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THE PRESIDENT'S FISCAL YEAR 2023 HEALTH AND HUMAN SERVICES BUDGET

HEARING

BEFORE THE

COMMITTEE ON FINANCE UNITED STATES SENATE

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THE PRESIDENT'S FISCAL YEAR 2023 HEALTH AND HUMAN SERVICES BUDGET

TUESDAY, APRIL 5, 2022

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

The hearing was convened, pursuant to notice, at 10:08 a.m., via Webex, 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, Warner, Whitehouse, Hassan, Cortez Masto, Warren, Crapo, Grassley, Cornyn, Thune, Portman, Toomey, Cassidy, Lankford, Daines, Young, and Barrasso.

Also present: Democratic staff: Shawn Bishop, Chief Health Advisor; Peter Fise, Health Counsel; Kristen Lunde, Health Policy Advisor; and Joshua Sheinkman, Staff Director. Republican staff: Erin Dempsey, Deputy Health Policy Director; Kellie McConnell, Health Policy Director; Gregg Richard, Staff Director; Conor Sheehey, Senior Health Policy Advisor; and Jeffrey Wrase, Deputy Staff Director and Chief Economist.

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 the committee meets with Secretary Becerra to discuss the year ahead for the Department of Health and Human Services. There is much to cover, and I will begin with telemedicine.

This committee began to open the door to telemedicine in Medicare with the landmark CHRONIC Care Act authored with Senator Hatch in 2017. Then in 2020, we shoehorned telehealth services into the CARES Act. In implementing the law, Medicare decided to cover telehealth audio-only on a temporary basis during the pandemic. That has been met with wide-open arms from people across the country, especially in rural communities.

In this year's appropriation bill, our colleague, Senator Crapo, and I pushed together to extend the audio-only flexibility beyond the public health emergency. There is, as you will hear this morning, Mr. Secretary, bipartisan interest in building on the telemedicine progress. We want to make it permanent, and we want to make sure that we are not going to turn the clock back on patients who have come to rely on these critical services.

I think you can count on plenty of discussion of that today.

Now, Senate Democrats and the administration are committed to protecting bedrock health-care programs, strengthening the Afford-

able Care Act, and upholding the Medicare guarantee. Sadly, Republicans in the Senate have other ideas. Senator Rick Scott, the campaign visionary for Senate Republicans, recently proposed phasing out Medicare in 5 years. I am curious how America's 60-year-olds are going to feel about that one. Next, Senator Ron Johnson has doubled down on a long-time crusade of repealing the Affordable Care Act altogether. Senator Johnson says Republicans ought to be preparing their repeal bill now, to have it ready to go when they take power.

If it looks like it did last time, it is going to gut health care in America for tens of millions and shower tax handouts to the wealthy. That is not what Oregonians and Americans I am talking to have on their mind. The biggest concern going today for millions of families in my State of Oregon and across the country is the rising cost of living. Bringing down health-care prices and protecting Americans from getting clobbered with huge bills is one of the best ways for Congress to take some of the pressure off the pocketbooks of Americans.

A couple of areas I will highlight. For one, millions of Americans are getting a better deal on their health insurance this year because of the Rescue Plan passed in March of 2021. Monthly premiums for Americans who get insurance on the individual market fell by more than 22 percent this year, adding up to hundreds of dollars or more over 12 months. People across all income levels save money. Six million new consumers got coverage. Go back some decades and Republicans would be shouting from the mountain tops about the incredible success of the private marketplace. Not so in 2022. These days, Republicans have gone on record against the tax credits that have made the success I just mentioned possible.

If Republicans have their way, millions of Americans are going to get hit by higher health insurance premiums in 2023. That cannot be allowed to happen, and Democrats will keep pushing to make sure those savings continue.

The administration and Democrats in Congress are also working in lockstep to bring down prescription drug prices. For so many Americans, every trip to the pharmacy counter means getting mugged by the drug companies. Instead of using the bargaining power of more than 60 million American seniors to get lower prices, Medicare's hands, under current law, are tied behind its back.

Changing that by giving Medicare the authority to negotiate a better deal for brand-name drugs is the single most important reform on offer. Democrats also plan to cap copays for insulin at $35 a prescription, and set an out-of-pocket cap for seniors' prescriptions in Medicare Part D at $167 per month.

The plan would also create a tough new price-gouging penalty for drug companies that increase prices over inflation. This plan also will save money for patients on Medicare and in the private market, and it is going to save taxpayers billions of dollar each year.

So, getting a better deal on health insurance and prescription drugs, these are the kinds of savings that, on our side of the aisle, we are going to insist on—not because of political reasons, but because millions and millions of Americans of all political views desperately need that help now. We have got to step up and deliver.

Finally, let me note the bipartisan work in the committee that is going on with respect to mental health care. Senator Crapo and I have talked about it often. This is one of the most important initiatives this committee has pursued, given the fact that there was a problem before the pandemic. That problem might have been here [raising hand]. After the pandemic, it has mushroomed [raising hand higher], and we hear it from kids, we hear it from families, we hear it from seniors, we hear it in rural communities. We hear about it every time we are home.

And adding Medicare coverage for seniors for sessions with a therapist or a counselor, getting rid of caps on Medicare coverage for care in a psychiatric hospital, smart proposals that the Biden administration is making with respect to Medicare and Medicaid, these are all important efforts, and we are going to support them, along with waiving cost sharing for up to three mental health visits a year in Medicare and private insurance. And let me note that my seatmate here has been leading the Congress in expanding Medicaid funding for Certified Community Behavioral Health Clinics. And we are making a special focus on that as part of our bipartisan efforts in the committee.

These proposals we are talking about, the proposals that are in the budget, the proposals that this committee is working on, are going to be a lifeline to people who are struggling to connect with mental health providers.

You are going to get some questions on this, for sure, Secretary Becerra, because members on both sides of this committee are laser-focused on mental health care. We look forward to working with the administration on these issues in a bipartisan way.

We want to thank you, Secretary Becerra, for being here. There is lots to talk about.

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

The CHAIRMAN. Senator Crapo?

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

Senator CRAPO. Thank you, Mr. Chairman, and thank you, Secretary Becerra, for being here with us today.

Our Federal health-care programs face a range of pressing challenges which demand serious solutions. Today's hearing provides a crucial opportunity to highlight both shared opportunities and priorities and concerns with respect to the proposals put forward by the President.

As a part of the Cancer Moonshot initiative, the administration has rightly acknowledged the value of multicancer early detection tests which have the potential to boost the cancer survival rate, while driving down costs. Earlier in this Congress, I reintroduced bipartisan legislation with Senator Bennet to ensure Medicare coverage for those screening tools, and I look forward to working with you, Secretary Becerra, to move this bill across the finish line.

The budget proposal's focus on mental health also offers potential for common ground. Unfortunately, other aspects of the budget request raise substantial questions. It is imperative that we work now to keep Medicare strong not only for current enrollees, but also

for future generations. The Medicare trustees have repeatedly cautioned that the program's financial shortfalls will require legislative action, with the hospital insurance trust fund projected to reach insolvency in 2026.

We have yet to receive this year's trustee's report, but the President's budget includes no proposals to shore up the trust fund's solvency. In fact, the document contains virtually no sources of Medicare savings at all, instead opting for a long list of coverage expansions, often with no cost estimates. Proposing dozens of new spending policies with no sense of their budgetary effect risks deepening the deficit and exacerbating inflation. A similar pattern persists for the budget request's Medicaid provisions, which would add billions in new spending without any meaningful cost savings reforms.

Compounding these onerous impacts, the budget includes a placeholder for a reckless tax and spending package, presumably the nearly $5-trillion House-passed Build Back Better Act that was defeated on a bipartisan basis last year and rejected across this country. The government price controls, Obamacare subsidy hikes, and other misguided policies included in that bill would intensify the hardships that many Americans currently face.

Under the package's price controls, we would inevitably see fewer cutting-edge treatments and higher launch prices for new drugs, and a drastic decline in innovative R&D, once again handing the Chinese Communist Party a competitive edge. Long-term Obamacare subsidy expansions, meanwhile, would double down on skyrocketing Federal spending and force taxpayers to fund coverage for Americans with six-figure salaries. These policies would worsen the economic outlook for working families. By continuing to push forward this problematic agenda, the proposed budget has missed a key opportunity to address urgent issues and needs.

As States and health-care providers across the country look to the budget for this year ahead, uncertainty abounds. The complex layers of flexibilities and coverage mandates tied to the public health emergency necessitate clear and comprehensive communication and accounting, particularly as stakeholders attempt to map out the path to post-pandemic normalcy. Without greater transparency both for Congress and the Nation, this process could prove unpredictable and needlessly costly. Coverage dynamics, for instance, will likely be volatile at the end of the public health emergency, yet this budget provides no plan for transitions in care.

Last year's $1.9-trillion partisan spending bill suffered from poor planning and prioritization, with only around 1 percent of the package's funding directed to vaccines and therapeutics. This year's budget request provided a chance to chart a more thoughtful return to normalcy, continuity, and fiscal responsibility. Disappointingly, the document does not rise to that occasion.

Secretary Becerra, I look forward to engaging with you on these and other issues in the months ahead, particularly as my colleague, Senator Wyden, mentioned, on telehealth, which continues to enjoy broad bipartisan support.

Thank you again for being here, and thank you, Mr. Chairman.

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

The CHAIRMAN. Thank you, Senator Crapo. We are going to you, Mr. Secretary, in just a minute. I just want to make one quick comment about the trust fund, because this, I am sure, is going to come up through the course of the morning.

We all understand that we are going to have to work on this in a bipartisan way. So the question is, where are you going to start? Are you going to start with cutting costs, or are you going to start with cutting benefits? We have made it clear in our work with respect to prescription drugs, we are all in on measures to cut costs. That is where we are going to start. We are going to work in a bipartisan way. We are not going to start with cutting benefits. We are going to start with cutting costs.

Please go ahead, Mr. Secretary, with your comments.

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

Secretary BECERRA. Chairman Wyden and Ranking Member Crapo, and each of the members of the committee, I want to thank you for this opportunity to discuss the President's Fiscal Year 2023 budget for the Department of Health and Human Services.

Today, if I could start, more than 255 million Americans have received at least one dose of a COVID–19 vaccine. Two-thirds of adults over age 65 have gotten their booster shots. We have also closed the gaps in vaccine rates that we usually see for communities often left behind.

It has paid dividends to surge resources, including tests and treatments, to our hardest-hit and highest-risk communities. Three hundred and twenty-five million free COVID–19 at-home tests have been shipped; 270 million free N95 masks.

From the $186 billion appropriated by Congress for the Provider Relief Fund, over 400,000 providers have received more than 766,000 payments for COVID services. Again, that is over 400,000 doctors, hospitals, community health centers, pharmacies, labs, nursing homes, and long-term care facilities, all receiving this critical support. That is real money, real relief, real results.

Now yesterday, I had a chance to meet with Medicare beneficiaries who are now able to purchase their over-the-counter COVID–19 tests with their red, white, and blue Medicare card. Mr. Chairman, this marks the first time that Medicare has covered an over-the-counter test at no cost to beneficiaries. That is a game-changer.

Beyond COVID–19, today more Americans have insurance for their health care than ever before. And that of course includes a record-breaking 14.5 million Americans who secured health insurance through the Affordable Care Act. That is a big deal, as we know someone once said. Also today, the Biden administration is issuing a rule that will fix the health insurance so-called "family glitch," which leaves out family members from affordable coverage. Less noticed, we launched Operation Allies Welcome, an HHS-led effort that has helped over 68,000 of our Afghan brothers and sisters resettle as refugees in America. And we are coordinating nearly $300 million in Nationwide support for the launch of the 988 national suicide prevention lifeline this July.

HHS has also made key investments to close holes in our public health system, areas like maternal health, where we have extended Medicaid coverage for postpartum care for a new mother and her baby from 2 months to 12 months.

The President's 2023 budget lets us build on that record of investment in Americans' health. It proposes $127 billion in discretionary budget authority and $1.7 trillion in mandatory funding, including a historic investment to transform the mental health infrastructure in our country, a priority I know you share.

It also asks for $82 billion for the President's pandemic preparedness proposal to get ready for whatever might come next after COVID–19. Considering that COVID has cost this country more than $4.5 trillion in direct support from the Federal Government so far, this is a no-brainer to prepare for the next pandemic. The funding we are requesting will be end-to-end for research and development, approvals, deployment, and effective response.

Budgets represent not just dollars and investments, but our values and our priorities. This budget turns hardship into hope, and inclusion into opportunity. And it is a commitment to finish the fight against COVID–19 and build a healthier America.

Mr. Chairman and members of the committee, I look forward to working with you to make the President's 2023 budget a reality, and to continue our efforts to give Americans real relief, real results, and real peace of mind.

With that, let me yield back and answer any questions you might have.

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

The CHAIRMAN. Thank you, Mr. Secretary. And it is going to be a little hectic even by Congress's standards this morning, because we are going to be going back and forth on some procedural votes with respect to our outstanding nominee to serve on the Supreme Court.

Mr. Secretary, I am going to start with you on mental health parity. And we had testimony a week ago from leading experts in the field that private insurers, the big private insurers, are making a mockery out of the parity law. You remember the history. We all looked at that and said what Senator Wellstone and Senator Domenici had achieved would finally be justice for families. And this is something that member after member on this committee knows personally, as the Wyden family does, with respect to experiences with family members.

One of the really shocking aspects of this is that the GAO, not a partisan organization, basically said that the insurance system is riddled with something they called ghost networks—their words not mine: ghost networks. When you have a ghost network run by one of these big insurance outfits, you cannot get to providers. You have a bunch of directories that are out of date, do not give you any information. And then the ultimate insult is, their payments are so puny that the person basically, and the family, is eating all the costs themselves. It just makes a farce out of the parity law, which of course said that mental health and physical health would be treated fairly.

What is the administration's agenda to take on these big private insurers? Because I think, Mr. Secretary—you and I worked together when we were in the Congress—somebody is going to have to make it clear that this is a priority, because they are using every trick in the book to get out of honoring the law.

At the Oregon Health Sciences Center, for example, they had, during the pandemic, all these bills that did not get paid. And I had visited with them, and they said, "Well, the insurer said we do not have any people, and nobody can process the bill." So I met with the GAO, and the GAO opened an investigation. And then, what a surprise. All of this money started gushing into the Oregon Health Sciences Center. And we all laughed a little bit, but you almost feel like crying because, essentially, you walked away with the judgment that these insurance companies would not pay unless they got embarrassed by the local member of Congress in the newspapers.

So what is the administration's plan—I know you are very interested in this topic—to really go after the big insurers, the big companies that make huge sums in the mental health field, and to really crack down on these abuses?

Secretary BECERRA. Mr. Chairman, what you have just articulated, I believe, would probably be expressed by the vast majority of American families who feel this. And what the President has essentially directed us to do is to figure out a way where we can get some progress. So for example, we are going to, in this budget, provide States with more money to enforce those parity laws, so that they can actually go out there and do that. We are going to try to support States that are trying to move towards those parity laws in ways that are meaningful so that you have true services that you can access as a family member.

We are going to try to eliminate the 190-day lifetime limit on psychiatric hospital services that are available to families under Medicare, working with you to do that. We are going to try to do what we can, like we did last year with the American Rescue Plan, where we put in a $3-billion investment in behavioral health services, half of it going to mental health services, half of it going to substance use disorder services, so we could prime the pump to get things moving.

But as you said, today we know, as a result of COVID especially, families are really suffering mental stress.

The CHAIRMAN. And, Mr. Secretary, I am going to let my colleagues ask their questions, because time is so short this morning. I think all of those steps are very good and very constructive, and I support all of them.

I just hope you will really hold some of these big private insurers accountable, because the foot-dragging takes your breath away. I saw in the press the other day, one of them said, "Well, we are just coming around to the law. We are just getting adjusted to it." And you say to yourself: "Are you kidding me?" This law has been on the books for 13 years—13 years of foot-dragging and excuse-mongering that is pretty much the order of the day. So I very much look forward to working with you on it. And let's really make an example. Make an example with two or three of these companies, and we will be in a position to get some real changes.

I have a couple of my colleagues voting. Senator Grassley, you are next.

Senator GRASSLEY. Thank you, Senator. And thank you, Mr. Secretary, for being here.

The first thing is to thank you for allowing transitional health insurance plans to be sold next year. Sixty-five thousand Iowans will benefit from that. This is something I have urged you to do. These are farmers and small business people who have chosen to keep their health insurance that they purchased between 2010 and 2013.

My first issue is about over-the-counter hearing aids. Thank you for your commitment to implementing this legislation by regulation. And the legislation that Senator Warren and I got passed ensures that FDA finalizes the rules in a timely way, and in a manner that Congress intended, not what special interest groups want. And I do not know how those special interest groups are interacting with anybody in the executive branch, but I sure know how four major players weighed in heavily for us not to pass this legislation in the first place.

The comment period ended January 18th. Can you give us any date when these regulations might be out?

Secretary BECERRA. Senator, those will be out very soon. I cannot give you the precise date, but pretty soon, and you can hold me to that. But can I just say "thank you" for giving us the chance to do this, because without the effort that you all undertook, we would still be trying to fight to give our family members decent hearing aids.

Senator GRASSLEY. It is obviously not your fault that it took 5 years, but we passed the legislation, I believe in 2017, or else early 2018.

Now the next question deals with—I don't know whether you are aware of it or not, but it took about 8 months to receive answers to our written questions from last June's budget hearing. And I know as a member of Congress that you would be frustrated with this. Could you commit to HHS being more responsive to our written questions?

Secretary BECERRA. Absolutely, Senator. As a former member of this body on the House side, I know exactly what you are going through. We received over 500 letters. We have had to do more than 500 briefings in this past year. It takes a little while, but I am committed to make sure we respond as quickly as possible, and are as transparent as we can be.

Senator GRASSLEY. According to the Medicare trustees, the hospital insurance trust fund is expected to be depleted in 2026. Unlike the Obama administration's budget requests, the Biden administration provided no major policies to improve the solvency of the fund.

Am I understanding that correctly? Does President Biden have a plan to address Medicare's solvency?

Secretary BECERRA. Senator, we are prepared, as I think Senator Wyden, the chairman, mentioned, to work with you on a bipartisan basis. We know that there are solutions there. We know there is bipartisan support for Medicare, and we agree with Senator Wyden that it is important that we look at the costs, not the benefits, of

Medicare as we move to reform the system to keep it going for a long time.

Senator GRASSLEY. Lowering prescription drug prices is on the mind of every member of Congress, and you and I have talked about my work in that area, and doing it in a bipartisan way. We are 16 months into a new administration, and both Houses are controlled by the Democrats. We have not made any progress on this issue. I continue to meet with Democrats and Republicans to move a bipartisan prescription drug bill. Recent public comments suggest that the administration may bypass Congress and take executive action.

Questions in regard to executive action: is the administration preparing any executive action on drug pricing, and if so, could you give us some details?

Secretary BECERRA. Senator, with one in three Americans reporting that they are not taking their medication because it is too costly, we need to do something. We certainly intend to use whatever available authority we have to try to lower the costs of prescription drugs, but we are also very intent in working with you on a bipartisan basis to get something done.

This is one area where everyone agrees the costs of prescription drugs are way too high, and we have to do something. So we will look to use whatever executive or available authority we have, but we hope that we can work with you to get something done in a real meaningful way.

Senator GRASSLEY. Just let me make a statement in my last 10 seconds. I hope the administration will engage in a bipartisan way to pass bipartisan price reform legislation, and I would suggest a good starting point would be the things that Senator Wyden and I have worked on.

Thank you, very much.

Secretary BECERRA. Thank you.

The CHAIRMAN. Thank you, Senator Grassley.

Senator Cardin?

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

Mr. Secretary, it is good to be with you. I want to start with an issue that I have raised before that I am pleased is included in the President's budget. And that is, the persistence of drug shortages here in America, which is kind of shocking when you consider the amount of resources we spend for prescription medicines in this country—far outpacing any other country.

The recent study by the American Society of Health Systems Pharmacists says there are over 200 prescription drugs that are currently in shortage. And these medicines are often lifesaving and a cornerstone of critical care in hospitals and other settings.

The FDA's authority to address drug shortages by requiring products to be labeled with the longest possible expiration date is something that I initiated with a legislative proposal, and I am glad to see it is in the President's budget. The President's budget also includes $21.6 million for a resilient supply chain and shortages program. I want to just give you a moment to assure us that we can work in partnership and as aggressively as we possibly can. There should be no drug shortages in the United States of America. Many times the shortages are simply an economic issue of the drug

manufacturer rather than the ability to have the drugs available in our market.

So, thank you for the initiatives that are in the budget, but I hope that this will have your personal attention.

Secretary BECERRA. Absolutely, Senator, because, as you said, this is not an issue of not knowing that there is a drug out there, it is just not having sufficient supply. Part of it is the supply chain. Part of it is the economics that drive some of these manufacturers to not produce as much as we need. Either way, we have no excuse to not have the supply of drugs that all Americans need.

Senator CARDIN. I appreciate that. But I hope that you will focus on the way that we can make sure the supply chain is there, with a carrot and stick approach, so that if necessary, we take action against the pharmaceutical companies with the power that we have to make sure that there is adequate supply in this country.

Let me go to a related point, and that is, the President's budget includes a $200-million increase for the National Institute of Minority Health and Health Disparities. President Biden has been very clear about his commitment to deal with equal opportunity in America, including access to health care.

In the Affordable Care Act, we legislated the National Institute of Minority Health and Health Disparities. It was our initiative, and I am glad to see that there is a priority being set by this administration in its budget. But it goes beyond that. There are a lot of systemic challenges to equal access to health care in America that go well beyond just dollars.

So, tell me your strategy to put a priority on the President's commitment for fairness in American health care.

Secretary BECERRA. Senator, the fingerprint of fairness and inclusion are on everything we do now. Equity is critical. We saw that as a result of COVID: how many people we have let fall through the cracks. And so, one of the things that we did was, rather than wait for people to come to us, especially people who are not accustomed to having access to some of these services, we went to them. And the result has been, when it comes to vaccines, the disparity that we used to see between White Americans who got vaccinated and people of color has disappeared.

The disparity we saw in people applying for enrollment in the Affordable Care Act is beginning to disappear. And what we have done is essentially gone to people who are not accustomed to having our government say to them, "There is a great service out here you could take advantage of."

The other thing I will mention is on the Affordable Care Act, for example navigators—those who help people understand the process and what is best for them. We quadrupled the number of navigators we put out there so people could make a good decision. The result was that 14.5 million Americans today have health insurance because of the Affordable Care Act.

Senator CARDIN. And I would just point out that there are multiple challenges to equity issues in getting access to health care, some of which go beyond your specific responsibility. And I just urge you to be a leader among the Cabinet to address the equity issues.

I want to underscore the chairman's point on telehealth. It works. We know it. People like it. It really does expand access. We have to break through the traditional barriers, as we were able to do for COVID–19, and make those changes permanent. And there is bipartisan support on this committee and in Congress to make that a reality. So I just really wanted to underscore that.

And lastly, let me just mention dental care, an area that has been particularly important to me as a Maryland Congressman with the tragic death of Deamonte Driver in 2007 for not being able to get access to oral health care. We have corrected that for the pediatric, but we have not yet for the general population, including the Medicaid population.

And I know that the administration is working on this. We had our challenges in some of our discussions, but I would hope that we will look for innovative ways that we can expand access to oral health care. It is relatively inexpensive compared to the positive results we get from access to oral health care, and I hope that you will work with us to see how we can expand coverage.

Secretary BECERRA. Absolutely. I think we have learned that for oral health care, we can do it, especially with Medicaid, for pennies on the dollar.

Senator CRAPO [presiding]. Thank you, Senator Cardin.

Senator Wyden and I are rotating, as we have a series of votes on the floor, so I will do my questions now.

Mr. Secretary, as we discussed yesterday, the current law mandates that the Medicare trustees release an annual report updating Congress and the general public on the financial status of the program, including the hospital insurance, or HI, trust fund. That report is due no later than April 1st of each year. Last year, with no real explanation, the report was issued 152 days late. It projected the HI trust fund would become insolvent in 2026, and we have yet to receive this year's report, which is now already late.

Mr. Secretary, as a member of that board of trustees, do you know what the revised exhaustion date of the HI trust fund is?

Secretary BECERRA. Senator, I know we have the latest report, which said 2026. We are waiting for the staff to give us the report that would let us issue to the public the latest version of that report for the Medicare trust fund, and we will get it to you as quickly as we can. And we look forward to working with you, as Chairman Wyden said, in trying to move forward with Medicare.

Senator CRAPO. Well, thank you. And as a member of that board, I would ask you if you would urge them to get moving. At this point we have no communication from the administration concerning the status of this year's trustees' report.

And following up on this, the Medicare trustees currently project that the trust fund will become insolvent anywhere from 4 to 5 years from now. And other than during the first few years of the Medicare program's existence, Congress has never allowed the trust fund to project fewer than 4 years of solvency without a legislative change. Acting early helps to minimize the overall impact on health-care providers, taxpayers, and beneficiaries.

Secretary Becerra, can you explain why the President's budget submission fails to include a specified package of Medicare savings proposals to address the trust fund's looming insolvency?

Secretary BECERRA. Senator, as you know, in the past the President has submitted proposals to deal with the future of Medicare. In this particular budget, we have some items that deal with, for example, the incentives to have physicians participate in value-based payment programs that will help drive costs down.

I think the important point is, as Chairman Wyden has said, that as we move forward in making reforms that improve and strengthen Medicare, we should be looking to reduce costs not benefits.

Senator CRAPO. Well, I certainly wish that the President's budget would have been much more focused on this trust fund, and I encourage you to work with me and with others to get that specificity outlined and implemented.

I want to move to mental health for a second.

I share the administration's commitment to address what the budget calls "the invisible costs" of the mental health crisis. That being said, for far too many of the policies that the administration has proposed, the cost implications are just that, "invisible." Budgetary estimates and projections for a sizeable list of provisions are just entirely unavailable. The budget includes $102 billion in new mental health spending, but that top-line figure fails to account for the bulk of the Medicare expansions outlined in the proposal, which would likely add billions if not tens of billions to this total.

Where does the administration propose finding the savings from Medicare, Medicaid, and other programs needed to finance this new spending without further straining our deficit, along with our State budgets?

Secretary BECERRA. Senator, first let me begin by saying that I think each of us here has not only the priority to deal with mental health the way we should have a long time ago, but to make sure we have the resources to make it happen.

The President has put forward proposals in the past. One of the things we would like to try to do is work with Congress to make sure that we can keep this permanently in place. I can try to give you the details of particular proposals, if you would like, but what I can tell you is, the President is committed to protecting and strengthening our efforts to try to have everyone receive mental health or physical health services in parity without any discrimination.

Senator CRAPO. Well, because my time is limited, I will not ask you to go through those proposals you just suggested you could provide, but I would ask you to provide those. We really need that detail.

[The questions appear in the appendix.]

Senator CRAPO. The last question I have is on transitioning beyond the public health emergency. As communities across the country continue to return to normalcy, our Federal policies should reflect that same shift. We have learned a lot of lessons—telehealth, for example, is one—on things that we should extend. But we need to give clarity on where we are headed as we try to deal with post-pandemic health-care issues. That means putting an end to needless and invasive mandates, but it also means moving our health-care system onto a more sustainable and predictable path.

We just cannot operate in a permanent state of emergency, and we need to move forward. With that in mind, our States, front-line providers, and working families deserve concrete timelines and plans for exiting the ongoing public health emergency, because we need a smooth transition.

Given the omission of any direction along these lines in the budget request, do you expect the public health emergency to end this summer? And could you please speak to the administration's progress on post-emergency transition planning across programs?

Secretary BECERRA. You have pointed out something that is critical for the American public and all of our industries, and that is the preparation it will take once we leave this state of public health emergency. We have committed to making sure that we give all providers at least 60 days notice of when we will bring down that public health emergency declaration. We are continuing to work to make the plans for what comes next. As I mentioned to you, the President has submitted a proposal, and it is in the budget, that would call for what comes next.

So, we go beyond COVID–19 to look at what might come next, the planning for that. We look forward to working with you on a bipartisan basis to make that happen. And what I can tell you is that everyone is seeing good signs of where we are today in COVID. In terms of Omicron, in terms of the number of vaccinations, in terms of the therapeutics that we have, good signs. We hope that Congress will continue to work to provide us the funding that lets us have that happen all the way through this crisis. But what I can tell you is that as we move forward on COVID–19, regardless of what happened in the breach with other pandemics, or what we have to prepare for, but on COVID–19 we will telegraph to you and the rest of the public what needs to happen, and as quickly as we can.

We have telegraphed that we need to continue resources to provide those therapies, those medicines, those vaccines that are needed by the American public.

Senator CRAPO. Thank you. Understood. And I look forward to working with you. And I urge expeditious attention to this issue.

Senator Stabenow?

Senator STABENOW. Well, thank you very much, Ranking Member Crapo, and good morning. It is wonderful to see you, Mr. Secretary. I appreciate so much all your work. There is a lot to celebrate and be excited about in this budget.

I do want to start, though, and just say as we debate the whole question of Medicare and strengthening Medicare for the future, and solvency, and so on—and I certainly support, and I know the President does, strengthening, reforming, and moving forward to protect Medicare for Americans. But what we do not support is the Republican plan that Senator Rick Scott of the campaign committee for the Senate Republicans put forward, which is to end every Federal program in 5 years and then debate whether or not it should be continued, which of course is Medicare, Medicaid, Social Security, and so on. And that has been the platform put forward if the majority goes back to Republican next year.

So, I certainly do not support that. But I do support, and want to thank you for the fact that you announced yesterday the over-

the-counter rapid COVID–19 test at no cost for people on Medicare. I wrote a letter urging that that happen. Thank you so much for doing that. This is really important for our seniors and others on Medicare.

No surprise that I want to talk about community mental health, addiction services. I have to say, when I saw this budget I was literally jumping for joy, because this budget is historic in terms of finally making the investments in the priorities that we have needed in our country for a long time, and certainly need now after the pandemic, in community mental health services, substance use disorder services in the community. This is an area of great bipartisan support. So I appreciate the chairman and ranking member putting this as a priority.

As you know, Senator Roy Blunt and I have been working for years to get comprehensive quality services in the community through our Certified Community Behavioral Health Clinics, which the President has now embraced expanding across our country. And so I want to thank him, and thank you for that, and I wondered if you might speak about the clinics, particularly because there are so many things we need to do.

Senator Daines and I are leading one of the work efforts here in the Senate Finance Committee on workforce, and we certainly know we need the people to be there. We need telehealth. We need a whole range of things. But if we do not have comprehensive services in the community to refer people to, if we do not have that available, we are never going to get anywhere. And so I was thrilled to see the new numbers that have come out that are even better than when we started a few years ago with the demonstration projects.

But could you talk about how Certified Community Behavioral Health Clinics improve care, and why it is time to make sure every community has the opportunity to have these services?

Secretary BECERRA. Senator, to you, thank you for the years that you have devoted to this. And hopefully through this budget, you will get to see the fruits of that labor, and millions of American families will benefit as a result.

What the President has essentially said is, we are not going to treat this as business-as-usual when it comes to mental health. We have to take a different approach. And so, he not only put forward a number of proposals to do this, but he also put his money where his mouth is. And he has committed substantial amounts of money, some $52 billion over the next 10 years, to transform our mental health system into one that actually provides decent quality care for all Americans who need it.

And so, we are going to work with you. We have a specific priority immediately to address the behavioral health issues for children. We are going to do everything we can to work with States to launch the 988 lifeline that will hopefully become like 911, but for mental health services. For those who are contemplating suicide, we want to make sure that really launches well. So we are working on that.

We are going to continue to work with you to see if we can embed into our health-care system the idea that mental health is no different than regular types of health-care services. And it will

take a lot of work. But behavioral health services, those where we go into community settings and we provide people with the opportunity to be cared for in their home, or in their local community, instead of being shipped off to some institution, that becomes critical. And that is where we are working with you. What we are going to try to do is make sure that we continue to bolster the support for those local facilities and supports. And we are going to also do everything we can in this budget to increase the salaries and wages of those who work in those community and home settings.

Senator STABENOW. Thank you very much. And let me just say, in conclusion, that certainly Senator Daines and I are interested in working with you on the workforce issues that are very important to make sure we have the personnel, the providers, the professionals to work with people.

But I do just want to underscore one thing. We have been working hard. We have now 435 quality clinics that are now funded the same as physical care—you know, health care above the neck the same as health care below the neck. And what is amazing to me is that the latest numbers show that when you do that in the community, we have a 73-percent reduction in people going to the hospital, 69-percent reduction in people sitting in the emergency room because there is nowhere for them to get help, and a 60-percent reduction in time spent in jail.

And so it is no wonder that the sheriffs and police chiefs across the country where we have these services are our biggest supporters. So we can save money. We can do the right thing. We can provide people these really important services. So thank you. I look forward to working with you.

Secretary BECERRA. Thank you.

The CHAIRMAN. Thank you, Senator Stabenow.

Senator Cassidy, who is always very helpful in working on these health issues, is next.

Senator Cassidy?

Senator CASSIDY. Thank you, Senator Wyden. Secretary Becerra, nice to have you.

Secretary Becerra, as you know, the U.S. District Court for the Eastern District of Texas recently ruled that the rebuttal presumption of a benchmark rate in the interim dispute resolution of the No Surprises Act was invalid. The judge ruled that this, quote, "conflicts with the unambiguous terms of the Act," end quote.

Now as you know, the majority of my colleagues and I who wrote this legislation have been sending you letters before and after the issuance of this ruling, stating that it violated congressional intent. Clearly it violated the plain reading of the law. And it violated the kind of delicate balance we had between all the stakeholders to get them to agree.

So on behalf of the administration, I guess I am asking, would you commit to accepting the will of Congress and the courts and finalize a rule promptly that does not include a rebuttable presumption of a benchmark in the IDR, but rather follows congressional intent? And when can we expect that rule?

Secretary BECERRA. Senator, thanks for your advocacy on this particular issue on the No Surprises Act. We have put in place guidance. The CMS has put in place guidance that has made clear

that we are updating our documents and other materials in light of the Texas decision.

But it would be difficult for me to comment more, since we are still in the midst of that——

Senator CASSIDY. May I ask, will you be appealing that decision, or accepting it?

Secretary BECERRA. That is a decision that will be made working with the Department of Justice. I cannot give you that answer right now, but what I can tell you is that we are continuing to work through that litigation as best we can. And——

Senator CASSIDY. And—I am sorry—do you accept what the judge says that it clearly violated the unambiguous terms of the act?

Secretary BECERRA. As I mentioned, we have updated our guidance. We are doing everything to make sure we stay compliant with the law, and we will continue to proceed forward. We are implementing other aspects of the No Surprises Act that were not implicated by the court's decision, and we will move forward in making a decision where to proceed on that particular litigation.

Senator CASSIDY. Then let me go on to Medicaid, and specifically outcomes. Maternal mortality continues to be abysmal. Medicaid pays for 60 percent of births in our Nation. And there is an old public health maxim: "that which is measured is addressed."

Now we have a way to measure outcomes in Medicaid. It is called T–MSIS. But it is my understanding that the method by which that data is presented to CMS is nonstandardized. And indeed different data sets are presented by different States, and some in PDF, and some digital, et cetera.

And so I just gave the pregnancy outcomes, but I could give many others where Medicaid is not coming up to where it should.

So the question is, what is CMS doing in order to kind of better standardize both the data that is collected and reported, and how it is reported, to make us better capable of viewing one State versus another?

Secretary BECERRA. Senator, you have touched on a—not a sensitive subject, but a subject that absolutely needs further attention. T–MSIS is something that has been, as you now, in progress for many, many years. We are trying to make as much progress as we can.

We saw with COVID how important it was to have accurate data. And Medicaid is no different. We have to make sure we continue to work to ensure that the States are giving us the data we need so we can make decisions, and States can make decisions that make total sense. And so, we look forward to working with you as we try to move forward with T–MSIS and getting that taken care of. But as you know, moving these systems, these databases, into a different shell is difficult.

Senator CASSIDY. I accept that, but it could just be asking them to report the same issues. You know, if one State is doing this, and no other State is doing that, then there is no way to have a comparator.

Secretary BECERRA. And it is easy to ask, but it is hard to get responses unless you have more than just a carrot to ask. And so we have tried. We learned the lesson with COVID that some States

have been very good about reporting data, even that data that they are not required to report. Other States have not. And it makes it difficult to make those full decisions, as you mentioned.

Senator CASSIDY. So it sounds like this committee needs to give you some tools in order to address that.

Secretary BECERRA. We would love to work with you on that.

Senator CASSIDY. That sounds great.

Next, talking about mental health, several issues. One is the RAISE initiative, which is the Coordinated Specialty Care, which Congress has given money for.

When I look at my own State, however, only two of my cities have actually begun it. And again, just for context, this is a wrap-around set of services so that when a young person has her first psychotic episode, those services are there so that that first is her last. But apparently it is so difficult to coordinate the different agencies that apply this, so that it has limited effectiveness and limited reach.

So my questions are, what steps is the administration taking to increase access to the Coordinated Specialty Care, and how is the administration prioritizing programs that serve this population like Medicaid and SAMHSA to work better together in order to achieve more people being enrolled in Coordinated Specialty Care?

Secretary BECERRA. And, Senator, you are raising one of the areas where it is clear that we need to do more, because there has not been that type of coordination, whether in the public-sector side of health care, or in the private-sector side. And what we are trying to do—and that is why the President's budget reflects that priority—is to make sure that we give everyone the tools, not just our agencies, but the private sector the tools they need to make it happen.

We also put some requirements out there so that we could ensure that we are actually providing the care that people need.

Senator CASSIDY. There must be coordination, because apparently it is so discoordinated it is just not happening. And like Pogo said, "We have met the enemy, and he is us."

Secretary BECERRA. Yes, I know. It is very disjointed. And trying to get all those different stakeholders to work together—they will tell you it costs money. We say it is going to benefit them and actually save them money in the long run. But it is getting them there. And we might need to provide some incentives to help push this along a little faster.

Senator CASSIDY. Okay, I yield.

The CHAIRMAN. Mr. Secretary, just on this point that my colleague has made with respect to the Medicaid data on postpartum care, I am very interested in working with you and the Senator on this. We ought to be getting better data on it, because the need is so urgent. We ought to be able to ring every bit of value out of those health-care dollars.

Secretary BECERRA. And, Senator, with the proposal to extend postpartum care to 12 months, we should be able to collect not only more data, but better data for a long period of time.

The CHAIRMAN. That was almost going to be my next sentence, but you said it much better.

Okay, Catherine Cortez Masto?

Senator CORTEZ MASTO. Thank you, Mr. Chair.

Mr. Secretary, it is great to see you. Thank you for joining us.

First and foremost, let me just say that I want to thank you and the administration for the clear prioritization of mental health in this budget. I am sure Debbie Stabenow said the same thing. It is one of the issues I hear most from Nevadans, whether I am talking with folks in the rural counties about infrastructure, or in Clark County about education. So often the conversation comes back to mental health. There is a lot in the budget to get to those concerns, including investments in the workforce, expanded coverage of therapy, better enforcement of mental health parity. I mean, there is a long list of them. So I thank you so much for that.

One thing I do want to talk to you about is the health crisis piece of it. You talked in your opening about setting up the 988 hotline in July, which I think is fantastic for people in crisis—whether it is a suicide hotline or a mental health crisis, or any type of crisis—to call.

Let me ask you this. My biggest concern, though, is—and I know this is happening in Nevada; we want to set up the hotline. But once they call, where do they go if we do not have a structure in place for services, essential services, to really provide for individuals in need?

So can you talk about the investments in mental health crisis services that you have proposed in this budget? And how will they help folks who need additional services on top of 988? In other words, at that crisis mode when they are calling, what types of services are you looking at? Because this is an area where Senator Cornyn and I have focused on providing and building up that essential crisis mode of services that we need, not only in Nevada but across the country.

Secretary BECERRA. Senator, thank you for the question, and for all the work that you have done on this particular subject.

As you know, the current system is a patchwork. We have different phone numbers that people can call to try to get help when they are facing a mental health crisis, or if they are contemplating suicide. 988 is our way—thank you, Congress—for helping us get these resources to bring it all together. It is almost a one-stop shop. You get to make one call, 988, and if you are facing a point of perhaps considering suicide, you are going to get services.

To your point, we are going to have call backup centers so that if a particular State is getting a lot of calls, there will be a backup center that will be available to take that call so folks are not waiting with busy signals or being put on hold to get services.

I mentioned earlier in a discussion with Senator Stabenow how we are going to increase our investments in community and behavioral health services. We are investing, in the President's budget, more than $200 million to make sure that we can provide those local community health centers, mental health centers, to people so that there is place where they can go. We can direct them, if they do indeed have a mental health-care crisis.

So there are a number of things we are doing, but ultimately what we have to do is glue together all those folks who are doing this work throughout the country so 988 will work really well.

Senator CORTEZ MASTO. Well, thank you. And I appreciate that.

The other thing—and I look forward to working with you. I know for Senator Cornyn and I, this is an issue that we both care deeply about, and we've got to really address bringing the essential services to someone when they reach out to that hotline.

One of the other areas of focus for us is to make sure that there is available to everyone insurance coverage to cover when they are reaching out in the crisis mode. So I am hopeful—can I get a commitment from you that you will be willing to work with us on our legislation to make sure we are providing those essential services right at the crisis mode when they are making that call?

Secretary BECERRA. Absolutely. We are committed to making mental health-care parity the law of the land.

Senator CORTEZ MASTO. Thank you.

The other thing that I see in here, not just in Nevada but across the country, is the workforce expansion piece, when it comes to behavioral health.

There is an emphasis I know, in this budget, on the great work that allied health professionals do to keep their community safe, which is especially true in behavioral health. Can you explain more about the provisions in this budget that would expand coverage of community health workers? Because it is something that I hear all the time that we need to do, and this budget and what this administration wants to focus on is really addressing that need.

Secretary BECERRA. Well, I mentioned the more than $200 million that we are going to be investing in Certified Community Behavioral Health Clinics to make that service more available locally to people. We are also, in this budget, proposing that we help States be able to provide better compensation to those who go into this workforce, the behavioral health workforce. It is often one of the most underpaid areas of coverage, yet it is one of the most indispensable areas of the health-care services.

We are going to continue to work with those local programs that exist to offer them new innovations. We, for example, changed completely—we are going in a different direction when it comes to how we treat substance use disorders. We want to go with the evidence. We want to go where people are. And we want to not only save lives, but keep people healthy.

So we are talking a lot more about harm reduction, not just about saving a life.

Senator CORTEZ MASTO. Well, thank you. And I know my time is up, but it is essential, because you are also opening the door for other specialists to be able to access and get services paid through Medicare. And these are folks who work in the behavioral health sector. So, thank you very much. I look forward to working with you, Mr. Secretary.

Secretary BECERRA. Thank you.

The CHAIRMAN. Thank you, Sentor Cortez Masto.

Senator Menendez?

Senator MENENDEZ. Well, thank you, Mr. Chairman. Mr. Secretary, it is good to see you.

The Maternal, Infant, and Early Childhood Home Visiting Program, known as MIECHV, is a critical resource for young families that improves maternal and infant health, school readiness, and family self-sufficiency. It reduces abuse and neglect, and it connects

families to community resources and supports. It is an evidence-based program that has shown the real impact early intervention and support can make for young families.

Unfortunately, the last reauthorization did not include a funding increase, and we know that just over 3 percent of high-priority families were served through home visiting pre-pandemic. While I am pleased to see support for expanding MIECHV in this budget, my hope and goal is that this program—which members on both sides of the aisle support—sees a meaningful funding increase in this year's reauthorization.

So, can I have your commitment to work with me and all of our MIECHV champions on this committee to make the critical investments in this program so that families can continue to get the support they need?

Secretary BECERRA. You have my commitment, Senator.

Senator MENENDEZ. Thank you.

Let me turn to the question of title 42. DHS intelligence officials are predicting an influx of migrants arriving at the southern border in the coming months. This is a seasonal trend matter, but it is also about the much-anticipated end to title 42.

Title 42 is being used to evade our asylum laws. We have a law on the books. It is our international, not only our domestic obligation. And it was abhorrent under President Trump, and it is abhorrent under President Biden.

Some of my colleagues who somehow think that it should be extended are making a huge mistake, because all title 42 does is, it has migrants making multiple efforts to cross versus knowing that there is finality in an adjudicated asylum claim.

So how is HHS preparing for the likely increase in unaccompanied children who will be arriving at our southern border this summer?

Secretary BECERRA. Senator, thank you for the question. We are in the process of projecting what our needs will be. I want to thank you and the members of the Senate and the House for providing us with additional resources to deal with the unaccompanied children who have come into this country, who are going through the asylum process.

We have stood up as many of the licensed facilities as we can. Those licensed facilities that care for these children are separate and distinct from the care facilities that offer services, for example, under foster care for our kids from America. But we have worked with that universe of licensed care providers to make sure we can offer these children, during their temporary stay with us, the best care that we can afford to provide them.

At the same time, we do prepare, in the event that we have to stand up additional facilities, those that can provide the emergency care necessary so that DHS, when they must transfer those kids over, will have a place where they can stay temporarily.

Senator MENENDEZ. So let me ask you this in that regard. Last spring, very concerning reports emerged regarding the conditions for unaccompanied children housed in HHS emergency intake sites. And at that time, the Department officials expressed their intention to depopulate and close these short-term facilities as soon as possible. However, as of April 1st, there were still two emergency

intake sites open, housing approximately 2,100 children. Is the Department still committed to closing these emergency intake sites and placing unaccompanied children with long-term shelters in your licensed care provider network?

Secretary BECERRA. That is the goal, Senator, because it is required by a court decision as well. And so we make every effort that every spot, every slot, every bed that we can find that is under a licensed care facility, we use. And because we do not have sufficient numbers—in previous years, many of those licensed care facilities disappeared because the system was dismantled by the previous administration.

We have worked hard to build it up, to increase the number of licensed care facilities. But when there are not enough, we still have the obligation to care for these children. That is when we do stand up those emergency facilities.

Senator MENENDEZ. Okay. And then we have a commitment by the President to give refuge to 100,000 Ukrainians. Is the Department making preparations for that as well?

Secretary BECERRA. We are, Senator. And thank you again for the resources to make that possible. Just as we provided that refuge for the 68,000 or so Afghani refugees who have come through, we will be prepared to do the same for those who come from Ukraine.

Senator MENENDEZ. I will close simply by saying I am disappointed that our COVID package does not include any international assistance. We cannot meet the President's goal of helping to vaccinate 70 percent of the world by September if Congress does not include any amount for the global VAX initiative. And you know, diseases and viruses know no borders. We cannot hermetically seal ourselves off. It is in our own interest to do this, and I hope you and the administration will continue to advocate for it.

The CHAIRMAN. Senator Menendez, before we go to Senator Carper, let me just say I very much appreciate your points. And especially that last one. The fact of the matter is, the main street in New Jersey in a community, or the main street in Oregon in a community is affected by these health practices that go on around the world.

The world keeps shrinking as a result of modern communications and modern transportation. And even if you do not accept the moral case, which you and I, I think, feel strongly about, just from a financial standpoint, a purely financial standpoint, it is just urgent business to make sure that these international health programs get funded, because they, in fact, are main streets.

Senator MENENDEZ. Mr. Chairman, I couldn't agree with you more. This is a national interest and a national health security interest. So to me and my operation in my office, this would be what we call a no-brainer.

The CHAIRMAN. Yep. Well said.

Okay, Senator Carper, I think you are online.

Senator CARPER. Mr. Chairman? Tom Carper. Am I up now?

The CHAIRMAN. We can hear you, Senator Carper.

Senator CARPER. All right; thanks so much.

I would like to start off with just a quick refresher on the Affordable Care Act. For those who maybe do not know or do not remem-

ber, in 1993 Republican Senator John Chafee introduced legislation that proposed an individual mandate and the establishment of an insurance pool. That bill looked a lot like the Affordable Care Act. In fact, it had over 20 Republican co-sponsors in the Senate, some who still serve today, including on the Finance Committee.

Fast forward to 2009, my first year as a member of the Finance Committee and the first year of a new administration. Our new President called on Democrats and Republicans to try anew to achieve what previous Presidents had talked about for more than half a century. But instead of coming to the table and pursing a productive discussion about how we could expand access to health care for millions of Americans, in the end Senate Republicans chose not to engage. But the President and the rest of us soldiered on and finally passed this historic law.

I might add that Mitt Romney, who was then Governor of Massachusetts, actually took the handoff from Senator Chafee and 20-some Republicans and actually created in the State of Massachusetts Romneycare, which is very much consistent with what we have done with the ACA today.

I will be the first to admit that the Affordable Care Act is not perfect. Very little that we do around here is perfect. It wasn't when we first passed it, but our challenge has always been, how do we improve the health-care system for more Americans?

And, as a result of the ACA, we were able to establish marketplaces in every State for people who did not have insurance to get coverage on the exchanges. Folks who were low-income could benefit from a sliding scale tax credit. Another important provision said if you are a health-care insurer and you want to stop people from getting coverage because they have a preexisting condition, you can't do that. You just can't do that.

That turned out to be a big part of the foundation of the Affordable Care Act. And the stuff that our Republican friends are most critical of is, to be honest with you, a lot of their stuff. So go figure.

Secretary Becerra, in your testimony you mentioned that a record 14.5 million people signed up for the 2022 health coverage open enrollment. A little over a year ago, President Biden signed the American Rescue Plan Act into law. It has continued to make coverage through the ACA more affordable for families, and they average about $2,400 on their annual premium. Four out of five consumers find quality coverage for under $10 a month.

Think about that: four out of five consumers finding quality coverage for under $10 a month. And guess what? The uninsured rate has fallen as a result. The ACA was not perfect. It took a while, but it worked, and millions of Americans have benefited because of our efforts to better our health-care system.

And there are still ways we can continue to fix it, and hopefully Democrats and Republicans will be working together.

Mr. Secretary, again welcome, but would you elaborate on how the President's budget request continues bolstering the health insurance marketplaces to ensure that every American has the opportunity to seek out health coverage that works for them? Mr. Secretary, welcome.

Secretary BECERRA. Senator, thanks for the question. And thanks for all the work in all the things you just pointed out. We

are going to continue to try to break records when it comes to the Affordable Care Act. The President has proposed the continued work to have navigators out there to help those Americans who did not sign up for a plan—and a very affordable plan as you just pointed out—under the Affordable Care Act's open enrollment period.

Last year, the President extended a special enrollment. We got over 3 million Americans to sign up who had not signed up before. And during the most recent open enrollment period, what we saw, as we said, was the record numbers: 14.5 million. We are going to continue to work on that. We are going to continue to do the work we can, as you may have heard, on mental health, how we try to expand services there and behavioral health services. So, we are going to continue to try to take this to a different level where we know that there are Americans who still do not have coverage, are not getting the services that they need, and as a result are suffering.

We look forward to working with you, but the President's budget makes historic investments in areas that have for too long been neglected, including for example in Indian health-care services where, for the first time, you are seeing a budget that not only proposes to make that funding mandatory so there is never a drop in services, but also to do a long-term 10-year commitment to get us to where we really should be going.

Senator CARPER. And one last quick question. Last month, you and Secretary of Education Miguel Cardona launched a joint department effort to expand school-based health services, something that we are big on in Delaware, ensuring that the children have the health services and supports necessary to build resilience and thrive. It's clear the budget demonstrates our shared commitment between the administration and Congress to tackle shortfalls in mental health care on a bipartisan basis.

My question: to that end, how can Congress partner with the administration to better provide resources and support to schools? How can we provide further guidance on the Federal funding available for school-based physical and behavioral health services, including how Medicaid can support the delivery of these services? Just briefly, please.

Secretary BECERRA. Sure. The President has asked us to work and coordinate so that we are not doing things in separate silos. So the Department of Education and HHS are working together to make sure children have access to the best services they can, oftentimes in schools, and we will look forward to working with you, because those schools are in your States, in the congressional districts. You know best how to make sure that that happens, so we will work with you.

Senator CARPER. Colleagues, and Mr. Chairman, in the State of Delaware when I was Governor, we decided to put a school nurse in every public school in Delaware. We also decided to put a wellness center in every high school in the State of Delaware. And we are now putting wellness centers in our junior high schools in the State of Delaware. All of which works, and we partner with local communities, school districts, and the Federal Government on this to find out what works, and to do more of it.

The CHAIRMAN. Thank you.

Senator CARPER. Thank you, sir.

The CHAIRMAN. Thank you, Senator Carper.

Senator Warner is next.

Senator WARNER. Well, thank you, Mr. Chairman. I see my good friend Tom Carper there was going through his litany of achievements as Governor. I will not try to match him on that, though I have some good stories as well.

Secretary Becerra, it is great to see you, at least remotely, and I want to thank you for what you and the administration are doing on dealing with the family glitch in the ACA, and the good work we all have been trying to do on implementation.

I want to hit a couple of subjects fairly quickly. One, first, is cybersecurity. This is an area I have been deeply involved in. I chair the Cybersecurity Caucus. The chairman here is a great member of the Intel Committee we are on, which I chair. We have been working and slowly moving forward. We have finally got some *de minimis* security requirements in for Internet of Things devices.

We recently passed and signed into law a cybersecurity reporting requirement. Literally only 30 percent of the cybersecurity incidents are even reported to the government. And that is not to expose; we give confidentiality to those individuals reporting, and some limited immunity. We have to make sure we can share with other members of the private sector to get this word out, and I think we can all expect, unfortunately, still to see Russia activate some of its very real cyber-capabilities in the coming weeks and months.

So I want to talk about cybersecurity as it deals with the health-care field. Obviously this is extraordinarily sprawling. I find that—I have been working on some comprehensive legislation here to look at cybersecurity in the health-care field broadly.

So, Mr. Secretary, I would like you to not talk about what you are doing as Secretary to protect HHS's assets, but more how HHS can work with all of the providers, hospitals, other pieces, device manufacturers. There is a long litany that makes up the health-care field in particular when we think about all of the smaller, in many cases legacy devices that may have some cyber-vulnerability. What do you see as HHS's role in this? And how do you coordinate with CISA and all of the other various components that are grappling with cybersecurity?

Secretary BECERRA. Senator, great question, because most people do not think about this. At HHS, one of the things we are going to do is move everyone, not just HHS but everyone in the private sector as well, towards risk-based decision-making, so that they are taking into account what might happen, not waiting until it does happen. We are asking people to take a look at what has already been done. There are a lot of best practices that we can learn from that will not cost that much to deploy, because somebody else has spent the time and made the investment to make it happen.

And I think you can help with this; the Senate and the House can help with this to make sure the administration can provide incentives in the private sector to move people in a particular direction, to get them to think more about this risk-based decision-making model.

And so, there are a number of things we can do, and I look forward to working with you.

Senator WARNER. Yes, I would like to pursue that, because I think we particularly see smaller hospitals, rural hospitals sometimes, make the tradeoff that cybersecurity is not that important until they get threatened with ransomware and then end up paying a much higher price. And that kind of merges into my next question.

I think this question was also raised by Congressman Fleischmann of Tennessee in your House hearings. And this goes to the area wage index questions. We see a real challenge about providing rural health care in small hospitals. I know the chairman has the same problem in Oregon. CMS, during COVID, provides some relief, but as you know, that is now being challenged in court on dealing with the area wage price index.

I have legislation, bipartisan legislation that would increase the Medicare reimbursement rates for about 850 rural hospitals around America, many of these hospitals that otherwise might be faced with closure. We have seen a dramatic increase in the closure on this wage index to kind of bring it a little bit closer to suburban and rural rates.

I know you were asked this and are supportive of rural health, but is this an area where CMS can do it on its own? Or do you think we actually need the kind of legislative, bipartisan fix that I proposed?

Secretary BECERRA. Our authorities are pretty expansive, but someone is always going to take the time to challenge us in court. It really does behoove us to try to work with you in Congress to try to make sure that we address this the right way.

We are making specific investments into rural communities on health care. But what you are speaking to really is, across the board, trying to make sure that we do this the right way. So we would look forward to working with you on this.

Senator WARNER. Mr. Chairman, I won't get to my last question. I just do think that this legislation needs the review of this committee. It would produce that national wage floor minimum, and I think that is one of the ways that we can guarantee rural health going forward.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Warner. We will be working with you on these rural hospital issues.

Senator Barrasso, I am going to run and vote. You are next, and Senator Crapo is back, so I appreciate all my colleagues' cooperation on this hectic morning.

Senator Crapo, Senator Barrasso is next.

Senator BARRASSO. Thank you very much, Mr. Chairman. Mr. Secretary, thank you.

I wanted to follow up on something that Senator Crapo asked a little earlier, and that is in terms of the Department of Health and Human Services implementing several emergency waivers for Medicare and Medicaid programs in response to the COVID–19 situation. Some of the waivers have granted patients more flexibility, like enhanced access to telehealth. Others have ensured that providers could do their jobs with less red tape, and with more finan-

cial certainty. All those things are positives. The world today is very different than it was when the virus first hit our shores. Cases, deaths, hospitalizations, are right now much, much closer to pandemic lows.

This is why, in Wyoming and most of America, life has returned to normal. I think it is why we must plan for the end of the public health emergency. And for us here in Congress, that means we have to ensure that providers and patients do not unexpectedly have the rug pulled out from under them after these flexibilities that, I think, have been helpful in Medicaid and Medicare—after those end.

So will you commit to providing detailed and specific information to Congress on those emergency flexibilities that you did use in Medicare and Medicaid and the CHIP program as a result of the pandemic?

Secretary BECERRA. Senator, I am absolutely committed to working with you, because a lot of those authorities will vanish, and we need to work together to make sure we deploy what we know has worked.

Senator BARRASSO. And will you provide detailed information on emergency waivers that your department believes Congress should extend, or make permanent beyond the public health emergency?

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

Senator BARRASSO. Great. Additionally, has your department specified plans to ensure that providers and patients are aware of some of the changes to Medicare, Medicaid, and the CHIP program when the emergency actually ends?

Secretary BECERRA. We have, Senator. But, you know what? You could help us a great deal if you continue to let your State leaders know that we are trying to make sure we are communicating everything that is around the bend. And so, whether it is the Medicaid wind-down, or whether it is what happens to those authorities we have for telehealth, we want to make sure that everyone has full sight and that we are working together to make sure we accommodate.

Senator BARRASSO. And Senator Warner before me talked about rural hospitals, and I want to continue on that because, as you know, I practiced medicine in Wyoming for over 20 years. And we have discussed previously ensuring that patients in rural America have access to health care in a very—well, it is a personal priority of mine to make sure people get what they need in rural communities. And rural hospitals have really been on the front lines of the pandemic. Those facilities provided essential care when their communities needed them the most. And despite their best efforts, many rural hospitals continue to remain under threat.

According to the University of North Carolina, 19 rural hospitals closed in 2020; 138 have closed since 2010. And the closure of a rural hospital means people have to drive much longer distances to receive essential health care. In a medical emergency when seconds count, driving these long distances, and most certainly in the dead of winter, can have deadly consequences. And when a rural hospital closes, it really has a significant impact on both the health and the economy of the local community. When a rural hospital

closes, it is much harder to attract and maintain businesses, teachers, doctors. There are all sorts of impacts on the community.

So I am concerned that your budget does not contain a comprehensive strategy for halting these rural hospital closures and building a sustainable rural health-care delivery system.

Can you discuss with me, please, how the Department is going to address this critical issue of rural hospitals?

Secretary BECERRA. Senator, let me try to persuade you that there is not only an investment made in this budget, but that there is a plan here. Let me, for example, mention the $374 million that we included in the budget that would be used specifically to improve access and quality, as well as coordinate care in our Nation's rural communities.

We are investing more money in trying to train those health-care practitioners in rural settings. So we are giving more money to some of those rural community facilities that can then house those future doctors, future nurses there. We know this from the studies that if you start your practice in a particular community, you may end up staying there. And so, what we want to try to do is drive people who are going through medical school and so forth into some of these rural communities so that they start practicing there, and hopefully they stay.

There are a number of other investments that we are making, but clearly with the Provider Relief Fund support that we got from Congress, we have been able to try to shore up a lot of our community health-care clinics, our hospitals, in some of these rural settings.

Senator BARRASSO. Thank you.

Thank you, Mr. Chairman.

Senator CRAPO [presiding]. Thank you.

Senator Thune?

Senator THUNE. Thank you, Mr. Chairman.

Mr. Secretary, earlier this year a number of colleagues and I sent a letter requesting that you rescind a rule that requires everyone in Head Start facilities to wear a mask, including children 2 years old and older, even when they are outside on the playground.

Though there is an injunction against this rule in several States, the rule has yet to be withdrawn. As the administration plans to drop title 42 public health measures at the border and continues to modify other recommendations, why hasn't HHS decided to rescind this Head Start rule?

Secretary BECERRA. Senator, thank you for the question and your interest. Most of those kids in Head Start have not had a chance to get vaccinated. There are still families that are very afraid of what could happen to one of their loved ones.

Those who say that children do not get COVID should talk to the hundreds of families across America who have lost a child under the age of 5 as a result of COVID. We are driven by the science when it comes to the work that we do on COVID, and we will continue to do everything we can to make sure we are protecting every human life in America, including our children.

Senator THUNE. The transmission of COVID–19 is really low among kids, particularly young kids, and it seems like masking toddlers on the playground seems completely unnecessary, and I

would say that even the World Health Organization has concluded that there is not any particular benefit, health or safety benefit, to masking kids under 5, and especially when they are on a playground. I mean, it just seems to me at least when you are outside and kids are playing—we know there are impacts, adverse impacts, with masks when it comes to their socialization skills, and to their learning skills.

But it just seems like when you even have the World Health Organization saying that masks for toddlers, or for children under 5, are not necessary, that we are really creating problems that do not need to exist.

So let me ask you this: when do you foresee that rule being rescinded?

Secretary BECERRA. You are talking about the public health emergency?

Senator THUNE. Or the masking.

Secretary BECERRA. Masking?

Senator THUNE. Yes.

Secretary BECERRA. So the masking requirements, and the instructions and guidance on that, as I mentioned, are driven by the science. When our scientists tell us that there are needs to take precautions because masks have been proven to be safe and effective, we issue those guidances, sometimes requirements, to move in that direction.

Once we see that the need for those types of protections is no longer necessary—no longer there—we will move forward in trying to make the adjustments. But while there is a chance to provide the most safe and effective way to keep a loved one alive, we are going to do that.

Senator THUNE. Well, again—and not to overstate this—but it does, I think, to me it just seems illogical. And particularly given when you weigh the consequences of the impacts on these kids—and they get adverse impacts, these kids, from wearing masks all the time. When you try and weigh this on the scale, it just seems like it clearly comes out on the side of common sense dictating this.

I understand your wanting to follow science, but you do have some scientists—you have the World Health Organization saying that masking for children under 5 is not necessary. And so, it strikes me at least that this is one of those requirements that is just a real overreach at a time when parents, a lot of parents at least, and a lot of kids are struggling. They are struggling with learning. They have gotten behind. And I think a lot of it is associated with the impact of masks and their ability to socialize with other kids, and also to, you know, to be able to learn at the fastest rate possible.

So I would urge you, encourage you, given where we are with the pandemic, that this is one—particularly when kids are on the playground, when they are outside—that makes no sense to me.

Very quickly—I do not have a lot of time—but we talked last year at the budget hearing about the Department's authority and resources to ensure the advancements we have made on telehealth during the pandemic, that those are not lost. And I see again that this budget does not describe administrative actions the Depart-

ment plans to take on Medicare telehealth, nor does it include a full legislative proposal for Medicare.

There is a single reference to extending pandemic flexibilities, but we need data. We need details on what you can and plan to do administratively so we can focus our efforts accordingly. And it would help to have more certainty on the expected length of the emergency for sure, but can you tell us some specifics on what you foresee the Department doing administratively on Medicare telehealth at the end of the emergency?

Secretary BECERRA. Absolutely, Senator. Let me start by saying, first, thank you for extending for 5 months the authorities we have on telehealth. We would like to work with you to extend coverage for services for patients to be able to use their home as the originating site for that health-care service.

We would like to continue to offer those Federally Qualified Health Centers and rural health clinics the ability to provide the services from distant sites. We would like to move towards payment parity for behavioral health telehealth services so that we can continue to have providers willing to do that. There is strong evidence that telehealth has been effective, or just as effective as standard in-person treatment in parts of the country. We would like to be able to do audio-only access for patients whose circumstances would necessitate that they get audio services instead of having to worry about trying to reach a particular provider in person.

So there are a number of things we would like to do. Again with the authorities that you could grant us, we could try to keep those extended services in place.

Senator THUNE. My time has expired. Thanks, Mr. Chairman.

Senator CRAPO. Thank you.

Senator Whitehouse?

Senator WHITEHOUSE. Thank you. Welcome, Mr. Secretary. It is good to be with you.

A couple of quick topics. First, the most significant issue that our Rhode Island hospitals are facing right now is nursing and health-care workforce. And this has two dimensions. One, they are unable to operate at full capacity and are having to stop procedures because they simply do not have the workforce to operate. And second, because of, I would call it a plague of contract nursing, where they are having to spend spectacular amounts of money for services that did not cost anywhere near as much before.

What are you doing to help hospitals that are facing these twin pressures? Should there be some form of special reimbursement for the added nursing costs so we can get them back on their feet again?

Secretary BECERRA. Well, one of the principal tools that we have used for some 440,000 providers throughout the country is to provide them with reimbursement of some of their claims relating to COVID. That Provider Relief Fund which you and your colleagues helped to put in place, $186 billion worth, has helped us provide substantial support to some of these facilities that are suffering from some of these conditions.

Unfortunately, that——

Senator WHITEHOUSE. They kind of burned through that, so the problem is still there.

Secretary BECERRA. It makes it tough, because——

Senator WHITEHOUSE. Would you mind following up with a—treat that as a question for the record and let me know what is being planned?

Secretary BECERRA. Of course. We look forward to working with you.

[The question appears in the appendix.]

Secretary BECERRA. We need authorities and resources to continue to help some of those providers.

Senator WHITEHOUSE. With respect to support for people who have addictions, we have always done prevention. We have always done treatment. It was only through CARA that we started providing recovery support. And because it had never been done before, we are kind of in a stranger-in-a-strange-land scenario with no real guideposts as to what works and what does not work.

Are you comfortable with the degree of flexibility that you have allowed for the recovery services to let people find their way, since there is not a huge track record of success and data, because we have never done this before?

Secretary BECERRA. Senator, you have touched on something very important. The data, the evidence—and usually at the Federal level, we are the last to try to move in a direction that could help save a life or keep someone in better health.

But what we have done with our new strategy on drug use is move away from the old paradigms. We are letting go of some of those taboos. We are looking at the evidence. And so, for example, fentanyl strips. Some people say that if you give people access to a fentanyl strip that lets you determine whether the drug you are about to take has fentanyl in it—which has caused some of the largest number of drug overdoses that we have seen—that it helps promote drug use. We think it helps promote saving of a life. The evidence shows it. So we are going to go in that direction. Clearly we are going to try to help those who are moving in a faster direction to help treat, but we are also going to move toward prevention.

Senator WHITEHOUSE. The point is, I think that it is important to be flexible with the recovery stuff, because people are having to kind of learn while doing, and report in. And later on, when there is a body of research that shows what works and what does not work, then I think you can narrow the aperture a little bit. But right now, I hope you continue to provide support, because it has always been underfunded before.

Secretary BECERRA. We are moving as best we can.

Senator WHITEHOUSE. The last point: you focus in the budget on what you call program integrity efforts, which have been around for a long, long time. I was the U.S. Attorney in Rhode Island, and Attorney General Reno put health-care fraud and program integrity at the top of her policy priorities. And it has been at the top of policy priorities for a long, long time. And I worry that there is just not a whole lot of "there" there because it has been focused on for so long. And once you actually get into the cases, they are hard to make.

So I think putting that as a priority with respect to lowering health-care costs is a strategic mistake, compared to focusing on delivery system reform—trying to get away from fee-for-service; trying to expand ACOs; trying to make sure that quality metrics are in place across the system. I think that probably fee-for-service is the biggest monster that is driving health-care costs right now.

We talked a lot during the Obama administration about the triple aim, and I would urge you to go back to that. In this committee, even when we were in our highest level of Obamacare hostilities, the parts of that bill that related to the delivery system reform—the ACOs, CMMI, payment reform—those things have been very popular, and there has been a lot of success across the country with actual cost savings.

So I would encourage you, particularly as we close in on a period when Medicare might get cash-negative, to really make that a focus. I think you may find that program integrity is a bit chimerical as a savings device.

Senator BECERRA. Senator, we agree with you that delivery reform is absolutely important, and we are working on that. But let me just persuade you that we can walk and chew gum. As a former Attorney General in the State of California, we did work on program integrity. There is abundant fraud out there, and we can tackle it.

And if we do not, then those who are doing it think they can get away with it, and will do more. And so I think we can walk and chew gum and do both areas of reform.

The CHAIRMAN. I thank my colleague.

Senator Portman is next, and he is online.

Senator Portman, are you online?

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

I would agree with what my colleague, Senator Whitehouse, just said regarding the Comprehensive Addiction Recovery Act and its implementation, particularly on the treatment side. We just did provide more funding for that in the Omnibus, and unfortunately, with the opioid crisis we have and broader drug prices, we need to focus even more on the demand side.

I am going to talk to you a little about that today. We have legislation, also with Senator Whitehouse, called the TREATS Act. Basically, it permits us to do something that is working, which is to provide prescription drugs, medication-assisted treatment in particular, MAT, without having to go to a personal, in-person visit first. So it is telehealth, and it has worked incredibly well during an otherwise very difficult period during this pandemic. This is one thing that emerging research shows is actually helping, particularly with regard to Suboxone. And it is permitted under a waiver that we have currently, but the waiver is—although again very important, and back home folks are calling it a game-changer—the waiver is temporary. In fact, the waiver ends when the public health emergency ends. And I am concerned, as we have been talking about today, that the public health emergency would not continue.

So what do we do about it? Well, one is, you have the ability through HHS to issue a rule on this and permit this kind of tele-

health. Again, the research is out there. It works. In 2008, you and I both supported it—actually, I was out of Congress at that time, but you were still in Congress—what was called the Ryan Haight Act, which gave DEA the authority, and HHS the authority to issue a rule. Ten years later, they had not done it, so Congress in 2018 said, "Please do it," and then again in the Appropriations Act of 2021.

So here we are 14 years later, and still we do not have this rule out. Senator Whitehouse and I are frustrated because we cannot get technical assistance from your folks on our legislation, the TREATS Act. But my view is, if we cannot get technical assistance which we would like to have, at least if we could get this rule out, it would be helpful to have an administrative decision.

So my question to you today is, would you commit to working with Congress to ensure we do not have an interruption in this treatment, particularly the really important treatment like Suboxone via telehealth, when the public health emergency ends?

Secretary BECERRA. An absolute commitment, Senator, to work with you on that. And I have some of my team here, and they heard that admonition you just gave about not being able to get certain technical assistance. We will make sure that whatever you need, we will try to get it to you.

And as you know, one of the things that makes it more difficult is, it is not just up to HHS. We have to work with our drug enforcement partners, and we look forward to your support in trying to get together all the different agencies that have to have a say in this.

Senator PORTMAN. Well, thank you. I appreciate it, Mr. Secretary. And we will follow up with you right away on that. It has been 2 years, by the way, of us trying to get the technical assistance. And in any case, you know you have the ability to do the rule, and I think it is really important that we have a law eventually. But immediately, you need to let people know they can continue to get access to this medication-assisted treatment.

Title 42 and the border—this is a mess. As you know, we have 7,000 people a day coming across the border, which is a historic number. These are unlawful migrants coming to the border and being allowed in, typically under the asylum rules, 7,000 people a day. We are turning away about half the people under title 42, so another 7,000 people a day would logically be coming in addition to the current 7,000. However, DHS has told us it is more likely to be something like 18,000 a day because more folks will come to the border. They are already doing so, apparently, knowing that this title 42 is going to be expiring.

That is going from a crisis to a catastrophe, I guess you could say, because that is over half a million people a month coming across our border who are unlawful. So this is a huge problem. It exacerbates an already very difficult issue we have. Obviously, we need to do something to deal with the asylum policy, which is the underlying problem, but in the meantime, we need more time.

I guess my question to you is, I am wondering why CDC all of a sudden has decided that pandemic conditions have improved enough to terminate 42 when HHS is also asking us for billions of dollars—and I think we are about to vote on a $10-billion package

of emergency funding to address the pandemic—and you continue to extend the COVID–19 public health emergency, most recently in January, and I assume you will do it again in April?

So you may have been asked this already today. I am sure you have; it is a big concern along the border and for all of us who live in States that are affected by what happens on the border, including the drugs that come across.

Any thoughts on that, Mr. Secretary?

Secretary BECERRA. Plenty of thoughts, Senator. Thanks for the chance to try to clarify. Title 42 is authority that we have under law to address a health-care emergency that relates to the need to quarantine—the ability for us to take measures which otherwise would not be lawful—to try to keep Americans safe. That quarantine authority has been used very rarely, and it is for the purposes of something like this pandemic that we have suffered.

The public health emergency authority that I have to declare a public health emergency throughout the country applies different law in different ways with different standards. And so that is why you see a different treatment of title 42 and the public health emergency. What you talked about on the border is one of the conditions that was reviewed for purposes of title 42. But title 42 is not an immigration-related law. It is a health care-related law.

When the science and the evidence tell us that we no longer need the use of quarantine authority under title 42 because of health-care conditions, then title 42 must come down. That is why you see the actions being taken by the administration.

The evidence, based on the science, is telling us where to go on title 42. The public health emergency takes into account many other things beyond quarantining necessity and authorities. And that is why you see a difference.

I will close by simply saying this. Using title 42 for immigration purposes is a misapplication of the law. The President, on his first day in office, sent to Congress a proposal to fix our broken immigration system. That is where we need to go if we want to deal with the border situation that we have, not using a health care-related authority to try to deal with immigration challenges.

The CHAIRMAN. The time of the gentleman has expired.

Senator Brown is next.

Senator BROWN. Thank you, Mr. Chairman.

Mr. Secretary, it is nice to see you. Thirty years in this city, so congratulations. Thanks for the work you are doing. Just a few things I would like to mention in your work of lowering drug costs, addressing pharmacy fees, CMS's announcement just yesterday that it will be covering up to eight at-home COVID tests for Medicare beneficiaries. Thank you for all of those things.

There is a lot to like in your budget. I would like to pick one thing that I know you agree on. You were helpful in this in the House when you were there.

Some time ago, 25 years ago I think—yes, 25 years ago—Akron Children's Hospital came to the House and asked that we begin something called Children's Hospital GME, because they did not have the dollars through Medicare reimbursement to fund children's hospitals the way that we should. It is clearly the best way to ensure the future of our pediatric provider workforce. It is the

single best way to train pediatricians. You know that from your family. You know that from your work.

The President's budget proposes $350 million for CHGME, a slight decrease in funding. We had included $375 million in the omnibus just passed recently. Will you work with me and Senator Casey on this committee—who has been a real leader—and other champions here in Congress to make sure we go in the right direction, not the wrong direction, in CHGME funding?

Secretary BECERRA. Absolutely, Senator. And remember that those numbers that we put out in the budget were what we thought we would have, based on the CR. And so we had to be realistic about where we could go, and the CR was way below what the Omnibus is. So do not take those numbers so literally, because they were based on what we knew at the time of the budget being prepared, not what ended up happening with the Omnibus.

Senator BROWN. Thank you. And we will count on that. I know your history, and I know your heart on this.

Cincinnati is home to two CDC NIOSH facilities—National Institute of Occupational Safety and Health—where 550 Federal employees conduct cutting-edge research. It is not nearly as well-known as it should be. It is really an institution—there is no facility in the world like this NIOSH facility, where we really do learn so much through the collection of data and study about occupational work injuries, and occupational work illnesses. And it really is something I am particularly proud of in my State.

HHS several years ago set aside $110 million to consolidate and upgrade the current NIOSH facilities into one building, or one set of buildings, bordering the University of Cincinnati campus. Unfortunately, the Trump administration sidetracked it, or worse, and we need to make sure that we move forward on this facility, which is state-of-the-art by any measure.

Share any update on this project today, if you would, to reassure the NIOSH workforce and the city of Cincinnati, and workers around the country, that this is going forward?

Secretary BECERRA. Senator, we are committed to it, because there is no way that OSHA can do its work if NIOSH is not operating properly. And NIOSH has a great responsibility to make sure we are getting real evidence, real data to OSHA so we can make sure that we are protecting workers against the occupational hazards that we know exist throughout the workplaces in America.

So we are very committed to it.

Senator BROWN. Good.

Two other statements. One, I would like you to come visit Cincinnati at some point during this so you can see NIOSH in person.

Secretary BECERRA. I appreciate that.

Senator BROWN. And second, the President recently put out an executive order in support of the use of project labor agreements for large-scale construction projects like the Cincinnati project. It is my expectation that HHS, or CDC as its proxy, will support the use of a project labor agreement for the construction of this new facility. My staff will be working with your office, with folks at CDC. I am looking forward to making sure this project, which is about workers, centers workers in its construction, in what we need to do.

Secretary BECERRA. I'm with you all the way.

Senator BROWN. Thank you, Mr. Chairman.

Thank you, Mr. Secretary; good to see you.

The CHAIRMAN. Thank you, Senator Brown. As always, sticking up for the consumer. Thank you.

Next is Senator Bennet.

Senator BENNET. Thank you, Mr. Chairman. Can you hear me?

The CHAIRMAN. Yes.

Senator BENNET. Okay; I really appreciate it. Secretary Becerra, I want to thank you for joining us this morning, and it was great to see you in Denver a few weeks ago discussing the important topic of youth mental health, which I know is of great concern to both of us. I deeply appreciate your attention to that.

And as you know—and I know you know—rising costs are a concern for many Coloradans and people across the country. We have a real opportunity to do something this year on prescription drugs.

I believe very strongly that we should work to cap insulin at $35 a month. At the very least, we need to make sure we are not increasing costs at this time, which is why we need to extend the advance premium tax credits that were expanded under the American Rescue Plan.

In Colorado, 75 percent of people on the exchange are receiving financial help to make health insurance premiums more affordable this year as a result of these expanded credits. And if we do not extend them, Coloradans could lose $74 million in support for premiums for 2023.

I have seen Congress do everything they can to extend tax cuts for the wealthiest people in the country, and for the largest businesses. It seems to me that the least we could do is extend this support for middle- and low-income Americans.

Secretary Becerra, could you highlight how important it is for Congress to extend these premium tax credits as soon as possible?

Secretary BECERRA. Senator, as you know, there is a cliff that exists for those in the middle class to be able to afford health insurance coverage for their families. There is nothing like having a good quality health insurance plan to give you peace of mind, to know that if you ever need it, your child can go to the hospital when necessary, and you will not go bankrupt as a result.

Extending these tax credits is indispensable in continuing the progress in getting more and more Americans covered. We saw an additional 20 million Americans get health insurance coverage under President Biden's plans, and we want to continue that progress. Because, as I said, there is nothing like having the peace of mind knowing that you can take your child or loved one to the hospital when necessary.

Senator BENNET. And can you connect that to the tax credit extension?

Secretary BECERRA. Without the tax credit, many of these families, middle-class families that received affordable insurance coverage under the Affordable Care Act, would not be able to hold it. It would be too expensive. And it could be something as simple as getting a small raise in your salary from one month to the next, and that puts you over the top of what allows you to quality for a tax credit. That is insane. That is the cliff that people fall over.

Senator BENNET. That is truly insane. And by the way, if you want to inspire people to work, you have to do away with these kinds of cliffs.

Just in the last couple of minutes I have left, Mr. Secretary—we spend a significant amount of time on mental and behavioral health in this committee, and I am glad that the budget reflects the importance of addressing this issue as a crisis.

The budget includes a number of proposals we are considering, including improving Medicaid, which would help the poorest and most vulnerable children and youth in this country.

Could you talk a little bit about why we need to make strategic investments to address this mental and behavioral health crisis for young people in this country?

Secretary BECERRA. Senator, today, if you were to talk to families across the Nation about mental health, about half of those who are parents would tell you that their children—they have had to think about taking their child in to get mental health services. About half. We have seen the numbers skyrocket for ER, emergency room visits by young adults and adolescents, especially among girls. It is a crisis, and we know it is somewhat under the table, but it is a crisis. And we need to start acting now. That is why the President makes substantial investments in this.

I will tell you that the more help we have in making sure that we launch well the 988 national hotline number that will be used to help those who call, whether it is because of suicide or other mental stress—anyone who is thinking about committing suicide who takes the time to make a call and reaches out for help should not receive a busy signal or be put on hold. 988 will launch in mid-July. We are putting together this network of detached providers who are out there right now in the country. We want to make it into one holistic approach. 988 should become the equivalent of 911 for mental health.

Senator BENNET. I agree with that, Mr. Secretary, and I will also say that, in Colorado, we are having a mental health crisis among our young people, our adolescents, that is unlike anything that we have faced before. Part of that is COVID, but it is lots of other forces that are tearing at our young people as well, and especially in rural places where there really is no access to services. This has become a huge, chronic problem.

Mr. Secretary, thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Bennet.

Senator Daines is next.

Senator DAINES. Mr. Chairman, thank you. Mr. Secretary, thank you for coming up here today.

For 50 years, title X family planning funding has been managed successfully by the State of Montana's health department. In fact, last year Montana passed a law that prioritizes awarding these funds to comprehensive health-care providers like community health centers, rather than abortion centers like Planned Parenthood. Last week, your Department pulled more than $2 million in funds from the State of Montana and awarded it instead to a pro-abortion nonprofit that has pledged to funnel these funds to Planned Parenthood. This loophole does an end-run around Mon-

tana State law. It violates the Federal title X law itself, which says that funds cannot be used as support for projects where abortion is a method of family planning.

This is not the first time that you have abused taxpayer dollars to get around State laws, since last year you also deployed title X funds to try and counter Texas's life-saving Heartbeat Act. You have told this committee repeatedly you would follow the law. What we have seen here in these two examples is, that is not the case.

Mr. Secretary, why should Congress give you a 40-percent increase in title X funds that you have requested when you are abusing these funds to get around my State's and other States' pro-life laws, contrary to Federal law and the will of Montanans who do not want to subsidize the abortion industry with their tax dollars?

Secretary BECERRA. Senator, first let me thank you for the way you posed the question, because I know that we all have some very deeply held beliefs when it comes to the issue of abortion. But our beliefs are not the law. We must be guided by the law.

And as I said when I was first here for confirmation, we will not only follow the law but we will make sure we enforce the law.

Senator DAINES. Have you reviewed, has your team reviewed the Montana State law that is very clear on this issue, that prioritized—for these exact reasons—that the feds would not come in and pull $2 million, basically usurping the laws of Montana because of a certain agenda that you are driving here relating to abortion?

Secretary BECERRA. Senator, with due respect, it is not an "agenda." It is the law that we have to follow——

Senator DAINES. Have you looked at the Montana law? We just passed this law, and you have circumvented the law and pulled $2 million and reallocated it against the will of the people of Montana and the laws of Montana.

Secretary BECERRA. Senator, as a Federal department, we must abide by Federal law. That is what we are doing when it comes to our family planning program money. And we will continue to abide by the law. We respect what a State may wish to do in deploying some of its resources, but we have an obligation to follow Federal law.

Senator DAINES. Well, we will look forward to further discussions on this, as you have gone around the laws of Montana, literally dollars allocated and then pulled back.

I want to talk about title 42 for a moment. In Montana, we are a northern border State, so you are probably wondering, why is a northern border State raising the question of what is going on in the southern border? Well, it is because we are a northern border State with a southern border crisis.

Our communities in Montana have been devastated by the inflow of drugs, particularly Mexican cartel meth, and now fentanyl, as well as heroin. And what is happening is that our Border Patrol agents are overwhelmed by the flood of illegals coming across our southern border. It is a zero sum game. It is a zero sum battle, because the resources are being used to apprehend the illegals coming across, and they cannot spend the time needed here to stop the

drugs that are flooding across the southern border by these Mexican cartels.

With this drug crisis that we see in Montana, there comes as well a massive increase in violent crime, nearly all of which, if you speak with law enforcement on the ground, is tied directly to the drugs flowing across the southern border.

Now, instead of being tough on the border, this administration has taken an outrageous step of ending title 42 removals. There was a border sheriff, a southern border sheriff, here last week who says we have a crisis on our hands today. Removing these title 42 provisions turns it into a disaster. It has been widely reported that the DHS is making preparations for as many as 18,000 illegal immigrants per day.

Mr. Secretary, given the CDC's role in this decision, can you discuss the extent to which you consider the potential impact rescinding title 42 would have on illegal immigration?

Secretary BECERRA. Senator, thank you for the question. And if we focus on what title 42 is, it is an authority that is granted under statute to deal with health conditions in the country, usually for purposes of quarantining.

What CDC had to do in implementing title 42 is determine whether or not, based on the health conditions in the country, we could take measures which otherwise would not be allowed by law to try to isolate or quarantine individuals. That is the purpose of title 42.

CDC has considered current public health conditions and recent developments within the COVID–19 pandemic and made the decision based on health considerations. What you have spoken to—and you raised some really important considerations when it comes to immigration law and also our border enforcement—those are not necessarily public health-related conditions.

On President Biden's first day in office, he sent to Congress a proposal to reform a very broken immigration system. But we cannot use a health-care law——

Senator DAINES. And President Biden rescinded the Remain in Mexico policy when he was sworn in as well, which has been a direct contributor to the flood of illegals we are seeing on the southern border.

So, I am out of time. Thank you, Mr. Chairman.

The CHAIRMAN. I thank my colleague. And since there was a question about title X, I just want to make sure everybody who is following this understands that under Federal law, title X can be used for contraception and for family planning. That is under Federal law what it can be used for, and we are going to put into the record some further analysis of that.

[The analysis appears in the appendix beginning on p. 120.]

The CHAIRMAN. Let's see. Next will be Senator Lankford.

Senator LANKFORD. Mr. Chairman, thank you. Mr. Secretary, thanks for being here. This is a long day for you already. We have been popping in and out heading to votes. You have been trapped in the chair for a while going through this, so I appreciate your engagement.

Let me do the unusual thing between the two of us, and give you some compliments at the beginning. Can I do that?

Secretary BECERRA. Absolutely.

Senator LANKFORD. Your team at CMS and their work on DIR fees is something that—I have pushed for a long time on this. I am pleased to be able to see the work going on with CMS in the DIR fees. That is a very big issue, especially for rural pharmacies continuing to be able to do the work. There are a lot of people who are counting on access to rural pharmacies and other pharmacies based on that work. Just don't allow entities out there to be able to water everything down with what actually needs to be done. Keep going all the way through.

The second thing I would say to you is, you and I had a banter back and forth about "birthing persons" last year in your budget. Your budget does not use the term "birthing persons" this year; you use the term "mothers." Thank you. You have "pregnant people" in there as well. That is close enough on it. So I appreciate just the terminology on being able to use that as well.

Let me talk to you about a couple of things on this that I do want to be able to get in on. Switching over, the questions for the record and the responses from your team have been exceptionally slow, or nonresponsive entirely. I am not trying to be difficult in some of the questions, but when you were before us last summer it took all the way until February to be able to get an answer, and when we got the answers, they were non-answers. When we have asked some other questions to be able to follow up earlier this January, we got a non-answer back in March. We've got to be able to get dialogue.

So even if you and I just get time on the phone to be able to get answers, we have to be able to work through answers and try to be able to figure this out. You have been in the House of Representatives. You know what that is like. You want to actually get answers and try to figure out which direction the administration is going.

So my first question is really just, can we find a process where we can actually get answers to questions?

Secretary BECERRA. Senator, I hope I can give you an answer that says you are going to get what you need. And why don't we do this? I will make sure I give you my cell number before this hearing is over so you can call me directly.

But we have gotten questions where we have had binders full to answer. It is tough when you get over 400 questions asked, more than 500 different briefings that you have to provide. But having served as a member, sitting where you are, absolutely we want to be responsive.

Senator LANKFORD. I will be judicious with that, but let's find a way to be able to just get answers to questions. We are looking for directional issues.

Following up on what Senator Daines was talking about with title 42, this has been used as an immigration policy piece. For instance, the administration came in and changed title 42 and said if you are coming in with a young child, then title 42 does not apply to you anymore. There is no more pandemic for you. So there are some things that have actually worked it as an immigration policy.

I think our biggest issue is that at the same time, there is a request from the administration saying we need 10 billion more dollars because of the pandemic. There is also a decision to say the pandemic is over and the risk is over at the border. And there is not even a requirement for individuals crossing the border to get a vaccine when they cross. It is made available to them, but is not a requirement to be able to do that.

I think that is the biggest issue that we are seeing from everybody.

Secretary BECERRA. And I won't try to give you a full response, but I will simply say that with regard to children, the reason there was an exception made to children—and by the way, that has been questioned by some courts—is because if a child is not allowed to come in, we have no idea what will end up happening to that child.

Senator LANKFORD. Right. These are even family units, though, coming with small children. So it wasn't just a child who was an unaccompanied minor. These were family units of any size, that if they had a 4-year-old with them, then they were all allowed to come in. And again, we can follow up on that. I have 10,000 questions I want to go through.

One of the entities in my State had done testing for at-home antigen COVID tests, which they had great responses from in their labs, and they had a really positive piece. I want to fill you in on what happened on the FDA side on this, though, and the frustration that they have had.

They had a very difficult time hearing back from the reviewers. The lead reviewer that they had went on leave for a while, and no one else was assigned to their case, so they had an extended period of time where they got no responses at all.

When they started getting responses back, they were asked to send information in by email, but the email servers kicked it back and said it was too large. And there was no way to actually be able to submit it online as well, to be able to do it.

When they finally did get an answer just this past week, after all this long process they had gone through for months, this was the answer they got back: "FDA has determined that further review of your EUA request is not a priority. FDA therefore declines to issue an EUA for the product at this time."

Here is the concern. The sense is for these at-home antigen tests that are coming out dealing with COVID, that it seems to be that the larger companies are getting through the process, and the smaller companies are getting the response "this request is not a priority at this time."

Tell me that is not so. And how are we able to document that the larger companies are not navigating the system, and the smaller companies are getting from FDA "you're not a priority"?

Secretary BECERRA. Senator, thanks for the question. Let me first say that if you wish, we could try to follow up on that particular company and find out where things went.

But what I will tell you is, when you are dealing with volume in the tens of millions, we do look for those manufacturers that can produce quickly, because those tests are needed now. And so we do try to reach out to those who can give us the volume that we need.

Senator LANKFORD. But then again, the manufacturer is not necessarily the company that actually created it. So that becomes the challenge here: if you have a really good product, wherever it is coming from, how do you turn that around? If you get a hundred smaller units that are able to accomplish it, that may be the same as getting one larger one. So we are getting back to the biggest companies getting the preference and smaller companies that may have a good product hearing "you're just not a priority."

Secretary BECERRA. We will work with you on that, because we want any—especially a domestic manufacturer or provider, to be able to get that out.

Senator LANKFORD. I will have several questions for the record that I will follow up on, and I will be judicious on how many we give you. I understand you have gotten several, but there are some issues on gender dysphoria and other issues that are coming up. And decisions are being made, and we want to know how they are being made and what the science behind it is and how you are tracking it.

Secretary BECERRA. I look forward to getting them.

[The questions appear in the appendix.]

Senator LANKFORD. Thank you.

Secretary BECERRA. Thank you.

The CHAIRMAN. I thank my colleague. Senator Casey is next online, and then Senator Hassan, who is here, and we just urge colleagues who have not checked in either online or in person, we are getting ready to wrap up.

All right; Senator Casey?

Senator CASEY. Thank you, Mr. Chairman.

Mr. Secretary, great to be with you again. Let me start by commending you for your public service and the work you do every day, and your team does. It is hard, hard work you are doing in a very, very difficult political environment, and I appreciate the work you do and the services you provide to help people across the country.

I wanted to start with long-term care, and I do want to ask one question, a very specific question about children. But long-term care, of course, is a worry for so many families, so many tens of millions of families who worry about this. I know from your own life's story your family has wrestled with it as well. And I know how seriously you focus on this issue. And we know that all of the long-term care challenges that we had before are a hell of a lot worse because of the pandemic, just like everything else is worse.

We've got to ensure access to quality long-term care. And as you note in your testimony, the administration has been focused on several aspects of long-term care, including home and community-based services for seniors and people with disabilities.

We got a good start with this in the American Rescue Plan. We got a foot in the door: $12.7 billion to expand these services. It's never been done before like this, by the way, and the American Rescue Plan made that possible. But $12.7 billion is nowhere near what we need.

To make the investment, to give Americans what they are asking for every day of the week, with a waiting list of almost a million people, we've got to pass legislation. I have the bill, the Better Care Better Jobs Act, and we are going to do everything we can to make

sure that this bill passes, or that a policy is enacted into law that incorporates the bill.

This is obviously better care for seniors and people with disabilities in the place they want the care, either in their home or in the community. It is also, of course, better jobs and better pay for the workers. We cannot have the best caregiving in the world if we are paying workers 12 bucks an hour, and that is the reality in America today.

In addition to the home and community-based services, I have been working with Senator Toomey on legislation that focuses on the Special Focus Facility program, where we have tried to shed light on cases of abuse and neglect in the small number of underperforming nursing homes. We have legislation to do that. I saw that the administration has a 24-percent increase in funding for oversight of nursing homes.

So that is my question. How will these appropriations, or increases in appropriations, toward nursing home quality and oversight be beneficial to better protect residents?

Secretary BECERRA. Senator, by the way, thanks for your longstanding work on these issues. And what I will tell you, as you know, is that there are a lot of these service providers—these facilities are doing their darnedest, and COVID made life even more difficult for them, and it is tough. But it is tough to find the professionals that you need who are qualified. It is tough to pay them properly. All of those things add up.

And then, of course, you have those that do not try to provide that service with quality, and that are cutting corners. And that is where we are going to do much more in oversight and surveillance. The budget, as you said, reflects that with the more than 20-percent increase in funding to make sure we do that. And we are also trying to provide more services and resources so that we can actually help increase the pay of those workers who do indispensable work with our loved ones.

And so, we look forward to working with you, whether it means moving more of the services towards community-based, home-based services, or to make sure if you are going to go to a nursing home or some facility that may not be so close to home, that you are going to receive quality services for your loved one.

Senator CASEY. Thank you, Mr. Secretary.

I wanted to ask you a question about what the administration is doing to track and support children who have lost a caregiver, and how we can better support family members in this circumstance.

We have 200,000 kids in the United States who have lost a parent or a primary caregiver due to COVID–19. Research shows that unaddressed childhood grief and trauma can lead to difficulties like decreased academic performance, mental health issues, and early mortality.

So, what can you tell us about the administration's efforts in this area?

Secretary BECERRA. Senator, it is a tragic story. As you know, tens of thousands of children in America have lost their primary or secondary caregiver as a result of COVID. What we are trying to do is make sure that we provide services to families, whether it is that home or community-based service that makes it possible for

the child to receive at-home services with quality. We are also trying to beef up the support we provide to those kids who have to go through the foster care program, because we know there, we find a lot of kids are falling through the cracks.

We are going to make an emphasis as well on those kids who are aging out of the foster care system to make sure that there are continued resources even after they have to leave the foster care program and be on their own.

And so we are going to continue to make investments. This particular budget, as we have discussed over the course of this hearing—the investments in mental health services, substance abuse services—all of that is focused to make sure we get people back on the right track.

Senator CASEY. Mr. Secretary, thank you.

Mr. Chairman, thank you.

The CHAIRMAN. Thank you, Senator Casey.

Senator Hassan?

Senator HASSAN. Well, thank you, Mr. Chairman and Ranking Member Crapo. And, Mr. Secretary, thank you. Yes, you have been here for a good couple of hours now, so thank you for your patience and your service.

I want to start with a question about medication-assisted treatment. Health-care providers in New Hampshire and experts before this committee have made clear that medication-assisted treatment is critical for individuals with opioid use disorders. With medication-assisted treatment, more people can enter and remain in recovery.

What is the Department of Health and Human Services doing to expand access to medication-assisted treatment?

Secretary BECERRA. Well, we've been working with our partners in the Drug Enforcement Administration and the Department of Justice to make sure that we can move forward, because we have seen that the data proves it. The science and the evidence show that medication-assisted treatment works. And so we want to make sure that we give providers the flexibility to offer that treatment to a lot of folks who will benefit from it.

So we are going to be driven by the science and the evidence, working with you—and thank you for all the work you have done on this—to make it possible for folks to recover.

Senator HASSAN. Well, that is good to hear. There were obviously restrictions lifted and some flexibilities granted during the pandemic, and it sounds like you are going to continue to work with the DEA and States to make sure that we could perhaps make some of those permanent, again based on data.

Secretary BECERRA. Absolutely.

Senator HASSAN. Thank you.

As drug prices soar, Granite Staters are rationing lifesaving medications because they cannot afford them, choosing between filling their prescriptions and putting food on the table. One of my constituents stopped taking her blood pressure medication for periods of time and suffered a stroke, and is now in long-term care, something she was hoping to avoid as she aged.

Congress has to take immediate action to cut drug prices. How would allowing Medicare to negotiate drug prices save money for patients and reduce Federal spending?

Secretary BECERRA. Well, Senator, as you just pointed out with one of your constituents not taking medication as needed, that is so common. One in three Americans have reported to us that they do not take the medication they are supposed to because they cannot afford to continue to use it up as quickly as they would. And so, we have to do something.

We are ready to use whatever authorities we have. We do not believe we have the kind of authority that will not send us to court to be able to do as good a job as you all could do to change some of the law to give us more authorities. But if we were able to, for example, negotiate the price of drugs the way you negotiate the price of a car, the way you negotiate the price of that mechanic bill—there is no reason why when something is as important and precious as a medical service or a prescription drug, you cannot get the best price for your patient or your loved one.

Give us that opportunity through Medicare, and we will lower the price of prescription drug medication for Americans.

Senator HASSAN. Well, I hope we can find bipartisan support to do just that. Thank you for your commitment to lowering the cost for prescription drugs.

I want to move on to the issue of title X. State laws restricting women's capacity to make their own health-care decisions and, frankly, chart their own destiny, are forcing some family planning centers to close and others to serve entire regions using very limited resources.

New Hampshire's State Government's recent decisions to reject federally funded contracts to some family planning centers is going to make it harder for centers to serve their patients. How have State anti-choice restrictions influenced the budget requests for family planning funds?

Secretary BECERRA. Senator, first and foremost, we must enforce and comply with Federal law. And under Federal law, family planning services should be available to families who qualify. We are going to make sure that we provide that service, including contraception services, to families throughout the country.

We respect what States wish to do in terms of how they implement their particular laws and their enforcement and administration of their services, but we have an obligation to make sure that under our laws, our Federal laws, no one is discriminating. So we are going to make family planning services available to everyone who qualifies under Federal law.

Senator HASSAN. Well, I thank you for that commitment. That is why I am working to increase title X funding in the Fiscal Year 2023 Appropriations bill. I look forward to working with you to make sure that that happens so that we can support these critical services for women in New Hampshire and all across the country.

A quick question about child care and Head Start. The Office of Head Start and the Office of Child Care operate two very different but equally important programs to support early learning. Combined, these two offices help more than 2 million children access affordable child care across the country each year.

How will HHS most effectively use the current proposed budget increase to ensure that these two agencies work collaboratively to serve as many families as possible?

Secretary BECERRA. Senator, one thing I can tell you is that we wish to have those services be as seamless as possible. So, whether it is Early Head Start program, or whether it is just child care for the infant and toddler, we want to make sure that throughout that process, a family knows that their child will get the best care and educational services possible.

So we are going to try to be as coordinated as we can to make that as seamless a process as possible.

Senator HASSAN. Well, I appreciate that very much.

Thank you, Mr. Chair.

The CHAIRMAN. Thank you, Senator Hassan.

Senator Warren?

Senator WARREN. Thank you, Mr. Chairman.

So, President Biden has created a record 7.9 million jobs. There were more jobs created in the first 14 months than of any presidency ever. But even as we are trying to get our economy and our lives back to normal, families are getting hit by rising prices on essential goods from gas to groceries. And, as Americans are looking to get out and about again, to go back to restaurants and bars and gyms and movie theaters, those businesses are struggling to find enough workers to meet the surging demand.

So now economists are warning that inflation could spread from goods to services, especially if we do not get more workers into the labor force. But one of the big things that is holding back the labor force participation is a shortage of affordable child care.

Secretary Becerra, when parents cannot find affordable child care, how does that affect parents' ability to work, and in turn, businesses' ability to hire?

Secretary BECERRA. It brings things to a halt. It grinds to a halt, and you are stopping productive Americans from getting out there and helping businesses be profitable and prosper. It makes it very difficult for our economy to continue to be the leader when you cannot get people who are qualified to get out there and work.

Senator WARREN. Well, you know, you make a good point here. The American economy relies on working parents. And the parents rely on child care to be able to go to work. But even with record job creation across the economy last year, the child-care industry is still down 136,000 workers compared to early 2020.

So, Secretary Becerra, there is clearly strong demand for child care. Why isn't supply rising to meet it? Why hasn't the market solved this problem?

Secretary BECERRA. Well, if it is left in the private sector's hands, it becomes unaffordable for most families, including middle-class families. You are paying essentially college tuition to care for your 2-year-old child. At the same time States, with the support of the Federal Government, have been providing subsidies to help child-care providers get out there and offer those services.

Here is the difficulty: as you mentioned, some of the workforce is getting paid the lowest wages. They need to increase that, because those folks are now saying, "I do not have to do this job. I can go make more money flipping burgers." We have to increase

the wages that we pay to people who are essentially caring for the next generation of leaders, and at the same time we have to be able to expand the size of the care facilities so that they can take in more kids from these families.

And so, the proposal in Build Back Better actually made some of that possible. I hope that we are able to succeed in getting some of that across.

Senator WARREN. So let's just unpack that, though, a little bit in what you are talking about here. Child-care providers are operating on razor-thin margins. They just simply do not have money to pay their workers more than those workers could make right now by just moving over to McDonald's, or to the gas station down the street.

That means the child-care center cannot hire staff, and that means that our economy does not have the child-care slots that it needs for parents to be able to get back to work, and for our economy to get back to normal.

So let me just ask. I think you have already referred to this, but let me put the question to you directly: do you agree that to fix this problem, Federal investments in child care are essential, not just for tackling higher costs for families with young children, but also for reducing the drivers that are raising costs economy-wide?

Secretary BECERRA. Without a doubt. Just for the same reason we have public education in this country, we realize that if we left it in private hands, very few parents would be able to afford to send their kids to K through 12. The same thing applies to child care.

We need to be supportive, because there are caregivers who are trying to do the best job they can, but they are overwhelmed.

Senator WARREN. In other words, whether we have children individually or not, we all have an interest in making this economy work. And child care is part of making this economy work. Is that fair?

Secretary BECERRA. It takes a village.

Senator WARREN. Well, thank you very much. This is a critical moment in our economic recovery, and we need to make these investments in child care in order to keep our economy on track and to fight back against inflation.

Investments in child care will help lower costs for working families, and will help boost our economic recovery by ensuring that parents can go to work, preventing a labor shortage, and preventing further inflation.

These investments just cannot wait. American families cannot wait. Our economy cannot wait. So I hope we can get this done and get it done soon.

Thank you very much for your work on this, Mr. Secretary.

Secretary BECERRA. Thank you.

The CHAIRMAN. Thank you, Senator Warren.

Mr. Secretary, you have been very patient. We appreciate it. There is just one issue left that is really important to Oregonians, and I have to ask about it. That is this question of the pharmacy benefit managers squeezing these pharmacies. And we have seen it all across Oregon.

As you know, Oregon is not alone. This is happening everywhere. And essentially you have these small pharmacies, like the one I visited recently in southern Oregon, that have the PBMs and the insurance companies come in long after the sale has been made—in one instance, I was told about a year after the sale was made. And it is almost like the PBM says, "Gee, we are not making enough money this year. We are just going to come back and tell the pharmacist they have to send us another big chunk of money."

And the idea that in America, after you have purchased something, in effect you have a point of sale—you are an Attorney General; that is just kind of basic consumer protection law. You are not allowed to just come back months and months, and in this case, a year later—and this rise of what have euphemistically been called direct and indirect remuneration, or, quote, "DIR" fees, just strikes me as an absolute rip-off. And I see the pharmacists not being able to make these payments, which hurts the consumers, particularly in underserved areas, and you have this spiral that leads, as I have seen over the last few months, to folks just waiting in line because the existing pharmacies suddenly have all these new people who will deluge the facilities that remain.

And our CMS Director Chiquita Brooks-LaSure, in my view, is really doing good work in terms of trying to get some protection for folks, and to get a point-of-sale rule so that these PBMs could not come back and just indefinitely squeeze the small pharmacy. And I would just not be accountable to my constituents where this issue is front and center, particularly in rural communities—our State legislature is focused on it—I would not be accountable to my constituents if I did not ask you where we stand on this, and I want you to know that your CMS Director has been very responsive to my questions.

I just would like, before we wrap up, to get a sense of where we are with things.

Secretary BECERRA. Mr. Chairman, probably the best thing I can tell you is to stay in touch with Administrator Brooks-LaSure, because we are trying to move as quickly as we can on this.

Everywhere I go—and I have gone to a lot of community health centers, a lot of places dealing with vaccines and so forth. Everywhere I go, I always get tapped on the shoulder by someone who says, "Can we really deal with this? Because it is making it not only impossible for us as a provider, a pharmacy, to dispense, but it makes it tough for us to help those families who need those prescriptions right away."

And so, we want to tackle this, but as you know, this is an issue that has been around festering for years. I think CMS is going to try to move as quickly as we can. I suspect we are going to find ourselves in court at some point or another, but we are going to move, because it is too important to make sure we dispense these medications that people absolutely need.

The CHAIRMAN. There is unquestionably a powerful lobby out there for business as usual. And I just want to raise—I have been visiting a little bit with my friend and colleague Senator Crapo, because we have lots of these small pharmacies.

The PBMs clearly had a role 30 years ago when people did not have all the data that is out there now about pricing, and there

weren't people who could use it all. But somehow the PBMs just seem unwilling to change. They just want to do business as usual along the lines of what I described in Oregon and what you have people, in your words, tapping you on the shoulder about when you show up, for example, in a small town in Ohio or West Virginia or Montana, where people all have these kinds of concerns.

So I just thought it was fitting that we wrap up with that. We thank you very much for your taking the time to bring us up to date on the administration's priorities. And I just wanted to wrap up with an issue that really has a human face in communities all across the country. And I can see that you are very much aware of that, and we look forward to working with you on this issue and others.

Questions for the record are due to the committee on April 12th at 5 p.m. I also want to thank my colleague, Senator Crapo, for his assistance, especially this morning, but on so many things. And you could probably tell, as you take off, Mr. Secretary, how committed the members here on both sides of the aisle are with respect to the mental health issue, which we will also be working closely with you on.

With that, the committee is adjourned.

[Whereupon, at 12:35 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

Chairman Wyden, Ranking Member Crapo, and members of the committee, thank you for the opportunity to discuss the President's Fiscal Year (FY) 2023 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.

HHS addresses many of the challenges facing our country today—ending the COVID–19 pandemic, reducing health-care costs, expanding access to care, improving health equity, ending HIV/AIDS, enhancing child and family well-being, addressing the overdose epidemic, and strengthening behavioral health—and we are making meaningful progress on these priorities. Our work has never been more important, and I am honored to lead HHS at this critical moment.

The budget advances the HHS mission to enhance and protect the health and well-being of all Americans. We are proud to be Congress's partner in supporting the American people, and we are grateful for the funding you have provided in support of the HHS mission. We take very seriously our commitment to ensure we are good stewards of every dollar in our budget.

Before I dive deeper, I first want to reflect on the Department's incredible achievements over the past year to save lives and improve health. Thanks to our work to develop and distribute vaccines and boosters, over 215 million Americans are fully vaccinated against COVID–19, and two-thirds of adults over age 65 have gotten their booster shots—an unprecedented accomplishment that saves lives every day. HHS procured and provided life-saving antivirals, monoclonal antibodies, and ongoing testing support, with more to come. To date, HHS has provided critical support that resulted in the emergency use authorization (EUA) of 3 vaccines (2 of which are now fully licensed), 7 therapeutics, and 29 diagnostics against COVID–19. HHS has procured millions of COVID–19 treatment courses for Americans, and is supporting the President's pledge to directly provide 1 billion tests to American households for free. Testing capacity has dramatically increased, and we've supplied free, high-quality masks to the American people. HHS has invested $250 million in U.S.-based manufacturing of personal protective equipment (PPE) and $950 million in manufacturing the supplies and equipment needed for vaccines, therapeutics, and diagnostic tests to strengthen the public health supply chain. We distributed Provider Relief Funds to support health-care providers hit hard by the pandemic, and to reimburse providers for testing, treatment, and vaccine administration for uninsured patients. We provided guidance to support the safe return to the classroom, enabling schools nationwide to reopen.

As the President has said, it is critical to get Americans back to our more normal routines, while still protecting people from COVID–19, preparing for new variants, and preventing economic and educational shutdowns. HHS contributions over the past 2 years position our country to move forward safely, and we look forward to working with you to continue these efforts.

The country has seen historic increases in health insurance enrollment through the marketplaces, with a record 14.5 million people signed up for 2022 health-care coverage during the latest Marketplace Open Enrollment Period. Uninsured rates fell last year after the American Rescue Plan Act took effect, and continue to fall due to the success of innovative and targeted consumer outreach campaigns. We are

implementing initiatives like the No Surprises Act, which establishes new Federal protections against certain kinds of surprise medical bills. We are preparing for the expansion of the Suicide Lifeline with the 988 implementation that will launch this summer. Working with our interagency partners, we also launched interagency initiatives like Operation Allies Welcome, a whole-of-government effort that helped over 68,000 Afghans to permanently resettle in 2021.

HHS has made key investments to address disparities and improve equity and launched new efforts to protect vulnerable communities who bear the brunt of climate change. We are prioritizing rural health and the needs of our Tribal partners. We released a new HHS Overdose Prevention Strategy and made significant investments in behavioral health. It is also an administration priority to advance legislation that helps lower costs for families, including for child care, preschool, and long-term care, and I look forward to working with Congress to achieve this together.

The President's budget will enable us to continue these critical efforts and achieve our mission in FY 2023. The FY 2023 budget proposes $127.3 billion in discretionary and $1.7 trillion in mandatory budget authority, including newly proposed mandatory funding for the Indian Health Service and a historic mandatory funding request to transform our ability to protect the Nation from future pandemics and other biological threats. These investments support families through early education, behavioral health, and access to care. The budget demonstrates the administration's commitment to reinvesting in public health, research, and development to drive growth and shared prosperity for all Americans by making major investments in priority areas, including overdose prevention, mental health, maternal health, cancer, and HIV/AIDS. COVID–19 has shown that health inequities and insufficient Federal funding leave communities vulnerable to these crises. The budget advances equity and helps ensure our programs serve people of color and other underserved communities with the opportunities promised to all Americans.

TACKLING COVID–19 AND PREPARING FOR THE NEXT BIOLOGICAL THREAT

First, I want to highlight that although HHS has made tremendous progress in the fight against COVID, we now face a dire moment. As you know, the administration requested $22.5 billion for immediate needs to avoid severe disruptions to our COVID response. We requested these funds as emergency resources, in the same way Congress provided multiple times on a bipartisan basis under the prior administration. We face unavoidable impacts of not receiving these resources. Testing and treatment capacity will decline. The uninsured fund—which offers coverage of testing, treatments, and vaccinations for tens of millions of Americans who lack health insurance—will run out of money and stop paying provider claims. Already, it has stopped accepting provider claims for testing and treatments reimbursement, with the same soon to follow for vaccinations. Many Americans will no longer be able to access life saving monoclonal antibodies and antiviral drugs. We will be unprepared for a new variant and unable to provide life-saving vaccines to the American people. It is critical that we work together to avoid these and other severe consequences.

Beyond the need for investment in immediate COVID–19 response requirements, the FY 2023 budget builds on Congress's response investments to transform our preparedness for biological threats and strengthen national and global health and health security. The budget includes a historic $81.7 billion in mandatory funding over 5 years across the Office of the Assistant Secretary for Preparedness and Response (ASPR), CDC, the National Institutes of Health (NIH), and the Food and Drug Administration (FDA) to support the administration's vision for pandemic preparedness.

This request provides $40 billion to the Office of the Assistant Secretary for Preparedness and Response to invest in advanced development and manufacturing of countermeasures for high priority threats and viral families, including vaccines, therapeutics, diagnostics, and personal protective equipment. It provides $28 billion for the Centers for Disease Control and Prevention (CDC) to enhance public health system infrastructure, domestic and global threat surveillance, public health workforce development, public health laboratory capacity, and global health security. It provides $12.1 billion to NIH for research and development of vaccines, diagnostics, and therapeutics against high-priority biological threats; biosafety and biosecurity research and innovation to prevent biological incidents; and safe and secure laboratory capacity and clinical trial infrastructure. The budget also includes $1.6 billion for the Food and Drug Administration to expand and modernize regulatory capacity information technology, and laboratory infrastructure to support the evaluation of medical countermeasures.

Collectively, these activities will build capabilities the Nation urgently needs to respond to future pandemics and biological threats from any source, strengthen international systems so that we can detect threats early and respond to threats quickly, and enable us to boldly and decisively act on the lessons from COVID–19.

In addition to this mandatory investment, the budget also funds critical ongoing response and preparedness efforts through discretionary budgets. The HHS Coordination Operations and Response Element (H–CORE) within ASPR is responsible for coordinating the development, production, and distribution of COVID–19 vaccines and therapeutics. The budget requests $133 million for H–CORE, which is critical to beat COVID–19 and for future emergency response efforts beyond the pandemic, as ASPR builds an enduring response infrastructure. These resources will support the necessary staffing, acquisition support, and data analytics for COVID–19 countermeasures when emergency funding is no longer available to cover these costs.

The budget requests $828 million for the Biological Advanced Research and Development Authority (BARDA), to develop novel medical countermeasure platforms to enable quicker, more effective public health and medical responses to detect and treat infectious diseases. The budget also requests $975 million for the Strategic National Stockpile to sustain and expand the current inventory of supplies to ensure readiness for potential future pandemics.

COVID–19 has shown the importance of timely, reliable data to respond effectively to public health threats. The budget makes robust investments in science and public health to improve and protect health at home and abroad, including at CDC for public health infrastructure and capacity, data modernization, global public health protection, and the Center for Forecasting and Outbreak Analytics. The budget also includes $197 million to expand State, local, Tribal, territorial, and international capacity to combat antibiotic resistance at CDC, as well as an HHS-wide mandatory proposal to encourage the development of innovative antimicrobial drugs.

ADVANCING SCIENCE AND RESEARCH

The budget prioritizes research and scientific advancement. We are grateful for the support from Congress to establish the Advanced Research Projects Agency for Health (ARPA–H), and the budget proposes $5.0 billion to revolutionize how to prevent, treat, and even cure a range of diseases including cancer, infectious diseases, Alzheimer's disease, and many others. This funding is part of a proposed $49.0 billion in discretionary funds for NIH to continue its incredible track record of turning discovery into health. NIH invests in basic research and translation into clinical practice to address the most urgent challenges including preparing for future pandemics, reducing health disparities and inequity, driving innovative mental health research, and ending the overdose crisis.

The budget proposes investments in NIH, CDC, and FDA to reignite the President's Cancer Moonshot with an ambitious goal to reduce the death rate from cancer by at least 50 percent over the next 25 years, improve the experience of people and their families living with and surviving cancer, and end cancer as we know it today. The budget includes increases for CDC to enhance a range of cancer related programs and for FDA's Oncology Center of Excellence.

The budget proposes $6.8 billion for FDA to continue to work with developers, researchers, manufacturers, and other partners to help expedite the development and availability of therapeutic drugs and biological products, and to apply the best science in its food and tobacco work. The budget also proposes $527 million in program-level resources for the Agency for Healthcare Research and Quality (AHRQ) to support evidence-based research, data, and tools to make health care safer, higher quality, more accessible, equitable, and affordable for all Americans.

Importantly, the budget also includes $25 million for CDC and $20 million for AHRQ to launch Centers for Excellence to study long COVID conditions and equip health-care providers and systems to deliver patient-centered, coordinated care for this patient population.

REDUCING HEALTH-CARE COSTS AND EXPANDING ACCESS TO CARE

To enhance the health and well-being of all Americans, the budget makes access to more affordable health care a top priority. The Affordable Care Act (ACA), bolstered by the American Rescue Plan, has expanded health insurance coverage to historic numbers of Americans, and the budget builds on that legacy.

The American Rescue Plan made groundbreaking investments in the ACA by expanding premium subsidies to make coverage affordable for millions more Americans. As I mentioned earlier, a record-breaking 14.5 million people have signed up for 2022 health-care coverage through the marketplaces during the latest Marketplace Open Enrollment Period, including nearly 6 million people who have newly gained coverage. The American Rescue Plan lowered health-care costs for most consumers and increased enrollment to record levels. In fact, consumers saw their average monthly premium fall by 23% compared to the prior open enrollment period. As you know, the American Rescue Plan subsidies will expire at the end of 2022 and without new legislation this will result in millions of Americans losing this more affordable coverage. I look forward to working with the Congress on this key priority. We are also concerned about millions of vulnerable Americans who could lose their Medicaid coverage when the COVID–19 public health emergency ends. To address this concern, CMS has provided multiple rounds of guidance to State Medicaid and CHIP agencies that include a robust selection of best practices and recommended strategies allowed under current law when returning to routine operations after the public health emergency ends. For example, recently, CMS released a State Health Official Letter that extends the time States have to process Medicaid redeterminations after the end of the public health emergency from 12 months to 14. HHS is also working to increase awareness of coverage options through targeted outreach campaigns and making renewal of coverage for those eligible easier to navigate. We also look forward to working with the Congress to find solutions to providing coverage options for the nearly 4 million Americans in non-covered States. Additionally, the administration supports strengthening home and community-based services as an alternative to institutionalized care, to ensure people have access to safe options that work for them.

Rising health-care costs affect all Americans. HHS has taken steps to increase competition, improve transparency, and strengthen consumer protections. Under the No Surprises Act, a critical bipartisan law passed by Congress, HHS continues to implement the law that shields consumers from certain kinds of surprise medical bills and requires greater transparency from providers. HHS also issued a proposed rule to make hearing aids available to individuals over-the-counter that can help provide consumers with more affordable options and lead to a more competitive market.

I look forward to working with the Congress to lower health-care costs and expand and improve coverage for all Americans. Reaffirming the President's charge in his State of the Union Address, we will work to lower the costs of prescription drugs, such as by capping the cost of insulin at $35 per month, and to allow Medicare to negotiate payment for certain high-cost drugs.

During the COVID–19 public health emergency, telehealth has been a reliable resource for providers to reach patients directly in their homes to ensure access to care and continuity of services. The administration is committed to supporting a temporary extension of broader telehealth coverage under Medicare beyond the declared COVID–19 public health emergency to study its impact on utilization of services and access to care. I want to thank Congress for provisions included in the FY 2022 Omnibus spending bill that extend Medicare telehealth flexibilities for 5 months after the end of the public health emergency.

Additionally, the COVID–19 pandemic highlights the importance of vaccines and prevention. Longstanding, deep disparities exist in adult vaccination coverage based on race and ethnicity, particularly among Black and Hispanic populations as compared to other groups. The budget proposes Vaccines for Adults, a new mandatory program modeled after the existing Vaccines for Children (VFC) program, to provide uninsured adults with access to vaccines, free of charge, that are recommended by the Advisory Committee on Immunization Practices. The budget further expands the VFC program to include all children under age 19 enrolled in the Children's Health Insurance Program. The budget also includes a proposal to consolidate Medicare coverage of vaccines under Part B, which will make vaccines more accessible, remove financial barriers, and streamline the process for Medicare beneficiaries and providers.

The budget continues to support the fourth year of the Ending the HIV Epidemic initiative with $850 million in funding across CDC, HRSA, IHS, and NIH for FY 2023. The initiative is critical to achieve President Biden's plan to end the HIV/AIDS epidemic by 2030 and ensure access to HIV prevention, care, and treatment. HHS works closely with communities to support the four key strategies—Diagnose, Treat, Prevent, and Respond—to end the HIV epidemic. The budget also creates a

national program that invests $9.8 billion over 10 years to provide a financing and delivery system to ensure everyone has access to pre-exposure prophylaxis, also known as PrEP, and essential wraparound services.

TACKLING HEALTH AND HUMAN SERVICES DISPARITIES

Advancing equity is at the core of the budget. HHS works to close the gaps in access to health care and human services to advance equitable outcomes for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. HHS is committed to carrying out the President's Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Even before the pandemic, we were not doing enough to provide equitable preventive measures, services, and treatment options in every community—and COVID has only made this disparity worse.

Maternal mortality in the United States is significantly higher than most other developed nations and is especially high among Black and Native American/Alaska Native women, regardless of their income or education levels. The Biden-Harris administration is committed to promoting maternal health and ensuring equitable access to affordable, quality health care for our Nation's mothers. The budget invests over $470 million across AHRQ, CDC, HRSA, IHS, and NIH to reduce maternal mortality and morbidity. This includes increased funding to CDC's Maternal Mortality Review Committees and other Safe Motherhood programs, HRSA's State Maternal Health Innovation Grants program and a new Healthy Start program initiative, and other maternal health programs across HHS.

The budget also invests in maternal and broader women's health and health equity, including $86 million for the Office of Minority Health to focus on areas with high rates of adverse maternal health outcomes and areas with significant racial or ethnic disparities. In addition, the budget also includes $42 million for the Office on Women's Health to fund prevention initiatives that address health disparities for women.

Black and Latino/Hispanic people, along with American Indian/Alaska Native people, are much less likely than White people to have health insurance. Evidence shows that expanding coverage is not only essential for facilitating equitable access to health care, but also is associated with reduced morbidity and mortality, poverty reductions, and protection from debilitating financial bills. The budget supports policies to promote a stronger and more equitable health insurance system beginning with new requirements for data on race and ethnicity in Medicare.

The budget also invests $35 million for a new initiative to systematically identify and resolve barriers to equity in each Centers for Medicare and Medicaid Services (CMS) program through research, data collection and analysis, stakeholder engagement, building upon rural health equity efforts, and technical assistance. CMS is committed to obtaining more accurate and comprehensive race and ethnicity data on Medicare beneficiaries, and to require reporting on social determinants in post-acute health-care settings. CMS also proposes to add Medicare coverage for services furnished by community health workers who often play a key role in addressing public health challenges for underserved communities. These proposals will help identify, mitigate, and lessen health disparities.

Health centers are the first line of defense in addressing behavioral health issues nationwide when resources are available. This is particularly true for underserved populations, including low-income patients, racial and ethnic minorities, rural communities, and people experiencing homelessness. The budget provides $5.7 billion for health centers, including $3.9 billion in mandatory resources.

The COVID–19 pandemic has further disrupted access to reproductive health services and exacerbated inequalities in access to care. HHS commits to protecting and strengthening access to reproductive health care, and the budget proposes $400 million to the title X family planning program to address increased need for family planning services. Title X is the only Federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services in communities across the United States.

The budget increases services to prevent child maltreatment and the need for foster care, and supports States in moving towards child welfare systems that provide more tailored and comprehensive prevention services to a broader, more diverse group of families. Prevention services and support are particularly important for at-risk Black, Latino, Indigenous, Native American, and members of other under-

served communities, which have disproportionate involvement with the child welfare system.

The budget provides $3.1 billion for the Administration for Community Living (ACL), reflecting significant demand increases for critical services caused by population growth and pandemic impacts. ACL supports caregivers and advances equitable access to health care, education, employment, transportation, recreation, and other systems, resources, and opportunities. ACL advances equity by targeting those in greatest social and economic need, with particular attention on people with disabilities and older adults who are marginalized due to race, ethnicity, sexual orientation, gender identity, poverty, language spoken, and who are at risk of institutionalization.

Lastly, the budget takes a historic first step toward redressing health disparities faced by American Indians and Alaska Natives by proposing all funding for the Indian Health Service (IHS) as mandatory. In FY 2023, the budget provides $9.3 billion, which includes $147 million in current law funding for the Special Diabetes Program for Indians. This substantial funding increases of $2.5 billion above FY 2022 enacted will support direct health-care services, facilities and IT infrastructure, and management and operations. It also provides targeted increases to address key health issues that disproportionately impact American Indians and Alaska Natives such as HIV, hepatitis C, opioid use, and maternal mortality. With current law funding for the Special Diabetes Program for Indians, the total program level for IHS is $9.3 billion in FY 2023.

To address chronic underinvestment in IHS, the budget increases funding for each year over 10 years, building to $36.7 billion in FY 2032. This increase of 296 percent over the 10-year budget window accomplishes funding growth beyond what can be accomplished through discretionary spending. Over a 5-year period, the budget will reduce existing facilities backlogs, fully fund the level of need identified by the Federal-Tribal Indian Health Care Improvement Fund workgroup and support the modernization of the IHS electronic health record system. Additionally, the budget grows IHS funding to keep pace with inflation and population growth. This request responds to the longstanding recommendations of Tribal leaders shared in consultation with HHS to make IHS funding mandatory, and HHS will continue consulting with tribes to inform future policy and budget requests. HHS appreciates the strong partnership with Congress to grow funding for the IHS budget over the last decade, and looks forward to continuing our shared efforts to improve health care in Indian Country.

STRENGTHENING BEHAVIORAL HEALTH

HHS is committed to combating America's mental health and substance use crises. The pandemic has had a devastating impact on mental health, particularly for young people, by dramatically changing Americans' experience of home, of school, of work, and in their communities. The President has outlined a bold strategy for tackling the Nation's mental health crisis, calling for an increased focus on building system capacity, connecting more people to care, and creating a continuum of support to keep people healthy and help Americans thrive. I also recently launched a National Tour to Strengthen Mental Health, to hear directly from Americans across the country about the mental health and substance use challenges they're facing and to engage with local leaders to strengthen the mental health and crisis care system in our communities. We are also working with the Department of Education to develop and align resources to ensure children have the physical and behavioral health services and supports that they need to build resilience and thrive. Individuals who develop substance use disorders are often also diagnosed with mental disorders—the budget addresses the significant connection between mental health and substance use by investing in a broad spectrum of behavioral health services.

The budget includes new, historic mandatory investments totaling $51.7 billion over 10 years to address the Nation's behavioral health crisis. In support of the President's call for reforming our mental health-care system to fully meet the needs of our communities, the budget includes a new $7.5-billion Mental Health Transformation Fund, allocated over a 10-year period, to increase access to mental health services through workforce development and service expansion, including through health care and community settings that have not traditionally provided mental health services but that are well-positioned to reach more people. The Mental Health Transformation Fund will also support the expanded use of evidence-based practices for mental health care, to ensure that families and communities affected by mental illness receive the highest-quality care and supports.

The budget improves Medicare coverage of mental health care and makes access to such care more affordable by eliminating the 190-day lifetime limit on psychiatric hospital services and requiring Medicare to cover three behavioral health visits per year without cost sharing. In addition, the budget would recognize licensed professional counselors and marriage and family therapists as independent practitioners who are authorized to furnish and receive direct Medicare payment for their mental health services, aligns the criteria for psychiatric hospital terminations from Medicare with that of other health-care providers, and applies the Mental Health Parity and Addiction Equity Act to Medicare.

Additionally, the budget establishes a Medicaid provider capacity demonstration program for mental health treatment and establishes a performance bonus fund to improve behavioral health services in Medicaid. The budget also expands and converts the Demonstration Program to Improve Community Mental Health Services into a permanent program. Further, the budget prevents States from prohibiting same-day billing and allows providers to be reimbursed for Medicaid mental health and physical health visits provided to a Medicaid beneficiary that occur on the same day and requires that Medicaid behavioral health services, whether provided under fee-for-service or managed care, be consistent with current and clinically appropriate treatment guidelines.

For people with private health insurance, the budget requires all health plans to cover mental health and substance use disorder benefits and ensures that plans have an adequate network of behavioral health providers. The budget also establishes grants to States to enforce parity between mental and substance use disorder and other medical benefits.

The budget also proposes $20.8 billion in discretionary funding for behavioral health programs in FY 2023, including significant investments in mental health programs such as the National Suicide Prevention Lifeline, a free, confidential 24/7 phone line that connects individuals in crisis with trained counselors across the United States. The Lifeline receives calls from people with substance use; depression; mental and physical illness; economic worries; loneliness; and concerns about relationships and sexual identity. Ensuring the success of the Lifeline particularly as it transitions to the universal 3-digit number 988 is a top priority for HHS.

To support the health workforce, the budget includes $397 million for Behavioral Health Workforce Development Programs and $25 million in the National Health Service Corps funding specifically for mental health providers. The budget also includes $50 million for the Health Resources and Services Administration (HRSA) for Preventing Burnout in the Health Workforce. This investment will provide crucial support for health workforce retention and recruitment, which is essential for addressing current and future behavioral health workforce shortages.

Suicide remains the second leading cause of death among young people between the ages of 10 and 34. Many youth, especially young people of color, Indigenous youth, and LGBTQ+ youth, still lack access to affordable health-care coverage that is necessary for them to receive treatment for mental health conditions.

The budget also includes $308 million for Project AWARE and the Mental Health Awareness Training program to expand support for comprehensive, coordinated, and integrated State and Tribal efforts to adopt trauma-informed approaches and increase access to mental health services. School and community-based programs like Project AWARE have been shown to improve mental health and emotional well-being of children at low cost and high benefit. Prevention is an investment in our future, and it lowers adverse outcomes with high societal impact.

According to CDC data, drug overdose deaths increased nearly 30 percent in 2020. Last fall, I announced the release of a new, comprehensive HHS Overdose Prevention Strategy for the Nation, designed to increase access to the full range of care and services for individuals with substance use disorders and their families. This new strategy focuses on the multiple substances responsible for overdose and the diverse treatment approaches needed to address them.

The budget invests $11.0 billion to combat the overdose crisis across HHS in support of four key target areas—primary prevention, harm reduction, evidence-based treatment, and recovery support—and reflects the Biden-Harris administration principles of equity for underserved populations, reducing stigma, and evidence-based policy.

The budget also proposes $553 million for Certified Community Behavioral Health Centers Expansion Grants to provide coordinated, high-quality, comprehensive be-

havioral health services. The budget also proposes to remove the word "abuse" from the agency names within HHS—including the Substance use And Mental Health Services Administration, the National Institute on Alcohol Effects and Alcohol-Associated Disorders, and the National Institute on Drugs and Addiction. Individuals do not choose to "abuse" drugs and alcohol; they suffer from addiction, which is a chronic medical condition. It is a high priority for this administration to move past outdated and stigmatizing language that is harmful to these individuals and their families.

SUPPORTING CHILDREN, FAMILIES, AND SENIORS

HHS has a responsibility to ensure our programs serve children equitably, and the high-quality care of children positively impacts their success later in life. The budget proposes $20.2 billion in discretionary funding for the Administration for Children and Families' early care and education programs. This includes $12.2 billion for Head Start to provide services to more than a million children, pregnant women, and families, $7.6 billion for the Child Care and Development Block Grant, and $450 million for Preschool Development Grants to increase capacity of States to expand preschool programs.

The budget expands home visiting programs over 5 years to provide economic assistance, child care, and health support for up to 165,000 additional families at risk for poor maternal and child health outcomes. This funding will help strengthen and expand access to home visiting programs that provide critical services directly to parents and their children in underserved communities.

The mandatory budget includes a $4.9-billion expansion of services to prevent child maltreatment and the need for foster care. For children who must be removed from their parents, the budget includes $1.3 billion in support for States to prioritize placing children with kin, as well as a $3-billion increase for programs to stabilize and support families and adoptive families, and a $1-billion increase in support for the transition to adulthood for youth who experienced foster care. While not part of HHS's budget, the budget proposes to make the adoption tax credit fully refundable, so that more families can benefit, and to expand the credit to include qualifying legal guardianships.

We face a public health crisis of violence in our communities, which disproportionately affects communities of color. The budget includes $250 million for CDC for the community violence intervention initiative, in collaboration with Department of Justice to implement evidence-based community violence interventions at the local level, as well as funding for firearm violence prevention research. The budget also promotes prevention of and early intervention after adverse events, like community violence, to mitigate longer term impacts, including $15 million for CDC to advance surveillance and research aimed at preventing Adverse Childhood Experiences. The budget also includes $519 million for ACF's Family Violence Prevention and Services programs, including $250 million to provide direct cash assistance to survivors of domestic violence.

The budget supports FDA's public education campaigns to educate youth about the dangers of e-cigarette use; provide resources to educators, parents, and community leaders to prevent youth use; and provide resources to help kids who are already addicted to e-cigarettes quit using these harmful products. The budget includes $812 million for FDA's tobacco program, an increase to enhance product review and evaluation, research, compliance and enforcement, public education campaigns, and policy development.

The Administration for Community Living (ACL) protects seniors and persons with disabilities from abuse through investments in Adult Protective Services and the Long-Term Care Ombudsman Program. As the populations served by ACL continue to grow, the budget provides $139 million to protect vulnerable older adults. The budget also bolsters ACL's role as an advocate for older adults and people with disabilities.

REFUGEES AND UNACCOMPANIED CHILDREN

Amid the COVID–19 pandemic, large numbers of unaccompanied children continue to arrive at our southern border. HHS is committed to fulfilling our legal and humanitarian responsibility to care for all unaccompanied children (UC) referred to us by Federal partners. The FY 2023 budget includes $6.3 billion in discretionary funding for the Office of Refugee Resettlement, including $4.9 billion for the unaccompanied children program so that HHS may continue to care for UC safely and humanely, in alignment with child welfare best practices. The budget also proposes

a mandatory contingency fund to provide additional funds if there is a surge in UC referrals, as well as mandatory funding to build towards universal UC legal representation. HHS is committed to unifying these children with vetted sponsors, usually a parent or close relative, as safely and quickly as possible, and the budget includes funding to implement critical programmatic reforms and service expansions. The budget also builds on the Nation's refugee infrastructure to support resettling of up to 125,000 refugees in 2023, and requests authority to use these funds to support the successful reunification of families who were cruelly separated under the Trump administration.

IMPROVING SAFETY AND OVERSIGHT OF NURSING HOMES

Building on the President's State of the Union Address, the budget is committed to ensuring nursing homes are safe and providing high-quality care to vulnerable Americans by increasing funding for nursing home health and safety inspections by nearly 25 percent. Additionally, by increasing nursing home owners' accountability for minimum quality standards, noncompliant facilities can be held financially responsible for poor safety and care. The budget also requests authority to publish accreditation surveys for other health-care facilities, like hospitals, rural health clinics, and ambulatory surgical centers, which will better inform the public when selecting care locations for loved ones. The administration also supports strengthening home and community-based services to ensure people have access to safe options that work for them.

FUNDING CORE PROGRAM OPERATIONS

While the service provided by HHS continues to grow, investment in the Department's operational needs ensures HHS can carry out its mission to enhance and protect the health and well-being of all Americans while maximizing our resources. This investment strengthens administrative and operational resources throughout the Department needed to ensure proper stewardship of resources entrusted to HHS by Congress.

PROVIDING OVERSIGHT AND PROGRAM INTEGRITY

Given the importance and magnitude of HHS's work, ensuring the integrity of our spending is a core value and responsibility of HHS. The budget increases discretionary Heath Care Fraud and Abuse Control program spending to a total of $899 million to provide oversight of CMS health programs, strengthen OIG investigations, and protect beneficiaries against health-care fraud, yielding a return on investment of $13.6 billion over 10 years. The pandemic has unleashed new health-care fraud risks related to the implementation of billions in new Federal spending, as well as multiple provider regulatory and other flexibilities. These funds are critical to help HHS root out bad actors and ensure program integrity.

CONCLUSION

I want to thank the committee for inviting me to discuss the President's FY 2023 budget for HHS. The budget offers a vision for the Nation that reinvests in America's health, supports growth and prosperity, and meets our commitments to the American people and especially to the most vulnerable. I look forward to working with you to fulfill that vision. If we step up in this moment, we can lay the foundation now. These are critical programs and issues that deserve attention and adequate funding. 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

ORGAN PROCUREMENT ORGANIZATION REFORM

Question. HHS has taken important initial steps to reform the U.S. transplant system. However, a legislative proposal summarized in the President's 2023 budget appears contrary to reforms to establish and enforce performance metrics for the Nation's 57 organ procurement organizations, reforms that I have previously supported and urged immediate implementation of.

Specifically, the budget proposes legislative changes to allow CMS to "recertify certain organ procurement organizations that do not meet the criteria for recertifi-

cation based on outcome measure performance, but which have shown significant improvement during a re-certification cycle."[1] HHS's stated goal is to avoid organ procurement disruptions; however, I am concerned it would undermine the government's ability to hold underperforming Organ Procurement Organizations (OPOs) accountable. Reform of the U.S. transplant system has bipartisan support from this committee and particular relevance amidst the COVID–19 pandemic, which causes kidney damage and is widely expected to cause long-term organ failure in COVID–19 survivors.

It is imperative that the U.S. organ procurement and transplantation system functions at its optimal level to prevent any missed opportunity for organ donation, as no American should die while waiting for a transplant. In July 2021, I along with other bipartisan members of this committee, wrote to CMS to voice our concern with the protracted timeline for enforcement and encouraged CMS to consider ways to hold OPOs accountable during the interim. The budget proposal allowing underperforming OPOs to be recertified goes in the wrong direction on this issue. In light of these concerns, please address the following:

If this legislative proposal is passed by Congress, how would HHS and CMS intend to hold OPOs accountable during the interim period?

And, if OPOs that fail to meet these metrics are recertified, as proposed, how will CMS measure improvement and ensure the improvement is maintained through the certification cycle?

Please provide CMS's rationale for this proposed change.

Please provide any additional details that CMS has developed for this proposal.

Answer. Organ Procurement Organizations (OPOs) are vital partners in the procurement, distribution, and transplantation of human organs in a safe and equitable manner for all potential transplant recipients. The role of OPOs is critical to ensuring that the maximum possible number of transplantable human organs is available to individuals with organ failure who are on a waiting list for an organ transplant.

On December 2, 2020, CMS published, "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations." This rule finalized new outcome measures for the OPOs to achieve to be recertified in 2026. This rule was published with the intention to increase donation and organ transplantation rates by replacing the previous outcome measures with new transparent, reliable, and objective outcome measures that are used to make better certification decisions and increasing competition for donation service areas (DSAs) that were open to competition. At the end of the recertification cycle, each OPO will be assigned a tier ranking based on its performance for both the donation rate and transplantation rate measures, as well as the recertification survey. The highest performing OPOs will be assigned in Tier 1 which means the donation and transplantation rates of the top 25 percent of OPOs, and automatically recertified for another 4 years. OPOs with rates that are below the top 25 percent will be in either Tier 2 or 3. Tier 2 OPOs are not automatically recertified but they will have to compete to retain their DSA. Tier 3 OPOs are the lowest performing OPOs and will be decertified and lose their service area. CMS believes that increasing competition between the OPOs will incentivize them to maximize their performance and consequently increase the number of organs available for transplantation.

There are currently 58 OPOs that are responsible for identifying eligible donors and recovering organs from deceased donors in the United States (U.S.), with no current statutory authority to add new OPOs. Thus, under current law, CMS cannot certify any new entities as OPOs. This not only limits competition with existing OPOs but also excludes from the competition other entities that might perform well as an OPO if certified.

Additionally, if an OPO fails to meet the outcome measures set forth in 42 CFR § 486.318, it will be decertified, even if the OPO has demonstrated significant quality improvement in their DSA during the recertification cycle. An OPO taking over a decertified OPO's low performing DSA may have a significant undertaking to increase their performance to meet the Tier 1 top 25 percent benchmark to be automatically recertified. An OPO may only have 1–2 years in a DSA they took over from a low-performing OPO before being recertified. CMS believes that having the

[1] Health and Human Services FY 2023 Budget in Brief. Option 2, pg. 84. *See, https://www.hhs.gov/sites/default/files/fy-2023-budget-in-brief.pdf.*

explicit legal authority to apply discretion to determine whether to recertify OPOs that have recently assumed responsibility for servicing a previously low-performing DSA and are making significant improvement would provide the flexibility it needs to improve organ procurement in DSAs without disruption to organ procurement.

HOSPITAL PRICE TRANSPARENCY

Question. In September of 2021, Chairman Wyden sent a letter to Centers for Medicare and Medicaid Administrator Brooks-LaSure regarding the Calendar Year 2022 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule. The letter encouraged the administration to finalize proposals to strengthen the thoroughness, accessibility, and enforcement of hospital price transparency regulations under 45 CFR part 180, originally issued in the Calendar Year 2020 Hospital Price Transparency final rule. A recent report indicates that many hospitals may not be fully compliant with the requirements.[2] I am requesting the following information about compliance with this regulatory and statutory requirement.

How many hospitals to date have been issued a warning notice or request for a corrective action plan for noncompliance with the price transparency requirements?

Of the hospitals identified to be noncompliant, how many have subsequently come into compliance and how many have been issued a civil monetary penalty?

What methods under 45 CFR part 180, subpart C is CMS utilizing to monitor compliance with the rule and with what frequency is it engaging these methods?

Answer. Increasing access to affordable health care is a top priority for the Biden-Harris administration. That's why HHS is committed to ensuring that consumers have the information they need to make fully informed decisions regarding their health care.

Hospital price transparency helps people know what a hospital charges for the items and services it provides. Under CMS regulations, hospitals must post on their website a machine-readable file containing a list of all standard charges for the items and services they provide, as well as a consumer-friendly list of standard charges for at least 300 shoppable services. CMS expects hospitals to comply with these requirements, and is enforcing them to ensure people know what a hospital charges for items and services.

In January 2021, CMS began proactive audits of hospital websites as well as review of complaints submitted to CMS via the hospital price transparency website. In April 2021, CMS issued the first set of warning letters to noncompliant hospitals. These letters list specific areas of deficiencies identified through CMS compliance review and request hospital action to remedy the deficiencies. Hospitals that fail to submit a corrective action plan or comply with the requirements of a corrective action plan could be issued a notice of imposition of a civil monetary penalty (CMP). In the event CMS issues a civil monetary penalty, CMS will publish the notice of the CMP on a CMS website.

In the Calendar Year (CY) 2022 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule (86 Fed. Reg. 63,458), CMS finalized modifications to the hospital price transparency regulations to increase compliance. The modifications became effective January 1, 2022 and include the use of a scaling factor to increase the amount of the civil money penalties based on hospital bed count. CMS has issued the first round of warning letters under the new rule and is currently working with all identified hospitals to come into compliance.

HHS looks forward to working with its partners across the Federal Government, along with Congress and other stakeholders, to examine additional ways to increase price transparency across the health-care industry and improve access to affordable coverage and services.

PROPOSAL TO WAIVE MEDICARE COST-SHARING FOR THREE MENTAL HEALTH VISITS

Question. The President's Fiscal Year (FY) 2023 budget includes a legislative proposal to waive the Medicare Part B deductible and Medicare Part B coinsurance for three mental health visits per year. The FY 2023 budget also includes a proposal that would prohibit Medicare Advantage (MA) plans from applying the deductible

[2] Semi-Annual Hospital Price Transparency Compliance Report, February 2022, *https://www.patientrightsadvocate.org/semi-annual-compliance-report-2022.*

or cost sharing for the first three mental health visits that a Medicare beneficiary receives each year. Finally, the FY 2023 budget also includes a related legislative proposal to require that group health plans and health insurance issuers waive cost sharing for three mental health visits and three primary care visits each year.

The Senate Committee on Finance is developing bipartisan legislation to address barriers to mental health care and substance use disorder services. As a part of that process, the committee has examined many of the same policies that are proposed in the FY 2023 budget, such as breaking down statutory limits on psychiatric care in Medicare and allowing more types of mental health practitioners to bill for Medicare services. The proposal to waive Medicare cost sharing for three mental health visits is a policy where the committee would benefit from additional details.

How would "mental health visits" be defined in the President's budget proposal?

Would initial evaluations that result in the diagnosis of a mental health condition be included in the definition?

Would visits and services for individuals with substance use disorders be included in the cost-sharing waiver policy?

Would substance use disorder services be included even if there is not a cooccurring mental health disorder diagnosis?

Does HHS or CMS have a projected number of Medicare beneficiaries who would receive services each year for which the cost-sharing waiver would apply?

Answer. The President's FY 2023 budget includes new historic mandatory investments at HHS totaling $51.7 billion over 10 years to improve behavioral and mental health. Behavioral health is an umbrella term that includes mental health and substance use disorders, life stressors and crises, stress-related physical symptoms, and health behaviors. Among the numerous proposals that would increase access to affordable behavioral health care, the budget includes proposals to require Medicare and private insurance to cover three behavioral health visits per year with no cost sharing.

Currently, Medicare Part B includes coverage of behavioral health visits to a doctor, therapist, or other clinician for services generally received outside of a hospital, but the annual Part B deductible and coinsurance apply, with limited exceptions. This proposal would require Medicare to cover up to three behavioral health visits per year without cost sharing. Eligible visits would include those for routine and lower-intensity services, such as psychiatric evaluation.

The budget also includes a proposal that would require health insurance issuers, group health plans, and Federal Employees Health Benefits Program plans to cover three primary care visits and three behavioral health visits without imposing cost sharing. For high-deductible health plans, these services would be considered pre-deductible for meeting Health Savings Account requirements.

Eliminating cost sharing for individuals removes potential financial barriers to treatment and gives more patients access to the care they need. These proposals would have a positive impact on health equity by improving access and adherence to treatment, creating a pathway to better overall health outcomes.

PROPOSAL TO ESTABLISH MEDICARE COVERAGE FOR DIGITAL APPLICATIONS AND PLATFORMS FOR MENTAL HEALTH

Question. The President's FY 2023 budget includes a legislative proposal to establish Medicare coverage of evidence-based digital applications and platforms that facilitate the delivery of mental health services. As the Senate Committee on Finance develops legislation to address barriers to mental health care and substance use disorder services, it will be important to gain additional detail on this proposal.

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

Would this FY 2023 budget proposal require the creation of a new benefit category in Medicare or could coverage for these digital apps and platforms be incorporated into an existing Medicare benefit?

Does HHS or CMS have any criteria that Congress should consider for determining the scope of digital apps and platforms that should be covered by Medicare?

Would information sharing between the apps and a patient's physician or mental health provider be a required aspect of the operation of Medicare-covered digital apps and platforms?

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

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

Answer. The President's FY 2023 budget includes a proposal to modernize Medicare mental health benefits, including by providing for coverage of evidence-based digital applications and platforms that facilitate the delivery of mental health services. This proposal would also allow Medicare payment and billing by a broader set of practitioners who furnish mental health services, including licensed professional counselors and marriage and family therapists, and would remove limits on the range of covered services that clinical social workers can furnish under Medicare. HHS would welcome the opportunity to provide technical assistance and work with Congress on this proposal.

Also included in the FY 2023 President's budget is a request for increased funding for the Agency for Healthcare Quality Research (AHRQ) digital health research portfolio. AHRQ's Digital Healthcare Research Program provides foundational research to ensure that digital health-care systems are designed and implemented in ways that improve quality, safety, and equity while not resulting in excessive burden on physicians and other members of the care team. The program also funds research to create actionable findings around "what and how digital health-care technologies work best" for its key stakeholders: patients, clinicians, and health systems working to improve health-care quality. In executing this portfolio, AHRQ also operates in coordination with other Federal health programs, particularly the Office of the National Coordinator for Health IT, and its research findings have informed policy at Federal entities such as CMS and the Department of Veterans Affairs. HHS looks forward to working with Congress and other stakeholders to examine ways Medicare can increase access to mental health services, including through coverage of evidence-based technology such as digital applications and platforms.

MEDICARE ADVANTAGE PROVIDER DIRECTORY ACCURACY

Question. Inaccurate provider network directories can create barriers to care as patients try to find an in-network provider for their health needs. In addition, inaccurate directories raise questions about the adequacy of plan provider networks and whether these plans are maintaining a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population. A 2018 CMS report, Online Provider Directory Review Report, found that nearly 50 percent of the provider directory locations had at least one inaccuracy. Some of these inaccuracies included incorrect specialty, the provider should not be listed in any of the directory-indicated locations, and that the provider was not accepting new patients.

Since 2018, has CMS conducted any further studies of provider directory accuracy?

Since 2018, what enforcement actions has CMS taken to ensure Medicare Advantage beneficiaries have access to accurate and up to date provider directories?

What are the enforcement actions CMS can take should the agency find a Medicare Advantage plan directory to be non-compliant with CMS requirements?

Has CMS examined whether provider directory inaccuracies would have resulted in the Medicare Advantage plan falling out of compliance with CMS's network adequacy requirements?

Has CMS examined the provider directory accuracy with respect to mental health and substance use disorder professionals? If so, what are the results?

Answer. Provider directories are an important tool that Medicare Advantage enrollees use to select and contact their physicians and other contracted providers who deliver care. Beneficiaries and their caregivers rely on provider directories to make informed decisions regarding their health-care choices. Inaccurate provider directories can create a barrier to care and raise questions regarding the adequacy and validity of the MAO's network as a whole. CMS is committed to continuing to work with MAOs to improve the accuracy of provider directories.

CMS maintains and enforces guidance on provider directories for Medicare Advantage plans. CMS regulations require organizations to provide the number, mix, and geographic distribution of providers from whom enrollees may reasonably be expected to obtain services. This information must be provided to each enrollee in a clear, accurate, and standardized form. Regulations also require MAOs to adhere to all regulations and general instructions and to disclose information to beneficiaries in the manner and the form prescribed by CMS. Each MAO must post an online provider directory on its website. CMS is taking steps to enforce its requirement that MAOs, Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities make standardized information about their provider networks available through a Provider Directory API that is conformant with the technical standards finalized by HHS in the ONC 21st Century Cures Act final rule.

QUESTIONS SUBMITTED BY HON. MIKE CRAPO

TELEHEALTH

Question. Bipartisan and bicameral leaders of the Finance, Energy, Commerce, and Ways and Means committees recently worked to secure a crucial 5-month extension for key Medicare telehealth flexibilities, ensuring that seniors across the country can continue to access these vital services beyond the end of the public health emergency.

While the President's budget request signals support for temporary policies along these lines, it includes no longer-term telehealth coverage plan, exacerbating the risk of a coverage cliff for older Americans. The proposal also lacks meaningful sources of Medicare cost savings, which could make funding an extension of any length more challenging.

How does the administration envision the path forward for Medicare telehealth access, in terms of both policy substance and financing?

Answer. During the COVID–19 public health emergency, telehealth has been a reliable resource, allowing providers to reach patients directly in their homes to ensure access to care and continuity of services. The Biden-Harris administration is committed to supporting a temporary extension of broader telehealth coverage under Medicare beyond the declared COVID–19 public health emergency in order to study its impact on utilization of services and access to care. Telehealth, including audio-only telehealth, can greatly expand access to services for individuals who may not have access to broadband or technology to support 2-way audio-video. This is particularly true in rural and underserved areas, and among older populations.

The administration is also expanding access to mental health and beneficiary-centered care under Medicare through greater use of telehealth and other telecommunications technologies to provide behavioral health care, among other services. Medicare beneficiaries can access care directly in their homes thanks to recent regulations, including CMS's CY 2022 Physician Fee Schedule final rule, that allow for certain behavioral health services via audio-only telephone calls. In addition, the President's FY 2023 budget includes a proposal to remove statutory limits on the list of providers that are authorized to receive direct Medicare payment for their mental health services, which would expand access to mental health services in Medicare, especially in rural and underserved areas with fewer mental health professionals or in communities more likely to receive care from the referenced practitioners.

DRUG PRICE CONTROLS

Question. The budget request contains a concerning placeholder for a revived tax and spending package, which includes drug pricing policies with grave implications for new treatments, R&D, and front-line health-care providers. The House-passed Build Back Better Act, which appears to be the basis for these provisions, would create a government price-setting program enabling Federal officials to impose price controls on an ever-growing number of medications.

As part of this process, the bill would prohibit manufacturers, most of which are small businesses, from opting out or declining the price set by the Secretary. Noncompliance would trigger a seemingly unconstitutional 95-percent penalty on all gross sales, and the proposal permanently prevents judicial review, stripping the program of any accountability. These government price controls, in short, are negotiation in name only.

Under these proposals, the individual holding your position would have the ability to set prices for selected drugs unilaterally, with no recourse or appeal, even for an egregiously low price that could trigger shortages or take a medicine off the market. How would an unaccountable program along these lines preserve confidence in would-be startups, researchers and investors that incentives for American innovation remain strong?

Answer. HHS looks forward to working with the Congress to lower health-care costs and expand and improve coverage for all Americans. Reaffirming the President's charge in his State of the Union Address, we will work to lower the costs of prescription drugs. In September 2021, HHS released a comprehensive plan to lower drug prices.[3] The Drug Pricing Plan presents principles for equitable drug pricing reform through competition, innovation, and transparency; describes promising legislative approaches; and summarizes actions already underway or under consideration across HHS.

One of the key policies in this effort is legislation that would allow the Secretary of HHS to negotiate Medicare Part B and Part D drug prices directly with pharmaceutical companies and make those prices available to other purchasers, an approach that is projected to generate reductions in patient cost sharing and large savings for patients, government, and commercial payers. The Drug Pricing Plan also describes the administrative tools HHS can use to promote competition and reduce drug prices, including testing models through CMS's Innovation Center and collecting more data from insurers and Pharmacy Benefit Managers to improve transparency about prices and out-of-pocket spending on prescription medications.

HHS is committed to continuing our work to make health care more affordable for American families. By promoting negotiation, competition, and innovation in the health-care industry, HHS will ensure cost fairness and protect access to care.

MEDICAID AS A SOCIAL SAFETY NET PROGRAM

Question. Due to the continuous coverage requirement in place during the public health emergency, Medicaid and CHIP enrollment is now at record highs of over 86 million beneficiaries. However, rather than transitioning individuals to the most appropriate coverage when the public health emergency ends, recent guidance suggests that this administration seeks to keep people on Medicaid for as long as possible. This represents a concerning shift in the purpose of the program.

Care for the traditional Medicaid populations—children, individuals with disabilities, pregnant women, and the elderly—regularly fails to meet the standards those populations deserve, particularly when they are dually eligible for Medicare or receiving long-term care.

States play an integral role in the delivery and design of Medicaid benefits, and must budget appropriately for those services. Unfortunately, misaligned Federal Government incentives often result in the de-prioritization of traditional Medicaid populations. What reforms should Congress consider to reverse these trends?

Answer. Medicaid provides health coverage to millions of Americans, including low-income adults, children, pregnant individuals, elderly adults, and people with disabilities. The Biden-Harris administration is committed to ensuring that every eligible person can access the coverage and care to which they are entitled. It has been a top priority to ensure, when the public health emergency (PHE) eventually ends and States resume routine operations including terminations of eligibility, that renewals of eligibility and transitions between coverage programs occur in an orderly process that minimizes burden for all beneficiaries and promotes continuity of coverage.

In March, HHS released new guidance and planning and communications tools that offer States a road map to restore routine eligibility and enrollment operations after the PHE ends; promote continuity of coverage; and facilitate transitions between Medicaid, CHIP, the Basic Health Program, the Health Insurance Marketplaces, and Medicare. In April, HHS also released a proposed rule that would smooth transitions between Medicaid and Medicare during the unwinding period by allowing certain Medicaid enrollees to enroll in Medicare without late enrollment penalties. HHS is committed to working together with Congress to ensure that all beneficiaries remain a priority.

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[3] *https://aspe.hhs.gov/reports/comprehensive-plan-addressing-high-drug-prices.*

THE IMPORTANCE OF FAITH-BASED CHILD WELFARE ORGANIZATIONS

Question. According to your department, our foster care system served more than 400,000 children in FY 2020. While this represents a reduction from the previous year, we are hearing from States that they are struggling to find homes and placements for foster youth.

In many States, faith-based organizations provide the majority of child welfare services. In order to prioritize the well-being and safety of this vulnerable population, the Federal Government must continue to collaborate and support a wide variety organizations dedicated to providing these services.

How does your budget help to address the shortage of foster parents and foster homes, and how can faith-based providers help address this shortage?

Answer. The Administration for Children and Families' Children's Bureau recognizes that faith-based providers make important, longstanding contributions to human service programs, including in terms of recruiting foster parents.

The budget proposes to expand the use of evidence-based foster care prevention services, which would safely reduce the number of children entering the foster care system and needing foster parents and homes. When children do need to be removed from their home, the budget seeks to ensure more children are placed with family members or other adults with existing emotional bonds with the child, including by providing additional funds to help kin caregivers navigate the child welfare system and incentivizing States to focus on kin placements whenever feasible. The budget's proposals would help ease the challenges of finding additional foster care placements. In many States, faith-based providers would play a role in providing prevention services and/or working with kin caregivers, while ensuring all families have equal access to publicly funded child welfare services and are treated with dignity and respect by the child welfare system.

Additionally, on behalf of the Children's Bureau, the Capacity Building Center for States provides targeted and tailored technical assistance to State and territorial public child welfare agencies on identified needs that span the child welfare continuum. Priorities are identified through comprehensive assessments and services focus on ensuring the safety, permanency, and well-being of all children, youth, and families. Services are provided in response to requests from jurisdictions and may focus on everything from in-home and prevention-focused efforts to enhancing independent living services for youth and young adults, and promotion of successful transitions from foster care into adulthood. Services in support of diligent recruitment efforts and the recruitment and retention of foster parents and foster homes are available, including expertise in the engagement of faith-based providers to address shortages. In addition to direct technical assistance services, the Center for States facilitates learning and problem solving through the support of peer groups, such as the Diligent Recruitment Peer Group, as well as through the development of tools and resources including the Engaging Faith-Based Communities to Achieve Timely Permanency for Children and Youth Waiting to Be Adopted which provides strategies and examples of how to partner with faith-based communities and leaders on behalf of children and youth in foster care waiting to be adopted.

THE INCREASING RATE OF INFANT AND TODDLERS ENTERING THE FOSTER CARE SYSTEM

Question. A 2019 report by Child Trends analyzing the Adoption and Foster Care Reporting System (AFCARS) data found that during the last 10 years, the rate of foster care entries for infants and toddlers has far exceeded the rate for older children and has driven the overall increase in foster care entry rates.

What more can be done by the administration and jurisdictions to address infants and toddlers coming into care at such a high rate?

Answer. For Federal fiscal year 2020, there were 618,000 victims of child abuse and neglect in the United States. The victim rate was 8.4 victims per 1,000 children in the population. Children younger than 1 year old had the highest rate of victimization at 25.1 per 1,000 children of the same age in the national population. Children under the age of one also had the highest entry into foster care. Nationally, 43,694 infants under the age of 1 entered foster care in Federal fiscal year 2020, which represents 20 percent of the total number of children entering foster care during this period. As noted, the Capacity Building Center for States, on behalf of the Children's Bureau, provides targeted and tailored technical assistance to State and territorial public child welfare agencies on identified needs that span the child welfare continuum. Priorities are identified through comprehensive assessments and

services focus on ensuring the safety, permanency, and well-being of all children, youth, and families and are available to address specific challenges, including the frequency of infants and toddlers coming into care. Services are provided in response to requests from jurisdictions and may support the enhancement of in-home and prevention-focused efforts to keep families intact and avoid children and youth from unnecessary entry into care. Problem solving and practice sharing is also available through Center for States' supported peer groups including the In-Home and Promoting Safe and Stable Families Managers and the Family First Prevention Services Act Prevention Plan Leads.

The National Center on Substance Abuse and Child Welfare (NCSACW) provides two specialized technical assistance (TA) programs, In-Depth Technical Assistance (IDTA) and Regional Partnership Grants (RPG), that prevent infants' and young children's placement in out-of-home care by providing comprehensive services to families affected by substance use and mental health disorders. Both TA programs work with selected grantees or sites to increase their capacity to improve the safety, health, permanency, well-being, and recovery outcomes with equity for all infants, toddlers, and their families affected by substance use disorders (SUDs). The programs achieve this objective by helping States, counties, and tribes build linkages among SUD prevention and treatment systems, child welfare, courts, public health, health-care providers, early intervention, Early Head Start and Head Start, and other systems and agencies serving children and families. IDTA strengthens broader cross-system practices that support family-centered approaches, improved outcomes, and strengthens workforce development. Since 2017, the IDTA program has focused specifically on infants and their families affected by prenatal substance exposure and implementing plans of safe care (POSC) in concert with requirements in the Child Abuse Prevention and Treatment Act. Innovations implemented by IDTA sites include States that are moving beyond compliance with POSC requirements to prevent infant placements and future involvement in the child welfare system by implementing POSC during the prenatal period. Several States are also developing notification pathways for families, if there are no immediate safety concerns that would necessitate a mandated report, including families in this group with prenatal exposure to medication for opioid use disorder. They are implementing partnerships with home visiting, early childhood providers, and community-based information and referral programs to provide support in the community that prevents child placement.

ACF is currently initiating data collection for the program evaluation of the fifth and sixth rounds of RPGs, and previous rounds of evaluation have consistently found that the majority of children at risk of removal remained in their parent's custody following enrollment into RPG services. Among youth who were in an out-of-home placement, the rates of placement into permanent settings, including reunification with their parent(s), increased significantly in the year following RPG enrollment. In addition, the overall rates of child maltreatment decreased substantially in the year after enrollment in the RPG program. The 2023 budget proposes to triple the annual mandatory appropriation for RPGs to $60 million to ensure more children have access to this proven program to reduce the entry of children into foster care.

In addition to providing a broad scope of training and technical assistance in every State, the NCSACW convened a virtual 2020 Practice and Policy Academy: Developing a Comprehensive Approach to Serving Infants with Prenatal Substance Exposure and their Families, on August 25–27, 2020. The purpose was to advance the participating sites' capacity to improve outcomes for pregnant and parenting women with SUDs and their infants and families affected by prenatal substance exposure. Eight sites assembled a multidisciplinary team of leaders committed to strengthening their collaborations and to implementing POSC for infants and their families. Site teams engaged in peer-to-peer learning and TA to create a State-specific action plan to meet the multiple and complex needs of this population. The NCSACW is in the development phase of a 2022–2023 Policy Academy that will allow up to 10 States, Tribes, or large counties to participate in the 6-month pre- and post-Academy technical assistance as well as to apply for ongoing assistance through the IDTA program.

THE MATERNAL, INFANT, EARLY CHILDHOOD VISITING PROGRAM

Question. The Maternal, Infant, Early Childhood Visiting Program (MIECHV) program has successfully served many families across Idaho and the rest of the Nation. The trained workforce providing critical support to families from pregnancy through their child's first years of life has been a lifeline before, and especially during the pandemic.

As this committee works in a bipartisan fashion to reauthorize this program, how would the agency allocate the new funding included in your budget to better serve families across the United States?

Answer. The FY 2023 President's budget requests $467 million for MIECHV, a $67-million increase per year each year for 5 years, with the full program budget totaling $735 million in FY 2027. MIECHV-funded programs currently serve 71,000 families at the current appropriation level of $400 million per year. Over the 5 years, HRSA anticipates this funding increase would provide targeted evidence-based home visiting services to up to 165,000 additional families.

In FY 2023, new funding for the MIECHV program would address unmet needs by expanding service capacity in all 50 States, the District of Columbia, and five U.S. territories. The additional funding would allow awardees to address ongoing challenges such as shoring up workforce capacity, improving compensation for home visitors, and promoting stronger workforce recruitment and retention efforts. Home visiting programs have reported gaps in these areas.

By statute, the MIECHV program also includes a 3-percent set-aside for grants to Tribal organizations to implement home visiting programs in American Indian and Alaska Native communities. An increase in overall appropriation will also increase the dollar amount to this set-aside.

MCED LEGISLATION

Question. Multi-cancer early detection tests have the potential to transform the cancer screening landscape, detecting as many as dozens of different cancer types, often long before symptoms even emerge. Without Medicare coverage, however, these types of tests may remain out of reach for many seniors. Fortunately, legislation creating a coverage pathway for these technologies enjoys broad bipartisan and bicameral support.

In outlining goals for the reignited Cancer Moonshot, the President's budget references the promise of multi-cancer early detection tests. What role do you see for Medicare in ensuring access to these technologies, and can you commit to working with the bill's sponsors on advancing this vital legislation?

Answer. In February 2022, President Biden announced that he is reigniting the Cancer Moonshot initiative he launched as Vice President in 2016. The Cancer Moonshot sets ambitious goals: to reduce the age-adjusted death rate from cancer by at least 50 percent over the next 25 years, and to improve the experience of people and their families living with and surviving cancer. The President and First Lady Jill Biden also announced a call to action on cancer screening to jumpstart progress on screenings that were missed as a result of the COVID–19 pandemic, and to help ensure that everyone in the United States equitably benefits from the tools we have to prevent, detect, and treat cancer.

Today, we know cancer as a disease for which there are stark inequities in access to cancer screening, diagnostics and treatment across race, gender, region, and resources. This administration is committed to ensuring that every community in America—including those living in rural, urban, and Tribal communities—has access to cutting-edge cancer diagnostics, therapeutics, and clinical trials.

With regard to Medicare, CMS prioritizes expanding access to these essential preventative health-care services, including cancer screenings. Medicare beneficiaries pay zero cost sharing for cancer screenings that are preventive services recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population and that are appropriate for the individual. HHS looks forward to working with partners across the Federal Government, along with Congress and other stakeholders, to examine ways we can increase access to services for the prevention, diagnosis, treatment, and survival of cancer. All Americans are invited to share perspectives and ideas, and organizations, companies, and institutions to share actions they plan to take as part of this mission, at *https://www.whitehouse.gov/cancermoonshot/*.

THE MEDICARE COVERAGE OF INNOVATIVE TECHNOLOGY (MCIT) RULE

Question. Far too often, lags in Medicare's coverage process delay access to potentially lifesaving technologies, ranging from cutting-edge treatments to game-changing diagnostic tools. Backed by broad bipartisan support, the previous administration finalized a rule that would have expedited coverage for safe and effective breakthrough devices, increasing care quality for scores of American seniors.

Unfortunately, last year, the Biden administration rescinded this rule, preserving the status quo of access delays, including for truly groundbreaking advances in diagnosing, preventing and treating a broad range of conditions.

Could you provide an update on the administration's progress towards developing and advancing the regulatory changes to address these persistent coverage challenges, given the groundswell of bipartisan support for solutions?

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

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

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

A PLAN FOR SHORING UP HOSPITAL INSURANCE TRUST FUND SOLVENCY

Question. Current law requires the Medicare trustees to determine whether projected annual general revenue funding will exceed 45 percent of total Medicare outlays during the next 7 fiscal years. Two consecutive determinations along these lines trigger a Medicare excess general revenue funding warning. In 2021, the trustees once again established that Medicare will exceed the general revenue outlay threshold.

By law, when Medicare enters this situation, the President must, within 15 days of his next budget, submit a detailed plan to Congress that saves Medicare from bankruptcy and preserves the program for future generations.

If the 2022 Medicare trustees report includes yet another funding warning, will President Biden follow the law and immediately propose a detailed plan—including policy specifications and corresponding cost estimates—to extend the life of the HI trust fund?

DEBT, DEFICITS, AND MANDATORY SPENDING

The FY 2023 budget request would cause GDP growth to drop to just a little over 2 percent annually starting in 2023. It steadily increases overall debt held by the public year-over-year through 2032, in addition to adding more than $1 trillion to the deficit each year. The budget imposes over $2.5 trillion in tax increases and proposes more than $900 billion over 10 years in new, mandatory spending.

President Biden has promoted an unserious tax and spend budget—one that ignores the financial status of the Medicare hospital insurance trust fund. Every recent President, Republican and Democrat, has offered Medicare savings proposals in budget requests submitted to Congress. Many of those budgets even contained identical policy ideas.

Rather than use the budget as a platform to kick-start bipartisan discussions about ways we can shore up Medicare for the long haul, the document simply concedes that the Medicare HI trust fund is on the brink of insolvency, and that the Biden administration has absolutely no ideas to fix it.

The budget proposes some increases in Part A spending, but offers no specific Part A offsets to pay for that spending. Do you agree that this is irresponsible given that the HI trust fund is in near-term financial crisis?

Answer. The President is committed to protecting and strengthening Medicare so that Americans of every generation can count on it. The President's budget proposes investments in Medicare that incentivize physician participation in value-based payment models designed to help drive down overall health-care costs and improve patient outcomes by rewarding value and quality of care, rather than volume of physician services. The budget also proposes strengthening program integrity tools and authorities to identify and investigate fraud in services covered through the Medicare Advantage program, and enforcing new penalties on bad actors. Additionally, the budget invests in program integrity allocation adjustments that fight fraud, waste, and abuse in Medicare.

As we continue to make reforms that improve and strengthen Medicare, we should be looking to reduce costs, not benefits. HHS looks forward to working with you and the Congress to find bipartisan solutions to ensure that Medicare is strong for current and future beneficiaries.

ACCESS TO LOW-VOLUME, HIGH-COST THERAPIES

Question. Certain patients can face acute access issues in the hospital inpatient setting of care. Rare disease treatments, in particular, are provided to such small numbers of patients that they do not have a significant effect on the average cost for a Medicare Severity-Diagnosis Related Group (MS–DRG).

Last year, CMS acknowledged that it needed more time to consider how best to ensure access to low-volume, high-cost therapies, such as rare disease therapies, under the Medicare Hospital Inpatient Prospective Payment System (IPPS).

What is CMS doing to modernize the IPPS so that patients living with rare diseases have access to personalized treatments in the inpatient setting?

Answer. CMS is committed to ensuring beneficiary access to the treatment and care they need. In the FY 2023 Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Proposed Rule, the agency is soliciting public comments on how the reporting of certain diagnosis codes may improve our ability to recognize severity of illness, complexity of illness, and utilization of resources under the diagnosis related groups, as well as feedback on mechanisms to improve the reliability and validity of the coded data as part of an ongoing effort across CMS to evaluate and develop policies to reduce health disparities. In concert with that effort, we are also soliciting comments to explore possible mechanisms through which we can address rare diseases and conditions that are represented by low volumes in our claims data.

ENSURING ACCESS TO MEDICATIONS

Question. A number of front-line providers and cancer care advocates have expressed concerns over the Centers for Medicare and Medicaid Services' (CMS) interpretation regarding mail-order drugs being excluded from the in-office ancillary exception to the Stark Law prohibitions. Preventing cancer clinics from providing lifesaving treatments through their mail-order pharmacies risks severely disrupting care, in addition to placing undue burdens on patients who are forced to absorb travel costs, time away from work, and other strains. These disruptions could prove particularly problematic for patients living in rural communities.

In the context of the ongoing public health emergency (PHE), HHS has helped to address this dynamic by waiving certain portions of the Stark Law, including the "location requirement," enabling clinics to utilize mail-order drugs for patients who were observing social distancing in their homes. However, patients and providers face uncertainty as to what might happen when the PHE ends.

In the past, CMS has utilized language in the statute to carve out mail-order if there is no risk of program or patient abuse. In 2001, CMS issued a final Stark Phase One rule that allowed mobile facilities used exclusively by a group practice to count under the exception. It would be appropriate to make similar concessions in this context to ensure patients continue to have timely access to lifesaving treatment without additional cost burdens.

Can you clarify that under current Stark prohibitions, mail-order drugs are excluded from the in-office ancillary exception?

If so, will the agency explore using additional authority to provide an exception to the "location requirement" to prevent disruptions in patient care?

Answer. CMS strives to ensure that sufficient health-care services are available to meet beneficiaries needs. The "location requirement" at 42 CFR § 411.355(b)(2)

would not be satisfied if a patient receives an item by mail outside the physician's office, as it would not be dispensed to the patient in the office. However, CMS issued blanket waivers in March 2020 that apply during the COVID–19 public health emergency (PHE) to allow certain flexibilities, and under the waiver of a referral by a physician in a group practice for medically necessary designated health services furnished by the group practice in a location that does not qualify as a "same building" or "centralized building" for purposes of 42 CFR 411.355(b)(2), the furnishing of mail-order drugs is permitted. CMS is currently reviewing certain flexibilities to evaluate whether they are appropriate beyond the PHE and we will continue to consider ways to ensure that beneficiaries receive access to high quality, value-based care, while maintaining appropriate safeguards.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN, HON. CHUCK GRASSLEY, HON. ROBERT P. CASEY, JR., AND HON. JOHN BARRASSO

MEDICARE PHARMACIST PROVIDER STATUS

Question. We appreciate the steps CMS has taken throughout the COVID–19 pandemic to increase access to care, especially in rural and urban underserved areas. In particular, we support CMS's efforts to empower community pharmacists to serve as Medicare providers to increase access to testing and get shots in arms.

While we recognize that current statute limits the capacity of licensed pharmacists to provide and bill Medicare directly for professional services, we appreciate efforts by CMS to facilitate pharmacists as providers in the Medicare program through existing authorities and we are encouraged by the potential for pharmacists to continue to serve their communities as Medicare providers following the end of the COVID–19 public health emergency (PHE) designation.

Can you please elaborate on the efforts CMS has taken to expand pharmacist provider status/reimbursement during the COVID–19 PHE, and clarify which flexibilities granted to pharmacists can and will be extended beyond the PHE?

Specifically:

Will pharmacists continue to receive reimbursement for COVID–19 tests and vaccine administration if they are enrolled as a CLIA lab and mass immunizer, respectively?

Will pharmacists continue to receive reimbursement "incident to" another provider billing under their own NPI when the "direct supervision" requirement is met virtually?

Can Medicare Part B directly reimburse a pharmacy or pharmacist for administering vaccinations without mass-immunizer enrollment?

Can Medicare Part B directly reimburse a pharmacist for COVID–19, influenza, RSV, or strep testing services, including specimen collection, if the pharmacy does not have a CLIA Certificate or Certificate of Waiver?

Does CMS have the regulatory authority to expand pharmacist provider status beyond COVID-specific services? If so, do those authorities exist solely under mass immunizer and laboratory pathways to reimbursement under Part B, or are there other pathways to more permanent authorities for pharmacists to administer and get directly reimbursed for COVID-specific services as authorized under State scope of practice laws?

Answer. We believe that pharmacists are essential parts of our health-care system and are playing an important role in the response to the COVID–19 public health emergency. Pharmacists may perform certain tests if they are enrolled in Medicare as a laboratory, in accordance with a pharmacist's scope of practice and State law. In addition, pharmacists can enroll as mass immunizers and bill Medicare for administering Part B vaccines.

We have explicitly clarified that pharmacists fall within the regulatory definition of auxiliary personnel under our regulations. As such, pharmacists may provide services incident to the professional services and under the appropriate level of supervision of the billing physician or practitioner, if payment for the services is not made under the Medicare Part D benefit. This includes providing the services incident to the services of the billing physician or practitioner and in accordance with the pharmacist's State scope of practice and applicable State law.

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

COVID–19 ABROAD

Question. The administration requested $5 billion in supplemental funds to respond to the impacts of COVID–19 abroad, including $750 million for the CDC. It seems unlikely that Congress will appropriate any supplemental funds for global COVID operations in the immediate future. Many prominent health and development advocates have said that the U.S. needs to invest at least $17 billion if we want to meet our stated goal of vaccinating 70 percent of the world by the end of the year.

What will be the impact on our efforts to support President Biden's goal of helping to vaccinate 70 percent of the world by September if Congress falls short of the $5-billion request for the Global VAX initiative?

Answer. Ending the COVID–19 pandemic is a top priority for this administration both domestically and globally, because no country is safe until we are all safe. The best way to prevent the emergence of future variants that could threaten the health of Americans and undermine our economic recovery is to vaccinate the world. As more COVID–19 vaccine supply flows to low-and middle-income countries, the United States and other donors must redouble efforts to help countries efficiently receive, distribute, and administer doses. Without additional efforts, further COVID–19 variants that pose risks to not only other countries, but also to U.S. lives, our economy, and our national security will develop.

The pandemic has made it clear that we need effective international institutions that can quickly detect and respond to emerging health threats, and strengthen the health systems that will prevent future pandemics. As the United States' representative to the World Health Organization, HHS plays a critical role in strengthening and reforming the WHO—a priority for the US, according to National Security Memorandum 1. There are a wide range of important but complicated changes that can be made to the WHO, including reforms to the International Health Regulations, improving the sustainability of the WHO's financing, and negotiating an international instrument to strengthen pandemic preparedness, prevention, and response—the so-called "pandemic treaty."

Question. What is the administration's top priority in terms of WHO reform?

Answer. The United States wants to strengthen the role of member states in WHO governance, specifically in determining the strategic direction and core functions of WHO. In addition, several high-priority areas where we understand there is member state consensus to move forward quickly include WHO governance; budget and financial transparency and oversight; accountability and oversight; allocation of resources among headquarters, regional and country offices; human resources management; and compliance, risk management, and ethics.

Improvement in the integrity of WHO's misconduct investigation activities, especially those dealing with claims involving sexual exploitation, abuse, sexual harassment, and abusive conduct, and in their work to prevent and respond to such conduct is also a key area for reform.

The administration is pursuing targeted amendments to the International Health Regulations (IHR) 2005 to allow for more efficient and effective updating of this foundational legally binding instrument. The United States is currently leading discussions with member states to pursue proposed amendments, including working together to amend Article 59 of the IHR to shorten the effective date for amendments, and additional, more substantive amendments.

Question. Considering other countries' disagreements over some of the proposed reforms, how optimistic are you that the U.S. will achieve its goals to reform the WHO?

Answer. We believe that it is important for changes to be made to ensure that the world is prepared. At the World Health Assembly Special Session held last November, there was almost universal support for strengthening the WHO and the International Health Regulations. We expect member states to follow through on their political statements with concrete actions at this 75th WHA and will continue to push for action. We remain optimistic and committed to working with member states and WHO to strengthening WHO so that it may be more authoritative, effective, transparent, and agile.

Question. Where do things stand with effort related to negotiating a pandemic treaty?

Answer. The Intergovernmental Negotiating Body (INB) has begun its work on a pandemic instrument. The United States government is committed to the INB process and to developing an international instrument that enables meaningful action, transparency, and accountability for pandemic prevention, preparedness and response. The United States government is developing its proposals for substantive elements through an interagency and is looking to see what other member states will provide in the lead-up to the June 6–8 meetings in Geneva.

COMMUNITY VIOLENCE

Question. Last year, the President's budget proposed the creation of a new Community Violence Intervention (CVI) initiative to address gun violence. Under this year's proposal, your agency would receive $250 million to continue funding these Community Violence Intervention programs.

What is the importance of that funding for the Department's efforts to address gun violence in communities across the country?

Answer. In 2020, there were 45,222 firearm-related deaths in the United States—that's about 124 people dying from a firearm-related injury each day. More than half of firearm-related deaths were suicides and more than 4 out of every 10 were firearm homicides. Firearm-related injuries were among the five leading causes of death for people ages 1–44 in the United States. The Community Violence Intervention (CVI) initiative aims to reduce all forms of community violence, including violence perpetrated by firearm. With the funding proposed in the President's budget, CDC would fund up to 75 cities and communities that are highly impacted by homicide to establish a collaborative, community driven approach to reduce community violence.

Question. What plans does HHS have to expand existing CVI programs? What additional resources are needed to do so?

Answer. The FY 2023 President's budget proposes a $250-million investment in the new community violence intervention initiative for CDC. With these funds, CDC would build upon the foundation of our 20-plus years of science-based youth violence prevention effort to fund up to 75 cities and communities with high numbers of homicides and communities with high numbers of homicides per capita to establish a collaborative, community driven approach to reduce community violence. Funds will support scaling up existing community violence prevention efforts and implementing and evaluating evidence-based and evidence-informed community violence prevention strategies.

CDC would also fund community-based organizations that have expertise in partnering with communities most impacted by community violence to provide training technical assistance to funded communities. CDC would also expand research and evaluation investments to further build the evidence base for preventing violence in communities experiencing the greatest burden, and to reduce the racial, ethnic, and economic inequities that characterize such violence across our country. This would include expanding the scope of the Youth Violence Prevention Centers (YVPCs) to include young adults and funding up to seven more centers. This would also include additional awards to address critical research gaps to enhance what is known about what works to prevent community violence, including prevention strategies that address the structural determinants of health that contribute to violence inequities (such as concentrated disadvantage, structural racism, discrimination, disinvested communities, poverty, limited educational opportunities, and unemployment).

DIVERSITY IN CLINICAL TRIAL PARTICIPANTS

Health-care equity and reducing disparities are hot topics in Congress and the administration but real action has been slow to meet these challenges. As we think about all of our medical treatments we have—or in some cases don't yet have—it begins with research, and today we still have a long way to go to realize research equity. Our clinical trials must mirror our Nation and we will not see that reflection until we reduce barriers for traditionally excluded populations to participate in clinical trials.

What can HHS do to level the playing field, and do you think the provisions in the DIVERSE Trials Act, my bill with Senator Scott, would help—particularly those

provisions that create safe harbors to provide trial participants with technology and financial assistance?

Answer. Although progress has been made to increase the enrollment of diverse populations, there is still room for improvement. One strategy that has not been scaled up in a sustainable way is engaging community clinicians and investigators in research. There is considerable evidence that clinician recommendations play an important role in helping patients consider participating in clinical investigations.[4] In addition to clinicians' recommendations playing an important role, removing barriers to participation, such as bringing trials closer to where participants live, work, worship, and typically receive their health care, may also help achieve more diversity in both the workforce administering the trials and the participants in an investigation.

We understand the overall intent of the bill's language to be to ensure that research of medical products is equitable and represents the demographic populations that would benefit from their use. HHS strongly supports that goal and is committed to encouraging diverse participation in and equal access to clinical trials used to support marketing applications for regulated medical products.

Digital Health Technologies (DHTs) used for remote data acquisition are playing a growing role in health care and offer important opportunities in clinical research. Compared to intermittent trial visits, the use of DHTs to remotely collect data from trial participants may allow for continuous or more frequent data collection. This may provide a broader picture of how participants feel or function in their daily lives. DHTs provide opportunities to record data directly from trial participants (*e.g.,* performance of activities of daily living, sleep) wherever the participants may be (*e.g.,* home, school, work, outdoors). Some DHTs also may facilitate the direct collection of information from participants who are unable to report their experiences (*e.g.,* infants, cognitively impaired individuals). There is a large spectrum of DHTs available for potential use in a clinical investigation. FDA's draft guidance, *Digital Health Technologies for Remote Data Acquisition in Clinical Investigations,* when final, will provide recommendations for sponsors, investigators, and other interested parties on the use of DHTs for remote data acquisition from participants in clinical investigations evaluating medical products.

DISPARITIES IN DETECTION AND DIAGNOSIS OF DEMENTIA

Question. In addition to the lack of access to clinical trials, we know that many minority populations struggle to access timely diagnosis of ailments. For example, recent Medicare data shows that Asian, Black, and Latino patients were more likely to receive a later dementia diagnosis than their White counterparts. Across all racial and ethnic groups, only a minority of all beneficiaries received a timely dementia diagnosis and comprehensive evaluation.

What will the administration do to narrow these disparities in the detection and diagnosis of dementia among Medicare beneficiaries more likely to experience disparities?

Answer. Embedding health equity within our health-care system, including for dementia care, is a key focus of the Biden-Harris administration. HHS is working across the Department to close gaps in access to health care and human services in order to advance equitable outcomes for underserved populations.

Detecting cognitive impairment is a required element of Medicare's Annual Wellness Visit. Providers conduct a cognitive test and can evaluate health disparities, chronic conditions, and other factors that contribute to increased risk of cognitive impairment. If a patient shows signs of cognitive impairment during a routine visit, Medicare also covers a separate visit to more thoroughly assess cognitive function and develop a care plan. CMS has developed educational materials to ensure that providers are aware of this benefit.

HHS looks forward to continuing to work with Congress to reduce health disparities across the health-care system, and to ensure that all patients have access to critical services like the detection and diagnosis of cognitive impairment.

MANDATORY COVERAGE OF ADULT VACCINES

Question. The President's budget includes a proposal to consolidate coverage of adult vaccines under Medicare Part B.

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[4] *https://www.nejm.org/doi/full/10.1056/NEJMp2107331.*

How will this improve the access experience for beneficiaries and streamline the process for providers?

Adult rates of vaccination in the US, including for our most vulnerable older Americans, have historically fallen short of public health goals. These low vaccination rates are attributed to affordability and access barriers. However, one of the most confusing contributing factors to low vaccination rates is the lack of streamlined coverage that assures 100 percent of Medicare beneficiaries have access to affordable immunizations. How will the President's proposal to consolidate all vaccines under Medicare Part B vastly improve overall adult vaccination rates?

Answer. The COVID–19 pandemic has emphasized the importance of vaccines and the critical role they play in preventing severe disease and saving lives. In addition to proposing investments in the research and development of vaccines, the President's FY 2023 budget includes proposals to expand access to vaccines for both children and adults. Within Medicare, the budget proposes to consolidate all vaccine coverage under Medicare Part B.

Current Medicare coverage for vaccine administration is divided between Part B and Part D, which can be confusing and burdensome for both Medicare beneficiaries and providers. Part B is a more appropriate type of coverage for vaccines because more beneficiaries are enrolled in Part B than Part D and higher out-of-pocket costs in some Part D plans may create a financial barrier to access. This proposal shifts all Medicare coverage for vaccines, including administration costs, to Part B and requires that Medicare Advantage plans charge no greater cost sharing for any vaccines and their administration than is charged under original Medicare. For all vaccines, as recommended by CDC's Advisory Committee on Immunization Practices, and adopted by the CDC Director, with the exception of vaccination for travel-related purposes, there will be zero cost sharing for Medicare beneficiaries. These changes promote better access to vaccines among the Medicare population while making Medicare payment for them more in line with actual costs. Health equity is improved by removing potential financial barriers to CDC-recommended vaccines.

Question. In the House and Senate Appropriations Committee's explanatory statement regarding the Fiscal Year 2022 Omnibus, the committees required reports on HHS's plans to phase out the use of Emergency Intake Sites and increase its licensed bed capacity. What progress has HHS made on this goal?

Answer. ORR continues to evaluate capacity needs by closely monitoring and reviewing several variables: unaccompanied children (UC) referral numbers, projections and trends; COVID–19 infection rates and impact on staffing and bed capacity; and total operational bed capacity, including standard bed capacity. Out of the 14 EIS that were brought online in the spring of 2021, only two remain active as of April 2022: Pecos EIS and the ORR EIS at Fort Bliss. Though the number of UC in ORR care has declined significantly, from nearly 20,000 in April 2021 to approximately 10,000 in April 2022, referrals to the program continue to be higher than historical patterns.

ORR makes efforts to ensure that its decision-making is informed by conditions on the ground. Given DHS projections of referral increases as well as the potential for capacity needs that can accommodate COVID-positive UC, ORR has determined that it will need to extend the use of the facilities at Fort Bliss and Pecos. However, ORR plans to convert both sites into Influx Care Facilities (ICFs) within the next few months Influx Care Facilities provide services for children consistent with Flores Settlement Agreement (FSA) Exhibit 1 standards. In general, ORR's policies regarding ICFs are described in ORR Policy Guide section 7, Policies for Influx Care Facilities.

ORR's preference is to place UC into standard care provider facilities while sponsorship suitability determinations proceed, and currently funds the highest number of beds in the standard shelter network in the program's history. ORR consistently works on expanding its network of standard beds by awarding funding to existing and new grantees. For example, ORR published a Notice of Funding Opportunity (NOFO) for licensed shelters and transitional foster care beds on December 6, 2021, with award dates targeted for July and November 2022.

Moreover, a NOFO will be opened to organizations that have not yet secured a license for their facilities with a timeline of achieving the required licensure within 4 months of award, allowing ORR to partner with previously excluded entities that share in our mission and goal to ensure the safety and well-being of children in our care. This NOFO will be published on May 5, 2022, with an anticipated award of

November 2022. NOFOs for long term foster care, therapeutic, staff-secure, and secure programs are also expected to publish by September 2022.

Question. In the Department of Health and Human Services' Fiscal Year 2021 budget justification, the Department states that ORR plans to convert Fort Bliss and Pecos, currently emergency intake sites, into influx facilities. Like emergency intake sites, influx facilities are not licensed and lack independent State oversight on the treatment of children in their care. Prior reliance on influx facilities has been costly and caused harm to children. What is this administration doing to transition away from reliance on influx or emergency beds?

Answer. ORR establishes influx facilities to help address bed shortages during periods of sustained increases in referrals from DHS, and to ensure that children are transferred out of DHS's custody swiftly. Children in temporary influx care facilities receive services consistent with Exhibit 1 of the FSA, including case management, on-site education, medical care, legal services, and counseling; and can participate in recreational activities and religious services appropriate to the child's faith, just as children in licensed facilities. (For complete information, please see ORR Guide section 7.5: Influx Care Facility Required Services.) ORR is the primary monitor of temporary influx care facilities and is responsible for their oversight, operations, physical plant conditions, and service provision. While States do not license or monitor influx care facilities, the facilities operate in accordance with the Flores Settlement Agreement, the Homeland Security Act of 2002, the Trafficking Victims Protection Reauthorization Act of 2008, the Interim Final Rule on Standards to Prevent, Detect, and Respond to Sexual Abuse and Sexual Harassment Involving Unaccompanied Alien Children, and ORR policies and procedures.

ORR's priority is to unify UC with vetted sponsors as safely and quickly as possible following their arrival at an EIS, ICF, or State-licensed care provider facility. Average length of care (ALOC) has consistently decreased program-wide since the 2021 influx, when the length of care numbers ranged between 31–37 days; the ALOC program-wide as of April 2022 is 28 days. ALOC has also decreased for children eligible for all categories of sponsors, with every child's ALOC measured at less than 30 days.

ORR continues to ensure that vulnerable children with complex cases or special needs are not placed at EIS or, if identified after placement, are transferred out of an EIS, and promptly placed in a shelter suitable to their needs.

Consistently building its network to promote standard capacity that can adapt to the changing needs of the program, ORR considers EISs and ICFs a last resort. This notion is also reflected in ORR's plans to transition the two remaining EIS to ICF facilities that meet the same minimum standards as ORR's standard shelters. This commitment is clear in ORR's call for more partner organizations to expand ORR's network of standard beds.

Question. The Fiscal Year 2023 budget justification indicates that "ORR's long-term goal is to create a model of care delivery with sufficient family foster care and licensed capacity that can adapt to changing needs efficiently, such that influx care facilities or other emergency shelters are needed only in exigent or emergency circumstances." What is ORR's timeline for approaching this goal?

Answer. ORR is focused on bringing more standard beds online, including adding beds to existing awards and funding new awards. A NOFO for licensed shelters and transitional foster care beds was published on December 6, 2021 with award dates targeted for July and November 2022. Moreover, a NOFO is expected to be published in May 2022 that will be open to organizations who have not yet secured a license for their facilities with a timeline of achieving the required licensure within 4 months of award. This allows ORR to partner with previously excluded entities who share in its mission and goal to ensure the safety and well-being of children in our care. NOFOs for long term foster care, therapeutic, staff-secure, and secure programs are also expected to publish by September 2022. These awards allow ORR to ensure that as many children as possible are cared for in licensed or soon-to-be licensed facilities with access to the full array of services, regardless of exigent and emergency circumstances.

Additionally, ORR is working closely with the foster care network to recruit additional families through local events and outreach partnerships with non-governmental organizations, refugee resettlement agencies, and community organizations. ORR also formed a workgroup of individuals across these organizations that specifically focuses on the needs of the UC foster care network. Individuals who are inter-

ested in providing foster care to unaccompanied children can visit the ORR Foster Care webpage to learn more about each program and how to become a foster parent.

Question. What steps is it taking to meaningfully reach this goal, knowing that the number of child arrivals varies throughout the year?

Answer. ORR continues to focus on expanding standard bed capacity as the preferred placement option for children in ORR care. ORR reviews capacity needs throughout the year, based on historic data and DHS estimates. ORR considers several factors such as UC referral numbers, trends, projections, and COVID–19 infection rates and impact on staffing and bed availability.

By transitioning its two EISs into ICFs, which have equivalent standards to ORR's licensed facilities, adding beds to existing grants, and funding new grants for more standard facilities in 2022, ORR is strategically preparing to address influx capacity needs given the challenge with predicting with any degree of certainty the number of UC arrivals and referrals to ORR.

Question. President Biden recently announced that the United States would be accepting 100,000 Ukrainian refugees. Some unaccompanied Ukrainian children have already been apprehended at the southern border. What plans are in place to receive and care for Ukrainian unaccompanied children?

Answer. For Ukrainian UC who arrive at Ports of Entry (POE), ORR will follow the established policies and processes to accept referrals from DHS into its custody and care. Using the UC care provider network, ORR will base all placement decisions on the best interests of the child with the goal of placing UC in the least restrictive setting available per ORR Policy and Procedures, and relevant Field Guidance. As of April 5, 2022, ORR currently has 12 Ukrainian children in its care.

Question. How will ORR learn from the Afghan evacuation crisis to ensure that children and their families are not separated?

Answer. ORR does not play a role in the vetting of family units overseas, nor does ORR have any role in the separation of children from adults. However, ORR has been working with its interagency partners, through ongoing discussions, on the process under which Ukrainian unaccompanied children may travel to the U.S. As was the case during the Afghan evacuation, ORR will continue to receive referrals from DHS for Ukrainian children who arrive without a parent or legal guardian. Once in ORR custody, care providers provide family unification services (both domestic and international), educational and recreational services, health care, mental health services, access to legal services, access to child advocates, where applicable, and case management in a culturally and linguistically appropriate manner to ensure the safety and well-being of the child. During Operation Allies Welcome (OAW), ORR mobilized case workers, translators, and Federal field staff to the airports used by OAW and to OAW Safe Havens to provide sponsor vetting and family unification services onsite for unaccompanied Afghan minors (UAM). This process allowed Afghan families to stay together during ORR processing, since many children arrived with an adult family member who was not their parent or legal guardian. ORR's continued commitments to preserving the unity of family groups and to collaborating with interagency partners like the Department of State (DOS) are central to the work of ORR.

QUESTIONS SUBMITTED BY. HON. BENJAMIN L. CARDIN

VIOLENCE INTERVENTION PROGRAMS

Question. I am glad to see the proposed $250 million for the Centers for Disease Control for the Community Violence Intervention initiative, in collaboration with Department of Justice, to support evidence-based community violence interventions at the local level. Hospital-based interventions are among the most effective within this category.

By providing services for victims of violent crime while they are recovering from their injuries, these programs equip survivors to make lifestyle changes that prevent them from being re-victimized or reduce their likelihood of being involved in future violence. The program at the University of Maryland Medical Center's Shock Trauma Center has demonstrated impressive results. However, there are few Federal resources available for this work.

I have legislation to create HHS grants for hospital-based violence intervention or prevention programs. Federal funds would be used to establish or expand operations and study their effectiveness. Last May, the House of Representatives passed a companion, introduced by my colleague from Maryland, Congressman Ruppersberger, with strong bipartisan support.

As we continue to see a rise in people experiencing behavioral health challenges, can you discuss the administration's commitment to the Community Violence Intervention Initiative and the importance of this program in supporting the mental health needs of survivors of violent crime?

Answer. Through the Community Violence Intervention Initiative, CDC would focus on preventing violence from happening in the first place and reducing the impacts once violence has occurred. The initiative would also focus upstream on increasing resilience and reducing risk factors for the development of mental health conditions.

Question. In light of the 2021 GAO report that gun violence costs hospitals over $1 billion annually, can you comment on the potential returns on investments in violence intervention programs?

Answer. Hospital-based violence interventions have been shown to decrease violent reinjuries, high-risk behaviors, violent re-victimization, and violent arrests. They have also demonstrated cost savings to the health-care and criminal justice systems, as well as gains in employment among program participants. The available evidence suggests that there is the potential for substantial cumulative return on investment from hospital-based violence interventions Rigorous evaluation will be an important component of CDC's Community Violence Intervention Initiative to help us identify the most effective programs for reducing gun violence and reinjury to provide a more complete estimate of potential savings.

CDC is currently supporting multiple studies that can help describe the cost, savings, and return on investment from hospital-based violence interventions.

PRUDENT LAYPERSON ENFORCEMENT

Question. As you know, the "prudent layperson standard" is a critical patient protection that requires insurers to cover emergency care based on a patient's symptoms, not on their final diagnosis. I am deeply concerned by continued attempts to discourage patients from seeking emergency care that essentially requires them to self-diagnose. For example, in 2021, UnitedHealthcare proposed and rescinded a policy that would retroactively limit or deny coverage for emergency room visits they felt were "unnecessary."

Patients should not be expected to determine on the spot whether their condition is a life or death situation. Cost-cutting measures such as these lead patients to fear the health-care safety net instead of seeking it out and could ultimately cost Americans their lives.

Will you commit to working with me to determine if this policy is compliant with Federal law and, further, to ensure that the prudent layperson standard is appropriately enforced?

Answer. As we noted in Requirements Related to Surprise Billing, part 1 (86 FR 36872), we are aware that some plans and issuers currently deny coverage of certain services provided in the emergency department of a hospital by determining whether an episode of care involves an emergency medical condition based solely on final diagnosis codes. In addition, some plans and issuers might automatically deny coverage based on a list of final diagnosis codes initially, without regard to the individual's presenting symptoms or any additional review. Following an initial denial, plans and issuers might then provide for complete consideration of the claim, and apply the prudent layperson standard, only as part of an appeals process if the participant, beneficiary, or enrollee appeals. These practices are inconsistent with the emergency services requirements of the Affordable Care Act. This is true even if the process for complete consideration of the claim following an initial denial is not designated as a formal appeal. Instead, the determination of whether the prudent layperson standard is met must be made on a case-by-case basis before an initial denial of an emergency services claim. HHS is committed to its oversight and enforcement of the requirements included in statute and regulation. HHS looks forward to working with Congress and other stakeholders to make sure health insurance plans include appropriate consumer protections.

MEDICALLY NECESSARY DENTAL CARE

Question. While oral health is an integral part of overall health and general well-being, too many Americans are unable to access the dental care they need to maintain a healthy mouth and body. Millions of Medicare beneficiaries, particularly people of color and people with lower incomes, face significant health risks because they do not have access to medically necessary oral and dental treatment. Far too often, the lack of such treatment exacerbates beneficiaries' health and, thus, increases Medicare's costs for treating their illnesses.

As you may know, the Medicare program already provides limited coverage for medically necessary oral and dental treatment using the authority HHS already has. Examples include coverage of tooth extractions to prepare the jaw for cancer radiation treatment and dental examinations prior to kidney transplant.

In light of the strong support by medical, dental, and patient advocacy organizations, would you be willing to consider broader use of your existing authority to expand access, improve outcomes, and reduce overall costs by covering dental services in additional clinical contexts in which oral infections and inflammation can delay, prevent, or compromise important medical treatment?

Answer. Oral health is a critical part of overall health, and the Biden-Harris administration supports making dental coverage a standard benefit in Medicare. CMS looks forward to collaborating with Congress on legislation to expand Medicare beneficiary access to dental care. In the meantime, we plan to review our existing payment policies related to the coverage of medically necessary dental care under the Medicare program in order to determine whether we can expand on these existing policies under our existing statutory authority.

TELEHEALTH AND HEALTH EQUITY

Question. The COVID–19 pandemic has demonstrated the incredible benefit of telehealth services. I have been proud to partner on the CONNECT for Health Act with a number of bipartisan colleagues, including Finance Committee members Senators Warner and Thune. The CONNECT for Health Act proposes to make permanent the COVID–19 telehealth flexibilities, and I look forward to working with HHS to ensure the appropriate telehealth flexibilities are expanded post-pandemic.

However, Americans face varying levels of access to telehealth care. A recent HHS study found that as telehealth services expanded rapidly during the pandemic, utilization varied by race, ethnicity, income, age, and insurance status. There were significant disparities among subgroups in terms of audio versus video telehealth use. Video telehealth rates were lowest among those without a high school diploma, adults ages 65 and older, and Latino, Asian, and Black individuals. The report noted that policy efforts to ensure equitable access to telehealth, in particular video-enabled telehealth, are needed to ensure that disparities that emerged during the pandemic do not become permanent.

President Biden's budget includes a variety of investments in telehealth, including $44.5 million within the Health Resources and Services Administration (HRSA) to expand telehealth services.

President Biden also supports extending telehealth coverage under Medicare beyond the COVID–19 public health emergency to study its impact on utilization of services and access to care. Could you provide additional details on policies the administration would support in the expansion of telehealth as well as policies to reduce racial, ethnic, and geographic disparities in utilization?

How will you work to reduce disparities in telehealth modality utilization by Medicare, Medicaid, and CHIP enrollees, which have emerged during the COVID–19 pandemic, particularly communities of color, older Americans, and low-income individuals?

Answer. During the COVID–19 public health emergency, telehealth has been a reliable resource allowing providers to reach patients directly in their homes in order to ensure access to care and continuity of services. The Biden-Harris administration is committed to supporting a temporary extension of broader telehealth coverage under Medicare beyond the COVID–19 public health emergency declaration in order to study its impact on utilization of services and access to care. Telehealth, including audio-only telehealth, can greatly increase access to services for individuals who may not have access to broadband or technology to support 2-way audio-video, particularly in rural and underserved areas and among older populations.

The administration is also expanding access to mental health and beneficiary-centered care under Medicare via greater use of telehealth and other telecommunications technologies to provide behavioral health care and other services. Medicare beneficiaries can receive care directly in their homes thanks to recent regulations, including CMS's CY 2022 Physician Fee Schedule final rule, that allow for the provision of certain behavioral health services via audio-only telephone calls.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

CHILD CARE ACCESS AND AFFORDABILITY

Question. Since the onset of the pandemic, the child care industry has lost nearly one-third of its workforce due to low pay, burnout, and inadequate benefits for workers.[5] The limited availability of affordable and accessible child care options has also put additional strain on working parents to find care options that best suit their family needs. And, this issue is exacerbated for families in rural communities, low-income communities, and communities of color, where many people work non-traditional hours with low wages and limited access to affordable transportation options.

Investments in early childhood learning have multiple benefits: they lay the foundation for children to succeed throughout their education and later in life; they provide economic opportunities for child care workers; and they provide flexibility in working parents' schedules so that they may contribute to local economies. The President's HHS FY23 budget proposal would provide additional funding to help solve these care crisis issues by investing in the health and well-being of our country's future, including $20.2 billion for early care and education programs within the Administration for Children and Families (ACF).

How can additional investments in existing Federal early childhood education funding streams—like Head Start and the Child Care Development Block Grant (CCDBG)—be utilized to address the issues that contribute to the child care workforce shortage, such low wages and limited benefits packages?

Answer. The Biden-Harris administration is committed to supporting and growing the early care and education workforce. Unfortunately, because of the thin operability margins in child care, parents are paying as much as they can while early care and education workers often earn low wages and have low access to workplace benefits like health insurance or paid leave. Head Start programs provide free early education and other comprehensive services to eligible children from low-income families, but for decades programs have not had sufficient funding to raise compensation for their workforce. Adequate compensation is key to attracting and retaining a skilled workforce for both child care and Head Start programs.

The FY 2023 President's budget requests $7.5 billion in discretionary and $3.55 billion in mandatory funds, bringing total Child Care and Development Fund (CCDF) resources to over $11 billion, a $1.4-billion increase over FY 2022 enacted levels. These additional resources are needed to maintain and increase the support provided to children and families and to raise reimbursement rates for child care providers. Labor constitutes the majority of expenses in child care, and with increased subsidy reimbursement rates, child care programs can provide higher wages and more benefits to staff, which will increase supply, reduce turnover, and improve child care quality. ACF's Office of Child Care (OCC) encourages lead agencies to use fixed cost payment practices, such as paying based on children's enrollment rather than attendance, which results in providers having more predictable, stable revenue and to continue to pay workers when children are absent due to health or other reasons.

The FY 2023 President's budget requests a total of $12.2 billion for the Head Start program, which is a $1.2-billion increase over the FY 2022 enacted levels. This budget request includes funding to provide for a cost-of-living adjustment to allow programs to keep pace with inflation. Although this does not provide additional funding to improve staff compensation to be more competitive, this administration has raised and continues to support the goal of improving the compensation of Head

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[5] Wallace, Alicia (January 2022). *America's child care crisis: Parents struggle as facilities close nationwide due to staffing shortage.* CNN Business, *https://www.cnn.com/2022/01/28/economy/child-care-labor-force-declines/index.html.*

Start staff to support pay parity with elementary school staff, for those with similar qualifications.

Question. What resources and materials can HHS provide to States to facilitate efforts by child-care providers in rural and low-income areas to access Federal early childhood education funds and thus, best serve the children and families in their community?

Answer. The Biden-Harris administration supports efforts to ensure access to Federal child-care funding—both for child-care providers and children/families—in rural and low-income areas. The FY 2023 President's budget requests an additional $1.4 billion in discretionary Child Care and Development Fund (CCDF) resources over FY 2022 enacted levels—over $11 billion total—to increase resources for States, territories, and Tribes to expand the number of children receiving child-care subsidies, and to improve the provider payment rates for those subsidies, which in many jurisdictions are inadequate. In addition, States, territories, and Tribes would have additional resources to improve the quality and supply of child care—including in child care deserts, which often include rural and low-income communities.

This funding increase would build the administration's ongoing American Rescue Plan (ARP) implementation work, which provided $24 billion in child care stabilization grants to providers to support the stability of the child-care sector during and after the COVID–19 public health emergency. The Office of Child Care (OCC) has instructed States to target stabilization grants, which can be used for wages and benefits, among other operational activities, to underserved constituencies and required States to report on the demographics of providers receiving grants. As a result, several States used the Center for Disease Control and Prevention's (CDC) Social Vulnerability Index (SVI) to support equitable distribution of funds to child-care providers that serve communities most in need in their States. To make it easier for providers to access stabilization grants, OCC published a web page with links to State applications, and provided resources to assist providers, including hosting national webinars for child-care providers about the availability of stabilization grants. OCC developed a resource guide to help family child care business owners complete child care stabilization grant applications, thus providing application support to smaller, less-well-resourced providers.

The ARP also provided $15 billion in supplemental CCDF discretionary funding. In the guidance for this funding, OCC encouraged States to increase subsidy payment rates to providers and to improve payment practices that impact the value of the subsidy, such as the use of grants and contracts (rather than certificates/vouchers). The guidance noted that grants or contracts provide a more predictable funding stream for child-care providers and help build the supply of child care in underserved areas or for underserved populations, such as infants and toddlers, children in rural areas or low-income neighborhoods, dual language learners, children with disabilities, and children who need child care during non-traditional hours.

MEDICAID COVERAGE OF VACCINES

Question. Medicaid provides a safety net for our most vulnerable citizens—low-income older adults, pregnant and postpartum individuals, and the disabled to name a few. In Ohio it's estimated that nearly a quarter of insured Ohioans access health insurance through Medicaid or the Children's Health Insurance Program.[6]

As part of the Affordable Care Act, Congress acted to provide coverage for vaccines without cost sharing in States that opted to expand Medicaid.

While the ACA helped to extend coverage for millions of previously uninsured Americans and ensure adults can access recommended vaccines at no out-of-pocket cost, those who remain in traditional Medicaid continue to live with a patchwork of coverage for preventive care, including vaccines. That is why I introduced legislation, the Helping Adults Protect Immunity (HAPI) Act, which would extend the same coverage of vaccines without cost sharing to all individuals with Medicaid, regardless of where they live or if they are covered under traditional Medicaid or the ACA's expansion.

Will you commit to work with me to ensure that all Medicaid populations have access to potentially lifesaving vaccines without unnecessary restrictions?

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[6] *https://www.medicaid.gov/state-overviews/scorecard/percentage-of-population-enrolled-medicaid-or-chip-state/index.html.*

Answer. Preventing disease before it starts is critical to helping people live longer, healthier lives, and CMS is committed to helping States undertake efforts to expand access to preventive health care.

As an example, on May 12, 2022, CMS released a letter to States to provide information on Medicaid and CHIP coverage and payment for stand-alone vaccine counseling. The letter describes how CMS interprets the Medicaid Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit to require States to provide coverage of stand-alone vaccine counseling to Medicaid beneficiaries under the age of 21 who are eligible for EPSDT. This interpretation applies to standalone vaccine counseling related to all vaccines covered for beneficiaries eligible for EPSDT, including COVID–19 vaccines.

CMS continues to provide guidance and support to State Medicaid and CHIP agencies to address deeply embedded disparities in accessing medical services, and the agency looks forward to partnering with Congress to improve beneficiary access to quality care.

HRSA PROVIDER RELIEF FUND

Question. The HRSA Provider Relief Fund and specific set aside for rural hospital relief passed as part of the American Rescue Plan Act have helped keep hospitals across the country afloat as they've struggled with the impact of COVID–19. While I appreciate everything HHS and HRSA has done to help distribute these funds efficiently and equitably, I remain frustrated by the lack of transparency when it comes to pending applications.

I have heard from several Ohio hospital CEOs and leadership from other healthcare providers in Ohio who have front-line workers and systems that have been waiting months for funding or for status updates on their phase 3 reconsiderations and phase 4 applications. It's concerning that HRSA—or its contractor(s)—are unable or unwilling to provide meaningful updates on the status of applications that have been sitting with the Department for months, or share insight into the potential timeline for fund distribution moving forward. I understand that there are millions of applications that HRSA has had to work through, each one with its own complications. Despite this, it is important that providers receive timely information so that they can make the decisions necessary for them to continue to provide quality care to their communities.

Can you please commit to ensuring casework requests related to the HRSA provider relief fund and other associated COVID–19 relief measures are prioritized and receive meaningful responses in a timely manner?

Answer. Yes. HHS and HRSA understand the importance of the Provider Relief Fund (PRF) for health-care providers working to deliver care in their communities and will continue to prioritize responding to and working with applicants to address casework inquiries. About 89 percent of Phase 4 applications and 97 percent of American Rescue Plan Rural applications have been processed. Remaining applications are generally from complex entities that may have multiple taxpayer identification numbers and subsidiaries, where it is necessary to manually review detailed filings to ensure that there isn't duplication of payments and to otherwise ensure program integrity. HHS and HRSA are committed to timely processing and transparency and will continue to work as expeditiously as possible to finalize reviews.

ACTIVE PHARMACEUTICAL INGREDIENT SUPPLY CHAIN RESILIENCY

Question. Right now, the United States depends on other countries for a range of pharmaceutical products, including many active pharmaceutical ingredients (APIs) that are essential to create generic prescription drugs. Generic drugs make up 90 percent of all prescriptions filled in the United States, and about 87 percent of API facilities for generic medicines are located overseas. The pandemic has revealed gaping holes and vulnerabilities in our supply chains, and the fact that the U.S. relies almost entirely on a global supply chain for APIs and essential medicines poses a risk to our health and national security.

As you know, the essential medicine supply chain and active pharmaceutical ingredients were identified in President Biden's February 2021 executive order on American Supply Chains. It's past time to identify the gaps in this essentials supply chain and build emergency capacity for essential medicines here in the U.S.—there is no reason we should be relying on countries like China or India for nearly 90 percent of these critical pharmaceutical ingredients, when we have talented scientists and manufacturers right here.

What actions has HHS taken or plan to take to incentivize onshoring of API production and storage, and domestic manufacturing of these essential drugs?

Answer. ASPR is supporting a number of activities including: domestic manufacturing of PPE and active pharmaceutical ingredient manufacturing capacity; COVID–19 testing, including swabs, tests and kits, supplies such as reagents and resins; and enhanced vaccine production capacity. Each of these domestic manufacturing initiatives meet current, as well as future COVID–19 needs, and seek to create or sustain high-value domestic jobs.

In addition, ASPR made a $354-million investment in PHLOW, a consortium of organizations that will expand domestic manufacturing of raw materials and active pharmaceutical ingredients for drugs. This effort includes support for continuous manufacturing. The efforts will target drugs on the FDA drug shortage list that have become even more critical during the COVID–19 response. As we continue to move this effort forward and consider expansion, any modification will be dependent on available resources. I will be happy to keep you and your staff informed of activities related to this initiative.

HHS is also working to implement the Make PPE in America Act, included in the Bipartisan Infrastructure Law, to catalyze domestic investments and make America's health supply chain stronger and more resilient.

Question. Last year, Senator Cassidy and I introduced the PREPARE Act, which would create an emergency supply of key ingredients used in essential generic medicines and incentivize domestic manufacturing of these ingredients to build a more resilient domestic supply chain for essential medicines like antibiotics, which are no longer made in the U.S. Will you commit to working with our offices to ensure we fully leverage the work already begun by BARDA and ASPR to ensure we have a secure domestic pipeline available at all times for the medicines necessary to sustain the health of the U.S. population?

Answer. Yes, I am committed to working with Congress on efforts to support domestic manufacturing capabilities to enhance our domestic supply chain. It is critical that we have access to supplies in future response operations and I look forward to working with you on this effort.

CONTINUOUS ELIGIBILITY FOR KIDS

Question. Over the past 2 years, Congress has taken steps to increase the stability and consistency of coverage for Medicaid and CHIP enrollees. Early in the COVID–19 pandemic, Congress passed the Families First Coronavirus Response Act, which included a provision requiring all States receiving enhanced Medicaid funding to provide continuous Medicaid coverage to all enrollees throughout the COVID–19 public health emergency. This action helped reduce churn in Medicaid—usually a serious problem—to a temporary halt—allowing children and other beneficiaries to rely on continuous coverage throughout the pandemic even if their family's income varied month-to-month.

Later, Congress passed the American Rescue Plan Act, which gave States an option to extend continuous coverage to Medicaid and CHIP pregnant enrollees through one full year after the birth of a child. Several States have announced their intent to take up this option. The House-passed Build Back Better Act would have built on this State option to require States to provide 12-month continuous Medicaid and CHIP eligibility for children and 12 months of postpartum Medicaid and CHIP coverage for new moms. Each of these important legislative steps has helped move the country closer to ensuring stable health-care coverage for everyone on Medicaid and CHIP.

Are there additional steps the Centers for Medicare and Medicaid Services (CMS) can take to support these policies, reduce churn in Medicaid and CHIP, and provide continuous coverage for kids and new moms?

Could CMS encourage more stable Medicaid and CHIP coverage by publishing State Health Official letters and prioritizing continuous eligibility in 1115 demonstrations?

Answer. The Biden-Harris administration is committed to ensuring that every eligible person can access the coverage and care to which they are entitled. Federal law provides States with options to implement a variety of strategies to promote continuity of coverage, and we are committed to working with States on this important issue. In guidance CMS released in March 2022, CMS encouraged States to consider strategies that will help eligible individuals maintain coverage, prevent

churning on and off of coverage, and mitigate procedural denials based on the absence of a renewal form or other information needed by the State to complete a redetermination of eligibility. These strategies include State plan options such as adopting continuous eligibility for children, adopting 12 months of continuous postpartum coverage, and Express Lane Eligibility. States can also take steps to streamline renewals and improve communications and outreach to beneficiaries. CMS has issued tools to support States in these efforts, including communications tools to assist in beneficiary outreach.

With respect to continuous postpartum coverage, we are pleased that seven States and counting have received approval to extend 12 months of postpartum Medicaid and CHIP coverage to their beneficiaries, and CMS is now working with at least a dozen States and the District of Columbia on this important policy.

CMS is also developing a more comprehensive access strategy in the Medicaid and CHIP programs. In February 2022, CMS issued a Request for Information (RFI) on access to care and coverage for people enrolled in Medicaid and CHIP. Feedback obtained from the RFI will aid in CMS's understanding ofenrollees' barriers to enrolling in and maintaining coverage and accessing needed health-care services and support through Medicaid and CHIP.

This year, CMS committed over $49 million in Connecting Kids to Coverage Outreach and Enrollment Grants to continue efforts to reach out, enroll, and retain eligible children in Medicaid and CHIP. Funded organizations will provide enrollment and renewal assistance to children and their families, as well as pregnant people.

QUESTION SUBMITTED BY HON ROBERT P. CASEY, JR.

TRANSITIONAL COVERAGE FOR EMERGING TECHNOLOGIES (TCET)

Question. I was pleased to see President Biden's continued commitment to medical research and innovative applications in the health-care system, an ongoing commitment to the safety and efficacy of medical products, in the FY2023 budget. This funding will provide significant new opportunities for researchers to identify and develop novel ways to prevent, treat and cure diseases. I am also encouraged that CMS is working on a new approach, known as Transitional Coverage for Emerging Technologies, or TCET, to create a clear pathway for Medicare coverage of safe and innovative medical technology.

What is the administration's timeline for the TCET rule to provide meaningful predictability and clarity for the Medicare coverage process for safe and innovative technologies?

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

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

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

QUESTIONS SUBMITTED BY HON. MARK R. WARNER

MEDICARE DIABETES PREVENTION PROGRAM EXPANDED MODEL

Question. The Diabetes Prevention Program works to improve the health of those with prediabetes and prevent diabetes, and Medicare pays for access to this CDC-recognized program through the Medicare Diabetes Prevention Program Expanded Model. However, despite the growing prevalence of prediabetes, Medicare only covers in-person programs, despite significant barriers to access; CDC data showing Medicare-age participant success in virtual programs; and a recent recommendation from the National Clinical Care Commission that "coverage of MDPP be expanded to include virtual delivery."

During the public health emergency, CMS expanded access to virtual DPP providers. I have legislation with Senator Tim Scott of South Carolina, the PREVENT DIABETES Act, which would permanently expand the program to virtual-only providers.

Does CMS plan to extend this beyond the expiration of the PHE, as Congress did for other telehealth provisions? You mention in your budget that HHS supported the extensions Congress made and hope this includes what you can extend on your end, as well.

Do you support permanently allowing coverage of virtual DPP providers in Medicare?

Answer. Innovation is important to advancing goals in health care, and the CMS Innovation Center is integral to the administration's efforts to promote high-value care and encourage health-care provider innovation, including virtual and digital health innovation. With respect to the Medicare Diabetes Prevention Program (MDPP) expanded model, it is true that CMS issued regulatory flexibilities in response to the COVID–19 pandemic, including waiving the limit on virtual sessions that can be provided by MDPP suppliers when in-person classes are not safe or feasible. MDPP suppliers must remain prepared to resume delivery of MDPP services in-person to start new cohorts and to serve beneficiaries who wish to return to in-person services when certain flexibilities granted during the pandemic are no longer in effect.

HOME INFUSION

Question. I led the effort in 2016 when Congress passed legislation creating a new home infusion benefit in Medicare after I saw the advances made by other payers to improve care and lower cost by moving infusion therapy home as much as possible.

However, I've been disappointed that fee-for-service Medicare's coverage remains not as comprehensive as other payers and even Medicare Advantage. Payments are just not reflective of the services provided so there are not enough providers, and recent data published by CMS acknowledges that utilization of the new benefit has been "low."

That's why I am working with my colleague Senator Scott of South Carolina and we've introduced legislation to improve this important benefit.

Do you believe that utilization of the new benefit is at least partially due to too-low payments to providers?

Will you commit to work with me to improve this benefit to ensure Medicare has as comprehensive a benefit as other payers?

Answer. The Biden-Harris administration supports strengthening home and community-based services as an alternative to institutionalized care, to ensure that people have access to safe options that work for them. People are happier and healthier when they live in their community, and living in one's own home and community usually costs less than care in an institution such as a nursing home. Home infusion therapy services can play in important role in allowing beneficiaries to continue receiving care within their own home instead of a hospital or physician office. Per the statute, the Medicare home infusion therapy services benefit covers professional services, including nursing services, training and education not already provided under the durable medical equipment (DME) benefit, remote monitoring and monitoring services. The home infusion therapy services benefit works in tandem with the DME benefit. DME suppliers are responsible for furnishing the infusion pump (including training the patient and/or caregiver on how to use the infusion pump), the drug or biological, and any pharmacy services associated with furnishing

the drug or biological. We note that patients and/or their caregivers must be able to self-administer home infusion drugs in order for the pump and drug to be covered under the DME benefit.

In November 2021, CMS issued the CY 2022 Home Health Prospective Payment System Rate Update Final Rule (CMS–1747–F). In addition to updating the geographic adjustment factor used for wage adjustment, the final rule updated the home infusion therapy services payment rates for CY 2022 as required by law. The overall economic impact of updating the payment rates for home infusion therapy services is expected to be an increase in payments to home infusion therapy suppliers of 5.1 percent.

HHS looks forward to working with Congress and other stakeholders to improve the critical home health-care services that allow beneficiaries to remain in their homes and communities.

ESSENTIAL MEDICINES AND SUPPLY CHAINS

Question. I have been so excited to see the great work done by BARDA to secure our Nation's essential medicines, many which have seen shortages even before the pandemic.

BARDA has made a long-term investment in stakeholders in the Commonwealth of Virginia to create end-to-end manufacturing capacity for essential medicines, as the supply chain of such medicines was identified as one of four key supply chains at risk of disruption in the 100 Day Supply Chain Review.

It has long been clear that the market is different for essential medicines, that it's geopolitical vulnerable, and that there's a role for Federal Government support for domestic manufacturing of essential medicines and their ingredients to protect the health of Americans and the health security of the United States.

Is there a plan to expand this framework to antibiotics, which have similar challenges?

Answer. The global pandemic has highlighted the vulnerabilities of the global supply chain for many products. It is critical that steps be taken to invest in expansion of domestic manufacturing capacity. As you are aware, ASPR made a $354-million investment in PHLOW, a consortium of organizations that will expand domestic manufacturing of raw materials and active pharmaceutical ingredients for drugs. This effort includes support for continuous manufacturing. The efforts will target drugs on the FDA drug shortage list that have become even more critical during the COVID–19 response. As we continue to move this effort forward and consider expansion, any modification will be dependent on available resources. I will be happy to keep you and your staff informed of activities related to this initiative.

Question. Will you commit to working with me to continue building on the work and investments already begun by HHS to ensure we have a secure domestic supply chain at all times for essential medicines?

Answer. Yes, I commit to working with you and your other congressional colleagues on efforts to support domestic manufacturing capabilities to enhance our domestic supply chain and access to essential medicines. It is critical that we have access to supplies in future response operations and I look forward to working with you on this effort.

QUESTIONS SUBMITTED BY HON. SHELDON WHITEHOUSE

COVID–19 WORKFORCE SHORTAGES

Question. I have heard from Rhode Island's providers about the strain the COVID–19 pandemic has put on the health-care workforce and providers' finances. Health-care workers are facing unprecedented and unrelenting levels of stress and burnout, leading to early retirements that can exacerbate workforce shortages. Hospitals and other facilities are paying more for labor, while reimbursement from Medicare, Medicaid, and private insurance stays the same. Nurses have borne the brunt of these stresses, and hospitals are struggling to fill nursing vacancies.

What authorities and resources does the Department of Health and Human Services (HHS) need to support providers, including hospitals, who are facing nursing and other workforce shortages?

Answer. HHS and HRSA are committed to strengthening the health workforce and connecting skilled health-care providers to communities in need. The need for a well-trained, quality health workforce that can address the diversity of communities in which health professionals practice is greater than ever and HRSA is focused on strengthening the workforce by training and connecting skilled health-care providers to communities in need through grants, loan repayment and scholarship programs and helping to build the health workforce pipeline.

A critical tool in our health workforce efforts is the National Health Service Corps, which provides scholarships and loan repayment in return for a commitment to practice in high need communities. Through additional congressional support in the CARES Act and the American Rescue Plan (ARP) Act, HRSA was able to expand the reach of this program and make more awards/fund more individuals than ever before. Moreover, the CARES Act provided additional flexibilities for NHSC clinicians who are currently serving in Health Professional Shortage Areas and whose service obligation was negatively impacted by the pandemic.

HRSA also funds physician training and nurse training programs as well as critical programs like nurse faculty programs that aim to grow the opportunities for more individuals to enter the health professions by building training programs' capacity to serve students. In addition, appropriations to HRSA support behavioral health workforce training programs and the community-based health workforce such as community health workers. The size and scope of these efforts are contingent on annual appropriations.

HRSA's continued goal is to ensure patient access to high-quality care, especially for underserved populations. We look forward to continuing to work with Congress to strengthen and support our health-care workforce serving our communities of greatest need.

ADULT VACCINES MANDATORY COVERAGE PROPOSAL

Question. Last fall, HHS reported that Congress could provide all adults access to all CDC-recommended vaccines without cost sharing.[7] More recently, the President's Fiscal Year 2023 HHS budget includes a proposal that would eliminate vaccine cost sharing for older adults across country.

I introduced S. 912, the Protecting Seniors Through Immunization Act, with my colleagues Senators Hirono and Tim Scott to provide Medicare beneficiaries access to all recommended vaccines at no additional cost. Does the administration support this bipartisan legislation?

Answer. The COVID–19 pandemic has emphasized the importance of vaccines and the critical role they play in preventing severe disease and saving lives. In addition to proposing investments in the research and development of vaccines, the President's FY 2023 budget includes proposals to expand access to vaccines for both children and adults. Within Medicare, the budget proposes to consolidate all vaccine coverage under Medicare Part B.

Current Medicare coverage for vaccine administration is divided between Part B and Part D, which can be confusing and burdensome for both Medicare beneficiaries and providers. Part B is a more appropriate type of coverage for vaccines because more beneficiaries are enrolled in Part B than Part D, and higher out-of-pocket costs in some Part D plans may create a financial barrier to access. This proposal would shift all Medicare coverage for vaccines, including administration costs, to Part B and require that Medicare Advantage Plans charge no greater cost sharing for any vaccines and their administration than is charged under Original Medicare. For all vaccines recommended by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices and adopted by the CDC Director, with the exception of vaccination for travel-related purposes, there will be zero cost sharing for Medicare beneficiaries. This proposal would also modify the way Medicare pays for vaccines from 95 percent of the Average Wholesale Price, which often has little relationship to market prices, to 103 percent of the Wholesale Acquisition Cost, the price at which the manufacturer sells the vaccine to the wholesaler. These changes promote better access to vaccines among the Medicare population while better aligning Medicare payment with actual costs. Health equity is improved by removing potential financial barriers to CDC-recommended vaccines.

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[7] *https://aspe.hhs.gov/sites/default/files/2021-09/Competition%20EO%2045Day%20Drug%20Pricing%20Report%209-8-2021.pdf.*

Additionally, the budget requests new mandatory resources at CDC to provide uninsured adults access to recommended vaccines at no-cost. Modeled after the highly successful Vaccines for Children (VFC) program, the proposed Vaccines for Adults (VFA) program would build on the investments made in response to the COVID–19 pandemic and provide a crucial—and missing—component of the public health infrastructure toward achieving vaccinations across the life span. CDC has proposed $2.1B in mandatory funding in FY 2023 and a total of $25 billion over 10 years.

While CDC has authority under section 317(j)(1) of the Public Health Service Act (42 U.S.C. 247b(j)(1)) to provide grants for "preventive health service programs to immunize without charge children, adolescents, and adults against vaccine-preventable diseases," this is an annually appropriated program that is limited to serving only those as its funding allows. At current levels, this discretionary funding has been used to vaccinate a small proportion of the uninsured adult population and facilitates rapid vaccination response in outbreak settings; however, these efforts represent a small portion of discretionary immunization activities. There has been no dedicated program to ensure vaccination of uninsured adults.

The VFA program will provide uninsured adults access to recommended routine and outbreak vaccines at no cost. The creation of this new mandatory program will be a significant step toward filling existing gaps in vaccine coverage among US adults and provide sustained support for immunizations from year to year. CDC will also work with jurisdictions to leverage base immunization funding ("317") and other resources to support associated program operations costs, vaccine confidence and vaccine equity activities, including communications, partnerships, education, and technical assistance.

QUESTIONS SUBMITTED BY HON. ELIZABETH WARREN

DRUG PRICES

Question. The Department's Comprehensive Plan for Addressing High Drug Prices, released in September 2021, stated that HHS will give petitions for the use of march-in rights and government use rights "due consideration," and will engage other government agencies to "address barriers to accessing government-funded inventions."

HHS has received a petition for the use of march-in rights for enzalutamide, also known by its brand name Xtandi. Will HHS hold a public hearing on the enzalutamide petition to allow petitioners and patent-holders to present arguments and accompanying evidence on this case?

Answer. The NIH, as the funding agency named, is currently reviewing the information submitted in the 2021 petition per the march-in provision of the Bayh-Dole Act (35 U.S.C. § 203), implemented by 37 CFR § 401.6, which authorizes the Government to require the funding recipient or its exclusive licensee to license a federally funded invention to a responsible applicant or applicants on reasonable terms, or to grant such a license itself, if the Federal agency determines that any of the following conditions are met:

- Action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
- Action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
- Action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
- Action is necessary because the agreement required by section 35 U.S.C. § 204 (regarding a requirement to manufacture in the United States) has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

If NIH determines there is sufficient information to initiate a march-in proceeding per the criteria above, regulations permit an administrative hearing with fact finding, due process, and witnesses.

Question. What tools does HHS intend to use to "address barriers to accessing government-funded interventions"? Which other government agencies has HHS identified as potential partners?

Answer. There are several strategies by which HHS works to promote commercialization of inventions with ties to investments in basic research. For example, NIH's Small business Education and Entrepreneurial Development (SEED) program aims to accelerate the conversion of scientific discoveries into impactful health-care solutions.[8] Technology transfer programs, governed by the Bayh-Dole Act and the Federal Technology Transfer Act, guide the transfer of innovative technologies to the private sector for commercialization and ultimately public benefit.

NIH also works to promote broad access and adoption of inventions funded with taxpayer dollars. For instance, under a new initiative, NIH licensed early-stage technologies from the NIH Intramural Research Program to WHO's COVID–19 Technology Access Pool (C–TAP) for greater access to companies developing products for use in Low- and Middle-Income Countries (LMIC).

VACCINE SUPPLY

Question. The importance of increasing the global COVID–19 vaccine supply remains urgent. In many low-income countries, less than 20 percent of the population has received at least one vaccine dose, compared with 80 percent in many middle- and high-income countries. As White House Coronavirus Response Coordinator Jeff Zients recently said, "This virus knows no borders, and it's in our national interest to vaccinate the world and protect against possible new variants." On January 13, 2022, I sent a letter to the Biden administration requesting that the administration (1) invoke the Defense Production Act to facilitate mRNA vaccine technology transfer, and (2) prioritize contracts for government-owned and contractor-operated manufacturing models when establishing new domestic mRNA manufacturing capacity.

Does the administration plan to invoke its authorities under the Defense Production Act to facilitate the transfer of mRNA vaccine technology? If so, when and how? If not, why not?

Answer. HHS works with vaccine manufacturers and with our colleagues at the White House and other agencies on vaccine production. However, at this time, there are no plans to utilize Defense Production Act (DPA) authorities related to the transfer of mRNA vaccine technology.

One authority under DPA allows Federal agencies to require companies to prioritize government contracts for medical supplies to address national emergencies. Each request is specific to an individual component and priority rating is only used to support critical response needs; every priority rating has an impact on the medical supply chain and other medical manufacturers so we make every attempt to minimize that impact prior to rating any contract or product. To date, HHS has issued 71 approvals for priority rating under the DPA title I authorities.

Question. Has the administration considered using public, government-owned, contractor-operated manufacturing models to fulfill its November 2021 commitment to drastically expand domestic COVID–19 vaccine manufacturing? If so, what is the status of the administration's vaccine manufacturing initiative? If not, why not?

Answer. BARDA within HHS has examined and recommended against a Government-Owned, Contractor-Operated (GOCO) model to fulfill efforts to expand COVID–19 vaccine manufacturing at this time. GOCO is effective when the needs of the government cannot be met by the market, such as nuclear weapons or military ammunition but not necessarily vaccine manufacturing where the commercial market is well established. A GOCO vaccine manufacturer would essentially be a Contract Manufacturing Organization (CMO), able to manufacture products on demand, rather than being dedicated to one particular product. There is a robust, and expanding, domestic CMO market already. It is ASPR/BARDA's goal to build upon that strength to bolster pandemic preparedness.

The administration has taken significant steps to invest in expansion of domestic vaccine manufacturing capabilities. Under the CARES Act of 2020 and the American Rescue Plan Act of 2021, BARDA is executing an Industrial Base Expansion (IBx) program. One of the most important advantages of IBx over GOCO is sustainment. Emphasis on leveraging existing planned capacity expansion is to gain

[8] *https://grants.nih.gov/aboutoer/oer_offices/seed.htm.*

from industry's perspective on market growth and to mitigate reliance on USG sustainment.

Question. What resources does the administration have available to support a public, government-owned, contractor-operated manufacturing facility capable of meeting its stated target of producing 1 billion additional mRNA vaccine doses per year? Given the constant threat of new variants and the increased importance of mRNA vaccines, what additional resources would be required to scale this plan to produce billions more doses per year?

Answer. As highlighted in response to question 85, BARDA examined and recommended against a Government-Owned, Contractor-Operated (GOCO) model to fulfill efforts to expand COVID–19 vaccine manufacturing. Instead, the administration has taken significant steps to invest in expansion of domestic vaccine manufacturing capabilities. Under the Cares Act of 2020 and the American Rescue Plan Act of 2021, BARDA is executing an Industrial Base Expansion (IBx) program. The goals of the IBx plan are multifaceted and address all of the identified needs for a robust domestic vaccine manufacturing capability to manufacture one billion doses per year.

These include:

- Expand domestic manufacturing capabilities to mitigate pandemic surge demand and bottlenecks.
- Invest in products and services that support existing supply chain offering high volume manufacturing capacity for COVID–19 vaccines (large and small businesses).
- Establish diverse and robust program portfolios to support at least 100 million doses/month.
- Require industry cost share by capitalizing on existing industry partner expansion plans.
- Focus on efforts that can be operationalized within 3 years of award.
- No government sustainment of capability—rely on industry perspective in their relevant markets.
- Seek Industrial Base Expansion investment consideration from industry for future product/service contracts during declared public health emergency for period of 10 years following completion of capacity expansion.
- Preferred pricing.
- Priority Access without Defense Product Act.

The IBx program addresses all levels of the vaccine manufacturing ecosystem and assures sustainability and pandemic preparedness through strengthening the market, not creating a competitive government-owned system.

Question. What support is the administration providing to the World Health Organization's mRNA vaccine technology transfer hub to expand the availability of mRNA vaccines in low-and middle-income countries?

Answer. The United States Government is committed to accelerating progress toward widespread and equitable access to safe and effective COVID–19 vaccines. The administration continues to work with other countries and organizations including pharmaceutical companies to accelerate manufacturing, increase vaccine donations, and strengthen the supply chain. The United States called on countries, vaccine manufacturers, and other partners to expand global and regional production of mRNA, viral vector, and/or protein subunit COVID–19 vaccines for low- and lower-middle-income countries and to enhance transparency of data on production, availability, and projections for dose manufacturing. We support increasing local manufacturing vaccine capacity in low- and middle-income countries, including through technology transfer hubs in various regions, such as the newly established mRNA hubs in South Africa, Brazil, and Argentina, and HHS has had conversations with the World Health Organization regarding their mRNA vaccine manufacturing hub strategy. We remain committed to trying to strike a balance between ensuring that those who need access to vaccines get them and continuing to foster innovation in this field.

DECRIMINALIZING CANNABIS

Question. While Congress works to pass comprehensive cannabis reform, the Biden administration can act now to decriminalize cannabis. Taking this step would allow States to regulate cannabis as they see fit, begin to remedy the harm caused by decades of racial disparities in enforcement of cannabis laws, and facilitate valuable medical research. On October 6, 2021, I sent a letter to the Department of Jus-

tice requesting that the Attorney General use his authority to initiate proceedings to determine whether to deschedule cannabis as a controlled substance. However, the Controlled Substances Act also States that the Attorney General may initiate these proceedings "at the request of the Secretary" of HHS. Importantly, if the process is commenced, the Secretary will conduct a scientific and medical evaluation and offer his recommendation to the Attorney General as to whether the drug should be controlled or removed as controlled.

Does HHS plan to invoke its authorities under the Controlled Substances Act to request that the Attorney General initiate proceedings to evaluate whether to remove cannabis from the schedules of covered drugs? If so, when and how? If not, why not?

Answer. FDA is aware of the interest in a regulatory pathway for products derived from cannabis. FDA has identified a need for additional toxicity and safety data in order to set cannabis product standards that appropriately protect public health. FDA has taken additional actions to encourage the development of this information, specifically issuing a draft Clinical Research Guidance related to the development of drugs containing cannabis or cannabis-derived compounds, as well as the Cannabis-Derived Products Data Acceleration Plan, which outlines initiatives focused on advancing data-driven safety signal detection and building advanced technology capabilities. FDA is also examining an AHRQ-authored living systematic review on cannabis and other plant-based treatments for chronic pain. The evaluation of this data is ongoing.

Question. What resources does HHS need in order to conduct such a scientific and medical evaluation of cannabis? How long would such an evaluation take to complete?

Answer. FDA estimates that the resources and time would be considerable and would likely exceed what was done for the most recent evaluation of cannabis, completed in 2015 to respond to two rescheduling petitions at the time (see documents from public dockets: *https://www.regulations.gov/document/DEA-2016-0011-0001* and *https://www.regulations.gov/document/DEA-2016-0012-0001*).

FDA is unable to provide a time frame for completion of such an evaluation if one were to take place. The following activities would need to be completed before any evaluation could be finalized. FDA's Center for Drug Evaluation and Research (CDER) Office of Surveillance and Epidemiology would need to complete a comprehensive evaluation for updated understanding of current epidemiology data. The Controlled Substance Staff (CSS) in CDER would need to conduct a new literature review and analysis of available clinical data and draw conclusions as to whether there is now sufficient evidence that would constitute a currently accepted medical use of botanical forms of cannabis, based on published data and results from large, adequate, well-controlled clinical trials. Additionally, CSS would need to update all other categories of data under the eight factors required to be analyzed in evaluating the scheduling of controlled substances and would require review, discussion, and clearance of the evaluation with: FDA/CDER senior management, NIDA staff and senior management, staff within the FDA's Office of Chief Counsel and Office of the Commissioner, and HHS' Office of the Assistant Secretary for Health. We also recommend discussion with DEA for their own estimates of considerable staff resources from their agency, and the Department of Justice broadly, to prepare updated findings, based on HHS input, and a Federal Register notice on this subject.

Question. Since January 1, 2010, for which drugs has HHS conducted a scientific and medical evaluation under 21 U.S.C. 811(b)? How long did such evaluations (if any) take to complete?

Answer. Since 2010, FDA has conducted and provided to HHS a total of 130 eight-factor analyses, including recommendations regarding scheduling as appropriate. Each analysis requires the review of a substantial body of data, and the specifics of each analysis differ substantially depending on whether those data are readily available as well as the quality of the data and any additional work FDA has to perform to complete the scientific evaluation. Given that, no single estimate can be provided as to how long the evaluations take.

MEDICARE ADVANTAGE

Question. The President's FY 2023 budget acknowledges that "payments to [Medicare Advantage] plans are 104 percent of what they would be to provide Part A and B benefits in fee-for-service, negatively affecting Part A solvency and increasing Part B premiums for beneficiaries."

What factors has HHS determined are contributing to overpayments to Medicare Advantage plans? What strategies is HHS exploring to limit these overpayments?

Answer. Contract-level Risk Adjustment Data Validation (RADV) audits are CMS's primary corrective action to recoup Medicare Advantage (MA) overpayments. RADV uses medical record review to verify the accuracy of enrollee diagnoses submitted by MA organizations for risk-adjusted payment. In April of 2022, CMS issued a Health Plan Management System (HPMS) memo on Data Accuracy to MA organizations reminding organizations of their obligation to submit accurate risk adjustment data to CMS. Moreover, CMS maintains that payment recovery will have a sentinel effect on risk adjustment data quality submitted by plans for payment because contract-level RADV audits increase the incentive for MA organizations to initially submit valid and accurate diagnosis information. In FY 2021, HHS has several RADV audits in progress. HHS completed the payment year (PY) 2014 RADV audit medical record review phase and the PY 2015 RADV audit medical record submission phase.

CMS is reviewing MA payment policies. In the Calendar Year 2023 Medicare Advantage and Part D Advance Notice, released in February, CMS solicited comments on whether enhancements can be made to the MA risk adjustment model to address the impacts of social determinants of health on beneficiary health status. CMS also continually reviews MA coding patterns and continues to assess how we calculate the MA coding pattern adjustment, how best to apply it, and what the appropriate level of the adjustment should be. CMS received a number of recommendations from stakeholders regarding approaches to estimate the MA coding pattern adjustment. CMS will consider the comments and recommendations received for future policymaking.

ACO REALIZING EQUITY, ACCESS, AND COMMUNITY HEALTH (REACH) MODEL

Question. In February, the Centers for Medicare and Medicaid Services (CMS) announced a redesign of the Global and Professional Direct Contracting (GPDC) Model in response to concerns about introducing privatization into traditional Medicare. Until the new ACO REACH Model takes effect in January 2023, CMS has said that it will conduct "more robust and real-time monitoring of quality and costs" of GPDC Model participants and that participants may face "potential termination from the model" if they do not meet model requirements.

Please describe the changes to GPDC Model oversight that CMS has instituted to ensure more robust and real-time monitoring of participants. What information is CMS collecting from program participants, and how often is CMS reviewing these data?

Please describe the findings from CMS's oversight efforts. Has CMS discovered any violations of GPDC Model requirements? If so, how many violations has CMS uncovered and what corrective actions has CMS initiated? Under what circumstances will CMS terminate a participant from the GPDC Model before December 31, 2022?

Under the new ACO REACH Model, CMS did not announce any limits to the number of participants or aligned beneficiaries, creating a risk that the size of the Model could grow well beyond what is required for a demonstration. In its Request for Applications, CMS states that it "may choose to limit the total number of accepted applications" depending on the volume of applications received. Has CMS identified a target number of participants or beneficiaries for the ACO REACH Model? If so, what is it? What criteria has CMS used to inform this limit?

Answer. CMS announced a redesigned Accountable Care Organization (ACO) model that better reflects the agency's vision of creating a health system that achieves equitable outcomes through high quality, affordable, person-centered care. The ACO Realizing Equity, Access, and Community Health (REACH) Model, a redesign of the Global and Professional Direct Contracting (GPDC) Model, addresses stakeholder feedback, participant experience, and administration priorities, including CMS's commitment to advancing health equity.

The ACO REACH model promotes health equity and focuses on bringing the benefits of accountable care to Medicare beneficiaries in underserved communities. The Model includes policies to ensure doctors and other health-care providers continue to play a primary role in accountable care. At least 75 percent of each ACO's governing body generally must be held by participating providers or their designated representatives, compared to 25 percent during the previous Model. The new cohort will begin participation in the ACO REACH Model on January 1, 2023. Current

Model participants must maintain a strong compliance record and agree to meet all the ACO REACH Model requirements by January 1, 2023 to continue participating in the ACO REACH Model. CMS will also ask for additional information on applicants' ownership, leadership, and governing board to gain better visibility into ownership interests and affiliations to ensure participants' interests align with CMS's vision.

OVER-THE-COUNTER HEARING AIDS

Question. In October 2021, FDA issued its proposed rule "Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids" to implement my Over-the-Counter Hearing Aid Act, which was signed into law in 2017. The public comment period for the rule ended on January 18, 2022, and the authorizing statute requires a final rule to be issued no later than 180 days after this date.

Is FDA on track to meet this statutory deadline? Will you commit to making the issuance of a final rule establishing over-the-counter hearing aids a priority?

Answer. FDA remains committed to establishing a science-based regulatory category for over-the-counter (OTC) hearing aids that assures safety and effectiveness while promoting access to devices that will help address a significant public health need. Issuing the final rule to establish a new category of OTC hearing aids is a priority for the agency. Please see FDA's hearing aid website for more information: *https://www.fda.gov/medical-devices/consumer-products/hearing-aids.*

NURSING HOME QUALITY

Question. In February 2022, the White House announced several new CMS initiatives to improve quality of care in nursing homes, including (1) establishing new national staffing standards for nursing homes; (2) enhancing accountability and oversight of nursing homes; and (3) increasing transparency of nursing home ownership and finances.

In March 2022, CMS announced that it would issue a proposed rule to establish new staffing standards within 1 year. Please provide a detailed timeline of the steps that CMS will take to meet this goal.

To the extent that CMS is conducting new studies of nursing home staffing needs, will the Department guarantee that the individuals involved in conducting and analyzing such studies are free of conflicts of interest or connections to the nursing home industry?

Answer. In April 2022, CMS issued its Fiscal Year (FY) 2023 Skilled Nursing Facilities Prospective Payment System (SNF PPS) proposed rule (CMS–1765–P), which includes asking for public feedback on how staffing in nursing homes and health equity improvements could lead to better health outcomes. In the proposed rule CMS solicits input to help the agency establish minimum staffing requirements that nursing homes will need to meet to ensure all residents are provided safe, high-quality care, and to ensure nursing home workers have the support they need. This input will be used in conjunction with a new research study being conducted by CMS to determine the optimal level and type of nursing home staffing needs. The agency intends to issue proposed rules on a minimum staffing level requirement for nursing homes within 1 year. The proposal also requests stakeholder input on a measure that would examine staff turnover levels in nursing homes for possible inclusion in CMS's Skilled Nursing Facility Value-Based Purchasing Program, which rewards facilities with incentive payments based on the quality of care they provide to people with Medicare.

The proposed rule would build on CMS's ongoing efforts to improve nursing home staffing and transparency. In January 2022, CMS began posting staff turnover rates and weekend staff levels for nursing homes on the on the *Medicare.gov* Care Compare website. Specifically, the new information provides the percent of nursing staff and number of administrators that have stopped working at the nursing home over a 12-month period and the level of total nursing and registered nurse staffing on weekends provided by each nursing home over a quarter. Having access to this information will help consumers understand more about each facility's staffing environment and choose a facility that provides the highest quality of care that best meets their health-care needs. Staff turnover data also helps providers to improve the quality of care and services they deliver to residents. This information will allow consumers the ability to review nursing homes' measures relative to other nursing homes and will also be included in the Nursing Home Five Star Quality Rating System in July 2022.

Question. According to the White House announcement, "CMS will implement Affordable Care Act requirements regarding transparency in corporate ownership of nursing homes, including by collecting and publicly reporting more robust corporate ownership and operating data." This requirement is more than a decade old and has not yet been implemented. What is CMS's timeline for doing so?

What, if any, additional statutory authority does HHS need to ensure that the Department can properly track the ownership of nursing homes by private equity firms and Real Estate Investment Trusts (REITs) and that these private equity and REIT owners are meeting the needs of the residents under their care?

Answer. Ownership information for currently active nursing homes enrolled in Medicare is available at: *https://data.cms.gov/provider-data/dataset/y2hd-n93e.* This includes detailed information about individuals and organizations that have direct or indirect ownership of, a partnership interest in, and/or managing control of the nursing homes.

In April 2022, HHS announced new actions to promote competition and transparency in our Nation's health-care system that can improve the safety and quality of nursing homes and hospitals. For the first time, CMS publicly released data on mergers, acquisitions, consolidations, and changes of ownership from 2016–2022 for hospitals and nursing homes enrolled in Medicare. This data, available on *data.cms.gov,*[9] is a powerful new tool for researchers, State and Federal enforcement agencies, and the public to better understand the impacts of consolidation on healthcare prices and quality of care. CMS expects to release updated change of ownership data on a quarterly basis. The CMS data will enhance transparency for hospitals and nursing homes patients, potential patients and their loved ones, as well as for policymakers and the communities where these facilities are located.

Question. The President's FY 2023 budget includes nearly $500 million in funding, a 25-percent increase, to support health and safety inspections in nursing homes. How will these funds be used? What will be the impact on nursing home quality if Congress does not provide these funds?

Answer. The budget requests $494 million for Survey and Certification, an increase of $97 million, or 24 percent, above FY 2022 enacted. This investment will strengthen health, quality, and safety oversight for approximately 67,000 participating Medicare or Medicaid provider facilities. Survey workloads and costs continue to increase due to factors such as a growing number of beneficiaries and surveyor wage growth, as well as an increase in serious complaints against facilities, which can lead to costly ongoing enforcement activities once a deficiency is identified. The COVID–19 pandemic has underscored the Survey and Certification program's critical oversight role for holding nursing homes and other facilities accountable to meet minimum infection control standards and protect public health for beneficiaries in these facilities from COVID–19.

The Coronavirus Aid, Relief, and Economic Security Act provided a minimum of $100 million to Medicare Survey and Certification for infection control efforts prioritizing nursing homes. This supplemental funding helped State Survey Agencies conduct focused infection control surveys and respond to the backlog of high-level complaint survey results, recertifications, and other survey activities. Building on lessons learned during the COVID–19 pandemic, the budget invests in improving care in long-term care facilities and improving oversight of accrediting organizations. At the FY 2023 request level, CMS projects that States would have the resources to fully complete surveys for all provider types, including complaint surveys, statutorily required surveys, and non-statutory surveys. This level of survey completion, which has not been projected since the submission of the FY 2017 President's budget, would permit the program to provide oversight for the relevant facility types and is the first step in shifting from a reactive to proactive posture. Timely certification surveys help to promote quality and avoid preventable patient safety adverse event issues, avoid patient harm, and may result in less severe enforcement action over time if issues can be detected earlier and corrected with education and training, rather than reactively responding to complaints. Furthermore, CMS will improve oversight of nursing facilities, including an overhaul of the special focus facility program to improve care more quickly for low-performing nursing homes. These changes will make the special focus facility program requirements tougher and more impactful.

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[9] *https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/hospital-change-of-ownership; https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/skilled-nursing-facility-change-of-ownership.*

Approximately 93 percent of requests for Medicare Survey and Certification are performed by State survey agencies. Surveys can include mandated Federal inspections of long-term care facilities (*i.e.,* nursing homes), home health agencies, and hospices, as well as Federal inspections of hospitals and other key facilities that occur on a non-mandated frequency interval. All facilities participating in the Medicare and Medicaid programs must undergo certification when entering the program and on a regular basis thereafter, which generally includes an onsite survey. The budget will enable CMS to significantly improve survey frequency levels where there is not a statutorily-required frequency, potentially preventing serious violations of safety standards and avoiding patient harm. In total, States will complete over 30,000 initial surveys and recertifications in FY 2023.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

RURAL HOSPITALS AND TELEHEALTH

Question. I've fought to protect rural health-care access. This includes most recently protecting rural health care clinic payments, reauthorizing the rural community hospital demonstration, and creating the voluntary Rural Emergency Hospital program. I'm also a strong supporter of making telehealth permanent—this is important to maintaining access to rural health care. The Trump and Biden administrations allowed critical access hospitals to bill for telehealth during COVID–19 pandemic.

Does the administration have a position on extending telehealth flexibilities for critical access hospitals following the end of the public health emergency?

Answer. During the COVID–19 public health emergency, telehealth has been a reliable resource allowing providers to reach patients directly in their homes in order to ensure access to care and continuity of services. The Biden-Harris administration is committed to supporting a temporary extension of broader telehealth coverage under Medicare beyond the COVID–19 public health emergency declaration in order to study its impact on utilization of services and access to care. Telehealth, including audio-only telehealth, can greatly increase access to services for individuals who may not have sufficient bandwidth or technology to support 2-way audio-video, particularly in underserved areas and among older populations.

CMS's goal is to develop programs and policies that ensure rural Americans have access to high-quality care, support rural providers and not disadvantage them, address the unique economics of providing health care in rural America, and reduce unnecessary burdens in a stretched system to advance our commitment to improving health outcomes for Americans living in rural areas.

PUBLIC HEALTH EMERGENCY

Question. In January 2021, HHS wrote to Governors communicating they will provide States with a 60 days' notice prior to termination of the public health emergency.

Is HHS still committed to that 60-day notice?

Answer. Yes.

CY 2023 NONENFORCEMENT BULLETIN

Question. On March 23, 2022, CMS extended the non-enforcement bulletin *(https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2023-and-later-benefit-years.pdf).* I want to thank CMS for allowing transitional health insurance plans to be sold in calendar year (CY) 2023. This is something I urged the administration to do. Your action will allow 65,000 Iowans to keep the insurance they like. They are farmers and small businesses, and chosen to keep the health insurance they purchased between 2010–2013. This was a bipartisan policy started under the Obama administration. I'm glad the Biden administration has maintained this bipartisan policy. The March 23rd bulletin permitted the non-enforcement policy for CY 2023 and it states the non-enforcement "will remain in effect until CMS announces that all such coverage must come into compliance with the specified requirements." While the non-enforcement creates regulatory certainty, especially in CY 2023, it actually creates uncertainty for 65,000 Iowans after CY 2023 (*i.e.,* CY 2024 and after).

What standard will CMS apply in taking regulatory action to permit transitional health plans to be sold in CY 2024 and into the future?

What policymaking process will CMS have in taking regulatory action to permit transitional health plans to be sold in CY 2024 and into the future?

Answer. On March 23, 2022, CMS issued a bulletin that extends the policy under which CMS will not take enforcement action against certain non-grandfathered health insurance coverage in the individual and small group market that is out of compliance with certain specified market reforms. The extended non-enforcement policy applies for policy years beginning after October 1, 2022, and will remain in effect until CMS announces that all such coverage must come into compliance with the specified requirements.

RURAL EMERGENCY HOSPITAL (REH) VOLUNTARY MEDICARE PAYMENT DESIGNATION

Question. Access to emergency and primary health-care services is a basic quality of life issue for a resident of any sized community. Section 125 of Public Law (Pub. L. 116–260) established the Rural Emergency Hospital (REH) voluntary Medicare payment designation. This bipartisan solution will support struggling rural hospitals by allowing them to voluntarily right-size their health-care infrastructure while maintaining essential medical services for their rural communities. I appreciate CMS issuing a request-for-information (RFI) to implement REH.

What is the status of issuing the proposed regulation(s) for REH?

Will the proposed regulation(s) be included in the upcoming CY 2023 Medicare payment policy proposed regulations or as a stand-alone regulation?

Answer. Section 125 of Division CC of the Consolidated Appropriations Act (CAA) of 2021 provides for Medicare payment for items and services furnished by REHs on or after January 1, 2023, and CMS continues to work diligently to ensure that this provision of the CAA is implemented by this date. REHs will offer the opportunity for current Critical Access Hospitals and rural hospitals with fewer than 50 beds to seek REH designation. In accordance with the CAA, REHs are required to furnish emergency services and observation care, and they may elect to provide additional specified medical and health services on an outpatient basis, as well as skilled nursing facility (SNF) services in a distinct part SNF.

By providing these services, rural communities will maintain access to health care that otherwise may not be available. CMS remains steadfast in its commitment to rural communities' access to health-care services and is focused on implementing the REH provision of the CAA through rulemaking by January 1, 2023.

ADMINISTRATION FOR CHILDREN AND FAMILIES GRANT PROGRAMS

Question. The budget request for the Administration for Children and Families calls for $100 million dollars in grants for the purpose of addressing racial inequities in child welfare, and reducing overrepresentation of children and families of minority heritage. These grants would be awarded to child welfare agencies and community partners to develop and implement new strategies in line with these goals. Some of the suggested purposes include referral lines, supportive services, and race-blind decision-making practices, among others. The budget request also calls for $2 million for training for the child welfare workforce related to anti-racist practices, increasing hiring and retention of a diverse workforce, and training on how to use data to analyze workforce for inequities.

Some of the proposed uses for the grant funding, in particular race-blind removals, have not been shown to actually reduce the share of children in color in foster care. The implementation of race-blind removals in Nassau County, NY saw the share of racial minorities in foster care fluctuate, and child welfare professionals have raised concerns that this practice overrides professional expertise and hinders their ability to fully evaluate a family and their situation. Other anti-racist training programs, such as those based on implicit associations and implicit biases, have not been shown to impact behavior of recipients of the training.

If this grant program were to be funded, what evaluation metrics would be in place to ensure that funds are used on practices that have been demonstrated to lead to real improvements in the number of children of color able to safely remain in their homes?

Answer. Child welfare systems need case-level strategies and community-supported interventions to reduce racial disparities in removal decisions and disproportionality in foster care systems. Evaluation metrics will assess the development

and training on case-practice and decision-making processes that reduce racial bias and increase racial equity. Additionally, we recognize it is critical to create collaborative community partnerships to develop systems of care that impact racial disparity within the larger community. ACF has a wealth of experience with evaluating systems of care grants to demonstrate which practices and partnerships that lead to real improvements. The grant program envisions a continuous improvement cycle involving both the child welfare agencies and the relevant stakeholders to routinely come together and evaluate their strategies. ACF expects that grantees would choose a variety of different strategies and the services identified above are meant to be illustrative and not exhaustive. ACF also expects that evaluation would be a critical component of these grants.

While our understanding of effective approaches to reducing overrepresentation is evolving, we will continue to rely on the Child and Family Services Review (CFSR) data/process to understand variation in outcomes and drive policy and practice change. This includes supplementing the data we collect so that we can understand differences in the experiences of children by race/ethnicity. The Child and Family Services Reviews (CFSRs) are designed to determine States' compliance with titles IV–B and IV–E of the Social Security Act, and to evaluate child welfare system performance and require States to make improvement in outcomes for children and families.

To create a system that is effective and equitable for all, we must pay particular attention to the experiences of those who may be marginalized and more likely to have disparate outcomes. Applying an equity lens in the CFSR and beyond—from the statewide assessment to the Program Improvement Plan— is essential to accurately assessing, identifying, and addressing system-wide improvement needs. During Round 4 of the CFSR, there will be a focus on using data and evidence to identify disparities in services and outcomes; understand the role that child welfare programs, policies, and practices may play in contributing to those disparities; and inform and develop systemic improvements.

As we continue to be innovative and even bold in trying to identify interventions that will address bias that we observe in child welfare outcomes and decision-making, that we want to be sure to subject such interventions to scrutiny. The CFSR is one such method for ascertaining the impact of new programs/processes/interventions introduced into State/local/Tribal child welfare systems. Another important method is to persistently partner with researchers and evaluators to help develop, implement, and rigorously evaluate the impact of such innovations. Finally, we regularly consult children, youth, adults with lived experience and expertise so that their perspective are reflect in program and planning decisions. We will prioritize these partnerships as we seek to further develop the evidence base.

JOHN H. CHAFEE PROGRAM FOR INDEPENDENT LIVING

Question. The budget request calls for a permanent increase in funding for the John H. Chafee Program for Independent Living, as well as making permanent the COVID-era flexibilities that allowed States to serve youth up to age 27, eliminate the cap for housing expenses, making driving and transportation an allowable expense, and expanding the eligible population for these services to include youth who experienced foster care after the age of 14.

For each of the individual program changes listed, does ACF have data or evidence to suggest that there are better outcomes for youth who receive services under this program with the flexibilities in place?

Answer. The request to increase funding and make permanent flexibilities that were allowed in the Supporting Foster Youth and Families through the Pandemic Act (Division X of the Consolidated Appropriations Act, 2021) was informed by input from States administering the Chafee program and from engagement with young people with lived experience in foster care. Data from the National Youth in Transition Database (NYTD) also provides insights relevant to the request. We also expect to learn more about the use and impact of the Chafee funding provided by Division X in upcoming narrative reports on the use of funding that will be provided in the Annual Progress and Services Reports due June 30, 2022.

From our conversations with agency representatives and young people, we know that many young adults formerly in foster care struggle to navigate the existing patchwork of services and eligibility requirements available through other programs. While many young people in early adulthood may be able to receive emergency financial support from a family member, young people formerly in foster care

often do not have this option. The additional funding and flexibilities provided through Division X allowed States to provide direct assistance to young people at a time of great need, enabling them to assist young people who had lost a job, were food insecure, were at risk of losing housing, needed money to pay utilities or needed to make car repairs to be able to continue to access employment and other community resources in areas with limited or no public transportation.

Research and data consistently show that young people leaving foster care often struggle and that being connected to the foster care system and/or after-care supports leads to better outcomes. For instance, the National Youth in Transition Database survey data shows that 30 percent of the young people who responded to the NYTD survey and who were not in foster care reported that they had experienced homelessness within the previous 2 years. However, 19- and 21-year-olds who remained supported in foster care fared better overall and reported fewer challenging outcomes than their counterparts who had exited care. They were half as likely to have been homeless at some point within the previous 2 years and more likely to be attending school or be employed. They were less likely to report having been incarcerated or having been involved with substance abuse; and were less likely to have given birth to or fathered a child. We expect that providing increased funding and flexibilities through the Chafee program will similarly support improved outcomes as young people transition to young adulthood.

The proposal also includes elements to address specific concerns that have been raised to ACF in the past. Currently, only youth who exited foster care to adoption or guardianship at age 16 or older may receive Chafee funded benefits which can create the unintended consequence of pitting permanency against post-foster care benefits. The proposal addresses this concern by making young people who are adopted or exit foster care to legal guardianship at age 14 eligible to receive Chafee benefits, on the same basis as other youth who experienced foster care at age 14 or older.

The proposal also includes a provision to make young people receiving a FYI or a FUP voucher through the U.S. Department of Housing and Urban Development an eligible population under Chafee for services and case management. A requirement of these housing voucher programs administered by HUD is that the public child welfare agency offer case management and supportive services to the young people receiving the housing vouchers. However, some young people formerly in foster care who qualify for a HUD voucher do not qualify for Chafee-funded services due to their current age or the age at which they experienced foster care. This limitation has prevented some communities from being able to make use of the FYI/FUP vouchers. Making FYI/FUP voucher recipients an eligible recipient of Chafee services would better align the programs, providing greater opportunity for youth who are homeless or at risk of homelessness to receive needed supports.

FEDERAL FOSTER CARE REIMBURSEMENT FOR KINSHIP FAMILIES

Question. The budget request proposes a higher Federal foster care reimbursement for kinship families compared to non-relative foster families.

Is there concern that a discrepancy in reimbursement rates will escalate the shortage of non-relative foster families that many States are experiencing?

Answer. The Administration for Children and Families' Children's Bureau recognizes the important role that both kin and non-relative foster families play in caring for children in foster care and we are committed to assisting title IV–E agencies to expand and retain diverse pools of qualified foster families to care for children, when needed. We do not believe that the proposal to increase the Federal Financial Participation (FFP) rate paid to title IV–E agencies for relative and kin families will negatively impact the pool of unrelated foster families. The proposal would not change the foster maintenance payment rates that title IV–E agencies pay to either kin or non-related foster parents, as Federal law does not allow paying licensed foster parents different rates based on whether the foster care provider is related or unrelated. Rather, the proposal would provide an added financial incentive for title IV–E agencies to prioritize placing children with relatives or kin when such placements are available and appropriate. This proposal would improve outcomes for children and families, while continuing to ensure that unrelated foster family homes are available to support children and youth for whom no appropriate kin placement is available.

When children cannot remain safely with their parents and must enter foster care, placement with a relative or kin can often be the best option; research is clear

that children in kinship care often experience less trauma and have better outcomes across a range of behavioral and developmental well-being measures. Current law recognizes the benefits of kinship care, as title IV–E of the Social Security Act requires agencies to identify and give priority consideration to relatives as foster care placements for children in care.

This proposal would further align Federal policy with the priority on relative placements by increasing the FFP Rate used to reimburse title IV–E agencies for maintenance and assistance payments paid on behalf of eligible children in both the title IV–E Foster Care and Guardianship Assistance programs. Currently, title IV–E agencies are reimbursed at the Federal Medical Assistance Percentage (FMAP) rate (which ranges from 50 percent to 83 percent, depending on the per capita income of the jurisdiction) for all foster care placements. This proposal would increase FFP to FMAP plus 10 percentage points (*i.e.,* 60 percent to 93 percent) for relative and kin placements, while non-relative family foster homes placements would continue to be reimbursed at the FMAP rate.

PHARMACY BENEFIT MANAGERS

Question. During my 2-year landmark bipartisan insulin investigation with Senator Wyden, we studied why and how the price of insulin has increased so dramatically in recent years. The investigation found that manufacturer rebates are associated with high list price in the insulin therapeutic class. PBMs leverage their size to extract higher rebates, discounts, and fees from insulin manufacturers, because PBMs consider insulin products to be interchangeable. While rebates are used to keep insurance premiums low, for those patients with high-deductible health plans, no insurance, or for those who are underinsured, the practice of offering rebates results in high list prices at the counter. This causes some patients to ration their medication or forgo their medication entirely. With Senator Cantwell, I have introduced and unanimously passed out of the Judiciary Committee the Prescription Pricing for the People Act to bring transparency to the PBM industry. The bill directs the Federal Trade Commission (FTC) to study PBMs and make recommendations on the effects of consolidation on pricing and anti-competitive behavior. I am concerned about the potential manipulation by PBMs (*e.g.,* copay clawbacks, DIR fee clawbacks, formulary exclusion, high cost tiering, contracting practices to keep small and independent pharmacists from competing), especially the impact of these practices on patient access and costs. Most recently, I pressed the FTC to investigate PBMs' role in consumer drug prices. I urged the FTC to find consensus and move forward on a study examining bipartisan concerns about competition within the PBM industry.

While I remain committed to passing the bipartisan and negotiated Wyden-Grassley Prescription Drug Pricing Reduction Act (PDPRA) along with the Grassley-Cantwell Prescription Pricing for the People Act, what is the Biden administration doing to address potential manipulation by PBMs that negatively impact patient access and costs?

Answer. HHS is committed to reducing drug prices and ensuring that Americans have access to affordable prescription drugs. In the CY 2023 Medicare Advantage and Part D Final Rule, CMS finalized a policy that requires Part D plans to apply all price concessions they receive from network pharmacies to the negotiated price at the point of sale, so that the beneficiary can also share in the savings. Specifically, CMS is redefining the negotiated price as the baseline, or lowest possible, payment to a pharmacy, effective January 1, 2024. CMS is applying the finalized policy across all phases of the Part D benefit. This policy reduces beneficiary out-of-pocket costs and improves price transparency and market competition in the Part D program.

AUTONOMOUS HEALTH CARE ARTIFICIAL INTELLIGENCE (AI)

Question. Autonomous health care artificial intelligence (AI) allows providers to test people with diabetes for diabetic retinopathy, the causes blindness, using technology produced in Iowa that has been validated for safety and efficacy. Also, other FDA-regulated health-care AI is improving patient outcomes and removing barriers for rural America. FDA's work to ensure AI "Software as a Medical Device" (SaMD) is safe and effective through the De Novo and 510(k) processes. However, this industry is evolving. Patient access to AI systems already authorized for marketing can be impacted by the existing 510(k) process that is required for each software/hardware update. This regulatory process could result in avoidable access to care challenges/outcomes, such as vision loss and blindness due to lack of access to im-

proved technology. The FDA published a discussion paper proposing the "Predetermined Change Control Plan" (PCCP) as a solution.

Is the FDA still considering PCCP as the solution?

Answer. Yes, predetermined change control plans (PCCP) may be used to help ensure that FDA's statutory standards are met for approval or clearance of artificial intelligence (AI) devices. Because device changes made in accordance with a PCCP do not require additional FDA premarket review before the change is deployed, PCCPs can allow patients to have more timely access to innovative devices and also to have the benefits of updates to devices more quickly.

Question. How can HHS ensure that patients have access to safe and effective innovations?

Answer. The predetermined change control plan (PCCP), by including the types of anticipated modifications to implement changes and associated methodology to implement those changes in a controlled manner, will allow FDA the oversight to enable responsible enhancements in a manner that manages risks to patients. FDA notes that it is critical for these plans to be evaluated as part of the premarket submission for an individual device or in connection to a specific device.

FDA considers a PCCP to be part of the technological characteristics of the device. Evaluating the PCCP outside of a premarket application, therefore, would be akin to evaluating part, but not all, of a device's technological characteristics with no context.

QUESTIONS SUBMITTED BY HON. JOHN THUNE

IHS ELECTRONIC HEALTH RECORD SYSTEM

Question. Thank you for including more specific information in the budget on the need to update the Indian Health Service's electronic health record system. I know I've asked about this just about every year to make sure we don't lose sight of it. That said, the information included in the budget seems to be in the context of a major change in how IHS is funded.

Can you tell me how the Department will continue to approach IT modernization if the larger IHS proposal is not adopted?

Answer. Significant delays in funding, or failure to fund fully, will continue to exacerbate the issues that have driven the need to modernize IHS Health IT, including outdated core technology requiring significant workforce and support, limited interoperability, fragmented data, and extended project timelines. If the proposal is not adopted in full, IHS will be in the position of partially modernizing, since the agency is in process of expending the funds already appropriated for this purpose. This will leave the agency with a combination of legacy and modern systems, which will be costly and high risk from the standpoints of performance, security, and patient safety, and ultimately will be unsustainable.

PRIOR AUTHORIZATION

Question. The Department recently responded to a letter Senator Brown and I led on the use of prior authorization under Medicare Advantage. Absent administrative action, I am hopeful we could possibly address this issue in the forthcoming Senate Finance mental health package.

Will you commit to working with this committee on either an administrative or legislative solution, like the Improving Seniors' Access to Timely Care Act?

Answer. CMS is committed to ensuring that the MA program provides high-quality care for beneficiaries and timely access to necessary and appropriate health-care services. We also continue to examine ways in which we can streamline processes like prior authorization, including through the use of technology, to make them less burdensome on patients and providers. As included in the current Unified Agenda and Regulatory Plan, CMS plans to publish a proposed rule that would place new requirements on MA organizations, as well as other entities, to improve the electronic exchange of health-care data and streamline processes related to prior authorization.

DURABLE MEDICAL EQUIPMENT REIMBURSEMENT

Question. As you know, the CARES Act provided 75/25 blended rate for durable medical equipment providers in non-rural, non-competitively bid areas during the pandemic. It's my understanding that CMS does not currently plan to continue that payment beyond the public health emergency.

How has the agency communicated its plans to providers that will still face some of the same travel and volume challenges that they did prior to the pandemic and have likely been exacerbated since?

Answer. In the December 2021 final rule (86 FR 73860), CMS finalized that the DMEPOS fee schedule will be equal to 100 percent of the adjusted payment amount established in non-rural, non-competitive bid areas (CBAs) within the contiguous United States after the public health emergency period ends. We stated we believed the purpose of section 3712 of the CARES Act was to aid suppliers in furnishing items under very challenging situations during the COVID–19 PHE (85 FR 27571). We have long maintained that the fully adjusted rates in non-rural non-CBAs are sufficient; for instance, we indicated in the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34382) that although the average volume of items and services furnished by suppliers in non-rural non-CBAs is lower than the average volume of items and services furnished by suppliers in CBAs, the travel distances and costs for these areas are lower than the travel distances and costs for CBAs. We stated that because the travel distances and costs for these areas are lower than the travel distances and costs for CBAs, we believe the fully adjusted fee schedule amounts are sufficient.

In addition, assignment rates were above 99 percent in non-rural contiguous non-CBAs when the fully adjusted rates were implemented. CMS will continue to monitor payments in all non-CBAs, as well as health outcomes, assignment rates, and other information.

QUESTIONS SUBMITTED BY HON. RICHARD BURR

COVID–19 AND PANDEMIC PREPAREDNESS

Question. We are now 2 years in to the COVID–19 pandemic. While we must remain vigilant against any future potentially dangerous variants, we also have multiple tools at our disposal—tests, treatments, and vaccines—that allow us to start living our lives again. The end date of a number of Medicare, Medicaid, and other coverage policies are tied to the end of the public health emergency. Our States, beneficiaries, and other stakeholders need a clear and transparent understanding of what to expect and when to expect it.

What steps are you taking to prepare to wind down the public health emergency declaration?

Answer. As a result of the continued consequences of the COVID–19 pandemic and after consultation with public health officials, Secretary Becerra renewed the public health emergency (PHE) on January 14, 2022, for up to an additional 90 days. The determination to renew the PHE ensures response efforts can continue at the level needed to address the ongoing impact of the virus. HHS will continue to evaluate whether a public health emergency exists and will modify the PHE, as needed. We have committed that we would provide a 60-day notice prior to removing the PHE.

The budget requests funding to prepare for and respond to future pandemics and high consequence biological threats. HHS's comprehensive plan of action meets the President's objectives to transform our national pandemic preparedness. The FY 2023 President's budget includes $81.7 billion in mandatory funding over 5 years across the Office of the Assistant Secretary for Preparedness and Response (ASPR), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and Food and Drug Administration (FDA) to support President Biden's plan to transform U.S. capabilities to prepare for and respond rapidly and effectively to future pandemics and other high consequence biological threats. This investment will fund transformative improvements in our capabilities to prevent, detect, and respond to emerging biological catastrophes.

The additional funding requested in the budget for HHS will help transform our capability to rapidly produce and deliver countermeasures against pandemics and other biological threats; strengthen our public health infrastructure and early warn-

ing capabilities; invest in basic research to enable an effective response to novel pandemics and biological threats; modernize and streamline our regulatory infrastructure; and, advance biosafety and biosecurity in the United States and globally to prevent biological incidents.

Question. How are you planning to provide the necessary clarity regarding current waivers and flexibilities and how to transition programs in advance of the emergency ending?

Answer. The Secretary of HHS may, under section 319 of the Public Health Service (PHS) Act, determine that: (a) a disease or disorder presents a public health emergency (PHE); or (b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists. If and when declared, a PHE lasts for the duration of the emergency or up to 90 days, but may be renewed as needed and as determined by the Secretary. Under section 319, PHEs can enable the Secretary to take a variety of discretionary actions to respond to the PHE, including waive or modify certain Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule requirements under section 1135 of the SSA.

COMMERCIALIZATION OF COVID–19 RESPONSE

Question. As we start to live with COVID–19, we need to consider how we begin to transition some of our Federal COVID response efforts to the commercial market. For example, the Federal Government is currently the sole purchaser of COVID–19 vaccines. Part of the additional funding requested for the COVID–19 response will help to ensure that there is a smooth transition to commercialization and that challenges are addressed with shifting vaccines and other countermeasures to the commercial market.

As these products continue to become more a part of everyday health care, how will you transition responsibilities for distributing and paying for them to the commercial market?

Answer. To date in the COVID–19 response, HHS has supported efforts to ensure that vaccines are available to all States and communities. As of April 1, 2022, HHS has procured approximately 2 billion doses of vaccine and 10.4 million therapeutics and has provided these resources to States and territories at no cost. As Congress fails to continue to fund these efforts, the Department is thinking through courses of action to manage the transition away from Federal acquisition. There are a number of potential issues that need to be considered related to licensure, access, and coverage, which may require possible statutory or regulatory changes to resolve. As part of the additional funding request for the COVID–19 response, funding is needed to ensure that there is a smooth transition and that challenges are addressed with shifting vaccines and other countermeasures to the commercial market.

Question. What are the biggest barriers, if any, that stand in the way of making this transition?

Answer. As noted in the response to question 118, many factors remain—including possible congressional action on our funding request—in order to transition vaccines from Federal acquisition to the commercial market. We look forward to working with Congress to ensure continued and equitable access to these lifesaving vaccines.

DRUG PRICING

Question. The budget proposal includes a placeholder for reckless tax-and-spend legislation that would include a proposal allowing you to dictate the price of medicines. The proposal is fundamental flawed and would have a chilling effect on innovation and Americans' health would be worse off as a result.

What assumptions does the President's budget make as to how you would value different clinical factors when determining the price of drugs?

How do the President's proposed drug price controls make our domestic life sciences industry more competitive with China?

Economists from the University of Chicago have estimated that the proposed drug price controls would result in 135 less new medicines through 2039.[10] For what dis-

[10] *https://cpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/08/Issue-Brief-Drug-Pricing-in-HR-5376-11.30.pdf.*

eases or conditions are the Biden administration willing to forego new innovative treatments and cures?

Answer. HHS looks forward to working with the Congress to lower health-care costs and expand and improve coverage for all Americans. Reaffirming the President's charge in his State of the Union Address, we will work to lower the costs of prescription drugs. In September 2021, HHS released a comprehensive plan to lower drug prices. The Drug Pricing Plan presents principles for equitable drug pricing reform through competition, innovation, and transparency; describes promising legislative approaches; and summarizes actions already underway or under consideration across HHS.

One of the key policies in this effort is legislation that would allow the Secretary of HHS to negotiate Medicare Part B and Part D drug prices directly with pharmaceutical companies and make those prices available to other purchasers, an approach that is projected to generate reductions in patient cost sharing and large savings for patients, government, and commercial payers. The Drug Pricing Plan also describes the administrative tools HHS can use to promote competition and reduce drug prices, including testing models through CMS's Innovation Center and collecting more data from insurers and Pharmacy Benefit Managers to improve transparency about prices and out-of-pocket spending on prescription medications.

HHS is committed to continuing our work to make health care more affordable for American families. By promoting negotiation, competition, and innovation in the health-care industry, HHS will ensure cost fairness and protect access to care.

CLINICAL LAB FEE SCHEDULE

Question. The Protecting Access to Medicare Act of 2014 (PAMA) reformed the Clinical Laboratory Fee Schedule (CLFS) from a collection of over 50 regional fee schedules to a single, national fee schedule with market-based rates. For Medicare beneficiaries to have sustained access to clinical laboratory services, CLFS rates must be based on accurate and representative private market data from all clinical laboratory segments that provide services to beneficiaries.

Implementation of PAMA, however, excluded large segments of the market, which has resulted in drastic cuts to clinical laboratories that Congress has now mitigated multiple times. Does the President's budget propose changes to the CLFS to ensure sustainable access to high-quality services for beneficiaries?

Answer. CMS and HHS continue to ensure increased access to equitable quality care, including clinical laboratory services. The Department of Health and Human Services cannot comment on the subject of ongoing litigation.

HEALTH INSURANCE REGULATION

Question. Section 1311(e)(1) of the Affordable Care Act allows exchanges to certify a health plan as a qualified health plan if it meets certain requirements. One such requirement affords the exchanges the ability to make determinations as to whether or not a health plan is "in the interests of qualified individuals."

How many times has a health plan not been determined to be in the interests of qualified individuals?

For States that operate their own State-based exchanges or handle their own plan management functions, are you deferential to those States in making such a determination? How do you take into account the opinion of those States?

Answer. Ensuring that all Americans have access to quality, affordable health care is one of the Biden-Harris administration's top priorities. Patients and their families deserve the security of knowing that the insurance they buy will be there for them when they need it, and we need to make sure consumers are protected and understand the health insurance they are buying. This is why CMS ensures that all health plans, including dental, must meet a number of statutory and regulatory standards in order to be certified as QHPs in the Federally Facilitated Marketplaces (FFMs). States that operate their own marketplaces are responsible for certification of QHPs on those marketplaces. For States that perform plan management functions for the FFMs in those States, CMS works collaboratively with the State but CMS makes final determinations regarding QHP certification.

ACCESS TO INNOVATIVE PRODUCTS

Question. During your nomination process, you responded to my question for the record on FDA-CMS coordination with the following: "I will support appropriate measures to enable payors to make informed decisions earlier in the process."

Since that time, CMS has rescinded a regulation that would have expedited Medicare beneficiary access to innovative technologies and promulgated a coverage decision that would subject treatments that have met the FDA's gold standard of safety and efficacy for terminally ill Alzheimer's patients to coverage with evidence development. In other words, another round of trials.

Please provide specific examples of what you have done to improve patient access to innovative treatments and technologies through increased coordination of FDA and CMS.

Answer. Ensuring the availability of innovative interventions is a shared priority for both CMS and the FDA. HHS recognizes the important and related—but different—roles of these respective agencies and know that CMS and FDA decisions have an outsized impact on the U.S. health-care system, as well as implications for the rest of the world. Underpinning both agencies' work is the unwavering commitment to use reliable data to ensure that effective treatments are made available to patients. The FDA's decision to approve a new medical product is based on a careful evaluation of the available data and a determination that the medical product is safe and effective for its intended use. In some instances, the FDA has the authority to require additional studies after approval to provide additional information like for example additional information regarding the anticipated clinical benefit of a medical product.

CMS can conduct its own independent review to determine whether an item or service should be covered nationally by Medicare, including examining whether it is reasonable and necessary for use in the Medicare population. The work of both agencies is critical to ensure that medical products are available to people across the country.

The agencies also have in place a Memorandum of Understanding to promote collaboration and enhance knowledge and efficiency by providing for the sharing of information and expertise. In addition, the Parallel Review Program allows both agencies to simultaneously review submitted clinical trial data with the goal of decreasing the time between FDA's approval of a premarket application and the subsequent CMS national coverage determination.

QUESTIONS SUBMITTED BY HON. ROB PORTMAN

BUILD AMERICA, BUY AMERICA PROVISION IN INFRASTRUCTURE INVESTMENT AND JOBS ACT (IIJA)

Question. The Infrastructure Investment and Jobs Act (IIJA) contains new requirements related to Buy America. Specifically, the IIJA includes my "Build America, Buy America" (BABA) provision, which requires all iron, steel, manufactured products, and construction materials used in all federally assisted infrastructure projects are produced in the United States.

To apply the Buy America standard government-wide, section 70913 of the IIJA requires the head of each Federal agency to catalog all Federal financial assistance programs administered by the agency, review existing domestic content preferences, and identify all "deficient programs" that do not meet the Buy America policy in the bill. In its report to OMB pursuant to section 70913, HHS acknowledges that it provides Federal support for infrastructure-related construction activities under the law, but does not consider this Federal financial assistance to be subject to the BABA requirements. This is inconsistent with the requirements of the law.

What is HHS's legal rationale for claiming that its Federal financial assistance for infrastructure projects is not subject to BABA? Is there a rationale for these claims, which are inconsistent with the new law?

Answer. HHS conducted an iterative and thorough review of all HHS programs pursuant to section 70913 of the Infrastructure Investment and Jobs Act (IIJA). Using the definitions outlined in section 70912, we determined that the Build America, Buy America (BABA) requirements extend beyond the scope of HHS's programs. Specifically, the financial assistance programs funded by HHS focus on medical re-

search, health services, and essential human services. As part of this focus, HHS occasionally provides construction support for health centers, medical centers, and research facilities. The IIJA through the BABA, focuses on sectors of domestic infrastructure well beyond the scope of HHS's programs. Therefore, in HHS' assessment, the new requirements it imposes on Federal financial assistance do not apply to HHS financial assistance spending. If it is determined on a case-by-case basis that the BABA requirements apply to any particular Federal financial assistance provided by HHS, HHS has agreed to evaluate whether pursuing a waiver authorized by statute is appropriate.

MATERNAL, INFANT, EARLY CHILDHOOD HOME VISITING PROGRAM

Question. Ohio families have benefited from the MIECHV program—it is a bright spot among so many programs that serve low-income families in that it's voluntary and evidence-based. MIECHV models show well-documented evidence of how trained professionals support better newborn care and improved maternal mental health.

I'm glad that the administration sees the value in this program and I look forward to partnering with my Democratic colleagues to move a bipartisan reauthorization bill before the program expires on September 30th.

I look forward to working with you on this program that serves disadvantaged communities. You are aware of my interest in working on behavioral health issues; in what ways are home visitors helping mothers manage mental health issues?

Answer. Thank you for your support for the MIECHV program, and we look forward to working with you on its reauthorization. As you know, the program supports voluntary, evidence-based home visiting services for pregnant individuals and parents with young children up to kindergarten entry living in communities at risk for poor maternal and child health outcomes. Home visitors connect families to health, mental health, child care and other community services, and support a focus on positive parenting and early childhood development. Home visiting programs directly support maternal mental health through the identification of mental health issues, including regular screening for maternal depression and the connection of families with needed mental health treatment and services through coordination and referral. In FY 2021, 81 percent of primary caregivers enrolled in home visiting were screened for depression using a validated tool within 3 months of enrollment or 3 months of delivery.

HRSA also funds the Home Visiting Collaborative Improvement and Innovation Network (HV–CoIIN), which builds capacity for quality improvement in local home visiting agencies to improve maternal and child health outcomes, including methods to better identify and address maternal depression. Among home visiting programs participating in the HV–CoIIN, 91 percent of mothers were screened for depression at the time of enrollment and 71 percent of mothers who screened positive for depression accepted referrals for treatment.[11]

Many MIECHV programs also implement infant early childhood mental health consultation, which connects a mental health professional with home visitors. The goal of infant early childhood mental health consultation is to provide home visitors with the knowledge and skills needed to identify and work with families with behavioral health challenges. Infant early childhood mental health consultation training helps home visitors address the complex needs of families impacted by substance use disorder, mental illness, intimate partner violence, or other issues. Home visitors engaged in infant early childhood mental health consultation are able to conduct screenings with caregivers and children, address behavioral health and child development needs, and connect families to mental health and other supports.

QUESTIONS SUBMITTED BY HON. TIM SCOTT

PRESERVING PATIENT ACCESS TO HOME INFUSION ACT

Question. I applaud the focused and prioritized efforts HHS and CMS are taking to address health disparities. One of the tools we have to help address these disparities is providing care in the home, connecting with patients where they are. This

[11] *https://hv-coiin.edc.org/sites/hv-coiin.edc.org/files/HV%20CoIIN%202.0%20MD%20Fact%20Sheet%20-%202021.pdf.*

is especially important in rural or underserved communities, like those across South Carolina that lack certain health-care resources.

In support of Medicare beneficiaries that rely on IV medications to treat their health conditions, Congress passed legislation in 2016 to create a new home infusion therapy benefit to allow them to receive their infused medications at home without having to travel to a doctor's office or hospital to receive their infusion. While recent data published by CMS acknowledges that utilization of the new home infusion therapy benefit has been "low," the agency has failed to address the concerns that Congress has raised with the way it's been implemented.

That's why I'm working with my colleague from Virginia to address a concerning trend in access to home infusion therapy services that has occurred since this law was implemented. We recently introduced the Preserving Patient Access to Home Infusion Act that would ensure that the benefit is being interpreted according to congressional intent and would build on the successful private market model, creating better access to home infusion for vulnerable home infusion recipients.

Will you commit to working with us on this bipartisan bill to address the health disparity challenges in home infusion?

Answer. The Biden-Harris administration supports strengthening home and community-based services as an alternative to institutionalized care, in order to ensure that people have access to safe options that work for them. People are happier and healthier when they live in their community, and living in one's own home and community usually costs less than care in an institution such as a nursing home. Home infusion therapy services can play in important role in allowing beneficiaries to continue receiving care within their own home instead of in a hospital or physician office. Per the statute, the Medicare home infusion therapy services benefit covers professional services, including nursing services, training and education not already provided under the durable medical equipment (DME) benefit, remote monitoring and monitoring services. The home infusion therapy services benefit works in tandem with the DME benefit. DME suppliers are responsible for furnishing the infusion pump (including training the patient and/or caregiver on how to use the infusion pump), the drug or biological, and any pharmacy services associated with furnishing the drug or biological. We note that patients and/or their caregivers must be able to self-administer home infusion drugs in order for the pump and drug to be covered under the DME benefit.

In November 2021, CMS issued the CY 2022 Home Health Prospective Payment System Rate Update Final Rule (CMS–1747–F). In addition to updating the geographic adjustment factor used for wage adjustment, the final rule updated the home infusion therapy services payment rates for CY 2022 as required by law. The overall economic impact of updating the payment rates for home infusion therapy services is expected to be an increase in payments to home infusion therapy suppliers of 5.1 percent.

HHS looks forward to working with Congress and other stakeholders to improve the critical home health-care services that allow beneficiaries to remain in their homes and communities.

PUBLIC HEALTH EMERGENCY AND WAIVERS

Question. Does this administration envision ending the public health emergency tied to COVID–19, and if so, what data points will drive that decision—hospitalization or community transmission?

Answer. As a result of the continued consequences of the COVID–19 pandemic and after consultation with public health officials, Secretary Becerra renewed the public health emergency (PHE) on January 14, 2022, for up to an additional 90 days. The determination to renew the PHE ensures response efforts can continue at the level needed to address the ongoing impact of the virus. HHS will continue to evaluate whether a public health emergency exists and will modify the PHE, as needed. We have committed that we would provide a 60-day notice prior to removing the PHE.

Question. We've seen a lot of innovation throughout this pandemic, and while we're ready to leave COVID in the rearview mirror—these innovations shouldn't be left behind. How much lead time will this administration provide to Congress in order to consider which health waivers should continue past the public health emergency?

Answer. The Secretary of HHS may, under section 319 of the Public Health Service (PHS) Act, determine that: (a) a disease or disorder presents a public health emergency (PHE); or (b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists. If and when declared, a PHE lasts for the duration of the emergency or up to 90 days, but may be renewed as needed and as determined by the Secretary. Under section 319, PHEs can enable the Secretary to take a variety of discretionary actions to respond to the PHE, including waive or modify certain Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule requirements under section 1135 of the SSA.

TELEHEALTH

Question. Telehealth is certainly popular (and for good reason). The administration's budget extends Medicare's telehealth waiver flexibilities past the anticipated expiration of the public health emergency tied to COVID–19.

Could you elaborate and provide more detail on the policies this administration would support for the expansion of telehealth?

How does this administration plan to work with Congress to ensure millions of Medicare beneficiaries don't lose access to telehealth services and abruptly fall off the "telehealth cliff"?

Answer. During the COVID–19 public health emergency, telehealth has been a reliable resource to allow providers to reach patients directly in their homes in order to ensure access to care and continuity of services. The Biden-Harris administration is committed to supporting a temporary extension of broader telehealth coverage under Medicare beyond the declared COVID–19 public health emergency to study its impact on utilization of services and access to care. Telehealth, including audio-only telehealth, can greatly expand access to services for individuals who may not have access to broadband or technology to support 2-way audio-video. This is particularly true in rural and underserved areas, and among older populations.

The administration is also expanding access to mental health and beneficiary-centered care under Medicare through greater use of telehealth and other telecommunications technologies to provide behavioral health care, among other services. Medicare beneficiaries can access care directly in their homes thanks to recent regulations, including CMS's CY 2022 Physician Fee Schedule final rule, that allow for certain behavioral health services via audio-only telephone calls. In addition, the President's FY 2023 budget includes a proposal to remove statutory limits on the list of providers that are authorized to receive direct Medicare payment for their mental health services, which would expand access to mental health services in Medicare, especially in rural and underserved areas with fewer mental health professionals or in communities more likely to receive care from the referenced practitioners.

ACUTE HOSPITAL CARE AT HOME WAIVER

Question. In November 2020, CMS announced its Acute Hospital Care at Home Waiver program in an effort to decompress the Nation's hospitals during the COVID–19 pandemic. This program, in which over 200 hospitals across 34 States are currently participating, provides full inpatient payment for providers delivering hospital-level care in the home.

As Congress considers potential extension of certain waiver authorities past the public health emergency, does the agency have any data available on the value of this program and, if not, when does the agency expect to have that data and will it be made publicly available?

Answer. Hospitals participating in the Acute Hospital Care at Home program must submit monitoring data to CMS on a monthly or weekly basis, the frequency of which depends on whether the hospital was approved for participation via the expedited waiver pathway or the detailed waiver pathway. The data they must submit includes patient volume, unanticipated mortality during an acute episode of care, and the escalation rate (how many patient discharges involved a transfer to the traditional inpatient hospital setting from the acute hospital care at home program). An article was published in the New England Journal of Medicine Catalyst on December 7, 2021, entitled "Acute Hospital Care at Home: The CMS Waiver Experience," which provides information about the waiver design, requirements for hospital waiver approval, geographic distribution of waiver uptake, and monitoring for patient safety. The article contains aggregate data collected from hospital, as of Oc-

tober 27, 2021 on total patients served, escalations, and unexpected mortality. Although a thorough analysis of the program is not yet possible, the article explains what CMS has learned from the program thus far.

DIVERSE TRIALS ACT

Question. Last year, HHS put forward five strategic goals, and several touch directly on access to participation in cutting edge clinical research for everyone regardless of socioeconomic status. While the U.S. conducts some of the most advanced medical research in the world, and South Carolina is proud to have world-class research institutions, the reality is that today not everyone can participate in a clinical trial because they can't afford the extra costs involved with travel to distant sites where trials are being run. Those South Carolinians living in the most rural parts of the State farthest from academic research centers are disadvantaged the most. During the pandemic, we saw a dramatic uptick in the use of telemedicine and remote care, even crossing over into how clinical trials were run, with FDA temporarily allowing clinical trial participants to get some of their care in their home, or closer to home in a model known as"decentralized trials."

Recently, I joined my colleague from New Jersey in introducing the bipartisan DIVERSE Trials Act to enable decentralized clinical trials and allow clinical trial sponsors to be able to provide financial assistance to participating patients for things like travel and parking without fear of being charged by HHS with violating Federal anti-kickback laws.

As the pandemic phase draws to a close, is HHS considering making some of these remote research practices permanently allowable so that South Carolinians representing a diverse array of background and locations, who have been traditionally left out of clinical trials, can continue participate?

Answer. Even before the pandemic, FDA supported, and sponsors were utilizing, decentralized clinical trials to bring the trial to patients and facilitate broader access to clinical research. Due to the restrictions on travel and other logistics to control the spread of disease, the COVID–19 pandemic increased the use of these trial designs, and the agency expects such use to continue after the pandemic ends. Decentralized clinical trials were not a temporary or interim measure employed solely for the purposes of the pandemic. When appropriately implemented in accordance with regulatory requirements applicable to all clinical trials, such trials have significant potential to broaden the availability of clinical research to historically underrepresented populations and FDA expect sponsors will continue to utilize them.

Question. Given the reality of inflation—its disproportionate impact on rural communities, low-income communities, and communities of color—should clinical trial sponsors be able to provide financial assistance to patients for costs, like travel and parking, that are incurred while participating in a clinical trial to help increase the diversity pool of participants?

Answer. As a general matter, FDA does not consider reimbursement for travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging to raise issues regarding undue influence. Similarly, consideration may be given to paying participants in exchange for their participation in research. Such payments are a common and, from FDA's perspective, may be an acceptable practice. FDA recognizes that payment for participation may raise difficult questions that should be addressed by the institutional review board (IRB). Other than reimbursement for reasonable travel and lodging expenses, IRBs should be sensitive to whether other aspects of proposed payment for participation could present an undue influence, thus interfering with the potential subjects' ability to give voluntary informed consent. In addition, FDA recognizes that other laws, such as the Federal anti-kickback statute, could apply to reimbursement for travel expenses and associated costs, as well as payments for clinical trial participation. For any questions regarding the application of the Federal anti-kickback statute, please consult with the Department of Justice and the Department of Health and Human Services Office of Inspector General.

MEDICARE ADVANTAGE

Question. In February, I co-led a letter to CMS signed by 63 bipartisan Senators urging the agency to maintain stability for the over 27 million seniors that rely on Medicare Advantage—including over 447,000 South Carolinians. Medicare Advantage seniors report high beneficiary satisfaction rates and have access to benefits not available in Medicare fee-for-service, such as out-of-pocket cost limits, in-home care, fitness, and meal and nutrition services.

How will you work with Congress to ensure that this coverage is protected in the future for Medicare Advantage seniors, which is supported by nearly two-thirds of senators?

Answer. HHS is committed to providing affordable, high-quality, equitable coverage to all beneficiaries. Our goals for Medicare Advantage mirror our vision for HHS programs as a whole, which include advancing health equity; driving comprehensive, person-centered care; and promoting affordability and sustainability of our programs. We look forward to continuing to work with Congress to ensure a strong Medicare Advantage program.

PREVENT DIABETES ACT

Question. According to the CDC, on average, 48 percent of adults over age 65 are pre-diabetic. According to the CMS actuary, people over 65 who successfully complete a CDC fully recognized diabetes prevention program can save by preventing diabetes, on average, $2,600 over 3 years in avoided medical costs. Recent data from CDC shows that almost 11,000 people over 65 have successfully completed the Diabetes Prevention Program from 2015–2019. In contrast, since 2018, only 2,200 people have participated in CMS's Medicare Diabetes Prevention Program (as of March 2021). We also know that CDC recognizes three modalities of diabetes prevention program delivery: in-person, on-line, and video/synchronous, while Medicare allows only in-person programs.

Can you explain why Medicare doesn't allow any CDC recognized program to serve its population, since obviously, more modalities would increase supply substantially and align with CDC's evidence based program?

Answer. Innovation is important to advancing goals in health care, and the CMS Innovation Center is integral to the administration's efforts to promote high-value care and encourage health-care provider innovation, including virtual and digital health innovation. With respect to the Medicare Diabetes Prevention Program (MDPP) expanded model, in the Calendar Year 2022 Physician Fee Schedule final rule CMS finalized a policy to use the CMS Innovation Center's waiver authority to waive the provider enrollment Medicare application fee for all organizations that submit an application to enroll in Medicare as an MDPP supplier on or after January 1, 2022. This change waives the Medicare enrollment fee for MDPP suppliers beyond the end of the COVID–19 public health emergency (PHE). We believe that granting a waiver of the enrollment fee for MDPP suppliers will increase MDPP supplier enrollment, which will ultimately improve beneficiary access to the expanded model.

CMS issued regulatory flexibilities in response to the COVID–19 pandemic, including waiving the limit on virtual sessions that can be provided by MDPP suppliers when in-person classes are not safe or feasible. While CMS is committed to working with Congress to consider which pandemic flexibilities should potentially be extended, MDPP suppliers must remain prepared to resume delivery of MDPP services in-person to start new cohorts and to serve beneficiaries who wish to return to in-person services when the flexibilities granted during the pandemic are no longer in effect.

Last summer, I requested technical assistance from CMS on the PREVENT DIABETES Act, a bipartisan, bicameral bill that would ensure that Medicare beneficiaries have the opportunity to have MDPP through the same choice of modalities (in person, online, virtual) as to people in the commercial insurance marketplace. To date, we have not received that technical assistance.

Question. Can you provide an update with the status of that technical assistance?

Answer. HHS always appreciates the opportunity to provide technical assistance to Congress on important health-care issues. It is my understanding that my team has sent your office the requested technical assistance, and we regret the delay.

QUESTIONS SUBMITTED BY HON. JAMES LANKFORD

GENDER DYSPHORIA

Question. On March 2nd, HHS Office for Civil Rights issued "HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy." This guidance, as well as HHS's concerning decision to reinterpret and greatly expand the scope of sex discrimination in Section 1557 of the Affordable Care Act, suggests that

doctors and other medical professionals are required to provide potentially harmful, experimental procedures on children who are experiencing gender dysphoria. The guidance goes further to affirm such treatment by claiming that it "improves their physical and mental health." It also refers to the procedures as "lifesaving."

I'm concerned by the steps this administration and HHS are taking to affirm—and even encourage—the medical transition of children with gender dysphoria, regardless of parental involvement. Similarly, this guidance and other statements made by you and other administration officials suggests a desire to compel medical professionals to provide such treatment and demand States do nothing to protect children from potential harm.

What studies is HHS and this administration relying on to determine the long-term health implications that medical treatments for gender dysphoria have on children?

What are the known long-term effects of puberty blockers for the purpose of responding to gender dysphoria if such treatment begins at 8 years old? What about 12 years old? What about 16 years old?

What are the known long-term effects of cross-sex hormones for the purpose of responding to gender dysphoria if such treatment begins at 8 years old? What about 12 years old? What about 16 years old?

Based on the medical evidence that exists, do you believe that it is appropriate for children to receive such treatment?

If so, at what age do you think it is medically and ethically appropriate for a child to give consent to receive a treatment with such lasting and adverse effects such as permanent damage to brain development or infertility?

Do you agree that at a minimum, parental consent is necessary for children to engage in any transgender care?

Would you agree that no taxpayer dollars should be used to perform a transition procedure on a child who cannot reasonably provide informed consent?

Answer. HHS would recommend consulting with medical associations regarding standards of care. Generally speaking, care is between a patient, their family, and their health-care provider.

Question. Would you agree that medical professionals should not be compelled to participate in such treatment if it goes against their sincerely held religious beliefs, conscience, or best medical judgement? Will the HHS OCR Conscience and Religious Freedom Division enforce conscience protections for medical professionals who object to participating in such treatments?

Answer. As in most other areas of practice, medical providers with conscientious objections to providing gender-affirming care are not obligated to provide this care. The Department takes seriously its obligations to comply with the Religious Freedom Restoration Act, 42 U.S.C. 2000bb, *et seq.* and the range of Federal conscience protections that apply to the provision of medical care. The Department treats any violation of civil rights or religious freedoms seriously and will continue to ensure that individuals are protected by reviewing, investigating or taking other appropriate measures in response to complaints received by the Office for Civil Rights regarding these issues.

FLAGS

Question. In addition to other actions HHS continues to take to promote gender ideology, on March 31, HHS flew the "transgender pride flag" on top of the agency's building. Can you provide a list of all other flags HHS has flown over the building?

Answer. HHS flies the American flag, the HHS Department flag, and the Public Health Services flag each day to symbolize HHS's commitment to the health and well-being of all Americans.

FAITH-BASED CHILD WELFARE PROVIDERS

Question. The FY 2023 budget proposes to prohibit States and federally funded child welfare providers from discriminating on the basis of "religious beliefs, sexual orientation, gender identity, gender expression, or sex." This would as you know put faith-based foster care and adoption agencies in a position of needing to choose between violating their sincerely held religious beliefs or losing funding and possibly licensure.

Senator Tim Scott (SC) and I sent you a letter about this in December, which the Office for Civil Rights responded to in March without answering a single question.

If this budget request is adopted, and faith-based providers are no longer able to serve, what is your plan to make up for the loss of those providers to find safe, loving and permanent families for children in foster care?

Answer. The Administration for Children and Families' Children's Bureau acknowledges the significant contributions that faith-based providers make to delivering human and social services. We also note that faith-based providers have different approaches to foster and adoptive parenting recruiting, and some will continue to be involved with foster and adoptive parent recruiting if the budget request is adopted. Regardless, we will continue to encourage title IV–E agencies to actively recruit foster and adoptive parents in manners that can increase the pool of prospective parents for children who need care when they cannot safely remain with their parents.

Question. What is your understanding of the holding in the unanimous Supreme Court decision, *Fulton v. Philadelphia?* How does this budget proposal align with *Fulton?*

Answer. A reasonable summary of the holdings of the majority opinion is contained in the syllabus prepared by the Supreme Court's Reporter of Decisions. The child welfare non-discrimination proposal contained in the President's budget, if enacted, would be implemented in a manner consistent with the Court's decision.

MEDICARE PART D FORMULARY TIERING

Question. In 2018, generic drugs accounted for 22 percent of all drug spending despite the fact that 90 percent of dispensed prescriptions were generic drugs. Additionally, the average copay of a generic prescription ($5.63) is nearly one-seventh that of a brand-name prescription ($40.65), offering significant savings for patients.

However, the current structure of Part D has shifted to incentivize plans to favor rebates over lower-priced generic and biosimilar alternatives. As a result, we have seen the number of generics placed on the lowest-cost sharing tier drop dramatically in recent years. I'm concerned about this trend and am working on legislation that would address this problem.

As you know, in 2019, CMS proposed to prohibit Medicare Part D plans' ability to place generic drugs on non-generic tiers and branded drugs on non-brand tiers. CMS also suggested setting up a second specialty tier for lower-cost drugs, but the data shows that very few Part D plans have actually used this new tier.

It took CMS 6 months to provide initial feedback and technical assistance to my team regarding my proposals. Will you commit to continuing to engage with me on this in a timely manner to make sure beneficiaries actually have access to low cost drugs?

Answer. The administration is advancing a multi-pronged approach to improving competition in the prescription drug market, including supporting greater availability and use of biosimilar biological products and generic drugs in order to lower the prices Americans pay for prescription drugs. CMS stands ready to work with Congress on this issue.

QUESTIONS SUBMITTED BY HON. STEVE DAINES

REPRODUCTIVE HEALTH ACCESS TASK FORCE

Question. This past January you announced a new "Reproductive Health Access Task Force," to promote abortions at home and abroad, and to combat pro-life State laws including parental involvement laws and bans on late-terms abortions. Additionally, your budget once again calls for eliminating the Hyde Amendment to allow taxpayer funding for abortion on demand up to birth.

If the Supreme Court in the *Dobbs* case overturns *Roe v. Wade* and returns to the States the power to protect pre-born children from abortion, will you respect and comply with the decision of the Court, including in the activities of this task force?

Will you commit, in the operation of this task force, to following and enforcing the Hyde Amendment, the Federal ban on partial birth abortion, and other Federal laws that protect pre-born children?

Does the task force intend to use Federal funds to advocate against State laws that protect pre-born children from abortion or the laws of sovereign nations?

Answer. I will continue to enforce the law.

HOSPITAL PRICE TRANSPARENCY FINAL RULE

Question. Rising health-care costs impact Montanans and Americans across the country, which is why I recognize the importance of efforts to lower costs, empower patients, and improve transparency to help folks make informed decisions about their care. As you may know, studies have shown non-compliance with the Hospital Price Transparency Final Rule. In fact, a study published in February 2022 by Patient Rights *Advocate.org* reviewed 1,000 hospitals nationwide and found only 14.3 percent of hospitals are compliant with the rule that went into effect over 1 year ago.

What actions do you plan on taking to assess non-compliance and ensure hospitals comply with the rule so that price transparency is available to all Americans?

Answer. Increasing access to affordable health care is a top priority for the Biden-Harris administration. That's why HHS is committed to ensuring that consumers have the information they need to make fully informed decisions regarding their health care.

Hospital price transparency helps people know what a hospital charges for the items and services it provides. Under CMS regulations, hospitals must post on their website a machine-readable file containing a list of all standard charges for the items and services they provide, as well as a consumer-friendly list of standard charges for at least 300 shoppable services. CMS expects hospitals to comply with these requirements, and is enforcing them to ensure people know what a hospital charges for items and services.

In January 2021, CMS began proactive audits of hospital websites as well as review of complaints submitted to CMS via the hospital price transparency website. In April 2021, CMS issued the first set of warning letters to noncompliant hospitals. These letters list specific areas of deficiencies identified through CMS compliance review and request hospital action to remedy the deficiencies. Hospitals that fail to submit a corrective action plan or comply with the requirements of a corrective action plan could be issued a notice of imposition of a civil monetary penalty (CMP). In the event CMS issues a civil monetary penalty, CMS will publish the notice of the CMP on a CMS website.

In the Calendar Year (CY) 2022 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule (86 Fed. Reg. 63458), CMS finalized modifications to the hospital price transparency regulations to increase compliance. The modifications became effective January 1, 2022 and include the use of a scaling factor to increase the amount of the civil money penalties based on hospital bed count.

HHS looks forward to working with its partners across the Federal Government, along with Congress and other stakeholders, to examine additional ways to increase price transparency across the health-care industry and improve access to affordable coverage and services.

QUESTIONS SUBMITTED BY HON. TODD YOUNG

ORGAN PROCUREMENT ORGANIZATIONS (OPOS)

Question. I have long advocated for the Department of Health and Human Services (HHS) to hold organ procurement organizations (OPOs) accountable for their performance, including by decertifying failing OPOs, and was happy to see HHS finalize a rule last November to do so. This rule is projected to save more than 7,000 lives every year, and I, along with bipartisan, bicameral leaders, wrote to you last summer calling for the timeline of the rule to be accelerated, given how many lives it would save.

I was disappointed to see a proposal in the President's budget that would allow CMS to recertify failing OPOs. This proposal would hinder OPO accountability and much needed reform to the organ transplant system.

Can you commit to upholding HHS's OPO rule, ensuring that all failing OPOs will be swiftly decertified?

Answer. Organ procurement organizations (OPOs) are vital partners in the procurement, distribution, and transplantation of human organs in a safe and equitable manner for all potential transplant recipients. The role of OPOs is critical to ensuring that the maximum possible number of transplantable human organs is available to individuals with organ failure who are on a waiting list for an organ transplant. HHS is dedicated to improving health equity and access in the organ procurement and transplantation system, including by holding OPOs accountable for their performance.

In December 2020, CMS published "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations." This rule finalized new outcome measures OPOs are required to meet for recertification and was published with the intention of increasing donation and organ transplantation rates by replacing the previous outcome measures with new transparent, reliable, and objective outcome measures that are used to make better certification decisions and incentivize better performance. At the end of the recertification cycle, each OPO will be assigned a tier ranking based on its performance for both the donation rate and transplantation rate measures, as well as the recertification survey. The highest performing OPOs will be assigned in Tier 1 which means the donation and transplantation rates of the top 25 percent of OPOs, and automatically recertified for another 4 years. OPOs with rates that are below the top 25 percent will be in either Tier 2 or 3. Tier 2 OPOs are not automatically recertified but they will have to compete to retain their donation service area (DSA). Tier 3 OPOs are the lowest performing OPOs and will be decertified and lose their service area. CMS believes that increasing competition between the OPOs will incentivize them to maximize their performance and consequently increase the number of organs available for transplantation.

The President's FY 2023 budget includes a proposal that would recertify certain organ procurement organizations that do not meet the criteria for recertification based on outcome measure performance, but which have shown significant improvement during a recertification cycle. An OPO taking over a decertified OPO's low-performing DSA may have a significant undertaking to increase their performance to meet the Tier 1 top 25 percent benchmark to be automatically recertified. An OPO may only have 1–2 years in a DSA they took over from a low-performing OPO before being recertified. CMS believes that having the discretion to determine whether to recertify OPOs that have recently assumed responsibility for servicing a previously low-performing DSA and are making significant improvement would provide the flexibility it needs to improve organ procurement in DSAs without disruption to organ procurement.

ANTIMICROBIAL RESISTANCE—THE PASTEUR ACT

Question. I was pleased to see the President's budget included a proposal designed to combat antibiotic-resistant bacteria and fungi by encouraging the development of innovative antimicrobial drugs. This proposal, modeled after the PASTEUR Act, which I introduced along with Senator Bennet, would allow the U.S. to make strategic investments in antibiotic development much like those made for mRNA that eventually led to a COVID–19 vaccine in record time.

I helped author and introduce the PASTEUR Act because, among other reasons, I believe it will be more costly for the Federal Government to do nothing. If current trends continue, we may one day soon find that many surgeries are too risky to perform because physicians lack the antibiotics needed to ensure apatient's safety.

The antibiotic drug manufacturer market is experiencing a collapse—as identified in a *New York Times* article in 2019—and has only gotten worse since. What steps can the Department take to help the market survive until such time as Congress can act?

Answer. To mitigate the threat of antimicrobial resistance, the U.S. Government is taking a multi-pronged approach that includes surveillance, prevention, stewardship and innovation of new products to treat and prevent infections. Goal 4 of the National Action Plan to Combat Antibiotic-Resistant Bacteria (CARB), 2020–2025 (2020 CARB Plan) is to accelerate basic and applied research and development for new antibiotics, other therapeutics, and vaccines. Relevant activities are implemented by the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Agency (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Food and Drug Administration (FDA), and the Department of Defense (DoD). The 2020 CARB Plan recognizes that

the pipeline of new antibiotics must be continually primed through discovery and development research, and the plan includes multiple objectives to intensify support for basic, preclinical, and clinical research. Further, Objective 4 within Goal 4 of the 2020 CARB Plan is to enhance efforts to promote sustainability of the commercial market for new antibiotic products. It includes specific objectives of streamlining clinical trials, strengthening commercial markets through direct Public Health and National Security purchases, and supporting U.S.-based manufacturing infrastructure. The CARB Task Force continues to monitor and analyze the landscape of product development; as part of this monitoring, it focuses on difficulties experienced by developers and health-care providers in generating and using treatment options.

In addition to these objectives within the 2020 CARB Plan, HHS recognizes that the value of reduced morbidity, mortality, and disease duration is not currently captured by many antimicrobial products' current market value, and the development pipeline is at significant risk of falling short of current and future needs. Therefore, the Fiscal Year 2023 President's budget includes a proposal to create a novel payment mechanism to stimulate future innovation in antimicrobial products while enhancing stewardship of their appropriate use. Sponsors of selected products would be eligible to enter into contracts with HHS, valued between $750 million and $3 billion per contract, paid out in increments annually over up to 10 years. HHS would work to identify critical-need infections, desirable characteristics of eligible products, establish values for contracts, ensure reliable supply chains, facilitate appropriate patient access, and prioritize antimicrobial stewardship plans to ensure appropriate use of newly developed products. Sponsor revenue from Federal insurance programs for the selected products would be subtracted from the annual contractual payment.

MEDICARE COVERAGE FOR MEDICAL DEVICES

Question. Last November Senator Hassan and I led a letter to the Centers for Medicare and Medicaid Services (CMS) signed by eight other Senators expressing our strong support for the timely creation of a new Medicare Coverage for Innovative Technologies (MCIT) rule. Innovative medical technologies improve the quality of life for Americans experiencing disabilities, injuries, or chronic conditions. A new rule would ensure that Medicare patients have access to new and innovative medical technologies soon after they are cleared by the Food and Drug Administration. In our letter, my colleagues and I encouraged CMS to continue ongoing efforts to develop a flexible coverage pathway and improve access to innovative devices while addressing operational and patient protection concerns raised during the MCIT comment process. We stated that CMS should move forward with a pathway for coverage that allows for collection of appropriate evidence, if necessary. Finally, we urged CMS to move quickly in issuing a new proposed rule.

The Office of Information and Regulatory Affairs regulatory calendar now lists a Q3 target date for a new proposed rule listed as Transitional Coverage for Emerging Technologies (CMS–3421) that would establish the criteria for an expedited coverage pathway to provide Medicare beneficiaries with faster access to innovative and beneficial technologies. Can you assure us that CMS will propose a new rule in the third quarter of 2022 that will lead to expedited coverage of innovative and demonstrably beneficial medical technologies?

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

Improving and modernizing the Medicare coverage process continues to be a priority for HHS and we remain committed to providing stakeholders with more transparent and predictable coverage pathways. CMS intends to explore coverage process improvements that will enhance access to innovative and beneficial medical devices in a way that will better suit the health-care needs of people with Medicare. This will also help to establish a process in which the Medicare program covers new technologies on the basis of scientifically sound clinical evidence, with appropriate health and safety protections in place for the Medicare population. CMS is working as quickly as possible to advance multiple coverage process improvements that provide an appropriate balance of access to new technologies with necessary patient protections. As part of this effort, CMS is conducting several listening sessions to

learn about stakeholders' most pressing challenges and to receive feedback from stakeholders about which coverage process improvements would be most valuable. HHS looks forward to hearing your feedback as we move forward with our efforts.

QUESTIONS SUBMITTED BY HON. BEN SASSE

COVID FUNDING AND POLICIES

Question. Can you elaborate on why the administration's request for supplemental COVID funding has shifted so many times? Which programs need immediate funding now in order to continue?

Answer. The administration's supplemental request, which was formally submitted to Congress on March 2, 2022, is $22.5 billion for the COVID–19 response, of which $18.25 billion is for the U.S. Department of Health and Human Services (HHS). This request is to support immediate needs to avoid disruption to ongoing COVID response efforts. Already, the administration has had to ramp down critical programs that care for and protect people from COVID–19. For example, the Health Resources and Services Administration's COVID–19 Uninsured Program and Coverage Assistance Fund are no longer accepting claims due to a lack of sufficient funds. This program was unable to accept claims for testing and treatment as of March 22nd and claims for vaccines on April 5th.

This $22.5-billion supplemental request will cover immediate needs for tests, treatments and vaccines, investments in research and development of next-generation vaccines, and responding globally, including getting more shots in arms around the world. The Federal Government does not have adequate resources to purchase enough booster vaccine doses for all Americans, if additional doses are needed. The shortages will be even more acute if we need a variant-specific booster vaccine, since we will not have any existing supply.

Question. The White House recently said that it has $300 billion left in COVID–19 relief funding, with $60 billion of that unallocated. Can you explain why this funding can't be used for these programs?

Answer. I am unaware of these statements or what these specific figures refer to. HHS is using remaining COVID–19 supplemental funding to provide lifesaving vaccines, therapeutics, and diagnostics, relief to providers, support for public health, and other elements of the response. HHS will soon exhaust available funding for buying antivirals and vaccines, continuing ongoing clinical trials, providing tests, and supporting the Center for Disease Control and Prevention's ongoing operational costs. Without additional supplemental funding, the Federal Government does not have adequate resources to purchase enough booster vaccine doses or lifesaving antivirals. The shortages will be even more acute if we need a variant-specific booster vaccine or if a variant were to render our therapeutics ineffective.

Question. Could this issue be solved through Congress giving your agency more flexibility in how existing funds are spent, rather than allocating new funding? If not, can you explain why?

Answer. No. Although sufficient flexibility is necessary for HHS to be adequately responsive to the changing dynamics of the pandemic, HHS plans to exhaust all remaining resources for buying antivirals, other therapeutics, and vaccines, continuing ongoing clinical trials, providing tests, and supporting CDC's ongoing operational costs. Our immediate needs are not hindered by a lack of flexibility but because of a lack of adequate resources.

Question. When it comes to funding therapeutics, is there a plan for the administration to transition out of being the sole purchaser and distributor and instead allow these products on the commercial market in the coming months?

Answer. To date in the COVID–19 response, the U.S. Department of Health and Human Services (HHS) has supported efforts to ensure vaccines are available to all States and communities. As of April 1, 2022, HHS has procured approximately 2 billion vaccines and 10.4 million therapeutics and has provided these resources to States and territories at no cost. As Congress fails to continue to fund these efforts, the Department is thinking through courses of action to support the transition away from Federal acquisition. There are a number of limitations, however, including licensure of products, congressional statute, and insurance regulations. Let me be clear, the administration's top priority is continued and equitable access to these lifesaving vaccines. Additional funding is required to ensure that there is a smooth

transition and that challenges are addressed as we move forward with shifting vaccines to the commercial market.

Question. When will the administration release COVID vaccines to routine distribution channels to permit innovative multi-jurisdictional strategies to increase vaccination, such as occupational health activities of companies with employees in multiple States?

Answer. As noted in the response to the previous question, many factors remain for transition vaccine to routine distribution channels—including possible congressional action on our funding request. We look forward to working with Congress to ensure continued and equitable access to these lifesaving vaccines.

Question. While widespread vaccination has been crucial in limiting severe illness and death, we also know that in rare cases the COVID–19 vaccines have led to extreme and lasting side effects, including tinnitus and myocarditis. Is there money in the President's budget to study these side effects and potential treatments for them? How widespread is the data collection on this issue and how can Congress be helpful?

Answer. Beyond base funding to support safety monitoring of routine vaccinations, CDC's FY 2023 President's budget request includes additional proposed funding for immunization safety to enhance existing safety systems and networks through two separate legislative proposals: Pandemic Preparedness Early Warning and Situational Awareness activities and Vaccines for Adults budget initiative.

Additional funding under the Pandemic Preparedness: Early Warning and Situational Awareness activities would be allocated for immediate priorities like enhancements to the Vaccine Adverse Events Reporting System (VAERS); sustaining the Vaccine Safety Datalink (VSD) sites, adding more sites to increase the geographic and demographic diversity of the VSD study population, and further studies on vaccine adverse events in pregnant women; and expanding the Clinical Immunization Safety Assessment Project (CISA) to increase timeliness, improve clinical consultations for providers with questions on adverse events, and expand efforts to analyze emerging vaccine issues (*e.g.,* myocarditis, TTS, etc.) with experts specializing in fields relevant to vaccine safety.

Additional funding as part of the Vaccines for Adults budget initiative would expand routine and COVID–19 vaccination efforts for adults to protect more Americans from preventable diseases.

As of March 2022, approximately 800,000 U.S. reports have been submitted to VAERS after COVID–19 vaccination. Through follow-up, including medical record reviews, as of March 10, 2022, CDC and FDA have verified 1,367 reports of myocarditis or pericarditis with a majority of these occurring following mRNA COVID–19 vaccines, particularly in male adolescents and young adults. Understanding long-term health effects is critically important to explaining the risks and benefits of COVID–19 vaccination to the public and informing clinical guidance. Therefore, CDC is conducting surveys of patients (or their parents or guardians) and healthcare providers to gather information about myocarditis after mRNA COVID–19 vaccination.

The FY 2023 President's budget includes $81.7 billion in mandatory funding over 5 years across the Office of the Assistant Secretary for Preparedness and Response (ASPR), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and Food and Drug Administration (FDA) to support President Biden's plan to transform U.S. capabilities to prepare for and respond rapidly and effectively to future pandemics and other high consequence biological threats. This investment will fund transformative improvements in our capabilities to prevent, detect, and respond to emerging biological catastrophes.

The additional funding requested in the budget for HHS will help transform our capability to rapidly produce and deliver countermeasures against pandemics and other biological threats; strengthen our public health infrastructure and early warning capabilities; invest in basic research to enable an effective response to novel pandemics and biological threats; modernize and streamline our regulatory infrastructure; and, advance biosafety and biosecurity in the United States and globally to prevent biological incidents.

Question. Cases are steadily declining each week, all States are now seeing their lowest level of cases since last July, and hospitalizations have decreased 33 percent. Given all of this, what is the rationale for a continued "public health emergency" designation? What numbers would the U.S. have to hit for it to end?

Answer. Based on the level of COVID–19 cases in communities across the Nation, Secretary Becerra renewed the PHE on January 14, 2022, for up to an additional 90 days. The determination to renew the PHE ensures response efforts can continue at the level needed to address the ongoing impact of the virus. HHS will continue to evaluate the infection rate of COVID–19 and will modify the PHE, as needed. We have indicated that we would provide a 60-day notice prior to removing the PHE.

Question. In your hearing a few weeks ago before the House Appropriations Subcommittee, you said that title 42, the policy used to restrict immigration at our borders due to the public health risk to Americans, would remain in place as long as there is reason and justification. The next day, the administration announced the end of title 42, saying that migrants at our Southern border have "ceased to be a serious danger to public health." How are you working with your counterparts at DHS and other agencies to handle what will likely be a large surge in migration as a result of the termination of this policy?

Answer. CDC has provided, and will continue to provide, technical guidance to the U.S. Department of Homeland Security (DHS) and other interagency partners to help prevent the transmission of COVID–19 and other communicable diseases among the staff and migrants in Border Patrol stations and other congregate facilities for immigration processing. CDC's technical assistance and guidance have enabled DHS to implement additional COVID–19 mitigation protocols, such as a program for providing COVID–19 vaccinations to age-eligible migrants. Please contact DHS for more information regarding this program and other DHS-led COVID–19 mitigation efforts.

We note that the CDC Order and Termination are subjects of ongoing litigation in multiple jurisdictions. CDC cannot comment on pending litigation; however, we acknowledge that judicial actions may impact the implementation of the termination.

UNACCOMPANIED CHILDREN PROGRAM

Question. The budget also requests $4.9 billion for the Unaccompanied Children program, a more than $3-billion increase from FY 2021 when less than $2 billion was requested.

Is the program currently housing more than double the number of children as it was previously?

Answer. Though the number of UC in ORR care has declined significantly, from nearly 20,000 in April 2021 to an anticipated 10,000 in April 2022, referrals to the program continue to be higher than historical patterns. In FY 2021, ORR received more than 122,000 referrals, the highest number of referrals in the UC program's history, especially compared to FY 2020 when ORR received 15,000 referrals. As a specific point of comparison, ORR received referrals for 1,530 children in October 2020, but received 19,131 referrals in April 2021.

Question. What is the current number of children in HHS custody?

Answer. As of April 5, 2022, there are 10,370 children in ORR care.

Question. Will these funds be used to support the children without a sponsor who end up in the U.S. foster care system?

Answer. Unaccompanied children are not placed in the U.S. domestic foster care system. ORR funds a network of programs, which includes ORR-operated transitional and long-term foster care programs. ORR provides long term foster care placement for children who are expected to have a protracted stay in ORR custody because they have no viable sponsor. For additional information regarding placements in long term foster care, please see ORR Policy Guide section 1.2.6.

Unaccompanied Refugee Minors are served by the Unaccompanied Refugee Minors Program (URM), which is distinct from the Unaccompanied Children (UC) program.

Question. What is your plan to strengthen oversight of this program, which has been reported to detain children in CBP facilities for 100+ hours on average and to occasionally lack stringent oversight when vetting sponsor placements for minors?

Answer. To be clear, ORR does not detain children in U.S. Customs and Border Protection (CBP) facilities. Children in CBP facilities are in the custody of DHS until they are referred to ORR care. By statute (6 U.S.C. 279; 8 U.S.C. 1232(b)),

Federal agencies with custody of unaccompanied children, as defined, must transfer such children to HHS within 72 hours, absent exceptional circumstances. When DHS (and in rare circumstances other Federal agencies) refer UC to ORR's care, the children are transported to an ORR-funded care provider, typically a State-licensed shelter, group home, or foster care home.

The extended holding period for children in CBP facilities last spring and summer was due to the drastic increase in UC arrivals at the southern border. For its part, ORR responded by mobilizing additional capacity through emergency intake sites (EIS) and one influx care facility (ICF). As a result, children have been moved out of CBP custody promptly, and on average children have been spending less than 72 hours in DHS custody since spring of 2021.

Once a child is placed into ORR care, ORR works to place the child with a vetted sponsor, usually a parent or a close relative who can care for the child's physical and mental well-being while the child's immigration case is adjudicated.

ORR's safe and timely release process includes several steps to vet sponsors: the identification of sponsors; sponsor application; interviews; and the assessment of sponsor suitability, including verification of the sponsor's identity and relationship to the child. ORR requires a background check of all potential sponsors and their adult household members, as appropriate. In some cases, ORR requires a home study be performed prior to releasing a child. A home study consists of interviews, a home visit, and a written report containing the home study case worker's findings. A home study assesses the potential sponsor's ability to meet the child's needs, educates and prepares the sponsor for the child's release, and builds on the sponsor assessment conducted by the care provider staff to verify information gathered during that process. See ORR Policy Guide section 2.2 for more details on the sponsor application process.

In addition, all children released to a sponsor receive a Safety and Well-being Follow-Up Call. For any case requiring a home study, ORR assigns a post-release service provider to provide follow up services for the child. Additionally, ORR assigns post-release services to UC with mental health or other physical needs who could benefit from the ongoing assistance. Currently, ORR is in the early phases of implementing a plan to expand PRS, with the goal of eventually being able to serve all children who are released from ORR care, as well as to enhance the services provided, as resources allow

HYDE AMENDMENT/ABORTION POLICY

Question. For the second year, the administration failed to include the Hyde Amendment in its budget request. I am obviously strongly opposed to this decision and to the radicalization we have seen in your party from "safe, legal, and rare" to what we see today.

Can you elaborate on the decision-making process that led to the elimination of the Hyde Amendment?

Answer. The Hyde Amendment is a discriminatory policy that reduces access to health care. Everyone, no matter where they live, how much money they make, or how they are insured, should have access to the health care they need. Ultimately, Congress passes laws and so the Hyde Amendment still exists in the law, and HHS will continue to follow the law.

MIFEPRISTONE

Question. I am also disappointed with the FDA's decision to permanently end the in-person requirement for dispensing the abortion pill, mifepristone.

Are you able to share the number of severe, life-threatening, and fatal adverse events that have taken place as a result of chemical abortions?

Answer. In December of 2021, FDA posted a summary of reports received by FDA of adverse events, including deaths, that occurred among patients who had taken mifepristone for medical termination of pregnancy. This summary is publicly available at the following link: *https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex,* and also is available directly at: *https://www.fda.gov/media/154941/download.* The adverse events cannot with certainty be causally attributed to mifepristone because of concurrent use of other drugs, other medical or surgical treatments, co-existing medical conditions, and information gaps about patient health status and clinical management of the

patient. FDA has reviewed this information and did not identify any new safety signals.

Question. Has there been an uptick in hospitalizations, deaths, and adverse events related to chemical abortion since tele-prescribing began 2 years ago?

Answer. FDA routinely monitors post-marketing safety data for approved drugs through adverse events reported to the FDA Adverse Event Reporting System (FAERS) database, through the agency's review of published medical literature, and when appropriate, by requesting applicants submit summarized post-marketing data. For FDA's recent review of the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone for medical termination of early pregnancy (also referred to as the Mifepristone REMS Program), the agency searched the FAERS database, reviewed the published medical literature for post-marketing adverse event reports for mifepristone for medical termination of pregnancy, and requested that the Applicants for Mifeprex and the approved generic version of Mifeprex, mifepristone tablets, 200 mg, submit a summary and analysis of certain adverse events. FDA's review of this post-marketing data indicates there have not been any new safety concerns with the use of mifepristone for medical termination of pregnancy through 70 days gestation, including during the time when in-person dispensing was not enforced. A more detailed discussion of this review can be found in FDA's December 16, 2021, response to a Citizen Petition that requested certain modifications to the Mifepristone REMS Program and is available on *regulations.gov*.

Question. A recent report on the FDA's data on this issue found that over 500 cases were described as "uncodable" with women "lost to follow-up," and a separate study of Medicaid claims data found that more than 60 percent of chemical abortion-related emergency room visits were misclassified as miscarriages.

Will you commit to working together to ensure that the FDA's data collection is improved to keep moms and babies safe?

Answer. As it does for all approved drugs, FDA continues to closely monitor the post-marketing safety data on Mifeprex and the approved generic version of Mifeprex, mifepristone tablets, 200 mg. When FDA receives new information regarding adverse events, the agency reviews the new information and, as appropriate, takes necessary action, including providing updates to health-care providers and their patients so that they have information on how to use the drug safely.

CONSCIENCE PROTECTIONS

Question. Last year, the Department of Justice announced that it would be voluntarily dismissing a case against the University of Vermont Medical Center that it had brought after the Office of Civil Rights at your agency found that a nurse was forced to participate in an elective abortion against his or her personal religious beliefs. As you know, Federal law prohibits discrimination based on religion, and conscience protections ensure that no medical practitioner can be compelled to perform or assist in abortions.

Did the DOJ dismiss this case at your urging or the urging of other top officials at HHS?

Can you explain to me how you believe this incident was *not* a direct violation of Federal law?

Do you support protecting conscience rights when it comes to medical practitioners and performing abortions?

Answer. As stated in our letter to the University of Vermont Medical Center, "OCR takes seriously its role in protecting the rights of medical providers, including those protected by Federal conscience laws."[12] HHS will continue to ensure the statutes protecting providers are applied in accordance with applicable law.

Question. Can you explain your decision to revoke the Conscience and Religious Freedom Division's independent ability to investigate these claims?

Answer. As stated in OCR's letter to the University of Vermont Medical Center, "Based on these subsequent legal developments and concurrent with the Department of Justice filing today, we are withdrawing the August 28, 2019 [Notice of Violation] and will continue to evaluate the underlying complaint. OCR takes seriously

[12] Letter from Robinsue Frohboese, Acting Director and Principal Deputy, Office for Civil Rights, U.S. Department of Health and Human Services, to David Gacioch (July 30, 2021), at 2, *https://www.hhs.gov/conscience/conscience-protections/uvmmc-letter/index.html.*

its role in protecting the rights of medical providers, including those protected by Federal conscience laws. We are taking these actions to ensure the statutes protecting providers are applied in accordance with applicable law."

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.

Our Federal health-care programs face a range of pressing challenges, which demand serious solutions. Today's hearing provides a crucial opportunity to highlight both shared priorities and concerns with respect to the proposals put forth by the President.

As part of the Cancer Moonshot initiative, the administration has rightly acknowledged the value of multicancer early detection tests, which have the potential to boost the cancer survival rate while driving down costs. Earlier this Congress, I reintroduced bipartisan legislation to ensure Medicare coverage for these screening tools, and I look forward to working with you, Secretary Becerra, to move this bill across the finish line. The budget proposal's focus on mental health also offers potential for common ground.

Unfortunately, other aspects of the budget request raise substantial questions. It is imperative that we work now to keep Medicare strong, not only for current enrollees, but also for future generations. The Medicare trustees have repeatedly cautioned that the program's financial shortfalls will require legislative action, with the hospital insurance trust fund projected to reach insolvency in 2026.

We have yet to receive this year's trustees report, but the President's budget includes no proposals to shore up the trust fund's solvency. In fact, the document contains virtually no sources of Medicare savings at all, instead opting for a long list of coverage expansions, often with no cost estimates.

Proposing dozens of new spending policies with no sense of their budgetary effects risks deepening the deficit and exacerbating inflation. A similar pattern persists for the budget request's Medicaid provisions, which would add billions in new spending without any meaningful cost-saving reforms.

Compounding these onerous impacts, the budget includes a placeholder for a reckless tax-and-spending package, presumably the nearly $5-trillion, House-passed Build Back Better Act that was rejected on a bipartisan basis last year and across this country. The government price controls, Obamacare subsidy hikes, and other misguided policies included in that bill would intensify the hardships many Americans currently face.

Under the package's price controls, we would inevitably see fewer cutting-edge treatments and cures, higher launch prices for new drugs, and a drastic decline in innovative R&D, handing the Chinese Communist Party a competitive edge. Long-term Obamacare subsidy expansions, meanwhile, would double down on skyrocketing Federal spending and force taxpayers to fund coverage for Americans with six-figure salaries.

These policies would worsen the economic outlook for working families. By continuing to push forward this problematic agenda, the proposed budget has missed a key opportunity to address urgent issues and needs.

As States and health-care providers across the country look to budget for the year ahead, uncertainty abounds. The complex layers of flexibilities and coverage mandates tied to the public health emergency necessitate clear and comprehensive communication and accounting, particularly as stakeholders attempt to map out the path to post-pandemic normalcy. Without greater transparency, both for Congress and for the Nation, this process could prove unpredictable and needlessly costly.

Coverage dynamics, for instance, will likely be volatile at the end of the public health emergency, yet this budget provides no plan for transitions in care.

Last year's $1.9-trillion partisan spending bill suffered from poor planning and prioritization, with only around 1 percent of the package's funding directed to vaccines and therapeutics. This year's budget request provided a chance to chart a more thoughtful return to normalcy, continuity, and fiscal responsibility. Disappointingly, the document does not rise to that occasion.

Secretary Becerra, I look forward to engaging with you on these and other issues in the months ahead, particularly with respect to telehealth, which continues to enjoy broad bipartisan support.

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

PREPARED STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON

The Finance Committee meets this morning with Secretary Becerra to discuss the year ahead for the Department of Health and Human Services. There's a lot to cover, so I'll quickly tick through a handful of issues.

First, on telehealth. This committee began to open the door to telehealth in Medicare in the CHRONIC Care Act in 2017. Then in 2020, we pushed to include telehealth services in the CARES Act. In implementing the law, Medicare decided to also cover telehealth delivered audio-only on a temporary basis during the pandemic. That's been a health care game-changer for people across the country, particularly in rural areas. In this year's appropriations bill, Senator Crapo and I pushed to extend the audio-only flexibility beyond the public health emergency.

There is bipartisan interest in building on that progress on a permanent basis and making sure that the clock doesn't get turned back on patients who've come to rely on telehealth for basic services. I'm sure that issue will be part of our discussion today.

Second, Democrats and the administration are committed to protecting our bedrock health-care programs—strengthening the Affordable Care Act, upholding the Medicare guarantee. Republicans have other ideas.

Senator Scott, the campaign visionary for Senate Republicans, recently proposed phasing out Medicare in 5 years. I'd like to know how America's 60-year-olds feel about that. And Senator Johnson has doubled and tripled down on the same old crusade: repealing the Affordable Care Act. He says that Republicans should be preparing their repeal bill now to have it ready to go whenever they next take power. If it looks anything like it did last time, it'll gut health care for tens of millions and shower tax handouts on the wealthy. In my view, that's not what Americans are interested in seeing right now.

The biggest concern going today for millions of families in Oregon and all across the country is the rising cost of living. Bringing down health-care prices and protecting Americans from getting clobbered by huge bills is one of the best ways for Congress to take some of the pressure off their pocketbooks.

A couple of areas to highlight. For one, millions of Americans are getting a better deal on health insurance this year because of the rescue plan Democrats passed in March of 2021. Monthly premiums for Americans who get insurance on the individual market fell by 22 percent this year—adding up to hundreds of dollars or more over 12 months. People across all income levels saved money. Six million new consumers got coverage.

Go back a few decades and Republicans would be shouting from the mountaintops about the incredible success of the private marketplace at work. Not so in 2022—these days, every Republican has gone on record against the tax credits that made that success possible. If the Republicans have their way, millions of Americans are going to get whacked by higher insurance premiums in 2023. That cannot be allowed to happen. Democrats must keep those savings going.

The administration and Democrats in Congress are also in lockstep when it comes to bringing down prescription drug prices. For too many Americans, every trip to the pharmacy counter means getting mugged by drug companies. Instead of using the bargaining power of more than 60 million American seniors to get lower drug prices, Medicare's hands are tied behind its back.

Changing that by giving Medicare the authority to negotiate a better deal for brand-name drugs is the single most important reform on offer. Democrats also have a plan to cap copays for insulin at $35 a prescription and set an out-of-pocket cap for seniors' prescriptions in Medicare Part D at $167 per month. The plan would also create a tough new price-gouging penalty for drug companies that increase prices faster than inflation. This plan would save money for patients in Medicare and in the private market, and it would also save taxpayers billions every year.

Getting a better deal on health insurance and prescription drugs—those are the kinds of savings that millions and millions of Americans need desperately right now. Congress must step up and deliver them.

Finally, this committee is working hard on a bipartisan basis to guarantee that every American can finally get the mental health care they need when they need it. The budget includes smart proposals to help make that a reality, particularly within Medicare and Medicaid: getting rid of caps on Medicare coverage for care in a psychiatric hospital; adding Medicare coverage for sessions with a therapist or counselor; waiving cost sharing for up to three mental health visits a year in Medicare and private insurance; and permanently expanding nationwide Medicaid funding for Certified Community Behavioral Health Clinics, which Senator Stabenow has long championed.

These proposals from the budget could open doors to treatment for a lot of people who are struggling to connect with mental health providers today, or people who could face a crisis in the future. Members on both sides of this committee are laser-focused on mental health care, and we look forward to working with the administration on these issues.

Rebuilding Title X: New Regulations for the Federal Family Planning Program

By Brittni Frederiksen, Ivette Gomez, and Alina Salganicoff

November 3, 2021

On October 4, 2021, the Biden Administration released new final regulations for the federal Title X family planning program. The new regulations replace those issued by the Trump Administration in 2019,[1] which made significant and well documented[2] changes to the Title X program leading to a significant reduction in the size of the Title X network and the number of low-income and uninsured clients served by the program. This brief presents new state-level data on the status of the Title X network on the eve of the implementation of the new regulations and summarizes the impact of Trump era regulations on the number of clients served and status of participation by clinics across the country.

The Impact of the 2019 Trump Regulations

The 2019 Trump Administration regulations substantially diminished the Title X family planning network by disqualifying family planning clinics with co-located abortion services and disallowing the provision of abortion referrals to clients that wanted them. In its 2020 Family Planning Annual Report,[3] the federal Office of Population Affairs (OPA) documented the impact of both the Trump Administration's regulations and the pandemic on the number of clients they served, as well as the change in the number of grantees and clinic sites from 2018 to 2020 (Table 1). In this two-year period, the number of clients served fell from 3.9 million to 1.5 million people. The report estimated that the Trump Administration's final rule accounted for nearly two-thirds (63%) of the precipitous reduction in the number of family planning clients served while the COVID–19 pandemic accounted for one third of the falloff.

Table 1: Changes in the Title X Network from 2018 to 2020

	2018	2019	2020
Clients served	3.9 million	3.1 million	1.5 million
Family planning visits	6.5 million	4.7 million	2.7 million
Grantees (receive funding from HHS OPA)	99	100	75

[1] *https://www.federalregister.gov/documents/2019/03/04/2019-03461/compliance-with-statutory-program-integrity-requirements.*
[2] *https://www.kff.org/womens-health-policy/issue-brief/current-status-of-the-title-x-network-and-the-path-forward/.*
[3] *https://opa.hhs.gov/sites/default/files/2021-09/title-x-fpar-2020-national-summary-sep-2021.pdf.*

Table 1: Changes in the Title X Network from 2018 to 2020—Continued

	2018	2019	2020
Sub-recipients (receive funding from grantees and can distribute to clinic sites or provide services themselves)	1,128	1,060	867
Clinic sites (receive funding from grantees or sub-recipients)	3,954	3,825	3,031

SOURCE: Title X Family Planning Annual Report 2020 National Summary, *https://opa.hhs.gov/sites/default/files/2021-09/title-x-fpar-2020-national-summary-sep-2021.pdf.*

With the large exodus of clinics from the Title X program in summer of 2019, there are still five states without any Title X funded clinic sites: Oregon, Washington, Vermont, Maine, and Hawaii, while New York currently has only two sub-recipient sites. Another seven states, including New York, have Title X clinic networks that are currently operating at less than 25% of their original capacity. Based on our analysis of OPA's Title X Family Planning Directories, 36 states have experienced a decrease in participating Title X clinics from June 2019 to August 2021, while OPA's Family Planning Annual Reports between 2018 and 2020 show 49 states and DC have seen a reduction in clients ranging from 2%–100%, with a median reduction in clients of 52%.

A small number of entities have rejoined the Title X network in the past year. One of Utah's two grantees, Utah Navajo Health System, rejoined the Title X program in July 2020 as a sub-recipient under Arizona's grantee, Arizona Family Health Partnership. Maryland Department of Health rejoined the program in October 2020 after the state of Maryland was granted a permanent injunction against enforcing the 2019 Title X Final Rule. Most of the Planned Parenthood clinics left the Title X Program after the Trump Administration's Rule became final though few are now in the program, including those in Maryland, Washington DC, and Missouri.

The Trump Administration Final Rule allowed "non-traditional" Title X grantees to join the network and some of these grantees are no longer part of the program under the Biden Administration. The Trump Administration regulations extended federal family planning funds to organizations that only offered their clients fertility awareness or abstinence options. The new regulations do not qualify them to participate as grantees if they do not offer a broader range of contraception methods to their clients. Notably, the Obria Group, Inc., a Christian organization based in Southern California that did not provide contraceptive services based on religious objections to hormonal contraception, left the Title X program in April 2021. Another Christian-based organization, Beacon Christian Community Health Center, which joined the Title X network as a New York grantee in October 2018, left the Title X program in April 2021 as well. Two of the three new Title X grantees that joined the Title X program under the Trump Administration that are not religiously based, City of El Paso in Texas and Osceola Community Health Services in Florida, remain in the program.

Key Aspects of the Final Biden Administration's Title X Regulations

The new Biden regulations[4] restore many aspects of the program that were removed through the Trump Administration regulations, including:

- Allowing co-located abortion services and abortion referrals.
- Requiring clinics that are not able to provide clients with a broad range of family planning methods to provide a prescription or referral to the client if requested.
- Added confidentiality protections for adolescents—clinics may not require consent of a parent or guardian for the provision of services and cannot notify a parent or guardian before or after provision of any services.

The regulations have also added new provisions to the program, including:

- Adding telehealth as an option for providing medical services in addition to in-person care.

[4] *https://www.federalregister.gov/documents/2021/10/07/2021-21542/ensuring-access-to-equitable-affordable-client-centered-quality-family-planning-services.*

- Requiring family planning projects to provide services in a matter that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensure equitable and quality service delivery consistent with a nationally recognized standard of care.
- Adding a new funding criterion—the ability of the applicant to advance health equity.

The final rules will be effective November 8, 2021, and clinics will once again be able to provide their clients with the care that meets the quality standards established by the CDC and OPA,[5] including providing non-directive pregnancy options counseling with referrals for prenatal care, adoption services, or abortion services and confidential services for adolescents, but it will take time to restore the network of providers. On October 25, 2021, the state of Ohio, joined by 11 other states (AL, AZ, AK, FL, KS, KY, MO, NE, OK, SC, WV), filed a lawsuit[6] in the U.S. District Court for the Southern District of Ohio against HHS to block the implementation of the Biden Administration's regulations. These states claim the final regulations violate Section 1008 of the Public Health Service Act that says none of the funds appropriated under Title X can be used in programs where abortion is a method of family planning. The litigants claim that by reinstating the regulations that allow co-located abortion services and require participating providers to offer referrals for abortions to clients who seek them, that HHS is not in compliance with the intent of the law. The states are requesting a ruling as soon as practicable and no later than December 31, 2021. If the Court does not rule before November 8th, the Biden regulations will become effective.

If the final regulations remain in effect, additional funding that can be extended to grantees that left the network is not anticipated until Spring of 2022 after the grant applications due January 11, 2022[7] are reviewed and approved. Funding will likely be awarded by April 1, 2022. Grantees that are still part of the Title X program can bring clinics back into their network if they have current funding available. Current grantees' three-year grant cycle ends March 31, 2022.

In response to Texas' S.B. 8 law banning most abortions, HHS will award additional funding to Texas' largest Title X grantee to meet an increased demand for emergency contraception and family planning services. OPA is also planning to award an additional $10 million through a new funding opportunity entitled "Funding to Address Dire Need for Family Planning Services" that will provide grants to Title X entities that can demonstrate a need for additional funding for family planning services due to either an influx of clients as a result of Texas' S.B. 8 abortion ban or some other reason. A second funding opportunity that OPA is planning on releasing will provide $45 million in Spring 2022 to Title X grantees to expand and enhance their telehealth infrastructure and capacity, which will be particularly important given the ongoing COVID–19 pandemic and increased demand for telehealth services.

Looking Forward

The final Biden Administration Title X regulations will make significant changes to sites across the nation and allow clinics like Planned Parenthood, which were formerly disqualified because they have co-located abortion services or provide abortion referrals for individuals who want them, to once again apply for federal support to provide family planning services to low-income and uninsured individuals. These regulations are being challenged by several states by litigation that could take years to resolve. If fully implemented, however, the real impact of the revised regulations will be when federal funds become available to grantees and clinics to rejoin the program and allow more low-income people to receive health services from Title X sites. While many grantees and clinics that left the network are anticipated to resume participation in the safety net program, it remains to be seen whether all those grantees and providers that left the program will apply to return. Some were able to obtain state-level funding to bridge the loss of federal support. These decisions will likely depend on whether states will continue to subsidize their family planning providers or whether additional federal funds will be needed to maintain and strengthen state family planning networks and services in communities that have historically been served by these providers.

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[5] *https://opa.hhs.gov/sites/default/files/2020-10/providing-quality-family-planning-services-2014_1.pdf.*

[6] *https://www.ohioattorneygeneral.gov/Files/Briefing-Room/News-Releases/Title-X-PI-Motion.aspx.*

[7] *https://www.grants.gov/view-opportunity.html?oppId=334698.*

"Rebuilding Title X: New Regulations for the Federal Family Planning Program," Brittni Frederiksen, Ivette Gomez, and Alina Salganicoff, published: November 3, 2021, *https://www.kff.org/womens-health-policy/issue-brief/rebuilding-title-x-new-regulations-for-the-federal-family-planning-program/*.

COMMUNICATION

CENTER FOR FISCAL EQUITY
14448 Parkvale Road, Suite 6
Rockville, MD 20853
fiscalequitycenter@yahoo.com

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 2023 Budget Request.

There have been more than a few hearings this spring to set the stage for the release of this budget. I will briefly restate some of our comments. Links to our comments can be found on our Fiscal Equity blog and YouTube channel. These hearings include:

- Senate Finance: Behavioral Health Care When Americans Need It: Ensuring Parity and Care Integration, March 30, 2022.
- Ways and Means: America's Mental Health Crisis, February 2, 2022.
- Finance: Mental Health Care in America: Addressing Root Causes and Identifying Policy Solutions, June 15, 2021.
- Ways and Means, Worker and Family Support: Improving Family Outcomes through Home Visiting, March 16, 2022.
- Ways and Means, Health: Bridging Health Equity Gaps for People with Disabilities and Chronic Conditions, February 3, 2022.

Please also see our many Pandemic-related comments, which took the Centers for Disease Control to task for not correctly assessing the early symptoms of the virus. See especially:

- Ways and Means, Health: The Path Forward on COVID–19 Immunizations, February 26, 2021.

We agree with the President's proposals to add funding to prepare for a future pandemic and to fund the ARPA–H Cancer Moonshot. Discoveries relating to the former will likely help the latter.

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.

On the pandemic, we urge that there be a public examination of lessons learned—particularly mistakes. The largest mistake was to not identify COVID–19 as being spread like a cold.

Subsequent variants identified sneezing and a runny nose as early signs of the virus. This was true in the first round, but to save face, it was not mentioned and is still not admitted. Job one of preparing for the next coronavirus pandemic is to list cold or supposed allergy symptoms as the signal to self-quarantine (if not be quarantined).

Donald Trump did not kill a million people. Trying to downplay original symptoms did—which led to a loss of credibility among some populations. This social aspect must also be explored—especially if these populations are to comply with later instructions.

The President's proposals to expand behavioral health are most welcome, although only a start. Replacing mental health facilities—as well as policies which allow longer-term mandatory stays are what is needed—including conditions whereby readmission to a more controlled environment is automatic in the event of relapse or medication non-compliance.

Such a change in the rules of the game will demand 50-state cooperation, as local laws are impacted. The Department of Justice and state and local police agency participation is also required. Reform cannot only be for those with insurance—it must be for everyone. Parity is not enough—and is impossible without not only more beds—but more dedicated hospitals.

The Visiting Nurses program is worthy of expansion—not only in public sector funding, but in the private sector as well. When my daughter was born, a visiting nurse to screen for depression and help with lactation coaching would have been a godsend, although we were lucky for generous family leave policies and good health insurance through my wife's employer. Health Insurance Reform will allow an even greater expansion of the pilot program to all. I will come back to this shortly.

New mothers and their partners have unmet needs beyond the particular programs listed in the House Budget Committee Summary. We cannot take our eye off of the Child Tax Credit ball. It must be both refundable and more generous. So that families are not simply living off of their CTC, the minimum wage needs to go up—although with a higher Child Credit a lower amount can be agreed to. Childcare subsidies are also as essential now as they were last year.

We have attached a portion of our comments from last year having to do with the Affordable Care Act, enacting a public option, how the issue is related to Student Loan forgiveness (here's a clue—baselines) and how to reform Medicaid and Medicare to remove the biggest Medicaid contingent liability from state budgets.

Considering the problems getting Build Back Better over the line, I can see where opening discussions on the Public Option and Medicare for All might prove difficult—especially given the lack of agreement between the relevant committees.

I hope I am not shocking anyone by saying this. With that said, it is time for both CMS and the Budget and Revenue Committees to start discussing what might be done in the next Congress on a bipartisan basis.

Please allow me to offer questions for research and discussion:

Would a public option be more likely to pass if Affordable Care Act surtaxes (SMI) were repealed?

What would be the impact on passage and operation of a public option of ending pre-existing condition reform with automatic enrollment in the public option, with subsidies, if coverage were denied?

How large would subsidies have to be to hold those who cannot get insurance due to a pre-existing condition harmless?

Are Affordable Care Act deductibles and premiums too high? (It seemed so to me when I had them and suffered a broken rib—for which the provider was never paid).

Can a public option, or even the ACA as it exists, meet all of its goals without either immigration reform or ending the prohibition on covering undocumented workers?

To what extent is sick leave (Building Back Better), essential for the ACA to really cut prices?

To what extent would the public option replace Medicaid?

Would reform be easier to pass if long-term care were funded as Medicare Part E rather than being operated and funded by the States? (This would also require 50-state cooperation).

What is the best way to fund a public option (or Medicare for All)? Is some form of border adjustable goods and services tax better than a payroll tax? Would an employer-paid subtraction VAT be better?

SVAT would burden profits and would replace current funding of the Affordable Care Act and the tax exclusion for employer-provided health insurance. Corporate

Income Taxes and Schedules C and F for Form 1040 would be replaced with this tax. See the second attachment for details.

How long would it take for insurance companies to deny anyone who is sick coverage, thus forcing them into a subsidized public option? Would this become Medicare for All, given that much private managed care, Medicaid and Medicare Parts B and D or Part C are all offered by the same list of providers, albeit with different copays?

Income Security is also in need of advanced study.

While Social Security 2100 is the school solution preferred by most mainstream analysts, should some form of expanded employee ownership be part of the solution?

To study this, HHS, the IRS and the Department of Labor—as well as their authorizing committees—should look at how to expand employee ownership.

The same bodies must also explore the impact of increasing the minimum wage on benefit levels, assuming that any increase lead to a rebasing of employment history.

What is the impact of crediting the employer contribution on an equal dollar basis rather than as a match to the employee contribution?

Would rebasing income history with a higher minimum wage and an equal dollar employer contribution end poverty among the low income elderly and disabled? Is it a matter of degree? How much would the minimum wage have to change to make a significant impact?

How would addressing such questions impact Social Security 2100?

Thank you for the opportunity to address the committee. We are, of course, available for direct testimony or to answer questions by members and staff.

Attachment One—HHS Budget FY 2022

We address the funding of the Affordable Care Act, the need for an immediate COLA for retirees,funding the Social Security Administration's non-fund costs and the idea of cost savings for Social Security.

So far, the Administration has not yet addressed changes to the Affordable Care Act, at least not publicly. We suggest that the Committee ask the Secretary about any such plans.

At minimum, the individual and employer mandates, with associated penalties, that were repealed must be restored. The President campaigned on restoring and perfecting the Act, adding a public option. We agree, although the public option need not be self supporting. It must be subsidized through a broad based consumption tax. Such a tax burdens both capital and wage income.

The current funding stream seems to have been designed to draw opposition from wealthier taxpayers. It is an open secret that the Minority does not oppose most of the Affordable Care Act (which was designed by their own Heritage Foundation as an alternative to Mrs. Clinton's proposals). Broaden the tax base to fund the program and the nonsense on repeal will end.

The current funding stream from student loan initiation and interest, which was included in the baseline, should also be ended. Graduates (and non-graduates) with student loan debt cannot afford both their loan payments and insurance payments under the Affordable Care Act. When they apply for lower loan payments, which are always granted, they face either a balloon interest payment or capitalized interest, which makes their funding situation worse. No one should have to retire with student load debt, yet quite a few soon will (or already have).

Forgive capitalized interest and apply any overpayments to principal. There should not be a one-size-fits-all subsidy. Also, when payments are deferred, return to the practice of deferring interest (or allow debts to be discharged, at least partially, in bankruptcy).

To deal with these issues, whatever is budgeted for analytical support in the Department should likely be doubled.

The following analysis comes from the Single Payer attachment that has previously been provided. Because of the President's preference for establishing the public option, we will repeat those analyses here. Aside from a broader base of funding, other compromises are necessary to enact a public option.

To set up a public option end protections for pre-existing conditions and mandates. The public option would then cover all families who are rejected for either pre-existing conditions or the inability to pay. In essence, this is an expansion of Medicaid to everyone with a pre-existing condition. As such, it would be funded through increased taxation, which will be addressed below. A variation is the expansion of the Uniformed Public Health Service to treat such individuals and their families.

The public option is inherently unstable over the long term. The profit motive will ultimately make the exclusion pool grow until private insurance would no longer be justified, leading again to Single Payer if the race to cut customers leads to no one left in private insurance who is actually sick. This eventually becomes Medicare for All, but with easier passage and sudden adoption as private health plans are either banned or become bankrupt. Single Payer would then be what occurs when insurance companies are bailed out in bankruptcy, the public option covers everyone and insurance companies are limited to administering the government program on a state by state basis.

The financing of the Affordable Care Act should be broadened. It should neither be funded by the wealthy or by loan sharking student loan debtors. Instead, it should be funded by an employer-paid consumption tax, with partial offsets to tax payments for employer provided insurance and taxes actually collected funding a Public Option (which should also replace Medicaid for non-retirees). Medicaid for retirees and Medicare should be funded by a border adjustable goods and services tax, which should be broad based.

Why the difference? The goal is to not need a public option as employers do the right thing and cover every worker or potential worker. Using an employer based tax is an incentive to maximize employee coverage. Medicare, however, is an obligation on society as a whole.

State governments are under financial pressure as a result of the pandemic, especially in the area of healthcare costs, most especially for seniors in nursing homes who are "dual eligibles." The heart of President Reagan's New Federalism proposal was the transfer of state Medicaid expenses to the federal government, largely to fund baby boomers who would become dual eligible with time. Time is now up, or will be shortly.

Welfare has been reformed, allowing state and federal governments to save money—which was part of the New Federalism bargain that was not accepted at the time. We will address this part shortly, but the irony is that federal money was reduced without the second part of the trade-off.

Finish the process and create Medicare Part E for low income disabled and retirees. This will put investigation of nursing home conditions into the federal sector. States have done a poor job in enforcement of health and safety standards. It is time to make this a national responsibility.

One way to increase benefits generally is to increase the minimum wage, the higher the better, and rebase current benefits to consider such an increase to be wage inflation. Such a change will fund itself, because wages funding benefits will be increased across the board.

Attachment Two—Tax Reform, Center for Fiscal Equity, December 7, 2021

Individual payroll taxes. Employee payroll tax of 7.2% for Old-Age and Survivors Insurance. Funds now collected as a matching premium to a consumption tax based contribution credited at an equal dollar rate for all workers qualified within a quarter. An employer-paid subtraction value added tax would be used if offsets to private accounts are included. Without such accounts, the invoice value added tax would collect these funds. No payroll tax would be collected from employees if all contributions are credited on an equal dollar basis. If employee taxes are retained, the ceiling would be lowered to $100,000 to reduce benefits paid to wealthier individuals and a $16,000 floor should be established so that Earned Income Tax Credits are no longer needed. Subsidies for single workers should be abandoned in favor of radically higher minimum wages. If a $10 minimum wage is passed, the employee contribution floor would increase to $20,000.

Wage Surtaxes. Individual income taxes on salaries, which exclude business taxes, above an individual standard deduction of $100,000 per year, will range from 7.2% to 57.6%. This tax will fund net interest on the debt (which will no longer be rolled over into new borrowing), redemption of the Social Security Trust Fund, strategic, sea and non-continental U.S. military deployments, veterans' health benefits as the

result of battlefield injuries, including mental health and addiction and eventual debt reduction.

Our proposed brackets have been increased from $85,000 to $100,000 because this is the income level at the top of the 80% of tax paying households who earn the bottom third of adjusted gross income. Earners above this level are considered middle class. Likewise, the top 1% of income earners are at the $500,000 level, which will be used as the start of the highest rate.

Asset Value-Added Tax (A–VAT). A replacement for capital gains taxes, dividend taxes, and the estate tax. It will apply to asset sales, dividend distributions, exercised options, rental income, 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. These taxes will fund the same spending items as income or S–VAT surtaxes.

This tax will end Tax Gap issues owed by high income individuals. A 26% rate is between the GOP 23.8% rate (including ACA-SM surtax) and the Democratic 28.8% rate as proposed in the Build Back Better Act. It's time to quit playing football with tax rates to attract side bets. 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. For now, however, a 28.8% rate is assumed if reform is enacted by a Democratic majority in both Houses.

Subtraction Value-Added Tax (S–VAT). These are employer paid Net Business Receipts Taxes. 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.

The S–VAT is also used for personal accounts in Social Security, provided that these accounts are insured through an insurance fund for all such accounts, that accounts go toward employee ownership rather than for a subsidy for the investment industry. Both employers and employees must consent to a shift to these accounts, which will occur if corporate democracy in existing ESOPs is given a thorough test. So far it has not. S–VAT funded retirement accounts will be equal-dollar credited for every worker. They also have the advantage of drawing on both payroll and profit, making it less regressive.

A multi-tier S–VAT could replace income 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.

Invoice Value-Added Tax (I–VAT). Border adjustable taxes will appear on purchase invoices. The rate varies according to what is being financed. If Medicare for All does not contain offsets for employers who fund their own medical personnel or for personal retirement accounts, both of which would otherwise be funded by an S–VAT, then they would be funded by the I–VAT to take advantage of border adjustability. I–VAT also forces everyone, from the working poor to the beneficiaries of inherited wealth, to pay taxes and share in the cost of government. Enactment of both the A–VAT and I–VAT ends the need for capital gains and inheritance taxes (apart from any initial payout). This tax would take care of the low-income Tax Gap.

I–VAT will fund domestic discretionary spending, equal dollar employer OASI contributions, and non-nuclear, non-deployed military spending, possibly on a regional basis. Regional I–VAT would both require a constitutional amendment to change the requirement that all excises be national and to discourage unnecessary spending, especially when allocated for electoral reasons rather than program needs. The latter could also be funded by the asset VAT (decreasing the rate by from 19.5% to 13%).

As part of enactment, gross wages will be reduced to take into account the shift to S–VAT and I–VAT, however net income will be increased by the same percentage as the I–VAT. Adoption of S–VAT and I–VAT will replace pass-through and proprietary business and corporate income taxes.

Carbon Added Tax (C–AT). A Carbon tax with receipt visibility, which allows comparison shopping based on carbon content, even if it means a more expensive item with lower carbon is purchased. C–AT would also replace fuel taxes. It will fund transportation costs, including mass transit, and research into alternative fuels (including fusion). This tax would not be border adjustable unless it is in other nations, however in this case the imposition of this tax at the border will be noted, with the U.S. tax applied to the overseas base..

Tax Reform Summary

This plan can be summarized as a list of specific actions:

1. Increase the standard deduction to workers making salaried income of $35,000 and over, shifting business filing to a separate tax on employers and eliminating all credits and deductions—starting at 7.2%, going up to 28.8%, in $50,000 brackets.
2. Shift special rate taxes on capital income and gains from the income tax to an asset VAT. Expand the exclusion for sales to an ESOP to cooperatives and include sales of common and preferred stock. Mark option exercise and the first sale after inheritance, gift or donation to market.
3. Employers distribute the child tax credit with wages as an offset to their quarterly tax filing (ending annual filings).
4. Employers collect and pay lower tier income taxes, starting at $100,000 at 7.2%, with an increase to 14.4% for all salary payments over $150,000 going up 7.2% for every $50,000 up to $250,000.
5. Shift payment of HI, DI, SM (ACA) payroll taxes to employers, remove caps on employer payroll taxes and credit them to workers on an equal dollar basis.
6. Employer paid taxes could as easily be called a subtraction VAT, abolishing corporate income taxes. These should not be zero rated at the border.
7. Expand current state/federal intergovernmental subtraction VAT to a full GST with limited exclusions (food would be taxed) and add a federal portion, which would also be collected by the States. Make these taxes zero rated at the border. Rate should be 19.5% and replace employer OASI contributions. Credit workers on an equal dollar basis.
8. Change employee OASI of 7.2% from $18,000 ($20,000 for $10 minimum wage) to $100,000 income.are optional taxes for Old Age and Survivors Insurance.