $75,000, with a beginning rate of 6.25%. replace income tax levies collected on the first surtaxes in the same range. Some will use corporations to avoid these taxes, but that corporation would then pay all invoice and subtraction VAT payments (which would distribute tax benefits). Distributions from such corporations will be considered salary, not dividends.

Funding Orphan Drugs and the issue of PHARMA profits

PHARMA justifies its profits because it is burdened with high development costs for new and orphan drugs. We renew our call for a more "corporate approach" for government research and testing of new drugs.

Part of ARPA–H is the funding for research on orphan drugs and the lingering problem of their cost once research leads to product development. In comments to Senate Finance on March 16th of this year, we repeated our proposal in this area for NIH to retain ownership in any such drug and contract out its further development and manufacture. Keeping ownership in public hands ends the need for drug companies to charge extreme prices or increase prices for its existing formulary to fund development.

PHARMA would still make reasonable profit, but the government would eat the risk and sometimes reap the rewards. NIH/FDA might even break even in the long term, especially if large volume drugs which were developed with government grants must pay back a share of basic research costs and the attached profits, as well as regulatory cost.

Closing

We have serious concerns with the way President Biden is paying for the future of Medicare and extending Obamacare. Please share these with the Secretary and request a response.

Thank you for the opportunity to address the committee. We are, of course, available for direct testimony or to answer questions by members and staff.

Attachment: HHS Budget FY 2022

Single Payer

We address the funding of the Affordable Care Act, the need for an immediate COLA for retirees, funding the Social Security Administration's non-fund costs and the idea of cost savings for Social Security.

So far, the administration has not yet addressed changes to the **Affordable Care Act,** at least not publicly. We suggest that the committee ask the Secretary about any such plans.

At minimum, the individual and employer mandates, with associated penalties, that were repealed must be restored. The President campaigned on restoring and perfecting the Act, adding a public option. We agree, although the public option need not be self-supporting. It must be subsidized through a broad-based consumption tax. Such a tax burdens both capital and wage income.

The current funding stream seems to have been designed to draw opposition from wealthier taxpayers. It is an open secret that the Minority does not oppose most of the Affordable Care Act (which was designed by their own Heritage Foundation as an alternative to Mrs. Clinton's proposals). Broaden the tax base to fund the program and the nonsense on repeal will end.

The current funding stream from student loan initiation and interest, which was included in the baseline, should also be ended. Graduates (and non-graduates) with student loan debt cannot afford both their loan payments and insurance payments under the Affordable Care Act. When they apply for lower loan payments, which are always granted, they face either a balloon interest payment or capitalized interest, which makes their funding situation worse. No one should have to retire with student load debt, yet quite a few soon will (or already have).

Forgive capitalized interest and apply any overpayments to principal. There should not be a one-size-fits-all subsidy. Also, when payments are deferred, return to the practice of deferring interest (or allow debts to be discharged, at least partially, in bankruptcy).

To deal with these issues, whatever is budgeted for analytical support in the Department should likely be doubled.

The following analysis comes from the Single Payer attachment that has previously been provided. Because of the President's preference for establishing the public option, we will repeat those analyses here. Aside from a broader base of funding, other compromises are necessary to enact a public option.

To set up a **public option** end protection for preexisting conditions and mandates. The public option would then cover all families who are rejected for either preexisting conditions or the inability to pay. In essence, this is an expansion of Medicaid to everyone with a preexisting condition. As such, it would be funded through increased taxation, which will be addressed below. A variation is the expansion of the Uniformed Public Health Service to treat such individuals and their families.

The public option is inherently unstable over the long term. The profit motive will ultimately make the exclusion pool grow until private insurance would no longer be justified, leading again to Single Payer if the race to cut customers leads to no one left in private insurance who is actually sick. This eventually becomes Medicare for All, but with easier passage and sudden adoption as private health plans are either banned or become bankrupt. Single-payer would then be what occurs when insurance companies are bailed out in bankruptcy, the public option covers everyone and insurance companies are limited to administering the government program on a State-by-State basis.

The financing of the Affordable Care Act should be broadened. It should neither be funded by the wealthy or by loan sharking student loan debtors. Instead, it should be funded by an employer-paid consumption tax, with partial offsets to tax payments for employer provided insurance and taxes actually collected funding a Public Option (which should also replace Medicaid for non-retirees). Medicaid for retirees and Medicare should be funded by a border adjustable goods and services tax, which should be broad based.

Why the difference? The goal is to not need a public option as employers do the right thing and cover every worker or potential worker. Using an employer-based tax is an incentive to maximize employee coverage. Medicare, however, is an obligation on society as a whole.

Medicare Part E

State governments (were) under financial pressure as a result of the pandemic, especially in the area of health-care costs, most especially for seniors in nursing homes who are "dual eligible." The heart of President Reagan's New Federalism proposal was the transfer of State Medicaid expenses to the Federal Government, largely to fund baby boomers who would become dual eligible with time. Time is now up, or will be shortly.

Welfare has been reformed, allowing State and Federal Governments to save money—which was part of the New Federalism bargain that was not accepted at the time. We will address this part shortly, but the irony is that Federal money was reduced without the second part of the trade-off.

Finish the process and create Medicare Part E for low-income disabled and retirees. This will put investigation of nursing home conditions into the Federal sector. States have done a poor job in enforcement of health and safety standards. It is time to make this a national responsibility.

One way to increase benefits generally is to increase the minimum wage, the higher the better, and rebase current benefits to consider such an increase to be wage inflation. Such a change will fund itself, because wages funding benefits will be increased across the board.

Asset VAT—The President's Fiscal Year 2023 Budget, June 7, 2022

There are two debates in tax policy: how we tax salaries and how we tax assets (returns, gains and inheritances). Shoving too much into the Personal Income Tax mainly benefits the wealthy because it subsidizes losses by allowing investors to not pay tax on higher salaries with malice aforethought.

Asset Value-Added Tax (A–VAT) is a replacement for capital gains taxes and the estate tax. It will apply to asset sales, exercised options, inherited and gifted assets and the profits from short sales. Tax payments for option exercises, IPOs, inherited, gifted and donated assets will be marked to market, with prior tax payments for that asset eliminated so that the seller gets no benefit from them. In this perspective, it is the owner's increase in value that is taxed.

As with any sale of liquid or real assets, sales to a qualified broad-based Employee Stock Ownership Plan will be tax free. This change would be counted as a tax cut, giving investors in public stock who make such sales the same tax benefit as those who sell private stock.

The repeal of corporate profits taxes as part of the creation of a subtraction value-added taxes and repeal of capital gains taxes in the United States will lead to their repeal worldwide. If Asset Value-Added Taxes are adopted, the rate should be negotiated so that investors who are able do not market shop for the lowest rate. The recent OECD compact on minimum rates is an example of how tax cooperation on capital can work for other types of asset taxation. This tax will end Tax Gap issues owed by high-income individuals. The base 20% capital gains tax has been in place for decades. The current 23.8% rate includes the ACA–SM surtax), while the Biden proposal accepted by Senator Sinema is 28.8%. Our proposed Subtraction VAT would eliminate the 3.8% surtax. This would leave a 25% rate in place.

Settling on a bipartisan 22.5% rate (give or take 0.5%) should be bipartisan and carried over from the capital gains tax to the asset VAT. A single rate also stops gaming forms of ownership. Lower rates are not as regressive as they seem. Only the wealthy have capital gains in any significant amount. The *de facto* rate for everyone else is zero.

With tax subsidies for families shifted to an employer-based subtraction VAT, and creation of an asset VAT, taxes on salaries could be filed by employers without most

employees having to file an individual return. It is time to TAX TRANSACTIONS, NOT PEOPLE!

The tax rate on capital gains is seen as unfair because it is lower than the rate for labor. This is technically true; however, it is only the richest taxpayers who face a marginal rate problem. For most households, the marginal rate for wages is less than that for capital gains. Higher income workers are, as the saying goes, crying all the way to the bank.

In late 2017, tax rates for corporations and pass-through income were reduced, generally, to capital gains and capital income levels. This is only fair and may or may not be just. The field of battle has narrowed between the parties. The current marginal and capital rates are seeking a center point. It is almost as if the recent tax law was based on negotiations, even as arguments flared publicly. Of course, that would never happen in Washington. Never, ever.

Compromise on rates makes compromise on form possible. If the Affordable Care Act non-wage tax provisions are repealed, a rate of 26% is a good stopping point for pass-through, corporate, capital gains and capital income.

A single rate also makes conversion from self-reporting to automatic collection through an asset value-added tax levied at point of sale or distribution possible. This would be both just and fair, although absolute fairness is absolute unfairness to tax lawyers because there would be little room to argue about what is due and when.

Ending the machinery of self-reporting also puts an end to the Quixotic campaign to enact a wealth tax. To replace revenue loss due to the ending of the personal income tax (for all but the wealthiest workers and celebrities), enact a Goods and Services Tax. A GST is inescapable. Those escapees who are of most concern are not waiters or those who receive refundable tax subsidies. It is those who use tax loopholes and borrowing against their paper wealth to avoid paying taxes.

For example, if an unnamed billionaire or billionaires borrow against their wealth to go into space, creating such assets would be taxable under a GST or an asset VAT. When the Masters of the Universe on Wall Street borrow against their assets to avoid taxation, having to pay a consumption tax on their spending ends the tax advantage of gaming the system.

This also applies to inheritors. No "Death Tax" is necessary beyond marking the sale of inherited assets to market value (with sales to qualified ESOPs tax free). Those who inherit large cash fortunes will pay the GST when they spend the money or Asset VAT when they invest it. No special estate tax is required and no life insurance policy or retirement account inheritance rules will be of any use in tax avoidance.

Tax avoidance is a myth sold by insurance and investment brokers. In reality, explicit and implicit value-added taxes are already in force. Individuals and firms that collect retail sales taxes receive a rebate for taxes paid in their Federal income taxes. This is an intergovernmental VAT. Tax withheld by employers for the income and payroll taxes of their labor force is an implicit VAT. A goods and services tax simply makes these taxes visible.

Should the tax reform proposed here pass, there is no need for an IRS to exist, save to do data matching integrity. States and the Customs Service would collect credit invoice taxes, states would collect subtraction VAT, the SEC would collect the asset VAT and the Bureau of the Public Debt would collect income taxes or sell tax-prepayment bonds.

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July 10, 2023

The Honorable Kay Granger
Chair
U.S. House
Committee on Appropriations

The Honorable Rosa DeLauro
Ranking Member
U.S. House
Committee on Appropriations

The Honorable Patty Murray
Chair
U.S. Senate
Committee on Appropriations

The Honorable Susan Collins
Vice Chair
U.S. Senate
Committee on Appropriations

Dear Chairs Granger and Murray, Ranking Member DeLauro, and Vice Chair Collins:

We the undersigned former and acting Surgeons General are writing to bring to your attention the effect that the $84 million rescission, enacted in the Fiscal Responsibility Act, will have on the training and operations of the U.S. Public Health Service (USPHS) Ready Reserve and Public Health Emergency Response Strike Team (PHERST) over the next 3 years.

If additional funds are not provided in the fiscal year 2024 appropriations bill, 206 officers and civilians will be relieved of duty and/or reassigned. This workforce reduction will have detrimental effects on the nation's ability to rapidly respond to public health emergencies.

Since 1798, the USPHS Commissioned Corps has protected the health and safety of the nation. Recently, USPHS Ready Reserve officers provided direct support to the National Guard Bureau during COVID–19 pandemic; they responded to the opioid crisis by training and assisting state and local governments in the proper use of naloxone for the treatment of drug overdoses; ensured evacuated Afghanis received proper medical care during the Operation Allies Welcome Safe Haven and resettlement missions; and met the health needs of vulnerable populations through innovative readiness training missions.

We respectfully request that $48 million be provided in the FY24 appropriations bill for the USPHS Commissioned Corps Ready Reserve Corps and PHERST ($20 million already requested in the President's budget and an additional $28 million to restore the rescinded funds for FY24). This funding will enhance the rapid response of the USPHS Ready Reserve and Public Health Emergency Response Strike Teams to meet the nation's public health needs.

Thank you for considering this request.

Respectfully,

(In order of term served)

Vice Admiral Antonia Novello, M.D.
14th Surgeon General of the United States

Rear Admiral Robert A. Whitney, D.V.M.
Acting

Rear Admiral Audrey Manley, M.D.
Acting

Admiral David Satcher, M.D.
16th Surgeon General of the United States

Rear Admiral Kenneth P. Moritsugu, M.D.
Acting

Vice Admiral Richard Carmona, M.D.
17th Surgeon General of the United States

Rear Admiral Steven Galson, M.D.
Acting

Rear Admiral Donald L. Weaver, M.D.
Acting

Vice Admiral Regina Benjamin, M.D.
18th Surgeon General of the United States

Rear Admiral Boris Lushniak, M.D.
Acting

Rear Admiral Sylvia Trent-Adams, R.N., Ph.D.
Acting

Vice Admiral Jerome Adams, M.D.
20th Surgeon General of the United States

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March 13, 2024

Distinguished Chair, Ranking Member, and all Members of the Committee, it is a privilege to have the opportunity to speak out against one of the largest scandals in the Biden Administration. It is a scandal that trades childhood for cheap labor. It is a tragedy that transforms children from a shining future into present day heartbreaking headlines. The reason for this turn of events is no mystery. *The New York Times* has a series of reports that make clear precisely who is to blame for the exploitation of children: Secretary of Health and Human Services Xavier Becerra. This statement for the record will catalog his actions for posterity.

In February 2023, *The New York Times* wrote (emphasis added):

> "His (Becerra) 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.
>
> . . .
>
> Concerns piled up in summer 2021 at the Office of Refugee Resettlement, the H.H.S. division responsible for unaccompanied alien children (UAC). 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*."[1]

In April of 2023, *The New York Times* continued their investigation of child endangerment by the Biden Administration and Mr. Becerra:

> "Again and again, veteran government staffers and outside contractors told the Health and Human Services Department, including in reports that reached Secretary Xavier Becerra, that children appeared to be at risk. The Labor Department put out news releases noting an increase in child labor. Senior White House aides were shown evidence of exploitation, such as clusters of migrant children who had been found working with industrial equipment or caustic chemicals.
>
> . . .
>
> Under the law, the Department of Health and Human Services is responsible for vetting sponsors to ensure they will provide for children's well-being and protect them from trafficking or exploitation. But as shelters filled with children, the department began loosening some vetting restrictions and urging case managers to speed the process along.
>
> Longtime H.H.S. staff members complained that the changes endangered children. White House aides and administration officials grew exasperated, believing that these workers were clinging to protocols that kept children in shelters when it was better for them to be in a home with an adult.
>
> "It was maddening," said Vivian Graubard, a White House adviser who worked with Ms. Rice on migrant child issues.
>
> At least five Health and Human Services staff members filed complaints and said they were pushed out after raising concerns about child safety.
>
> Jallyn Sualog was the most senior career member of the H.H.S. division responsible for unaccompanied migrant children when Mr. Biden took office. She had

[1] Alone and Exploited, Migrant Children Work Brutal Jobs Across the U.S., *https://www.nytimes.com/2023/02/25/us/unaccompanied-migrant-child-workers-exploitation.html.*

> helped build the program after the passage of the 2008 law and, as a lifelong Democrat, had celebrated Mr. Biden's win.
>
> But soon, she said, she began to hear reports that children were being released to adults who had lied about their identities, or who planned to exploit them.
>
> She warned her bosses in a 2021 email, "If nothing continues to be done, there will be a catastrophic event." She continued to email about situations she described as "critical" and "putting children at risk."[2]

If you are wondering why Secretary Becerra would push vulnerable children into domestic trafficking, an HHS spokesperson explained (emphasis added):

> "An H.H.S. spokeswoman said the department was aware that some migrant children worked long hours because they are under intense pressure to earn money, but **the agency's legal responsibility for children ends once they are released.** Still, the department is working to provide a few months of case management to all unaccompanied migrant children, she said.
>
> For now, most children released to sponsors have little support aside from an H.H.S. hotline. According to internal documents obtained by *The Times,* reports of trafficking to that hotline increased by about 1,300 percent over the past 5 years."

So the real motivation for a speedy assembly line of child placement was to get the children out of the zone of legal interest for HHS. They passed children to known traffickers so the kids would no longer be their legal problem. Secretary Becerra would have brought more honor to himself and the government if he had just left the children on the doorstep of a known, trustworthy church or nonprofit.

This scandal cannot be overstated. Mr. Becerra has placed the political interest of his boss, President Biden, over the welfare of the children he is duty-bound to protect. The cost of Secretary Becerra's decision has been staggering.

A Florida Grand Jury convened to investigate treatment of unaccompanied alien children (UAC) and was horrified by what they found:

> "If any resident of Florida exposed U.S.-born children to this process, they would be justifiably arrested for child neglect or worse. We do not think children should be less-protected simply because they were born outside our borders and brought here by a government agency."[3]

The Florida Grand Jury also observed a pattern of cover-up from Secretary Becerra and his department:

> "We stand in company with the United States Senate and House members in being actively obstructed by this agency This obfuscation extends beyond just ORR in the immigration context. Last March, NBC News reported that Border Patrol agents and officials, who had previously been responding to public record and media inquiries about the number of border apprehensions and conditions (including releasing videos), were subjected to a gag order prohibiting any media requests or sharing data on their own. We also learned that ORR actively discouraged its employees, including case managers and those tasked with conducting sponsor verifications, UAC interviews and post release follow-up, and fingerprint and background checks, from questioning the process even internally; some were transferred, some terminated, some threatened, and some smeared simply for not processing the UAC as quickly as possible. One was fired for reporting a case of suspected human trafficking (of over 100 UAC shipped off to a single house in Texas) to a government hotline because her ORR superiors refused to investigate the matter. One facility went so far as to set up a "reporting station" for employees to bring their concerns to; it was purported to be staffed with FBI agents, but was later learned to have simply other ORR employees—the agency was reporting itself, to itself. In one memorable instance, a federal employee was told by an ORR attorney to stop asking questions about potentially unsafe sponsors because doing so caused delay, and **[W]e only get sued for keeping them too long. We don't get sued by traffickers. Are we clear?**"

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[2] As Migrant Children Were Put to Work, U.S. Ignored Warnings, *https://www.nytimes.com/2023/04/17/us/politics/migrant-child-labor-biden.html.*

[3] THIRD PRESENTMENT OF THE TWENTY-FIRST STATEWIDE GRAND JURY REGARDING UNACCOMPANIED ALIEN CHILDREN (UAC), *https://acis-api.flcourts.gov/courts/68f021c4-6a44-4735-9a76-5360b2e8af13/cms/case/651d8f68-f322-4cd0-831f-74dc9b0d77a8/docketentrydocuments/8437d6e2-1c46-4575-bd21-47de83302c61.*

It is clear that there is a pattern from the top down to systematically shuffle children in HHS custody to the first adult willing to take them. This is, in part, a response to the overwhelming numbers that have arrived at the border during the Biden Administration. However, lack of resources does not excuse abuse. It was Secretary Becerra's duty to follow the law and protect the children in his custody. Instead he clearly prioritized the political standing of his Administration over the safety and security of the children under his control.

In essence, Secretary Becerra shifted the cost of President Biden's campaign rhetoric on immigration from the government to the children they encouraged to enter illegally. And pay, the children have.

Marcos Cux, 14, was profiled in *The New York Times:*

> "The belt caught the sleeve of Marcos's baggy jacket and pulled him across the floor. Hard plastic teeth ripped through his muscles, tearing open his forearm down to the bone. By the time someone heard his screams and shut off the power, his arm was limp, a deep triangular gash running down the length of it. A rope of white tendons hung from his elbow to his wrist, horrifying the workers who gathered around him. He understood from their faces that something was badly wrong but didn't feel any pain as the wound began gushing blood and he started to lose consciousness."[4]

Marcos is one of the more fortunate:

> "But as more children come to the United States to help their families, more are ending up in these plants. Throughout the company towns that stud the 'broiler belt,' which stretches from Delaware to East Texas, many have suffered brutal consequences. A Guatemalan eighth grader was killed on the cleaning shift at a Mar-Jac plant in Mississippi in July; a federal investigation had found migrant children working illegally at the company a few years earlier. A 14-year-old was hospitalized in Alabama after being overworked at a chicken operation there. A 17-year-old in Ohio had his leg torn off at the knee while cleaning a Case Farms plant. Another child lost a hand in a meat grinder at a Michigan operation."

Thanks to the feckless assembly line policies of Secretary Becerra, child trafficking in the United States is a billion dollar industry for transnational criminal organizations.[5] It is also helping unscrupulous employers by providing a steady stream of vulnerable labor.

The examples of the booming Biden child labor market are voluminous, but just a few examples will illustrate the impact:

- March 6, 2024: OWNER OF 20 HWY 55 BURGERS, SHAKES & FRIES RESTAURANTS ENTERS COMPLIANCE AGREEMENT, PAYS $11K IN PENALTIES FOR CHILD LABOR VIOLATIONS.[6]
- February 28, 2024, US DEPARTMENT OF LABOR OBTAINS COURT JUDGMENT ORDERING IDAHO FALLS RESTAURANT TO PAY $319K FOR ILLEGAL TIP SHARING, CHILD LABOR, OVERTIME VIOLATIONS.[7]
- Feb. 13, 2024, ADMINISTRATIVE LAW JUDGE UPHOLDS US DEPARTMENT OF LABOR FINDINGS OF CHILD LABOR VIOLATIONS, $38K FINE FOR UPSTATE NEW YORK WATER PARK.[8]
- Feb. 21, 2024, US DEPARTMENT OF LABOR SEEKS INJUNCTION TO STOP USE OF 'OPPRESSIVE CHILD LABOR' BY FAYETTE JANITORIAL SERVICE AT MEAT PROCESSING FACILITIES.[9]
- Feb 7, 2024, ROOFING CONTRACTOR PAYS $117,175 PENALTY AFTER 15-YEAR-OLD'S FATAL FALL AT ALABAMA WORK SITE.[10]

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[4] The Kids on the Night Shift, *https://www.nytimes.com/2023/09/18/magazine/child-labor-dangerous-jobs.html.*

[5] Smuggling Migrants at the Border Now a Billion-Dollar Business, *https://www.nytimes.com/2022/07/25/us/migrant-smuggling-evolution.html.*

[6] OWNER OF 20 HWY 55 BURGERS, SHAKES & FRIES RESTAURANTS ENTERS COMPLIANCE AGREEMENT, PAYS $11K IN PENALTIES FOR CHILD LABOR VIOLATIONS, *https://www.dol.gov/newsroom/releases/whd/whd20240306.*

[7] *https://www.dol.gov/newsroom/releases/whd/whd20240228-0.*

[8] *https://www.dol.gov/newsroom/releases/whd/whd20240223.*

[9] *https://www.dol.gov/newsroom/releases/whd/whd20240221-0#:~:text=SIOUX%20CITY%2C%20IA%20%E2%80%93%20The%20U.S.,while%20the%20department%20continues%20its.*

[10] *https://www.dol.gov/newsroom/releases/whd/whd20240207.*

- Feb 6, 2024, US DEPARTMENT OF LABOR FINES MICHIGAN POPEYES FRANCHISE $48K; RESTAURANT ALLOWED CHILDREN TO WORK HOURS THAT VIOLATE CHILD LABOR LAWS.[11]
- Feb. 1, 2024, US DEPARTMENT OF LABOR INVESTIGATION FINDS PENNSYLVANIA EMPLOYMENT SERVICE AGENCY EQUUS WORKFORCE SOLUTIONS VIOLATED FEDERAL CHILD LABOR LAWS.[12]

Keep in mind, this is just a list of Department of Labor completed investigations for March and February of this year. To list all publicly available examples of child labor occurring in the United States today would require expanding beyond the 10 page limit for submissions for the record.

As this distinguished Committee and the Congress as a whole considers the FY25 budget request from Secretary Becerra, they should keep in mind the source. This is a man who has for over 3 years presided over what has functioned as taxpayer-sanctioned child trafficking, leading to the exploitation and death of innocent children.

Secretary Becerra has acted knowingly to pursue policies he was warned would place children in dangerous situations where they would be forced into hard labor. Some of these children have been killed and others have been mutilated. Secretary Becerra has also been defiant in retaliating against whistleblowers opposed to child endangerment, and he has persisted in obfuscating and stonewalling any investigations into his policies.

With all of this in mind, Secretary Becerra's budget must include clear safeguards for the treatment of children entrusted into his custody. Not one cent of taxpayer money should arrive in Secretary Becerra's coffers without strings attached that ensure U.S. taxpayers are not complicit in child exploitation.

If you can judge a society by how it treats children, then the United States is worthy of severe condemnation at the moment. We need to unite to stop this senseless child exploitation. This includes requiring HHS to only deliver unaccompanied alien children to their parents or family members verified by medical means or certified and retained documentation, HHS should not deliver children to aliens already in the country illegally.

Additionally, it makes no sense for vulnerable children to be placed with sponsors who already have multiple children in their custody. HHS has regularly placed children with strangers who already have sponsored multiple children. This is clearly placing the children at risk of exploitation.

Unless the Senate wants to provide a blank check to a Department with a documented history of child abuse and cosign the calamity unfolding under Secretary Becerra, it needs to rein him in and implement policies to protect the children he has neglected.

James Massa
CEO

RESERVE ORGANIZATION OF AMERICA
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www.roa.org

STATEMENT OF MAJ. GEN. JEFFREY E. PHILLIPS, U.S. ARMY (RET.)

The Reserve Officers Association of the United States, now doing business as the Reserve Organization of America, is a military service organization incorporated under Internal Revenue Service Code section 501(c)(19), and comprising all ranks of service members, veterans, and family members of our nation's eight uniformed services separated under honorable conditions. ROA is the only national military service organization that solely and exclusively supports the reserve components.

ROA was founded in 1922 by General of the Armies John "Black Jack" Pershing, during the drastic reductions of the Army after World War I. It was formed to support a strong national defense and focused on the establishment of a corps of reserve officers who would be the heart of a military expansion in the event of war. Under ROA's 1950 congressional charter, our purpose is unchanged: To promote the devel-

[11] *https://www.dol.gov/newsroom/releases/whd/whd20240206-0.*
[12] *https://www.dol.gov/newsroom/releases/whd/whd20240201.*

opment and execution of policies that will provide adequate national defense. We do so by developing and offering expertise on the use and resourcing of America's reserve components.

Executive Director:
Maj. Gen. Jeffrey E. Phillips, U.S. Army (Ret.) 202–646–7701

Director, Legislation and Military Policy:
Matthew L. Schwartzman 202–646–7713

DISCLOSURE OF FEDERAL GRANTS OR CONTRACTS

The Reserve Officers Association of the United States, now doing business as the Reserve Organization of America, has not received any grants, contracts, or subcontracts from the federal government in the past 3 years.

CURRICULUM VITAE

Jeff Phillips became the executive director of the Reserve Organization of America (ROA) on December 8, 2014.

Now retired from the U.S. Army, Major General Phillips last served as the deputy commanding general (U.S. Army Reserve) of the Army's Training and Doctrine Command, at Fort Eustis, VA. In this position, he was responsible for ensuring that the Army Reserve's requirements and capabilities were reflected in Army training and training doctrine.

His decorations include the Distinguished Service Medal, two Legions of Merit, two Bronze Star medals and the Army Parachutist Badge.

Chairman Wyden, Ranking Member Crapo, and distinguished members of the Senate Committee on Finance, on behalf of the Reserve Organization of America (ROA), the only national military organization that solely and exclusively supports the uniformed services' reserve components, thank you for the opportunity to submit a statement for the record on the Fiscal Year (FY) 2025 budget request for the Department of Health and Human Services (HHS).

HHS' FY 2025 budget request is significant, aiming at $130.7 billion in discretionary and $1.7 trillion in mandatory proposed budget authority.[1]

However, despite HHS advocating for needed benefits, programs, and authorities for the Ready Reserve Corps (RRC) of the U.S. Public Health Service (USPHS) in its *FY 2025 Justification of Estimates for Appropriations Committees,* its FY 2025 budget request **does not** include any resources to sustain the USPHS RRC.

In alignment with Resolution No. 23–02,[2] *Enact the Parity for U.S. Public Health Service Ready Reserve Act,* unanimously passed by our members at our annual convention this past year, ROA urges the leaders and members of this Committee to:

1) Ensure $28 million in funding is included in HHS' FY 2025 budget to sustain the USPHS RRC; and
2) Support S. 2297, the *Parity for Public Health Service Ready Reserve Act.*

Despite a rich history dating back to 1798, the USPHS did not have a functional RRC until the March 27, 2020, signing of Public Law No: 116–136, the *Coronavirus Aid, Relief, and Economic Security (CARES) Act.*

The USPHS RRC program, endorsed by 12 former and acting Surgeons General,[3] is part of a substantial modernization effort to enhance the USPHS' capabilities and support the medical readiness of its uniformed services counterparts. In particular, the USPHS RRC meets the current challenges of maintaining the nation's health security by:

- Supporting the USPHS' capacity to respond to regional, national, and global health emergencies.
- Improving access to health services and qualified health professionals for the Total Force.
- Preserving clinical care positions for USPHS Regular Corps officers by maintaining a surge capability of personnel available for deployment without jeopardizing the service of clinicians in hard-to-fill roles.

[1] *https://www.hhs.gov/about/budget/fy2025/index.html.*
[2] *www.roa.org/resource/resmgr/legislation/resolution_no._23-02_enact_t.pdf.*
[3] *https://www.coausphs.org/common/Uploaded%20files/Ready%20Reserve%20Legislation/Letter%20from%20SGs.pdf.*

- Enabling access to highly specialized skill sets that would be impractical in full-time active duty positions.
- Providing an additional avenue of service for mission-driven clinical and public health professionals who cannot commit to a full-time position in the USPHS Regular Corps but can provide a full-time capability.[4]

SEC. 3214 of the *CARES Act* was successful in providing a preliminary framework for the proper and effective usage of the USPHS RRC.

However, it failed to provide the RRC with a codified structure and access to the proper "tools" for recruiting and retaining qualified talent, including:

DUAL COMPENSATION

Under current law, workers cannot receive payment for two separate federal jobs. While an exemption is granted for a reserve component member of an armed force, it is not for a reserve component member of a uniformed service.

As a result, USPHS RRC officers cannot work for the federal government for their civilian job.

LEAVE

USPHS officers must be available for deployment or for emergencies on extremely short notice. They are available for activation 24 hours a day, 7 days a week.

The number of public health and emergency response missions executed by the USPHS has increased by 44 percent over the last decade.

Between 2013 and 2019, the USPHS deployed over 7,800 officers for a cumulative total of over 139,000 deployment days.

Between 2020 and 2023, the USPHS deployed its officers over 6,400 times in support of over 1,000 missions, contributing to 187,000 deployment days.

As USPHS officers have more frequent and longer deployments (responding to urgent public health demands across the nation) leave becomes even more necessary to allow officers respite time to recover and recuperate physically and psychologically.

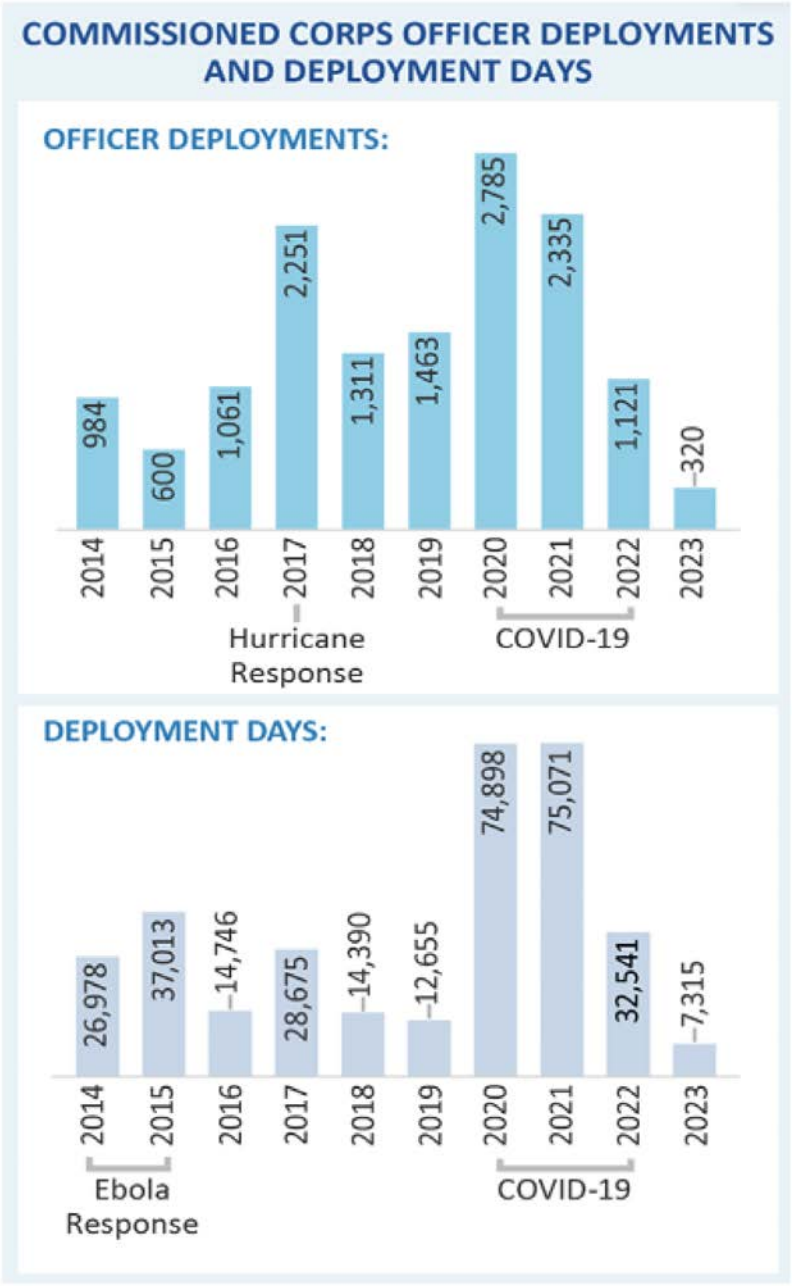
However, leave time is important not just for rest and recuperation, but also for emergencies and special needs.

Providing USPHS officers with the same leave opportunities as those in the other uniformed services goes beyond parity. It will also improve morale and officer performance, formally recognize the pressures faced by USPHS officers in the line of duty and provide USPHS officers with the means to meet the needs of their personal life.

Several examples of leave not currently offered to officers of the USPHS Commissioned Corps and its RRC include:

- Parental leave (including primary and secondary caregiver leave)
- Convalescent maternity leave
- Court appearance leave
- Emergency leave
- Child support leave
- Marriage leave
- Graduation leave

[4] *https://www.usphs.gov/ready-reserve.*



Source: *https://www.hhs.gov/sites/default/files/fy-2025-budget-in-brief.pdf*

TRICARE RESERVE SELECT, TRICARE DENTAL, AND TRICARE RETIRED RESERVE

Despite currently serving and retired members of the USPHS' Regular Corps having access to TRICARE, members of the USPHS RRC do not.

Extending TRICARE medical and dental coverage to currently and formerly serving members of the USPHS RRC would show that the government values all contributions of all the uniformed services' and is willing to invest in the health of their public health officers.

This will also ensure that all RRC officers receive healthcare coverage, regardless of their civilian employment status.

TRICARE LINE OF DUTY CARE

The USPHS RRC is the only component of a uniformed service that does not receive healthcare coverage for injuries sustained when staying overnight before or during inactive-duty training or while on funeral duty.

For example, a USPHS RRC officer would not receive healthcare coverage in the following situation:

> A USPHS RRC officer does their weekend inactive duty training (IDT) at a site several hours away from their home. The officer travels on a Friday (before training starts on Saturday morning) and spends the weekend in a hotel. If the officer sustains an injury (due to no fault of their own) sometime Friday, the officer still would not be covered for any healthcare associated with the injury. This would also apply if the injury were to occur sometime Saturday night after IDT.

If an identical fact pattern occurred with a reserve component member of an armed force, they would be provided with TRICARE Line of Duty coverage.

TRICARE Line of Duty coverage pays for healthcare that is needed due to an injury or illness that occurred during required (and voluntary) military training days, such as IDT.

This disparity is especially egregious when considering that the injury would likely have not been suffered if not for the service requirement.

Further, additional danger may be posed to the officer if they are forced to drive to and from their home to receive the care they need.

GI BILL

USPHS RRC officers currently do not have access to vital educational benefits, including the Post 9/11 GI Bill and Montgomery GI Bill Selected Reserve (MGIB–SR). This is not the case for their armed forces reserve component counterparts.

The good news is there is legislation that would resolve these disparities and enable the USPHS Commission Corps to recruit, retain, and mobilize RRC members: S. 2297, the *Parity for Public Health Service Ready Reserve Act.*

ROA thanks Sen. Tammy Duckworth (IL) and you, Chairman Wyden, for your sponsorship of S. 2297, which provides:

- A codified reserve component structure.
- Access to training exercises held by the other uniformed services.
- Access to medical and dental care under TRICARE Reserve Select, the TRICARE dental program, and TRICARE Retired Reserve.
- Access to dual compensation and military leave rights while deployed.
- Access to the Post-9/11 GI Bill and MGIB–SR.
- Representation on the Reserve Forces Policy Board, a federal advisory committee making recommendations directly to the Secretary of Defense to enhance reserve component readiness.
- $13.6 million in authorized annual funding for programmatic sustainment.

The bad news is this legislation has not been signed into law.

As a result, the USPHS RRC has yet to achieve its desired end-strength or realize its full capability.

This is presumably why funding for the USPHS RRC was eliminated by Public Law No: 118–5, the *Fiscal Responsibility Act* (FRA).[5] More precisely, the *FRA* eliminated

[5] *https://www.congress.gov/118/plaws/publ5/PLAW-118publ5.pdf.*

$84 million in funding over 3 FYs ($28 million per year) previously supplied by Congress via Public Law No: 117–2, the *American Rescue Plan Act of 2021.*[6]

To be clear:

- ROA **opposes** the *FRA*'s revocation of $84 million in funding, which may eliminate the USPHS RRC.
- ROA **opposes** HHS' exclusion of funding to sustain the USPHS RRC in its FY 2025 budget request.
- ROA **supports** restoring the USPHS RRC program with $28 million in funding for FY 2025 (a .021% increase in HHS' FY 2025 discretionary budget authority request).
- ROA **supports** S. 2297, the *Parity for Public Health Service Ready Reserve Act,* which provides the USPHS RRC with the tools it needs to further demonstrate its value and potential to the Commissioned Corps, the Total Force, and the nation.

That said, even without recruiting and retention tools, envisioned end-strength, and a codified structure, the USPHS RRC has proven its effectiveness and potential already by:

- Augmenting the National Guard Bureau's medical teams through delivering needed medical and public health expertise during times of crisis, including the COVID–19 pandemic.
- Supporting the Operation Allies Welcome safe haven and resettlement missions to ensure evacuees received medical care.
- Providing medical care at the National Park Service Yosemite clinic to avoid complete clinic closure.
- Delivering no-cost healthcare to vulnerable populations through the Department of Defense's innovative readiness training missions.

As such, ROA urges your support for rapidly replenishing the response capabilities of the UPSHS Commissioned Corps and Total Force medical corps by restoring the USPHS RRC program with $28 million in funding for FY 2025 and codifying S. 2297, the *Parity for Public Health Service Ready Reserve Act,* in public law.

CONCLUSION

Thank you again for accepting ROA's statement for the record on HHS' FY 2025 budget request.

All too often military and veterans' law and policy are developed without an understanding of or appreciation for the distinctions between reserve and active duty service. The members of the Reserve and National Guard invariably lose out. And so, too, their families. That means America's military readiness loses out. We cannot afford that loss.

ROA stands ready to provide added support to the issues covered in this statement and looks forward to working with you further on other areas of mutual interest.

LETTER SUBMITTED BY JESSE P. SAMLUK, PH.D.

Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Re: The President's Fiscal Year 2025 Health and Human Services Budget

March 14, 2024

To Whom It May Concern:

I am writing this statement for the record regarding the President's Fiscal Year (FY) 2025 Health and Human Services (HHS) Budget, with respect to the hearing that was held on Thursday, March 14, 2024.

The dialog between Secretary Becerra and members on the Finance committee surrounded various issues, including lowering prescription drug costs, combating the opioid epidemic, cybersecurity, healthcare in rural parts of the country, COVID–19, and unaccompanied minors at the border. Some of these goals are laudable and

[6] *https://www.congress.gov/117/plaws/publ2/PLAW-117publ2.pdf.*

should be pursued to the fullest extent, and others are arguably solely for political gain.

Regardless of political views and other idealogues, there is one important thing that Secretary Becerra and the rest of the committee did not discuss; the Commissioned Corps of the United States Public Health Service (USPHS). The lack of comment or any mere mention of this vital service was as though this service branch never existed. Each area of concern that the Secretary highlighted, a USPHS officer was connected to in one way or another. However, it appears that all too often this particular service is easy to forget about, even though the service has been in existence since 1798—well before HHS was a Department.

In that case, I will make it known that there are a multitude of issues facing the service as a whole. Mainly, as a result of the Fiscal Responsibility Act of 2023, funding for 2 components of the USPHS, the Public Health Emergency Response Strike Team (PHERST) and the Ready Reserve, were cut to the point that PHERST was all but discontinued, and the Ready Reserve has also been impacted to the point that members of that cadre are unsure if their component will survive. Training has also been impacted for members of the Regular (Active) component.

While this is concerning for members of the service given financial constraints and so forth, more importantly, the unfortunate wind down of the PHESRT and Ready Reserve affects the areas and the people that the USPHS serves. For example, the service was on the front lines of HHS' COVID–19 response, which led the USPHS to experience its largest deployment in history. The USPHS provided health care to our Native American populations and served thousands of unaccompanied minors when HHS was unable to obtain contractors. The Ready Reserve and PHERST officers were some of the key players during these responses. Even with all their success, out of the $1.7 *trillion* dollar budget for the entirety of the HHS portfolio, there is $0 for PHERST, the Ready Reserve, or Training *(which is a Secretarial requirement stated in 42 U.S. Code § 204a)* **Yes, $0. And this issue was not discussed—at all.**

I'll close on this note. I know the Armed Forces provide a necessary service to our country. So does the USPHS. Imagine, for example, if NDAA discussions "zeroed out" the entire budgets of the Armed Forces Reserves and National Guard. Of course every Congress member and Secretary concerned would be very vocal about this situation. When it comes to the USPHS, why is the same level of concern and urgency not present?

Jesse P. Samluk, Ph.D., Esquire
LTJG, USPHS Ready Reserve
Assistant Engineer Officer

TRANSPARENCY-RX, AMERICAN PHARMACY COOPERATIVE, INC.,
AND THE ERISA INDUSTRY COMMITTEE (ERIC)

March 13, 2024

The Honorable Ron Wyden
Chair
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Wyden and Ranking Member Crapo,

On behalf of Transparency-Rx, APCI, and ERIC, we write collectively to you to express continued support for the Senate Finance Committee's ("Committee") work and heightened attention on PBM reform as you consider the Fiscal Year 2025 (FY25) Health and Human Services (HHS) budget.

Our unique perspectives as employers, pharmacists, and pass-through, transparent PBMs reflects our shared values and point view that meaningful reform is both ripening and embraced in government and commercial markets but must be prioritized.

Transparency-Rx[1] is a non-profit coalition of pharmacy industry experts led by transparent PBMs representing over 16 million covered lives with operations, em-

[1] Transparency-Rx: 20130 Lakeview Center Plaza, Ste. 400, Ashburn, Virginia 20147, US.

ployers, patients, and plans in all fifty (50) states. Transparency-Rx's members are committed to increasing transparency in the prescription drug market and lowering costs. Jointly, we offer these comments in the hopes that they are helpful to the Committee in its work to rein in problematic practices of large PBMs—a priority for both organizations' members. American Pharmacy Cooperative, Inc.[2] ("APCI") is a member-owned cooperative consisting of approximately sixteen hundred (1,600) independent pharmacies in thirty (30) states and is committed to prescription drug pricing transparency and lowering costs. ERIC is a national nonprofit organization exclusively representing the largest employers in the United States in their capacity as sponsors of employee benefit plans for their nationwide workforces.

We write to urge continued consideration of badly needed PBM reform and transparency measures, at the administrative and legislative levels. Without forceful action, contemplated in legislation including MEPA and provisions in BETTER, Medicare beneficiaries and employers will continue to face stifled choice and competition, degrading quality of care and raising drug prices for America's seniors and working families.

It is now common knowledge that there is a high level of monopolization or in the words of one of your Senate colleagues, "cartels" in the commercial PBM marketplace, with the three biggest PBMs controlling ~80% of the market. However, in Medicare, Part D, it is less well known that levels of monopolization *are far worse, nearing 100%.* For Medicare, this market-concentration and control has been disastrous for seniors, pharmacists, and working families, driving unfettered use of spread-pricing, junk fees, and increasingly other frowned upon practices by big PBMs. Research shows, in fact, in seventy one percent (71%) of Medicare Part D cases, net costs were highest from vertically integrated PDPs to their vertically integrated pharmacies, meaning that, for these cases, *vertical integration likely have resulted in higher costs to Part D and their enrollees.*[3] A second study focused on Part D concluded despite Medicare being the largest buyer of Eliquis, a leading cure preventing strokes, corporate spread pricing PBMs hit seniors with the worst price increases, dramatically marking-up what drug makers will sell it for. Moreover, large PBMs were found to set drug prices higher when beneficiaries had out of pocket costs. The study concluded large PBMs not manufacturers set drug prices for patients at the counter, and created massive variability in drug prices even when the benchmarks of acquisition cost set by CMS were stable.

The pervasiveness and repetition of bad big PBM practices in Medicare, commercial sectors, and Medicaid, call out a demand for clear and comprehensive reform. Robust and actionable information on pricing, rebates, fees, and discounts through the GPO, is essential for employers, patients, and seniors to make informed decisions and maintain a functioning and free market for prescription drugs. The committee's initial introduction of MEPA and BETTER in 2023 are notable as the Committee's combined legislative proposals set a pioneering standard in the bubbling PBM reform debate. Specifically, the Committee aimed to take concrete steps to ameliorate the burden of high list prices that big PBMs have shifted onto patients, seniors and plans. MEPA and BETTER would prohibit PBMs from linking rebates paid by manufacturers to the list price of drugs, and instead implement a flat service fee. This policy is otherwise known as "delinking," and is the very essence of a transparent approach, which transparent PBMs along with local businesses already embrace. In a delinked or transparent approach, fees are disclosed, reliable, and knowable, and attempt to cure the drug affordability crisis in America, reducing employers' health care costs on average by 15–20%. Without delinking in Medicare and commercial markets, seniors and patients come second to PBM profits. We strongly support it in all markets.

Each of our organizations continues support the Finance Committee's work to consider legislative proposals which increase transparency, oversight, and enforcement of PBM practices, and we appreciate heightened attention by the Biden Administration to PBM reform.

Despite increased Congressional interest, the prescription drug pricing and reimbursement system remains opaque. If big PBM's bottom lines are cushioned by higher drug prices extracted from the pockets of hard-working Americans and seniors and job-creators, insurers or PBMs will never lower drug prices, without an innovative policy proposal advancing through Congress and the Executive Branch addressing their misaligned incentives, market control, and many conflicts of interest.

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[2] American Pharmacy Cooperative, Inc.: 5601 Shirley Park Drive, Bessemer, Alabama 35022.
[3] Chapter 2 of the MedPAC June 2023 report to Congress.

We deeply appreciate your leadership. Please let us know if there is anything we can do to help see your on-going impactful work succeed.

Sincerely,

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