

**PRESIDENT'S FISCAL YEAR 2021
HEALTH CARE PROPOSALS**

HEARING
BEFORE THE
COMMITTEE ON FINANCE
UNITED STATES SENATE
ONE HUNDRED SIXTEENTH CONGRESS
SECOND SESSION

—————
FEBRUARY 13, 2020
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PRESIDENT'S FISCAL YEAR 2021 HEALTH CARE PROPOSALS

THURSDAY, FEBRUARY 13, 2020

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

The hearing was convened, pursuant to notice, at 9:30 a.m., in Room SD-215, Dirksen Senate Office Building, Hon. Chuck Grassley (chairman of the committee) presiding.

Present: Senators Crapo, Roberts, Enzi, Cornyn, Thune, Burr, Portman, Toomey, Scott, Cassidy, Lankford, Daines, Young, Sasse, Wyden, Stabenow, Cantwell, Menendez, Carper, Cardin, Brown, Bennet, Casey, Warner, Whitehouse, Hassan, and Cortez Masto.

Also present: Republican staff: Brett Baker, Chief Health Policy Director; Erin Dempsey, Deputy Health Policy Director; Evelyn Fortier, General Counsel for Health and Chief of Special Projects; Ryan Martin, Senior Human Services Advisor; Stuart Portman, Health Policy Advisor; and Jeffrey Wrase, Deputy Staff Director and Chief Economist. Democratic staff: Anne Dwyer, Senior Health Counsel; Michael Evans, Deputy Staff Director and Chief Counsel; Elizabeth Jurinka, Chief Health Advisor; Kristen Lunde, Health Policy Advisor; Joshua Sheinkman, Staff Director; Beth Vrable, Deputy Chief Counsel and Senior Health Counsel; and Arielle Woronoff, Senior Health Counsel.

OPENING STATEMENT OF HON. CHUCK GRASSLEY, A U.S. SENATOR FROM IOWA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. Good morning, everybody. I think before I give my statement—we have several votes at 10:30, and I think we have worked it out with Senator Wyden and other people that we will keep this meeting going. So I am going to leave at 10:30 and vote once and then come back—and I think the first vote always takes a long time. And then when Senator Wyden gets back—no, then he will—in other words, for the second and third votes I am going to stay over there and do them together. You know how it works out. I may not explain it very well. [Laughter.]

I want to welcome our witness, our Secretary of Health and Human Services, the Honorable Alex Azar. I appreciate, Secretary Azar, your appearing before the committee to discuss the budget, the new budget.

Secretary Azar oversees a very sprawling department with programs that are crucial to the health and well-being of many Americans, and maybe you would say all Americans. The budget rep-

resents the administration's recommended funding for those programs, as well as key policy proposals.

While Congress decides funding levels and program changes, we have a duty, of course, to review the administration's budget proposal. And Secretary Azar is here to help us do that.

As with any budget submission, I disagree with some of the proposals, but I do want to speak to a few issues where it reflects priorities that I have. And a lot of these priorities are shared by a lot of Democrats, and particularly with Senator Wyden. So as I mentioned, Senator Wyden's and my working to lower prescription drug prices is a very top priority.

President Trump's focus on this issue has been a real game changer, particularly because, in the State of the Union message, he has brought attention to that.

Secretary Azar has been a point person in this effort as well. The Secretary has also helped greatly with our legislative effort, again referring to prescription drugs, because your team, as well as you, have provided guidance and technical assistance as we developed and refined the bipartisan bill the committee reported out 19 to 9 in July of last year.

I am pleased that the budget calls on Congress to quickly pass a bipartisan bill and includes a prescription drug place-holder for \$135 billion in reduced taxpayer subsidy to drug companies. I will ask the Secretary to expand on this when we have questions. For now, I will say that I look forward to continuing to work with the Secretary, the ranking member, and other Senators to provide relief on prescription drugs to these consumers.

The budget also contains a number of proposals to improve health care in rural communities. Ensuring access to health care in Iowa and other rural areas has long been a priority for me, but also for most of the members of this committee. It has not really been a controversial issue in most cases. The ranking member and I continue to discuss how to help rural and other under-served areas. The administration's budget further bolsters those efforts.

I would like to also take a moment to highlight efforts to help HHS be more effective in executing its mission. I understand that HHS's Office of National Security is forging new ground with the intelligence community to leverage technology in innovative ways to better streamline intelligence operation procedures and to mitigate counterintelligence threats.

I encourage the intelligence community to provide even broader access to the Office of National Security as it relates to its products and database, and to then allow HHS to access vital information that it needs to mitigate threats to the Department, its funded partners, and its interagency colleagues.

As you are aware, via my oversight efforts I have worked to make sure that the Office of National Security receives access to certain intelligence community-related material, and that you have gained access to some but not all that you want. However, more work needs to be done then.

Recently I sent two classified letters to the intelligence community components to help bridge the gap between the Office of National Security and the IC counterparts. As I have said before, the left hand and right hand work together for the taxpayers. As we

have found out, 9/11 may not have happened if we had had more cooperation between the intelligence people and the FBI, as one example. Now of course, hopefully that is better, but I will bet it is not as good as it should be.

I will conclude by noting that HHS has many important challenges. Some are longstanding, like the high cost of prescription drugs; others appear with little notice, such as the novel coronavirus. While there are sure to be disagreements on many items in the budget, the issues I have highlighted are a reminder that we can work together in a bipartisan way to get things done for the American people.

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

The CHAIRMAN. Senator Wyden?

**OPENING STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON**

Senator WYDEN. Thank you very much, Mr. Chairman. I appreciate your scheduling this so quickly, and I appreciate your working with me on a host of issues.

Mr. Secretary, we appreciate your being here, and that you are willing to come right after the budget comes out while these issues are ones we will all face when we are on our way home tonight and over the next week.

President Trump's health-care agenda, in my view, rips scores of new holes in the safety net that vulnerable Americans are sure to fall through. And the textbook example is Medicaid. Right now the administration is trying to do, on its own, what it failed to get through Congress: block-grant Medicaid. It is a policy, colleagues, we debated in this very room back in September 2017. It did not make it out of the committee. It did not get a vote on the floor. It did not go anywhere because it is really horrible policy—horrible policy that would hurt our people.

That said, the Trump administration does not seem to mind. Now it is trying to pull an administrative end-run around the Congress to push the dirty work of Medicaid block grants onto the States.

You hear a whole lot of Washington lingo now about flexibility. They even gave it a name that goes into the George Orwell Hall of Infamy. It is called "Healthy Adult Opportunity." Let us make no mistake. The Trump administration proposal to block-grant Medicaid, led by CMS Administrator Seema Verma, in my view would be the beginning of the end for the health-care safety net.

It is not about flexibility. It is certainly not about opportunity for healthy adults. It is about harsh, Draconian cuts. And it comes in addition to the other cuts the Trump administration has proposed for Medicaid. So I am going to take just a minute—and I see my good friend Bob Casey, who is so eloquent on this subject—and talk about what Medicaid really means for the American people.

Medicaid pays for two out of three nursing home beds in this country. That is because growing older in America costs a lot of money. Before I was elected to Congress, I was the co-director of the Oregon Gray Panthers, an organization for the elderly. I spent

a lot of time visiting the seniors in their homes. And the majority of them were folks who had to stretch every last penny to get by.

So this is an issue I take very personally. And even when our people do everything right, when they scrimp and they save over decades, when they give up vacations—they did not buy a boat, they lived modestly, they do everything they can to prepare for retirement—people run out of money when they get older. All it takes is one surprise illness or injury for the bills to start stacking up, or a family emergency, or damage to a home. Your savings dry up. That is the way real life is.

And that is on top of those who do not have savings, the millions who could not save just because they had to walk an economic tightrope. And half of our people struggle to come up with \$400 if they have an emergency. That does not mean that they have no right to see a doctor or get long-term care.

Protecting those people is what Medicaid and the nursing home guarantee—and that is what it is; it is a guarantee—that is what Medicaid is all about. Without it, where do seniors turn when their savings dry up? How are nursing homes supposed to stay open without cutting the services down to frighteningly poor levels? How are low-income seniors who want to stay in their homes going to afford their health care?

So when you hear all this talk, colleagues, about flexibility, innovative solutions, holding the States accountable, in my view it is code for big Medicaid cuts. The consequences are dangerous, and they are personal.

A couple of other points. The Trump administration has gone to court to have the entire Affordable Care Act thrown out. Protections for pre-existing conditions—gone. Tax credits for health care—gone. Rules banning the worst insurance company abuses—gone. Millions of people kicked off their health care.

And it would just be devastating for young people like Jasper, pictured on this card in front of me. He is a little guy, but he's got a really big heart. And he was born with serious medical issues. Jasper, one of my constituents, has cystic fibrosis, cardiac and pancreatic problems, and hearing loss. He gets a lot of costly treatment. And for them, he and his family, the Affordable Care Act is a lifeline to the peace of mind they absolutely consider vital.

Donald Trump has no backup plan for Jasper and his family if he successfully repeals the Affordable Care Act. That did not stop the President from saying during his State of the Union address that he had made an ironclad pledge to always protect seniors with pre-existing conditions.

Donald Trump protects pre-existing conditions like sea lions protect salmon on our mighty Columbia River. It is the kind of protection that comes with an uptick in the mortality rate.

So I am going to close with some comments about prescription drug prices. The President has had a lot of curtain-raising events on this. He was going to force big pharma to list drug prices on TV. That policy was blocked. He has talked about requiring rebates to go directly to patients. No follow-through. He was going to tie drug prices in the U.S. to drug prices abroad. Nothing there. He had a policy to speed approval of generics. No apparent effect. The reality

is, patients are still getting mugged at the pharmacy counter. Drug prices are up again in 2020.

Now, the Senate Finance Committee has worked long and hard on the prescription drug issue, as has the House of Representatives. And as I have said on a number of occasions, Chairman Grassley has been a good partner on this, and I hope that we can find a way to move all this good work forward.

The bottom line is, the President has been making promises about bringing down drug prices for 3 years, and it has not gotten done.

Again, Mr. Secretary, we appreciate your being here, particularly coming so quickly. There is a lot for us to talk about, so I look forward to hearing from the members.

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

The CHAIRMAN. Before I call on the Secretary, to repeat for some people who have just come in, we are going to keep things going while we have votes. So come back if you want to ask questions, because the Secretary has to leave at 12:30.

Mr. Azar is Secretary of the Department, as I have said. Prior to his current position, he served as general counsel at HHS for 4 years, 2001 to 2005, and Deputy Secretary from 2005 to 2007. Secretary Azar earned his bachelor's degree from Dartmouth College, and has a law degree from Yale University.

Proceed, sir. Welcome.

STATEMENT OF HON. ALEX M. AZAR II, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Secretary AZAR. Chairman Grassley and Ranking Member Wyden, thank you for inviting me to discuss the President's budget for fiscal year 2021. I am honored to appear before this committee for budget testimony as HHS Secretary for now the third time, especially after the remarkable year of results that the men and women at HHS have produced.

With support from this committee in many respects, this past year we have seen the number of drug overdose deaths begin to decline for the first time in 2 decades, another record year of generic drug approvals from FDA, and historic drops in Medicare Advantage, Medicare Part D, and insurance exchange premiums.

The President's budget aims to continue delivering these kinds of results and move toward a future where HHS's programs work better for the people we serve, where our human services programs put people at the center, and where America's health-care system is affordable, personalized, puts patients in control, and treats you like a human being and not like a number.

That is the vision behind this budget. I want to note that HHS has the largest discretionary budget of any non-defense department, which means that there are, again this year, difficult decisions made in order to put discretionary spending on a sustainable path. The President's budget proposes to protect what works in our health-care system and make it better. And I will mention two ways we do that: first, by facilitating patient-centered markets and health care, and second, by tackling key intractable health challenges.

The health-care reforms in the President's budget aim to put the patient at the center. It would, for instance, eliminate cost sharing for colonoscopies after discovery of a polyp, a life-saving preventive service. We would reduce patient co-insurance and promote competition by paying the same for certain services in hospitals and out-patient settings.

The budget endorses bipartisan, bicameral drug pricing legislation, like the plans formulated by Chairman Grassley and Ranking Member Wyden and supported by many members of this committee, as well as price transparency efforts that many of you have championed.

These reforms will improve Medicare and extend the life of the Hospital Insurance Trust Fund for at least 25 years. We propose investing \$116 million in HHS's initiative to reduce maternal mortality and morbidity, and we propose reforms to tackle the rural health crisis in America, including expansions of telehealth and new flexibility for rural hospitals.

The budget increases investments to combat the opioid epidemic, including the State Opioid Response Program, which we have focused on providing medication-assisted treatment while working with Congress to give States flexibility to address stimulants like methamphetamines.

We request \$716 million to expand implementation of the President's initiative to end the HIV epidemic in America by using the effective evidence-based tools we have at our disposal, as we have already begun doing, with Congress's help, in four jurisdictions.

Finally, the budget reflects how seriously we take the threat of other infectious diseases such as the China coronavirus, which has been a top priority for me as I have led the Federal Government's coordinated response as chairman of the President's Coronavirus Task Force.

The budget prioritizes funding for CDC's infectious disease programs and maintains effective investments in hospital preparedness. Last night we announced the 14th confirmed case of the China coronavirus in the U.S., and this morning CDC will be announcing the 15th, both of whom came from Wuhan and are in quarantine.

As of today, I can announce that the CDC has begun working with health departments in five cities to use its flu surveillance network to begin testing individuals with flu-like symptoms for the China coronavirus. Many questions about the virus remain, and this effort will help see whether there is broader spread than we have been able to detect so far.

On the human services side, the goals of the budget are similar. We cut back on programs that lack proven results while reforming programs like TANF to drive State investments in supporting work and all the benefits it brings for well-being.

This year's budget aims to protect and enhance Americans' well-being and deliver Americans a more affordable, personalized health-care system that works better rather than just spends more. I look forward to working with this committee, as always, to make that common-sense goal a reality.

Thank you, Mr. Chairman.

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

The CHAIRMAN. We will have 5-minute rounds of questioning. I am going to start out with what you probably would expect me to start out with. I referred to it in my opening statement. In that statement I commended you for your leadership in the effort to lower prescription drug prices, and particularly helping us with our legislation.

Can you speak to the proposal in the budget to reduce prescription drug costs and its notation of \$135 billion in reduced spending? Also, include in your answer your general thoughts on how this could be helpful to me and Senator Wyden and all the people on this committee who support our bill.

Secretary AZAR. Well, thank you, Mr. Chairman. And I have been delighted to work with you and Ranking Member Wyden on this legislation. This package is a reasonable package. It is bipartisan, and it can really help in terms of helping to control list price increases, to decrease out-of-pocket spending by patients—especially by our seniors—and to fix the incentives in the Part D program to really give the plans the incentive to really negotiate hard against big pharma.

I do not understand why big pharma is not supporting it. These are important reforms. Packages like this and other bipartisan efforts are important at saving seniors money, stopping list price increases, and getting better negotiations. And I think these are some of the best reforms that we can work on together.

The CHAIRMAN. Thank you.

I am interested in rural health care. This committee has been in the middle of that for at least 3 decades. It is difficult to keep high-quality medical care in those environments.

Over the past decades, I championed landmark rural health-care legislation. We have had some successes, but things change rapidly—well, maybe not “rapidly,” but they slowly change in rural America. So we have problems still developing.

I am very pleased to see in the President’s budget that it contains a renewed focus on rural health care. While the HHS budget material provides a broad outline of past accomplishments and future goals, it does not contain specific details about the policy.

That is why today I wanted to give you, Secretary Azar, an opportunity to explain in some detail how the administration plans to build rural delivery models, leverage technology, and create appropriate rural provider payments.

Secretary AZAR. Thank you, Mr. Chairman. And thank you for your decades-long advocacy supporting rural health care. It has been a passion of mine also. I am the product of rural health care in America. And rural health care is suffering, and we have developed a comprehensive agenda. And I am delighted to see how prominent it is in this year’s budget, and you will be seeing a lot of activity this year.

Some of the changes that we do propose in our budget—one of them is to help stop rural hospital closures. So what we would do is ask Congress to allow critical access hospitals in rural areas to voluntarily convert to emergency hospitals so that they do not have to comply with the regulatory requirements of also offering in-

patient beds. They would get the same Medicare payment rates as other emergency departments paid under the out-patient, prospective payment system, plus an additional payment.

We also are working to advance telehealth and telemedicine in our proposal, expanding regulatory flexibility for providers who participate in Medicare Advanced Payment Models by lifting telehealth restrictions. And we also want to modernize payments for rural health clinics.

These FQHCs in rural America deserve more money. We want to increase flexibility for critical access hospitals to convert to these out-patient-only facilities and continue serving their communities.

The CHAIRMAN. Ranking Member Wyden, Senators Young, Cardin, and I sent a letter to the United Network on Organ Sharing questioning the adequacy of their oversight. And I know you appreciate this as a problem. There are more than 600 people in Iowa waiting for organ transplants, and 113,000 nationwide. About 20 die a day without getting the help.

What is HHS doing to take a more active role in providing oversight over this system, to hold this government contractor and procurement organizations accountable? Because we think, except in a few cases, there is not really a very good effort made to harvest organs.

Secretary AZAR. So, Mr. Chairman, in regard to the particular issue of liver allocation policy, I just want you to know, as I have said before, that I share your concerns and other members' concerns and frustrations with UNOS and the decision-making process there.

I have been rebuffed also in my efforts. The oversight there that we have, as HHS, is limited by statute to protect the independence of the organ allocation policies. But we are happy to work with Congress, if it ever saw fit to address that question. More broadly, though, around the supervision of the organ procurement organizations, we have proposed a comprehensive rule bringing first-time-ever real accountability and metrics to these OPOs to get more organs procured, and more of them successfully transplanted.

So that is a major focus of our efforts there through the OPO accountability regulation that we have now proposed.

The CHAIRMAN. Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman.

Mr. Secretary, I am going to walk through a few facts that I think are on the record, and then I have a particular question for you.

The President talks about health care in terms of his vision. And yet, when I look at the specifics, it really looks like a nightmare to me. First, I touched on the Graham-Cassidy bill, in addition to the punitive approach to Medicaid. It would have gutted pre-existing condition protections. We have witnesses who actually said that at the witness table. The waivers, the 1332 waivers, basically are green-lighting junk insurance. Burdensome paperwork requirements led to thousands losing coverage in one State alone. And what do we have to show for it?

The uninsured rate has gone up each year since 2017, and the rate of uninsured kids is up for the first time in a decade. So to

me, this “vision” looks more like a nightmare. And that is because we are going to have worse health care and for fewer people.

Now I want to ask a specific question with my time about women’s health under TrumpCare. Since day one, the administration has taken aim at women’s health by making it harder and harder for women to access the health care they need.

Last month the administration approved Federal Medicaid funding for a Texas program that excludes qualified family planning providers like Planned Parenthood. So the administration has a clear agenda, making it harder for patients to see the providers they trust, and the administration is now proposing a budget that would gut even more women’s health protections.

Medicaid is a lifeline for so many women. It is the Nation’s primary payer of essential family planning services, and it would be slashed to the bone, putting coverage for millions of women and girls in jeopardy.

President Trump’s ACA repeal lawsuit would end the ironclad protections for pre-existing conditions—again, vital for women—taking America back to the day when a woman could be charged more for health care just for being a woman.

So my question, Secretary Azar, is why should the Department of Health and Human Services be in the business of telling women which doctors they can go and see?

Secretary AZAR. So, Senator Wyden, of course we do not have any role in telling women or men where they should go in terms of which doctors they would see. In our programs we grant flexibilities to States in running the Medicaid program. And we have made major investments, and we continue to make major investments, in direct health care service delivery for women’s health. It is a major priority of ours to ensure access to health care for women and girls across their entire lifespan, including community health centers, where 58 percent of our clients in community health centers are female, and 62 percent are racial and ethnic minorities. We are going to spend in this budget approximately \$137.5 billion on women’s health, and I look forward to working with you on ways we can keep advancing women’s health care.

Senator WYDEN. What I will say, Mr. Secretary, because I think I have outlined that the Medicaid cuts—I just would respectfully disagree with you on that particular point. You all are telling the States that they can tell women which doctors they are going to see, and that is what I think is particularly unfortunate.

It seems to me that women in this country, particularly women of modest means, should not in effect be excluded from the kind of health-care choices that millions of other Americans have. And you are basically green-lighting that kind of opportunity for the States.

And one last question, talking about how Medicaid and health care is, in my view, paying for tax cuts. Now confirm some of the numbers in the President’s budget for me. Let us just stick to the numbers.

Is it right that the President’s budget reduces Medicaid spending by \$920 billion?

Secretary AZAR. So the President’s budget has changes to Medicaid that would actually result, every single year, in an increase in Medicaid. Right now, Medicaid increases 5.4 percent per year,

which is twice what the average worker makes in a pay increase per year. We would change that to a 3.1-percent increase every year, putting it in line—

Senator WYDEN. Secretary Azar, doesn't the budget say that it would be \$920 billion less than it would be without the budget? Yes or no?

Secretary AZAR. That is less in the rate of growth. But it again grows every single year—

Senator WYDEN. That is a "yes."

Is it also correct that the President's budget reduces the net Medicare spending by \$450 billion?

Secretary AZAR. Again, Medicare spending is growing at 7.8—I believe it is 7.3 percent per year. We would reduce the rate of growth to 6.3 percent by making some common-sense changes that MedPAC and others have recommended, like moving graduate medical education and uncompensated care to general tax revenues, site-neutral payments, finally bringing some control to post-acute payments—nothing that impacts beneficiaries.

Senator WYDEN. My time is up, because I have two or three other kinds of examples. What I am concerned about is paying for unpaid breaks to professionals and big pharma on the backs of low-income Americans, and I think that is what this budget adds up to.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Portman, and then Senator Stabenow.

Senator PORTMAN. Thank you, Mr. Chairman,

First of all, Mr. Secretary, I appreciate the job you are doing. And I wanted to comment on a few things in the budget. There is a lot in there. I wish I had more time. But first on prescription drugs, let me just make this comment.

We voted, as you know, on a bipartisan package, I think 19 of us voted for it. I was one of them. And you put a placeholder in the budget, I noticed, that is roughly equivalent to the amount of savings that we would have through the prescription drug cost reductions that we passed in this committee. I thank you for that, and I urge you to continue working with us on a bipartisan basis to find a solution. It is really important to the constituents all of us have back home. And prescription drug prices is an area where I think we have the potential to find some common ground.

I also noticed that in the opioid area you have increased funding for the State opioid grant program, and also for the Comprehensive Addiction Recovery Act, which I appreciate. We need it badly. I would love to say that we have been victorious in this battle and that we are turning the tide.

We do have fewer overdose deaths, but the reality is that crystal meth and cocaine, which are psycho-stimulants, have come back with a vengeance. And so I really appreciate the flexibility you are providing in the State Opioid Response Grants, because that is what we are hearing back home in Ohio.

I just finished another round of visits in Ohio talking to folks about this, and unfortunately we had a spate of overdose deaths just in the last couple of weeks with this mixture of fentanyl, cocaine, and crystal meth. So, thank you for that flexibility.

I have a question for you on Money Follows the Person. This is a great program. Ohio is one of the leaders in it, as you may know. It is a demonstration program right now. We want to make it permanent. We keep trying to do that, unsuccessfully. You have put in the budget that it should be permanent. And it is a great program, because it is a win/win. It actually provides better care to get people out of institutional care into home care, but it also saves the government money. You know, what's wrong with that?

And so I would hope that, for our seniors in Ohio and people with disabilities in Ohio, your budget actually is successful in making it permanent. It has already transitioned 90,000 Americans from institutional care to home and community care.

You have a report from HHS saying this lowers hospital readmission rates among those who are coming out of nursing care, which is one of our great objectives. Additionally, it says that the average per-person monthly cost decreases from \$13,500 per month to \$9,500 per month. So it is providing better care, and it is also less expensive.

One of our challenges, frankly, has been that CBO is skeptical of the cost savings. Can you talk about that for a second and also commit to working with CBO to try to come up with more realistic costs based on the data you have given us?

Secretary AZAR. Yes, we certainly will work with them. I struggle with actuaries and how they do their calculations in terms of savings, because we have seen the MFP program. It is popular. The results of this demonstration have been positive, just as you said. And thank you for your leadership on that.

It is time for us to convert this from being a grant program, with the lack of predictability that comes with a grant program, to a State option where they can build that into the intrinsic fabric of their program. So we are happy to keep working with you on that.

Senator PORTMAN. Great. Thank you.

On hospice, I am a big supporter. Ohio is at the cutting edge of hospice. We were one of the States that pushed hard for Medicare coverage for hospice back in the day.

I am told that, based on a MedPAC study, that 2017 marked the first time ever that a majority of Medicare beneficiaries selected hospice services for their end-of-life care. And I think that is a good thing. In my own family, we have used hospice, to be sure. With end-of-life challenges, people are able to have the dignity that they deserve.

And yet, there are some hospice organizations that are not meeting the quality standards that we all want. Senator Cardin and I have been working on this issue. We have legislation we have introduced. Again, it is something I see in your budget, because you have said that you would like to see some similar penalties to the ones we have for bad actors in this space.

And so, what my request today would be is, would you be willing to work with us to provide more input into our legislation, specifically some technical assistance that apparently we have had a tough time getting? I know HHS is busy, but we really want to move this forward. We think it would be a good bipartisan accomplishment of this committee and, most importantly, can help so

many constituents back home who are looking for that dignity at the end of life, but also high-quality care.

Secretary AZAR. Absolutely; we would be happy to help you on that. We, in our budget, proposed that we have greater ability to make transparent the accreditation surveys for accredited facilities so that people can really make informed choices.

We also make a major investment, with \$442 million, in the survey and certification work to ensure that we are doing our job with the expanding number of providers.

And then finally, with regard to hospice in particular, we are proposing one of the OIG's recommendations there of how we can bring modified payments to hospice providers so that they reduce the incentives for hospice to actually seek out beneficiaries in nursing facilities.

Senator PORTMAN. We look forward to working with you on that, and again, to hopefully passing some legislation that will give you some statutory authority to do that.

Thank you. Thanks, Mr. Chairman.

The CHAIRMAN. Senator Stabenow?

Senator STABENOW. Thank you, Mr. Chairman and Ranking Member. Welcome, Secretary Azar.

I want to first start expressing concerns about the Medicare, Medicaid cuts, and other cuts. But then I want to transition to something that you and I have talked about a number of times where we can work together and actually improve people's quality of life and access to care. And we have an opportunity to do that this year.

But first I just want you to see Henry. This is Henry. He is 9 years old. He lives in Grosse Pointe, MI. He loves people. He greets everybody with a big hug. He loves performing. He is in dance class and sings karaoke at home. The challenge is, he is also living with a number of pre-existing conditions, including Down syndrome, autism, and severe reflux.

As you can imagine, he has been in and out of the hospital—a lot of challenges. And his mom Kera said, "If we did not have access to affordable health coverage, we would have been bankrupt before Henry was 1 year old."

And so first let me say, in addition to all of the cuts on Medicare and Medicaid, as well as health research—which I am very concerned about—that are in the budget, there is nothing that stops the lawsuit on the ACA going through the courts that would take away coverage on pre-existing conditions and everything else under the ACA.

And I am very concerned that when the court initially agreed with the fact that the ACA should be repealed, including pre-existing conditions, the President tweeted, "Great news for America." Not great news for Henry. And so I am very, very concerned about that.

The area where we have the opportunity to work together and to really make a difference is in the area of community mental health and addiction services. And when you said grants are not enough, boy, are you right. We have champions in this committee for efforts around addiction and opioid treatment and so on. It is always a grant, and when the grant runs out, so sorry.

So the only folks who are asked to do that in health care are the mentally ill and people with addiction. And so as you know, Senator Blunt and I—and now we have 12 members—10 Democrats, 10 Republicans. We are adding people in pairs, and we expect to add more people. We have a House bipartisan effort to expand an eight-State demonstration project that was set up that literally shows that we save money. People are not in jails. They are not in emergency rooms. But when you do quality community mental health out-patient care and addiction services, you not only save lives, you save money.

And so we want to expand that. The chairman is very supportive, the ranking member, many people. There are 19 States that actually meet the quality standards now and are ready to take that next step. And we are also doing grants to help every State be able to get ready.

But I wonder—there has been a study that has shown, in the last 2 years, some of the results, the positive impacts that have happened as a result of what has been done in the Excellence in Mental Health and Addiction Treatment Act. And I wonder if you might share some of those, if you are aware of the results that we have seen in just 2 years?

Secretary AZAR. Absolutely, Senator. And thank you for your leadership on the CCBHC issues. This program, the Certified Community Behavioral Health Clinics program, has already served over 24,000 individuals as of August of 2019.

These are clinics, as you said, that provide a comprehensive, coordinated range of evidence-based treatment and behavioral health services to individuals. And the results show that we see that they are making services more convenient. They are introducing more frequent appointments, tailoring services offered to diverse populations, such as school-aged youth and veterans. And they are expanding access to care in our communities.

So in our budget, we proposed to extend this program through fiscal year 2021 for the eight current participating hospitals, because we are believers in this program, and obviously we are happy to continue working with you as we think about expansion to other States.

Senator STABENOW. Well, thank you, Mr. Secretary. And I want to thank Chairman Grassley and Ranking Member Wyden for putting the full extension across the country to the States that have met the quality standards into your health-care bill that has come forward on health-care extenders.

We have a chance in May to do this right. I will also say that, if you want to talk to folks who are excited about this, talk to a sheriff in one of the communities where folks are no longer going to the jail. They are now getting community out-patient treatment. Talk to the hospital folks who are running emergency rooms who no longer have folks sitting in their emergency room, but they are getting care through the 24-hour psychiatric emergency centers that have been set up.

And the final thing I would say, Mr. Chairman, is that this is actually a good news story in that CBO, which we all struggle with around health-care savings, has actually dropped more than in half

their original estimate on what it would take for us to pass the Excellence Act this year.

And so I hope you will lean in heavily with us, because it is my intent to make sure the mentally ill and people with addiction are not left behind this year. Thank you.

The CHAIRMAN. I will pass over Senator Menendez and go to Senator Carper.

Senator CARPER. Mr. Secretary, welcome. Thank you for taking on a tough job. And we appreciate that and the work that you are doing. We do not always agree, but we appreciate it nonetheless.

I think Senator Grassley has already raised the issue of bipartisan legislation that he and Senator Wyden and others on this committee crafted in order to try to reduce prescription drug prices for Medicare beneficiaries.

It is not every day that we have the kind of consensus that we had in this committee on this issue, but we are encouraged by that. As you know, the legislation would lower drug prices for seniors, and it would lower drug prices for Medicare and Medicaid and require drug companies to publicly justify the prices for their products, in a day and age when we are trying to find ways to save money with respect to pharmaceutical costs and other health-care costs in ways that are humane to the people.

I think this is a very good effort, and we are proud of it. Let me just ask, do you and the President support the Finance Committee's bipartisan bill to reduce drug prices?

Secretary AZAR. So, we have been very active in working with the bipartisan leadership of this committee to try to advance this legislation. If we want to get this or some other comparable bipartisan package through, we need to do this. This is certainly one that fits the bill.

If there are other approaches that we need to take to try to get this to the floor and get it passed, we are open to that. But we have been very deeply engaged with the Democrats and Republicans on this committee to advance the Grassley-Wyden legislation.

Senator CARPER. Thank you. Some of our Republican colleagues believe that the Finance bill would amount to price controls in the pharmaceutical industry and jeopardize innovation for new therapies. And as a former CEO, a native I think of Salisbury, MD, who was a former CEO of a major drug company, do you agree with these concerns?

And the second half of that question would be, do you think drug companies can continue to innovate under the Finance Committee's bill?

Secretary AZAR. With all respect, I fundamentally disagree with the notion that the inflation penalty provisions that are in the Grassley-Wyden bill constitute price caps or price controls.

These are reasonable restrictions on price increases that create, basically, a financial disincentive to the year-after-year price increases that we see. And as long as those incentives are in the system, we will continue to see year-after-year price increases, and the Grassley-Wyden package would contain that.

It is important to remember, these drug companies already sign contracts with the middlemen with long-term price predictability guarantees. So this is not an alien concept to the drug companies.

It exists as a commercial practice already. We would just get the benefit for our seniors and our taxpayers through this program.

And I am sorry, Senator, was there a second part to your question? I want to make sure I get that.

The CHAIRMAN. Senator Carper, before you repeat that second question—without taking time away from you—would not another way of saying it be, since we pay \$138 billion of taxpayers' money for Medicare drugs, that we would be just capping the subsidy that we give to pharmaceutical companies?

Secretary AZAR. Well, it does. And that is one of the really important innovations of the Grassley-Wyden package: it actually changes the dynamic. Right now, interestingly, the middlemen who run these drug plants have every incentive actually for the drug companies to jack up their list price because it raises the senior to what is called "the catastrophic phase" where the government pays most of the cost of that insurance through the reinsurance.

This would be fixed by Grassley-Wyden.

The CHAIRMAN. Senator Carper?

Senator CARPER. Thank you, Mr. Chairman. The second half of my question I do not think you got to was, do you think drug companies can continue to innovate under the Finance Committee's bill?

Secretary AZAR. Oh, absolutely. The changes here still leave plenty of room for profit margin, innovation, and investment. There would be no material impact in any way to the R&D enterprise in the United States, which we are all committed to.

Senator CARPER. All right. My colleagues hear me quote from time to time Matthew 25, which goes something like this: "When I was hungry, did you feed me? When I was naked, did you clothe me? When I was thirsty, did you give me to drink?"

It does not say anything about, when I desperately needed pharmaceuticals, it saved my life. It does not say anything about, did you provide that? But I think the intent is clear.

And sadly, with respect to the President's budget, the answer to these questions is, "not entirely," but too often, "no." A hundred million Americans have, as you have heard, as you know, 100 million of our fellow Americans have pre-existing conditions. These folks depend on you for protections and delivery of health care and the promise of affordable health insurance regardless of their health conditions.

The President has doubled down, though, on the Texas lawsuit against the ACA, and this budget contains no plans, as far as I can tell, to replace the ACA if the court strikes down the law, which will leave millions of additional Americans stranded without health insurance, Medicaid, and high prescription drug costs, all while cutting taxes for the wealthiest among us.

My question, Mr. Secretary: how will the President protect Americans with pre-existing conditions if the ACA is struck down in the courts?

Secretary AZAR. So the President has been very clear that he will never sign legislation that does not—that would replace the Affordable Care Act if it does not have adequate protections for those with pre-existing conditions.

It is important to remember, though, that even under the ACA there is a statement of protecting against pre-existing conditions, but let us say you are a two-person family making \$70,000 a year in Missouri. You are going to pay over \$30,000 a year for premiums, and you are going to have over \$10,000 out-of-pocket.

So I do think we have to not over-glamorize the current situation in terms of the protection of those with pre-existing conditions, because for those people, that insurance card is in some respects a meaningless protection for pre-existing conditions. And we want to work with Congress, if there is the opportunity to replace it with something that really would work for people.

Senator CARPER. My time has expired. Let me just conclude with this quick comment, if I could. My understanding is, if the ACA is struck down in the courts, the President will not have to sign anything. That will be it. And I want us to keep our minds and our eyes on that. Thank you.

The CHAIRMAN. Senator Menendez?

Senator MENENDEZ. Thank you, Mr. Chairman.

Mr. Secretary, you are a named defendant in *Texas vs. U.S.*, correct?

Secretary AZAR. Yes; I am one of them, yes.

Senator MENENDEZ. Is it true that this administration has taken the position that it will not defend the Affordable Care Act in court and supports striking down the entire law?

Secretary AZAR. The position of the Justice Department is that the individual mandate is unconstitutional, and that as a result the other provisions in it are not severable from that individual—

Senator MENENDEZ. So in essence, it would strike down the entire law, and the Justice Department is part of this administration, is it not?

Secretary AZAR. Yes. They represent the administration in the Federal courts, yes.

Senator MENENDEZ. So therefore it is the administration's view that the entire law of the Affordable Care Act should be struck down.

So if it is struck down, what is your immediate plan to replace it? If tomorrow the court decides that in fact the entire law is struck down—millions have health insurance who did not have it before. Many under Medicaid expansion have health insurance who did not have it before. Millions have protections against pre-existing conditions who did not have those protections before. Millions have no more lifetime cap or ceiling on the expenditures that they have, especially if they have a serious illness.

So what is the administration's plan? I have not seen it yet, and I think this committee has jurisdiction.

Secretary AZAR. So the litigation still has a very long way to proceed. The Fifth Circuit, as you know, has remanded the case to the District Court for a very searching, detailed analysis of every provision—

Senator MENENDEZ. Why are we going to wait? Why would you wait, with the health care of millions of Americans and their fate, to see what the court decides? It seems to me we have been hearing about killing Obamacare since it was created. There have been years to have your own version of what it is.

Why would you wait till there is a disaster to then deal with the millions of Americans who have health-care insurance? Do you see this young man? He is alive today because of the Affordable Care Act. And like him, millions in my State and across this country are alive because of it.

I do not know what you are waiting for. If you have a better idea, show us. But I have yet to see one plan that the administration has put forward for the health care of millions of Americans. What are you waiting for?

Secretary AZAR. We would wait until there is a final judgment by the final court of authority. In this case, it would obviously be the Supreme Court.

There is a very long process to go through to even see whether the statute is struck down, or even in part is struck down by the Supreme Court. These are hypotheticals at this point. We are faithfully administering the ACA now—

Senator MENENDEZ. Well, let me say, Mr. Secretary, these are hypotheticals that we do not play with. This is not some abstract consequence, if it happens—not an abstract consequence, if it happens.

Let me ask you this. The President's 2021 budget calls for zeroing out CDC funding for gun violence research. Did the NRA tell the administration to do this? Did you have influence from the NRA to zero out funding for gun violence research?

Secretary AZAR. I have no idea about any interactions there. I can tell you why we did not put that in the budget is, we have a tight budget. We have a 9-percent cut at HHS, because the caps, the discretionary caps for this year go from, I think, 7.5 percent in 2020 to a +1.05-percent or a 1-percent increase. In 2021, we are one of the—we are the largest non-Defense discretionary part. We absorb a disproportionate share of that.

And so we had to prioritize. I prioritized towards infectious disease, global—

Senator MENENDEZ. Well, if we did not have \$1.5 trillion in tax cuts unpaid for, driving huge debt, and we were not further plussing up the military beyond everything that has been done, you would have some money.

It seems to me that understanding the consequences of gun violence, how we get around it, would save lives here in the United States. One of the priorities of a government is to save its people.

Let me just ask you one final question in the less than a minute that I have. The Remain in Mexico policy misleadingly called "The Migrant Protection Protocol" has forced over 60,000 asylum seekers to wait in dangerous conditions in Mexico for their U.S. immigration court hearing. Over 800 cases of murder, rape, torture, kidnapping, and other violent assaults against asylum seekers returned to Mexico have been reported.

What mechanism or process is there in the Office of Refugee Resettlement used to identify and track children affected by the MPP? What does ORR systematically notify when an MPP-affected child is identified?

Secretary AZAR. Well, as you know, HHS and ORR have no role in determining eligibility for the MPP, which aliens are enrolled in that, or whether an alien is allowed to enter into the United States.

And if a child comes in unaccompanied, then it would follow the usual unaccompanied alien children program protocols. If a child returns with their family to Mexico as part of the MPP, that is not subject to the statute and ORR's jurisdiction.

Senator MENENDEZ. Yes, but to the part where the child is unaccompanied and ultimately is returned to family in Mexico, are you doing any tracking?

Secretary AZAR. If children are determined to be enrolled in the MPP and ORR and DHS determine the child's parents are in DHS custody, or if they return to Mexico and leave the child here, we collaborate to ensure that we can safely reunify the child.

DHS determines whether there is a criminal history that would preclude reuniting. We coordinate to—DHS informs ORR's intake teams that the child's referral is with a family enrolled in the MPP so that we try to keep track of everybody. If a child comes to us at the family's request, that they decide to return to Mexico and leave the child here, we work with DHS to keep them in contact, as we do with any child in our care, to make sure they are in telephonic contact with the parents as regularly as possible.

So we track that between them, whenever we receive a referral like that.

The CHAIRMAN. Senator Cardin?

Senator CARDIN. Thank you, Mr. Chairman, and thank you, Mr. Secretary, for your service.

I want to follow up on prescription drugs first, if I might. You talked about the middle-person, the pharmaceutical benefit manager, who is supposed to be there to protect the patients. In reality, they are not doing that.

We have a chance of really passing a prescription drug bill in this Congress. So I hope we can follow the leadership of our chairman and ranking member and get a bill to the finish line.

But I want to tell you one of my pet peeves. We are the wealthiest nation in the world. We spend by far the most on prescription drugs, and we have 200-plus common drugs that are in shortage in America. These are relatively inexpensive drugs, and they are critically important for care.

We are talking about newborn babies, the drops that they need. We are talking about bladder cancer patients who need the therapy drug that is not available for treatment. That is outrageous! No one is speaking out in regards to these necessary drugs being available to consumers in this country.

We need your help to make sure that we include this, so that we do look after the people in this country, and we recognize today that the pharmaceutical benefit managers are not protecting the patients of this country.

Secretary AZAR. Thank you, Senator. First, I am happy to talk about shortages. But I did want to give you a little bit of good news. You have been an advocate for many years of ensuring that CMS has a Chief Dental Officer. I am very pleased to announce that CMS is working through an interagency agreement with HRSA to bring onboard a Chief Dental Officer. So, thank you for your continued leadership there.

Senator CARDIN. Wonderful way to dodge my question, so—
[Laughter.]

Secretary AZAR. But thank you for your leadership. I completely share your passion around dental health and its central importance.

In terms of drug shortages, there are several legislative proposals in our budget that would help us better prevent or mitigate medical product shortages. One of them would enhance FDA's ability to assess critical manufacturing infrastructure so we could collect better and more accurate information about supply chain management.

We have—the FDA task force on drug shortages has three key recommendations, though. One of them is to create a shared understanding of the impact of the shortages and the contracting practices, particularly on generics, that may be contributing to them—sole-source procurements, low pricing, et cetera, that may be driving that.

We also want to create a rating system around manufacturing quality, so that we could actually perhaps have a race to the top in generic quality on these drug shortages.

And the third is to really promote sustainable private contracting practices. We have had a bit of a race to the bottom, I am afraid, in terms of generic procurements. And it has led to these types of sole-source generic providers.

Senator CARDIN. I think every one of those suggestions are what you need to do. But you can get congressional backup to what you are doing in legislation that is moving through here.

Help us create the legislative mandates so we do not have drug shortages in America, of particularly essential drugs that are not being produced solely because they are not as profitable as other drugs. No one would argue that the pharmaceutical community is not making enough money. So why should we not have these drugs available?

So let us look for a legislative backup. Your budget is really good on telehealth; I appreciate that very much. We have bipartisan support here to expand telehealth into Medicare. We need technical assistance from your agency so that we can give you, again, the legislative backup to expand telehealth services in this country. That is another area where I think we can work together and provide a permanent legislative basis to make sure we do not have drug shortages and expand telehealth. So I welcome your help.

I want to cover one other issue. Yes, I have heard your explanation on the Medicaid cut that you call just a reduction in growth. I can tell you that, in Maryland and in every State in the Nation, in poorer neighborhoods it is difficult to get providers to provide the access of care that we need.

And the block grant-type proposal you are making could very well lead to lower reimbursement rates for Medicaid patients, fewer services being provided, and less eligibility, which means there will be additional pressure for providers not locating in under-served communities.

I just urge you, as you look at this, to develop the accountability system to make sure that we are providing top care to all communities in this country. Because today, we are not meeting that goal, and I am afraid that if you turn Medicaid into a block-grant pro-

gram, you are going to find a much more difficult circumstance for under-served communities to have adequate health care.

Secretary AZAR. Yes.

Senator THUNE. Mr. Chairman, can you tell us what the plan is for the vote series, in terms of questions? Are we going to keep rolling?

Senator ROBERTS [presiding]. We are going to keep rolling.

Senator THUNE. Okay; I would like to submit questions for the record.

[The questions appear in the appendix.]

Senator ROBERTS. Senator Hassan?

Senator HASSAN. Thank you, Senator Roberts. And I want to thank the chairman and Ranking Member Wyden for having this hearing. And thank you, Secretary Azar, for being here today.

As others have noted, this committee has passed bipartisan legislation addressing the high cost of prescription drugs, and Senator Cassidy and I have been working with our colleagues on the HELP Committee to end the practice of surprise medical bills.

The administration's focus should be on working with us to get those bills across the finish line to bring relief to patients and families, not on cutting Medicare and Medicaid.

Secretary Azar, according to the Kaiser Family Foundation, nearly four in 10 adults with opioid use disorder receive their care through Medicaid. State Medicaid programs cover the cost of naloxone, medication-assisted treatment, residential rehabilitation, and out-patient therapy.

Simply put, Medicaid saves lives. Moreover, according to your department, quote, "The evidence is strong that treatment in managing substance use disorders provides substantial cost savings," close quote.

Secretary Azar, this is a woman named Ashley Raymond who lives in Enfield, NH. This is a picture of her with her husband and her two children. She started using opioids at age 14 and was unable to access treatment until getting coverage through Medicaid.

I met Ashley last year when I visited Dartmouth-Hitchcock Medical Center's Moms in Recovery program for pregnant or parenting moms grappling with substance use disorder, where Ashley is a client. Without Medicaid, she would be unable to afford her treatment or her prescription medication.

Mr. Secretary, your own department recognizes the savings both in lives and in Federal spending achieved through a strong, sustained investment in Medicaid funding for treatment and recovery. How does that square with a budget that would cut almost \$1 trillion from Medicaid?

Secretary AZAR. So, thank you. I hope that we will have your support for a new State option in the budget that would actually extend Medicaid coverage for pregnant women who are suffering from substance abuse disorder from 60 days to 1 year post-partum.

Senator HASSAN. But how does an almost \$1-trillion cut square with our understanding that Medicaid saves dollars and saves lives? Because according to the CBO, your proposed cuts would cause States to start the process of ending their Medicaid expansion programs, which would put 17 million Americans at risk of losing coverage, including 57,000 people in New Hampshire.

Your budget does not slow the Medicaid growth rate by addressing the rising cost of health care; it does so by cutting funding and eliminating access to coverage.

Secretary AZAR. So I may be incorrect, but I think the CBO analysis relates to previous budget proposals as opposed to this one, which is a broader allowance in the budget for us to work together with Congress to address how we can fix some of the perverse incentives in Medicaid that, for instance, have an incentive towards able-bodied adults in the system over pregnant women, aged, blind, disabled, and children of traditional Medicaid.

Senator HASSAN. Let me say this. I will follow up with you, but those proposals too essentially are cutting eligibility and keeping people away from health care, as opposed to looking at the rate of growth in health-care costs.

So let us move on to a second question. As others have mentioned, your administration continues to support efforts to repeal the Affordable Care Act, including backing the lawsuit that would strike down the law in its entirety.

The President claims that he wants to protect patients with pre-existing conditions. Yet, if the Affordable Care Act is repealed, health plans will once again be able to deny coverage to individuals struggling with substance use disorder.

Now, in response to Senator Carper and Senator Menendez, you said that those protections were somehow meaningless. I will tell you, to the people in my State who have pre-existing conditions who can now get health care and do not face bankruptcy if they get sick, this is not “meaningless,” and this is not “abstract.”

Can you point to specific policies in your budget that would explicitly protect, not just patients struggling with substance use disorder, which would become a pre-existing condition, but also pregnant women or people with diabetes or heart disease, from receiving a coverage denial based on what their plan could once again deem a pre-existing condition?

Are there specific elements in your budget that provide those protections?

Secretary AZAR. There would be no change to the Affordable Care Act that does not protect pre-existing conditions. So, even if at some remote date, in the remote possibility of the Supreme Court’s final decision around the Affordable Care Act, the President—he will not allow there to be any statute come out that—he will veto it if it does not have adequate protections for pre-existing conditions. That is stated in our budget.

Senator HASSAN. And we would be a lot further along in the process of strengthening this bill, strengthening our health-care system, if you all were not in court trying to tear it up. To echo what Senator Menendez said, you have had 3 years to come up with proposals.

I am out of time. I will follow up with you and your office about some of the recent settlements that we have seen, and things we can do to prevent adverse incentives in terms of electronic health records and misuse of them. Thank you.

Senator ROBERTS. Senator Cornyn?

Senator CORNYN. Thank you, Mr. Chairman. Thank you, Mr. Secretary, for doing an outstanding job, and please convey our ap-

preciation to the good folks at HHS who do the work day in and day out, which we very much appreciate.

So I guess I am going to take the bait. Many of our colleagues have talked about the lawsuit involving the constitutionality of the individual mandate in the Affordable Care Act. And as you correctly point out, it could be years before that litigation is finally concluded by the Supreme Court.

In the meantime, the leading candidate for the Democratic nomination for President of the United States is proposing to do away with all private health insurance, including the Affordable Care Act, and replace it with Medicare for All.

So if you are a member of a labor union and you have negotiated a good health-care coverage, you would be prohibited from keeping that coverage and everybody would be forced into Medicare, without having even paid the premiums over your lifetime to be able to help contribute to the cost of it.

What would be the consequence to our public health system in America if Medicare for All became the law of the land?

Secretary AZAR. Medicare for All would be devastating to America's seniors, and the American people. You know, right now America's seniors get a real benefit through Medicare, and that is what we call cross-subsidization. Basically Medicare underpays doctors and hospitals, and as a result, commercial insurance has to overpay providers just to keep them in business.

If we move to Medicare for All, or even things like Medicare options that rely on Medicare rates, that gig will be up for America's seniors. That benefit will be gone. And what it will cause is, like we see in other socialist and European systems, a two-tier system of health care—the better hospitals, the better doctors will flee from that system and go off the books. And so it will reduce access for America's seniors.

And as you said, it would take away what people like: 180 million Americans have private insurance through their employer or through their labor union. That would be stolen away from them. People want improvement in health care, but they like their settled expectations there. That is why the President's philosophy is to protect what works and make it better. Do not take away what works for people.

Senator CORNYN. Secretary Azar, talking about prescription drug reform and bringing down the cost to consumers and to the government, I supported the Finance Committee bill, the bipartisan Finance Committee bill, and look forward to continuing to work on that as well as other proposals. But we actually have a couple of bills that have made their way out of the Judiciary Committee with regard to patent gamesmanship, one that addresses the patent thicket problem where drug companies, for example, that make the drug Humira, have over 120 separate patents which block competitors and preclude lower prices for American consumers.

Meanwhile, in Europe there are five different competitors available for consumers in Europe. We have this bill that I have introduced with Senator Blumenthal that was voted unanimously out of the Senate Judiciary Committee. We have tried to bring it up on the floor several times, but the Democratic leader has objected to it and blocked it on multiple occasions, even though he admits it

is a good bill. He says it does not do as much as he wants to do, and I am willing to do more, but let us bank what we have in hand right now.

If the Senate were to pass it and it were to come to the President's desk, would the President—would you recommend to the President that he sign that into law?

Secretary AZAR. So, I do not know if we have a formal statement of administration position on that piece of legislation. I will have to check on it, and I will get back to you on that. But your leadership on ending these patent thickets is vital. We need to address them.

So the particulars on that statute, I want to get back to you on, but you are absolutely correct. Just one drug alone, the savings from biosimilar market entry would be billions of dollars of savings, but they layer patent upon patent upon patent, late-filed patents, manufacturing process patents, just added, added, added, extending beyond anything that one would have thought of as the original deal for intellectual property when the original products are approved. And it is what is stopping us from having a robust biosimilar market here in the United States.

We are approving historic levels of biosimilars, but they have to get to market. They have to be reimbursed. There has to be a financial incentive to use them.

Senator CORNYN. Mr. Secretary, the Medicaid Fiscal Accountability Regulation is a concern to my Governor, and to the State. We are worried—their stakeholders are worried that the rule, as proposed, could lead to hospital closures, problems of access to care, and threats to the safety net.

I would just ask for your commitment here to continue to work with us and stakeholders in my State and around the country to make sure these concerns are addressed. Would you make that commitment?

Secretary AZAR. Absolutely. We, with the MFAR rule—we will work with States to help them recreate their practices in ways that are in conformity with the statute and try to be fair and equitable in all of our dealings with States.

Senator ROBERTS. Senator Casey?

Senator CASEY. Thank you, Mr. Chairman.

Mr. Secretary, it is good to be with you again. Thank you for being here. I am holding a picture, as a lot of our colleagues have, of folks whom we represent. These are the children of Erin Gabriel. She is from Beaver County. You were born in Cambria County, about five counties away to the west.

The three children—and you may be able to see it from a distance, but I think you can see at least the outlines of the picture—the three children in here are Abby, who is in the wheelchair; Bridget; and Colin. Each one of these children—all three of them have autism. They all receive the benefit of Medicaid. Thank God for that.

Erin's children depicted in the picture represent, I think, why we have a Medicaid program. Here is what Erin Gabriel said to me, quote, "My children's health and lives are so much better because of the Medicaid services they receive, and they need to see their

doctors and specialists much less because they receive these services early.”

So their lives are much better. But because they got services early through Medicaid, they need to see their doctors and specialists much less.

When we debate either the new regulation that Senator Cornyn just referred to, which is the subject of a lot of debate and real concern, or whether we debate the budget cuts to Medicaid, I, and I know so many colleagues on both sides of the aisle, will be thinking about families like Erin’s.

I am also thinking about a part of my State that you are familiar with, and I think a lot of people are. I represent a State that has 67 counties, but 48 of them are rural. I can show you a map of the State, but when you look at most of the State, it is a State of rural counties. We have I think, at last count, the largest rural population of any State in the Nation. We have about 3.5 million people who live in rural Pennsylvania. Some States have a huge rural population, they just do not have as many people.

So when I think of rural Pennsylvania and rural America, we are of course thinking about rural hospitals. And you spoke to some of the concerns you have about rural communities.

I think about the jobs at those hospitals. In my State, in 25 to 30 counties, the first or second largest employer in the county is the hospital. And they are already operating under very tight margins.

We know that rural children use Medicaid and CHIP at a higher rate than urban kids. It is actually a fact. Forty-five percent of rural and small-town kids get their health care through Medicaid and CHIP.

Rural children were 29 percent more likely than urban kids to live in poverty. So if you are a child in a rural community, the Medicaid program takes on even greater significance than it does for other children. We know that in 2018, the uninsured rate for children actually went up for the first time, as Senator Wyden said, in a decade.

So those are concerns that we have. And then we read the details of this year’s budget, and the Medicaid cut is \$920 billion. And then you have the regulation that, not only Senator Cornyn’s Governor, but a lot of other Governors in a bipartisan way, have real concerns with. In fact, the NGA letter dated January 29th says, quote, “We’re concerned that the proposed rule, as drafted, would significantly curtail the longstanding flexibility States have to fund and pay for services in their Medicaid programs.”

So I ask you, on behalf of Erin Gabriel and lots of other families and the worries that they have that the Medicaid cuts will hurt their family, and the changes to Medicaid expansion, the 17 million who were covered by Medicaid expansion, many of them with an opioid or addiction problem, how do you—the number one question is—how do you justify those cuts? And number two, can you guarantee Erin Gabriel that her children will never lose their coverage under Medicaid as long as you are the Secretary of Health and Human Services?

Secretary AZAR. Well obviously, any changes to Medicaid are going to have to be done on a bipartisan basis, given the makeup

of both houses of Congress. And so these are proposals that we think actually fix some of the poor incentives for children in our system.

You know, the Medicaid expansion created a very perverse financial incentive for States to focus on able-bodied adults over the traditional children, aged, blind, disabled, and pregnant women in those programs. And so, part of our budget is a focus on actually, how do you restore the focus there and make sure Medicaid is there for them?

Senator CASEY. But just answer the question about the children. Will they lose coverage, those children with autism? Will they lose coverage?

Secretary AZAR. There is nothing in our budget that proposes to change the mandatory eligibility categories of traditional Medicaid.

Senator CASEY. I just hope you could at least guarantee the three kids with autism will never lose coverage as long as you have power.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Roberts?

Senator ROBERTS. Thank you very much, Mr. Chairman. Thanks for coming back.

Mr. Secretary, thanks for coming. I think you are doing a good job. It is an even-numbered year, so you get adjectives and adverbs that are a little tough from the other side of the aisle. Maybe here too. But I think you are doing a good job.

I have 105 counties, by the way, and there are about 6 that are not rural. And we have 82 critical access hospitals in Kansas, and we are facing difficult situations way out there. And you are proposing a new model to allow these hospitals to convert to what we call "an emergency facility" that does not maintain in-patient beds. And we have seen this type of proposal recommended by MedPAC and other groups in the past, but it is new to the budget this year.

And the budget proposes these newly converted hospitals be reimbursed at Medicare out-patient rates, plus an additional payment to assist with capital costs.

Now last year, along with the rest of the Kansas delegation, we sent a letter to you—well, not to you, but to CMS—requesting that the agency work with Kansas hospitals in developing a pilot program for this type of model. They were just in to see me yesterday. And I told them I was going to see you.

So I am going to ask you in their behalf and my behalf for an update on when we can expect to see a new model from the agency.

Secretary AZAR. So I—I am afraid I do not know the details on that Kansas model. I would be happy to ask the CMS Administrator—

Senator ROBERTS. Well, there are several models, and you are working on yours. I am just—can you give me a time frame of those 86—I would imagine there are 10 to 12 on the edge. If we could just get some certainty and predictability, that is really what I am asking for.

Secretary AZAR. So the big change, the one that I am very supportive of, and I know you have been supportive of, the one you mentioned around critical access hospitals, boosting payments and allowing them to focus as emergency hospitals and not have to sup-

port the in-patient beds if they are not financially viable to them, that would require legislation, not models. So that would actually—

Senator ROBERTS. I have a bill on it, and I think a bunch of people are on it just as well.

Let me move really quickly. The 96-hour rule. If there is anything that I think our rural health care delivery system folks out there do not care for, it is that. And that requires our critical access hospitals as well to have a physician certify in writing for each admission that the patient is expected to discharge or transfer within 96 hours.

On top of the requirement to keep patients' average length of stay to 96 hours or less, this is a very burdensome and redundant regulation that can force hospitals to transfer or turn away patients. That is being done. They could have been provided with high-quality care. I know of several situations that have happened when a person came in with a diagnosis that was not correct, not the fault of the folks there, just the way it happened. Obviously, they could not come back in until 3 days, even though the situation was very dramatic.

Can you explain the decision process to include this policy in the last two budgets, considering the proposal was not included in budget requests prior to last year? Last year's budget indicated that repealing the decision for certification requirement would have zero budget impact. This year the request states that the budget impact for this policy is just not available.

So if you could—you know, what happened in the last year that accounts for this change?

Secretary AZAR. I do not know the difference in modeling there, but thanks to your leadership, our budget does propose to get rid of that 96-hour rule. It has all the absurdities that you have talked about. And so, we are going to keep pushing.

We want to make sure that providers can spend more time with their patients instead of complying with unduly burdensome regulations. And one of them includes removing this 96-hour physician certification requirement. That is an excess burden. I think even as you describe it there, it causes people to tilt their head and say, you have to be able to predict before somebody can come in exactly how it is going to work?

So we want to keep working with you to get rid of that.

Senator ROBERTS. I really appreciate that. Thank you again for doing that good work.

And, Mr. Chairman, I yield back 30 seconds.

The CHAIRMAN. Before Senator Whitehouse asks his questions, for the staff of people who are not here, I need to know if there are people coming back. Because we have to let Secretary Azar go by 12:30 anyway, but between now and 12:30 there is no sense of keeping him here if people do not have questions.

Senator Whitehouse?

Senator WHITEHOUSE. Thank you very much.

Mr. Secretary, I want to raise with you a Rhode Island situation that continues to bedevil me. For a while Rhode Island has been in kind of a reimbursement hole, with lower reimbursement rates than nearby Connecticut and Massachusetts.

We were not a high-cost reimbursement area. We were already under-compensated. Then came October of 2018. In October of 2018, your CMS Administrator, Ms. Verma, unilaterally undid a rule, something called “the imputed rural floor,” which made our payment discrepancy to neighboring Connecticut and Massachusetts worse by 20 to 25 basis points.

She created this situation where, here in Rhode Island [pointing to a map], we have Westerly Hospital at a 1.05, roughly, reimbursement rate, and half an hour down the road, at Lawrence and Memorial Hospital in Connecticut, 1.3525. Do the math. What’s the difference between 1.05 and 1.35? It is a 30-damn-percent discrepancy.

And if you go over here to St. Anne’s Hospital in Massachusetts, which is literally 5 minutes from the Rhode Island border, they are at 1.28, compared to 1.03. Do the math. That is a 25-percent discrepancy.

And what we got told at the time is, “Do not worry, there is going to be this big reform that is going to smooth it all out.” I feel I was lied to. I do not think there has been any sign of this “reform.”

And then comes this budget. In this budget, not only is there no reform, there is a demonstration project, which is the kind of thing that gets put together in 5 minutes overnight when you do not have a real plan. And guess what the demonstration project has the nerve to say? That it is going to be the purpose—here is the language from your budget: “The demonstration aims to reduce sharp differences in the wage index and Medicare payments between nearby hospitals.”

Does that not mean that your organization knows, that Ms. Verma knows, that sharp differences in the wage index and Medicare payments between nearby hospitals are a bad thing?

Secretary AZAR. So, Senator, I share your anger and frustration about these disparities that are very—that are impossible to explain simply by geography.

Senator WHITEHOUSE. This one you created.

Secretary AZAR. In fact, I—I keep—I keep this chart, because I do—I do share that concern with you. The way they index—

Senator WHITEHOUSE. Be specific to my question. You do agree that sharp differences in the wage index and Medicare payments between nearby hospitals, your language, are a bad thing. And that is why you want to reduce them?

Secretary AZAR. I do agree.

Senator WHITEHOUSE. Great.

Secretary AZAR. I would like to work with Congress to get—

Senator WHITEHOUSE. Well, could you please get Ms. Verma to undo what she did over a year ago? She unilaterally made these sharp differences in the wage index and Medicare payments between nearby hospitals worse by a factor of 20 to 25 percent. And we were already under-reimbursed. Lifespan Hospital reports a \$25-million loss in the last fiscal year because of the decision that she made.

You can go to other hospitals with similar patient mixes around the country, and they would be making money because of the way in which they are reimbursed. We had our reimbursement hole uni-

laterally dug deeper by 20 to 30 percent by your CMS Administrator. We were not told the truth about what was going on at CMS. We now have this bogus demonstration project coming out of no place, as best we can tell, that admits that it is wrong to be doing just what she did.

This is a real consequence for our hospitals. They are in real pain as a result of this. And it is tiresome to no end that your bureaucracy just sits around doing nothing about this, making it worse, actually making a problem that you identify as a purpose to solve, deliberately and unilaterally worse.

Secretary AZAR. And I—Senator, thank you. I just—I do want to say neither of us, the Administrator or myself, has the unilateral control over regulations on these policies. But—

Senator WHITEHOUSE. You did this one. She did. She did it.

Secretary AZAR. Even within the administration, none of us has the unilateral control. And the challenge with the wage index—and you and I, we have had such a good partnership, you and I, I enjoy working—

Senator WHITEHOUSE. I do not blame you. I blame her. I want you to fix it.

The CHAIRMAN. Senator Cassidy?

Senator CASSIDY. Hello, Mr. Secretary. How are you?

The antibiotic market is your wheelhouse as a person very familiar with the challenges in the pharmaceutical industry. We have these very resistant organisms, and you want to have an antibiotic that covers them, but you are going to use it on very few people. And most of the people whom you use it on are either on Medicare or Medicaid. If you throw in VA, it is going to be probably at least two-thirds, maybe four-fifths public payers.

One idea has been to carve out these extraordinarily important but rarely used antibiotics from the DRG and to put them into Medicare Part B, but making sure you had the accountability associated with the stewardship program.

Knowing that we may end up saving money if you have a shorter hospital stay—and of course lives if you have a more effective antibiotic—any thoughts about that? And maybe you cannot be official, but just because of your expertise?

Secretary AZAR. No, you actually put your finger on exactly the problem with antimicrobial resistance in the next generation antibiotics that we are developing, and it is something that I am actually wrestling with with our team right now.

We have essentially a market failure, as you describe it so rightly. We want drug companies to invent an antibiotic that will not get used.

Senator CASSIDY. Yes.

Secretary AZAR. That is an economic problem. So I am looking at different approaches. One of them could be—

Senator CASSIDY. More properly, it will be used rarely and appropriately.

Secretary AZAR. Exactly, as opposed to broadly. One approach could be around our payment policies, as you mentioned—direct pass-through payments. We—I will look at that. The other is, it is increasingly resembling our bioterrorism countermeasures pro-

grams where the government basically is the only purchaser for value of certain products.

Senator CASSIDY. Yes.

Secretary AZAR. It is almost a stockpiling, government purchase issue. I have actually commissioned work to look at this. We have tools to deal with market failures, and we need to look at how those tools could be used here for AMR.

Senator CASSIDY. And I will say that there is at least one antibiotic that the United States taxpayer invested hundreds of millions of dollars into the development of, and it was sold for like \$16 million to a company from India because the business model did not work. As you say, it is very expensive to develop but rarely used.

Secretary AZAR. Right. We have to ensure that there is either a commercial marketplace that is viable to sustain these, or a government market that will make them sustainable.

Senator CASSIDY. Now, you just said something which of course perks my ear up, that you are actually working perhaps on a solution regarding this. Now would this solution be in the offing? At what stage is this work?

Secretary AZAR. So it is still foundational, so I would love to hear your ideas, and we could work together offline about that. I have my teams working on this. I have identified with some of the recent things you've seen in *The Wall Street Journal*, some of the recent challenges of manufacturers of these novel products, and them even not surviving necessarily. And it is an economic problem.

Senator CASSIDY. And we will make an appointment to bring some ideas in to you, if you do not mind.

Secretary AZAR. Thank you. Thank you.

Senator CASSIDY. Next, another issue I am interested in is the mentally ill. Currently they lose their Medicaid when they go into a jail setting. And so, even before they are adjudicated, they lose their Medicaid. Now if they are on a mood stabilizer, for example, that works for them but is not on the jail formulary, they may get either not placed on something, or placed on something inadequate, and then they decompensate, and their behavior worsens, or when they are released they are now kind of wandering on the streets as opposed to holding a job and paying taxes.

I think the budget—the administration's budget allows them to continue coverage for 6 months while in jail, but I would ask, since the definition of a jail is that you stay there until you are adjudicated, basically, and that can be up to a year, why not extend it for an entire year? And if not for the entirety of the Medicaid coverage of care, at least for the mental health issue? I think that would go a long way to addressing the revolving door of the mentally ill going in and out of jail with disruption of care.

Any thoughts on that?

Secretary AZAR. So it is an important question. We were able to get in the budget this year this prohibition of States terminating Medicaid coverage for the first 6 months of incarceration and requiring that process to facilitate the enrollment on release, so that we can avoid relapse and other health crises. So we got that far.

But you raise an important issue about whether one should go further. I am happy to work with you on that. I share the concern

around serious mental illness and incarceration, and that transition, that handoff, both in the incarceration as well as the handoff from incarceration out to community integration.

Senator CASSIDY. Yes. There is at least some suggested data out of Los Angeles that the mentally ill are cycling through jails. And to the degree that we stabilize that, I think, is the degree to which we begin to fundamentally address the issue of homelessness.

I yield back, and thank you.

The CHAIRMAN. Senator Warner?

Senator WARNER. Mr. Chairman, Mr. Secretary, great to see you.

I am going to start on a question that has already been asked, but I want to give a slightly different frame on that, and that is the Medicaid Fiscal Accountability Regulation. Let me acknowledge on the front end, I get the goals of transparency, and I get the goals also that perhaps not everybody comes with fully clean hands. This has been a challenge that has been going on for some time.

In Virginia, where we finally expanded Medicaid a year ago, we have 375,000 people who have gained access to health care—critically, critically important. I absolutely agree with the bipartisan letter of the National Governors and the former Governor, myself.

I really want to make sure—you said you will work with the States. But, as you are probably aware, all States are going through the budgeting process right now. And the way I read this regulation is, it could potentially come out sometime later this year and dramatically affect Medicaid eligibility and the payment plans that are in place.

And that will wreak havoc in budgets, red States and blue States, all across the country. So I hope that you will also commit to working to make sure that we work with the States, but we do so to make sure that we limit the impact. Because this regulation will not be, I do not think, finished by the time most States have actually put forward their budget—and they are actually a little bit better than we are in terms of meeting their deadlines. They will mostly be done by mid- to late-spring.

Secretary AZAR. Yes. So we understand the changes that would be implicated here. I want to be fair and equitable, and we understand also the budget cycles of States and commit to working with the States to be reasonable in our approaches.

You know, not every State has these improper intergovernmental transfers. Some of this is transparency to even identify what is going on to make sure real money is being spent in the program. And we will work with States also to help them design ones that are compliant. In the future, we are going to try to be very reasonable. These are our partners in this program. We are in this together. We are not trying to cut Medicaid through the MFAR regulation. It is just to try to make sure it is the right kind of spending.

Senator WARNER. There are—having visited with some of the Governors—there are grave concerns, candidly, that that is part of the role of the administration, and I hear this from both Democratic and Republican Governors. And I think it is reflected a little bit in the President's budget.

So I hope you will—you know I am going to be following this very, very closely. And if there is a new systemic approach to this that allows everybody to bring a little cleaner hands, I get it.

Let me move in my 2 minutes left to your interoperability rule. I think we talked about this at one point. I think one of the grave mistakes—again, when there was large bipartisan agreement, the one piece around Obamacare was, you know, we need to move to EHR. We need to make sure we have better use of the data. And one of, I think, the major mistakes that we did make is, we spent all that money without any interoperability. My background was in cellphones. We would have never had a wireless industry in America if we had not required interoperability between systems.

So I support the effort. But we have also seen, in the years since it has been put in place, the privacy, cybersecurity concerns, the vulnerabilities of this approach that we have really got to be thoughtful about. And I, frankly, do not believe—you know, I took great exception to your CMS Administrator who said that, you know, technology companies are doing a good job of protecting this information.

I do not think that they are. It is not just the Equifaxes of the world that are grossly screwing up. And I think we have seen lots and lots of history amongst the health-care providers.

So I want to make sure you move forward with this ruling, but I also want to make sure that consumers have rights, for example, to delete information, to have privacy protections. How do we make sure, in this last 30 seconds—this is a much longer question, and I have other questions for the record on this topic—that we get this right and that we do not—I agree with you, we are getting to the goal of interoperability, but I am really concerned that we are not taking the cyber and privacy protections fully into consideration.

Secretary AZAR. So first, thank you for creating the cybersecurity caucus. If you would ever like to come see our cyber work, we would be very happy to host you with that.

Senator WARNER. One thing I should say is, we have had contact with almost all the health-care systems, and you would be amazed at how they will acknowledge—and we will share with the Department—how unprepared they are.

Secretary AZAR. For hospital and other health-care CEOs, I think cybersecurity is probably the number one risk management issue for them.

In the interoperability rules, we absolutely hear you. And we want to make sure the patients at the center of consenting to disclosure, interoperability use, transfer of their information—that is actually core to everything we are doing, is patient ownership of their information and that transfer, consenting to that.

So as we work on final rules on interoperability and information blocking, that kind of protection and patient ownership is the centerpiece of what we are trying to work towards.

Senator WARNER. My time is up. I just want to simply say, we want to work with you on that, because I think there are some very mixed signals coming from the administration.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Brown?

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

Colorectal cancer is the second leading cause of cancer death among men and women combined in the U.S. On top of that, the American Cancer Society estimates there will be more than 100,000 new cases of colon cancer diagnosed just this year.

The good news is, we can prevent or treat it successfully if we catch it early enough. Thanks to the ACA, colorectal cancer screenings are considered a preventive service, and as a result, they are available at no cost, no co-pay, no deductible—another thing that is important in the Affordable Care Act, in spite of your boss's efforts to repeal it.

Unfortunately, due to a glitch in the law, if you are a Medicare beneficiary and you get that cancer screening—I know you know this issue well—and polyps are removed to prevent the potential for cancer, you wake up with a hefty co-pay.

It does not make sense. It discourages folks from getting the life-saving screenings. I say all this because I am thankful the President's budget includes my legislative proposal to eliminate the unexpected out-of-pocket costs some beneficiaries experience when they get the screening. My bill, Removing Barriers to Colorectal Cancer Screening Act, ensures that preventive colorectal cancer screenings are fully covered by waiving the Medicare cost-sharing requirements for preventive colonoscopies, even if a polyp or tissue is removed.

My legislation has 61 co-sponsors—obviously, a lot on each side; 339 supporters on the House side. I would like to ask publicly, Mr. Secretary, for your commitment to working with me and with the chairman and Ranking Member Wyden in getting this done.

Secretary AZAR. Well, absolutely. You know—and I wanted to thank you, Senator. You were the one who brought this real anomaly in the statute to my attention. It is really absurd that a senior goes in for a colonoscopy expecting to have no co-pay, and if they happen to find a polyp—which is exactly what we are screening for—they come out of anesthesia and they get a bill, because then it is converted from a screening into a procedure.

So you raised this to my attention, and I have worked to champion that. I am just so delighted it is in the budget, and we are going to work with you to get this passed.

Senator BROWN. Good. And I thank Chairman Grassley and Senator Wyden for their interest too.

Two other issues, really quickly. At last year's budget hearing, I asked you to commit to a number of things related to FDA efforts to curb e-cigarette use. When I asked if you would, quote, "commit to reducing nicotine in cigarettes to nonaddictive levels," you answered, and I quote, "Absolutely. That is the nicotine rule we will be working on." You went on to say you would be driving forward with the effort to restrict flavors in e-cigarettes "with full vigor"—your words—that you would not hesitate to take, again your words, "more aggressive action if necessary to curb youth use."

Despite these strong commitments, HHS dropped its nicotine reduction proposal from the Unified Agenda. HHS also backtracked on its promise to remove all non-tobacco-flavored e-cigarettes from the market.

The final guidance, instead, released last month exempted disposable flavored vaping products and flavored e-liquids. Thousands of flavors of e-liquids, e-cigarettes remain on the shelves. The huge progress we made for 50 years, bipartisanly, is in jeopardy because of that.

Just, if you would, please tell me why has the Department decided to cave to the industry and political pressures and stepped back from those efforts?

Secretary AZAR. So actually, on the e-cigarettes and flavored e-cigarettes, where we ended up was at an even more aggressive posture than when we spoke last year about this issue, actually requiring that those child-friendly and child-used flavors come off the market pending PMTA authorization.

So we actually advanced to a more aggressive posture than even when we spoke before. Because at the time, Commissioner Gottlieb had only been speaking about site-of-sale restrictions there.

So I want to be very aggressive on this one. February 6th, the enforcement date, has hit us. In terms of disposable flavored cigarettes, if we see utilization there in disposables, a shift into that—we had seen really the pod-based items with the replaceable charge driving this. If we see movement there, we will certainly take enforcement action. Nothing has to be set in stone in terms of our enforcement policies here.

We want to keep these away from kids, even as we try to make the other products available for adults to move off combustibles.

Senator BROWN. Well, I appreciate your answer, and I do believe you are sincere and genuine. I also believe there is a White House that on Thursdays and Fridays looks like a retreat for tobacco executives. But I am so concerned about the flavored disposable products that are out there on the shelves, and you need to do better, and we need to do better.

The last point, Mr. Chairman, quickly. The President's budget recommends a cut of more than 9 percent to HHS. You can claim the budget prioritized spending on direct services, but the primary payer of direct services is Medicaid. The budget cuts more than \$900 billion from this essential program, contrary to a presidential promise in his campaign.

Whether it is the flu, addiction, coronavirus, or another public health threat that we do not even know about yet, Medicaid is the most important tool States have to prepare for the inevitable and ensure that people get care.

You may also try to argue that the budget is not for proposed cuts to Medicaid, but instead to slow the growth rate. That does not mean much to the hundreds of thousands of Ohioans who get left out.

Cutting Medicaid by hundreds of billions of dollars will cause hundreds of thousands, maybe millions of people to lose health care.

I remember chapter and verse working with Governor Kasich, a Republican in my State, to expand Medicaid. That meant so much for our State. The President claims to care about protecting pre-existing conditions. His support of the ACA repeal lawsuit, combined with his health-care vision in this budget proposal to slash

Medicaid, all to pay for huge tax cuts for the wealthy, just does not work for public health in our country.

Secretary AZAR. Well again, I just want—as we close, I just wanted to thank you for your support and work on the colorectal cancer issue. I just think that is going to be a huge event for patients if we can get this passed out of Congress.

Senator BROWN. I guess that means you do not want to say much about—

Secretary AZAR. To talk about Medicaid, on the Medicaid program, as you—we are reducing the rate of growth from 5.3 percent to 3.1 percent. In every single year of the budget outlook, Medicaid will increase its expenditures. And what we tried to do was, we set an allowance there to work with Congress together on how we can grant flexibility to States related to expansion populations of able-bodied adults, how we can control the rates of growth there, and how we can also fix the perverse incentive where we favor able-bodied adult coverage over kids and pregnant women, and aged, blind, and disabled—the traditional Medicaid beneficiaries that we now actually prejudice against in the system.

So that is sort of at the heart—

Senator BROWN. And the last statement, Mr. Chairman. Would you, the next time you are at a Cabinet meeting, or the next time you see the President—I do not know if he knows he is lying about this, or if he is just used to doing it, but would you correct him when he says he is supporting the consumer protections for pre-existing conditions? Because he is trying to take them away with the Texas lawsuit.

He tried to take them away legislatively here. And I assume it will not change him. He will still go on the campaign trail and talk about how he supports pre-existing conditions, but if somebody of your stature tells him he is lying, maybe that would be helpful.

The CHAIRMAN. Senator Hassan, you have one question, I was told.

Senator HASSAN. Yes, sir. Thank you.

The CHAIRMAN. And then we have to have members speak, other staff speak up here, because we are going to adjourn this meeting. I have to go vote too. Go ahead.

Senator HASSAN. And so do I. And, Secretary Azar, thank you again for being here.

One note: we are already hearing from pediatricians in New Hampshire that 1 week after the ban on pods, flavored pods, teenagers are already migrating to the disposables. They discovered they are cheaper in the bargain.

So it has taken 1 week for teenage behavior to begin to change, and they are still using these devices, and the harm is still happening. So I would like to follow up with you on that.

But the question I had was about transparency and recent anti-kickback settlements, because I think it is something we could work on together.

The Department of Justice recently announced a settlement with an electronic health records vendor that was paid by Purdue Pharma to display inaccurate data to providers so that they would unknowingly over-prescribe Oxycontin.

Patients and providers have to be able to rely on electronic health records as a source of accurate clinical information. What steps are you taking to keep this kind of misbehavior, to put it lightly, this illegal behavior from happening again?

Secretary AZAR. So, I just want to make sure I am understanding this, because I am not familiar with the particular aspects of litigation. Is this an issue where a drug company got basically in the electronic medical record, essentially an edit in there that coached towards a certain product?

Senator HASSAN. Well, no. It prompted physicians to prescribe an opioid again to a patient when the patient might not otherwise have needed it. So they were overprescribing, and the prompt was essentially paid for by Purdue to the electronic records.

Secretary AZAR. I would like to get back to you, if I could, on this one to make sure that I am correct. But I believe we have actually had efforts working with the major EMR vendors—Epic, et cetera, Cerner—to try to get them to actually put the non-opioids at the top of the list in terms of pain medication, so it is not right there.

But I am happy to—

Senator HASSAN. And this is really about the integrity of electronic health records. We have to be able to depend on them. Doctors do too.

There was a second settlement which goes to some of the same issues, about making sure that we are policing the drug companies correctly. A second settlement announced in January—a nonprofit co-pay assistance program was found to have taken money from the drug company Insys for the sole purpose of paying Medicare co-pays for their fentanyl-based pain medication. Of particular concern, this nonprofit knowingly facilitated access to this highly dangerous drug for off-label use.

We have seen an increasing number of these settlements in recent years as drug companies become more sophisticated in their efforts to drive over-utilization. One way to protect beneficiaries and save taxpayer dollars is to leverage transparency in order to identify these illegal relationships before they can take hold in the Medicare program.

So does your department collect data on payments from drug companies to nonprofit co-pay assistance programs, or payments to electronic health record vendors, that could help identify this costly and dangerous behavior in real time?

The CHAIRMAN. Can you give a short answer to that?

Senator HASSAN. I appreciate that, Mr. Chairman.

Secretary AZAR. I do not know for sure what level of disclosure there is. Let me check and get back to you on whether they submit that to Medicare and Medicaid on the price reporting. It may be in that context.

Senator HASSAN. All right; I would love to work more with you on it. Thank you.

And thank you for your indulgence, Mr. Chair.

The CHAIRMAN. Senator Daines?

Senator DAINES. Secretary Azar, thank you for being here today.

Like many of my colleagues, I hear from seniors across my home State of Montana who are struggling with high out-of-pocket costs when it comes to their prescription drugs. And that is why I am

working across the aisle of this committee to lower the cost of prescription drugs and establish an out-of-pocket maximum in Medicare Part D in order to provide Montana's seniors with some badly needed relief.

I am glad the administration voices support for such a proposal in the President's budget. My question, Mr. Secretary, is: can you explain how an out-of-pocket cap would affect the average senior in Montana?

Secretary AZAR. Thank you, Senator. And thank you for being willing to be part of this bipartisan effort on drug prices.

Let me give you a made-up example—because I do not have Betty's actual name—but let us say there is a Betty in Helena who uses a drug called Revlimid. This is used to treat multiple myeloma. Under the current Medicare Part D benefit, she would have to pay \$6,350 before she would hit what is called the "catastrophic cap" in Medicare Part D.

Once she hits that cap, after over \$6,000, she is going to pay 5 percent on all drug costs after that point, to infinity. That can add up to a lot when you are talking about these kind of expensive therapies.

Now, those costs also would be front-loaded in the benefit year. So she is going to pay more when she is in deductible and the doughnut hole period. She would likely move quickly through that deductible period and get to the catastrophic, that 5 percent.

Now in the plan, the Grassley-Wyden legislation out of this committee that you have supported, that is going to provide two important benefits to her.

First, because of the savings we get from the inflation penalty cap, we create a new catastrophic cap at \$3,100. And at that point, it is a complete cap. She will never pay again for drug expense during that year.

In addition, a critical innovation that has been made is to allow her the option of spreading that catastrophic cap over a 12-month period. She could elect to never pay more than \$258 a month for her drugs, no matter what her drug expense is. It is an incredible out-of-pocket change for the American senior, if we can do this.

Senator DAINES. Thank you. It is a great example, and it is an important policy that I am going to continue to advocate for, certainly in this committee and getting the vote here on the floor of the U.S. Senate.

I want to shift gears and talk about meth for a moment. Many States have been hit hard by the opioid epidemic, but in Montana we are facing a meth crisis. That is why it has been one of my top priorities in Congress to ensure that our communities, our families, Indian reservations, law enforcement, have the resources they need to help combat meth use.

In fact, I had the Vice President—the Vice President and Karen Pence came out to Montana in June to see firsthand what is going on when we visited Billings.

Efforts include, in States like Montana—we need to make sure we target these available resources where they are needed to prevent drug overdoses. In fact, I am pleased the President's budget increases funding for State opioid response programs and allows

States to use these funds to address the abuse of meth in addition to, of course, discouragement of opioids.

My question, Mr. Secretary, is: can you speak to the importance of allowing States and tribes to address their unique community needs when it comes to combating substance abuse and drug overdoses?

Secretary AZAR. Absolutely, Senator. As you said, each State is going to be different. Some are facing more of an opioid problem, and some are increasingly facing a meth problem. In 15 of the 36 States that report overdose deaths by drug type, meth use is responsible for more deaths than synthetic opioids even.

Between 2017 and 2018, we have seen a 30-percent rise in deaths from methamphetamine. So as you say, it is a very big issue. These gangs out of Mexico that brought us so much of the opioid crisis, as we have pressured them down on the opioids, they have expanded into commercial-grade and commercial-scale production and importation of methamphetamine.

So I was delighted when Congress, in the 2020 appropriation, allowed State opioid response grant money to be used by States also for stimulant methamphetamines. We have continued that policy recommendation in our budget for this year, that flexibility for States to address meth, to hopefully keep it from being the fourth wave of the addiction crisis.

Senator DAINES. And, Secretary Azar, in the time I have remaining, I want to thank you also for calling out the Mexican cartels. This is the shift that we are seeing in my home State of Montana. We are a northern border State with a southern border crisis.

And that is, once upon a time the home-grown meth had purities in the 20-, 30-percent range. This Mexican cartel meth, as you know, has purities north of 95 percent. So it is far more potent. Price has gone down. Distribution has increased. And this is why this is the battle that we have to fight right now back home as it relates to meth.

And thank you for your help in that effort. I am out of time, and I believe, Senator Lankford, you are up next.

Senator LANKFORD. Okay; thank you.

Secretary Azar, thank you for being here. Thanks for all the work. You have done a lot of work to be able to help folks have opportunities to get greater health care and greater health-care options. I appreciate that very much.

I want to bring up something that is new that you proposed, that my State actually was first in line to be able to engage in, and that is the Healthy Adult Opportunity initiative, to be able to allow greater flexibility on Medicaid so they can tailor it.

Oklahoma is not the same as Alaska. It is not the same as Illinois. It is not the same as New York. And so, allowing some greater flexibility—so where does that stand at this point for the Healthy Adult Opportunity initiative?

Secretary AZAR. So we have put the guidance out to the States and are now really open to working with States. I think it is very important to remember, because a lot has been said about this opportunity for States to apply for this flexibility, this would preserve—the insurance would have to cover essential health benefits. No individual would be deemed ineligible. The eligibility require-

ments for the Medicaid expansion under the Affordable Care Act would remain. There would not be other partial expansion or partial de-expansion.

So this really would be for States to come up with ways in which they can provide a more integrated approach for these able-bodied adults. This is the expansion population, not traditional Medicaid that is subject to this—and again, only if the State wishes to be doing this.

Senator LANKFORD. Right. Somebody in my State is currently exploring being able to go through that process.

You have also put out some proposals on Part D generic tiering to allow, basically, a secondary preferred specialty tier for drugs to try to get better benefits out there.

If there is any recommendation I can make on that, it is that we continue to be able to lean in on that, and to be able to target generics and biosimilars to be able to make sure it is not just a benefit across the board, but it is really a benefit to those folks who are the consumers, who are the purchasers.

Where does that rule stand at this point? And what are your thoughts on that?

Secretary AZAR. So we have proposed that, as part of the Part D regulations, to allow the drug plans to have this second tier for specialty drugs. Those are the more expensive drugs—

Senator LANKFORD. Right.

Secretary AZAR. The specialty tier right now may be around \$660 a month that triggers that. Right now, the regulations actually somewhat disable the insurance companies from negotiating bigger discounts from pharma because it has just the one tier.

This proposal would allow there to be a more favorable tier—so not more restrictive for patient access, but a more favorable one to entice drug companies to give even more discounts in order to secure access to that tier. And it would lower cost-sharing for the patient.

Senator LANKFORD. It is one of the things that several of us on this committee are working through right now to provide multiple tiers and some other options for that, and block some of the companies that are preventing drugs from going on the generic tier and pushing them onto the higher-priced tier. That is something we are trying to work out legislatively.

Several of us have mentioned things about the rural hospital relief. My State has seen seven rural hospitals that have closed of late. This is a big issue. Senator Durbin and I are actually working on some legislation dealing with critical access hospitals, and getting greater flexibility there.

I know you are also, in a regulation, trying to deal with that as well, to allow them to be out-patient, emergency hospital access, and that critical access. Where does that stand at this point?

Secretary AZAR. So I am actually very happy that it is in the President's budget this year to have Congress authorize us to allow that kind of flexibility so that a critical access hospital could have emergency function, out-patient, but not be subject to all the requirements of in-patient.

In addition, the budget proposes that we would have enhanced payments for those critical access hospitals that would elect for

emergency, so they could be reimbursed at the regular emergency rate as well as a supplemental amount of payment for them.

Senator LANKFORD. Right. Well, we look forward to getting a chance to be able to walk through that, because that will be very important for all of us in rural States. And Senator Durbin and I will continue on with our legislation, trying to be able to solve this legislatively long-term.

The University of Vermont Medical Center made a decision to have a nurse during an elective abortion be forced against her conscience to be able to participate in the abortion, even though there were other nurses who were available and willing to do it. She was compelled to participate, that against her conscience.

Your team has reached out to the University of Vermont Medical Center and has made requests of them to be able to find out where they are, what their standards are. It has been months on that.

Has there been a response back in that process?

Secretary AZAR. So as you know, we—with any of these cases in our Office for Civil Rights, we try to actually work towards resolutions that bring them into compliance.

The University of Vermont Medical Center refused to work with us on that. And, reluctantly, we had to issue a Notice of Violation in order to try to get their attention. Where things stand now—because that is a law enforcement matter, I could not go into detail about the back-and-forth on that. But the critical issue is, we try to work with providers so that they commit to bring themselves into compliance.

Senator LANKFORD. Right. Well, we will continue to watch for that and to see what we can do.

One last quick question is dealing with nicotine levels in vaping. There is not a standard level of nicotine. Obviously, several of the vaping devices choose to have very, very high levels of nicotine, which they know is the most addictive portion of this. The scenario that we have raised to FDA before, the year before, is to ask, is there a way to get a standard for nicotine so that these devices do not intentionally load them up with high levels of nicotine to increase addiction?

Where does that stand?

Secretary AZAR. So there is not a regulation under the PMTA. That is the authorization process for e-cigarettes that we have for novel tobacco products, a regulation setting a nicotine level. But in the course now of the May 2020 deadline that the court has set for these e-cigarettes to come in and apply for approval or authorization under the PMTA, looking at appropriate nicotine levels will be one of the factors that we can examine at FDA in determining if an e-cigarette's entry into the marketplace is supportive of furtherance of the public health.

So that would be one of the criteria that we can look at for the nicotine level.

Senator DAINES [presiding]. Senator Cortez Masto?

Senator CORTEZ MASTO. Thank you.

Secretary Azar, thank you for being here; so appreciated. Like my colleagues, many of us are concerned about the cuts to Medicaid. Similar to what I have heard earlier, in the State of Nevada

we are one of the States that, thanks to the Affordable Care Act, was able to expand Medicaid.

And many, like this young gentleman here—Alex Cambaris, who is 28 years old—are alive today because of Medicaid. My concerns are similar to what you have heard from my colleagues.

One, why are we making these cuts to Medicaid? Most importantly, why are we pitting vulnerable groups against one another? And how can you make those decisions to decide what life to save and what life not to save? Those are the concerns you are hearing from us to this administration.

But let me take this even further. I am also concerned about what I have seen happening in Indian country. And let me put this on your radar, because I know there is some good work that is being done, but I do not think people appreciate the impact that the ACA has had on Indian country.

The law designates IHS as the payer of last resort, helping stretch those dollars further. Medicaid expansion, the premium tax credits, have boosted coverage and care quality and enabled IHS to collect reimbursements that have allowed them to hire more providers and specialists. It has helped them to ensure that their facilities meet all required standards, including those required for ongoing accreditation, or to undertake any needed maintenance such as repairing roofs and heating systems.

The reality is that we know, right now in a court of law, this administration is trying to repeal and take away the Affordable Care Act, including coverage for pre-existing conditions. That is the law. That is what is happening. That is reality. It is not conceptual; it is reality.

And if that happens, I guess my question to you is: what happens to Indian country? How do we address their needs if we take away the Affordable Care Act? If we take away coverage, what are we going to do to help them move forward and continue to have access to care?

Secretary AZAR. So again, in terms of the litigation position, this has now been sent back to the District Court for a searching analysis, provision by provision. This is going to take a considerable time, go back to the Fifth Circuit, and then maybe the Supreme Court eventually. So this is a rather remote item.

And this point—

Senator CORTEZ MASTO. Well actually, let me stop you there, because I am an attorney. I was an Attorney General for 8 years. I know what litigation is about. And when you go into litigation, you are setting forth your values and your principles as part of that litigation.

So this administration has clearly said they think it is unconstitutional, and they want to take away the Affordable Care Act and pre-existing conditions, no matter how long it takes through that course of litigation.

You cannot sit here and tell me today that the administration's position is that they support the Affordable Care Act and they want to keep that coverage and pre-existing conditions. So do not try to walk around it somehow by saying this is going to be prolonged, so we do not care—it does not really matter right now.

It does matter. That is what this administration values, and it sets it out. And the American public needs to know that. So please do not start with that.

My concern is, if it is taken away right now—let us assume there is a ruling and it is taken away; what are we doing for Indian country?

Secretary AZAR. It is not going to be taken away right now. That cannot happen. And unless you decide to work with us on reforming or—

Senator CORTEZ MASTO. So I get that. So tell me, if it is taken—listen, let us speculate. Hypothetical. If it is taken away, what do we do for Indian country? What is the Plan B?

Secretary AZAR. So this administration actually has had historic funding for Indian country and Indian Health Service. So we have actually increased the budget by 10 percent since fiscal year 2018. We have an additional 3 percent in 2021.

We are making critical investments in the Indian Health Service. We have put \$85 million in this budget into quality improvement programs. We actually have created the first-ever quality office within IHS trying to bring better outcomes.

What I am trying to drive is—and I hope we will get Admiral Weahkee confirmed as our IHS Director—I want to bring a complete quality, safety, cultural transformation within the Indian Health Service. We owe this to Indian country to deliver the finest quality service to our beneficiaries there, and it is not just about getting various facilities to meet their CMS certification, which of course is a baseline, but it is actually, rather, quality that is ingrained in the culture and every aspect of what we do in the organization.

That is a part of what we are doing in our budget, but also, what Admiral Weahkee will bring, I hope, if confirmed as the IHS Director.

Senator CORTEZ MASTO. Good. Because I agree with you, and I have had conversations with the nominee. I think he is the perfect person for the job, and I think we have to work together to really address the needs of Indian country.

So I am glad to hear you say that, and I look forward to working with you on those issues.

Another area that I talk about is Alzheimer's research. In 2018 the President signed into law the BOLD Infrastructure for Alzheimer's Act. It was a bill that I co-sponsored. And it actually takes a public health approach to Alzheimer's by tasking the CDC with overseeing preparedness and surveillance associated with the disease.

In December, Congress funded the BOLD Act grants, and the CDC is now getting ready to send that money out to States and local centers of excellence. Those funds are going to support Alzheimer's intervention focused on increasing early detection.

This budget, in my understanding, proposes to discontinue CDC's work on chronic disease management and instead tasks States with that work using the new America's Health Block Grant.

It does not appear to include Alzheimer's activities, so I guess my question to you is, does it?

Secretary AZAR. So the America's Health Block Grant would actually create flexibility to States to fund the areas of highest concern. Right now, CDC's chronic disease programs are very siloed, micro-managed by this area, this area, this area. The America's Health Block Grant, if adopted by Congress, of course would grant flexibility for States to go where they find the greatest need; for instance, perhaps Alzheimer's surveillance, as you are talking of, through that program.

Senator CORTEZ MASTO. Okay, so——

Secretary AZAR. I believe that is correct. If I am making——

Senator CORTEZ MASTO. If I could, because we have been fighting for this funding, and I just want to make sure, pursuant to the Act, that the money is still going in and being targeted by the CDC. That would be very, very helpful. I appreciate that.

Thank you for being here.

Senator DAINES. Senator Wyden?

Senator WYDEN. Mr. Secretary, we have a vote on, so you can count on my being really brief. I am going to try to see if I can cover two things very quickly.

As you know, I have been strongly opposed to the Department allowing taxpayer-funded faith-based foster care agencies to refuse to work with otherwise qualified parents because they are Jewish or Catholic. Eight months later, your department expanded this taxpayer-funded discrimination in announcing it would allow all of your funded grantees to deny services to people on the basis of sex or religion.

So now, not only could vulnerable kids in the foster care system be denied access to qualified and loving parents, an early childhood center could turn away a child from their program because that child's parents are Jewish—or LGBTQ people could be refused domestic violence services, and you can go on and on.

How can you claim that this is protecting the religious liberty of Americans?

Secretary AZAR. So first, we believe all individuals should be treated with dignity and respect, whether it is in our health-care programs or our human services programs. That should be our expectation of every aspect of our programs.

But we also enforce discrimination laws that are passed by Congress, and we want to vigorously enforce those. The regulation that you mentioned was promulgated, really singling out one particular Supreme Court case imposing that as an obligation and also, violating, or at least risking the violation of the Regulatory Flexibility Act in its implementation.

And so, we did not feel we could enforce that. We have a proposed regulation out that would require our grantees to comply with all Supreme Court case law, not singling one particular rule out, and also require compliance with the anti-discrimination laws as passed by Congress.

But at our core, we believe everybody should be treated with respect in our health and human service programs.

Senator WYDEN. All I can tell you, Mr. Secretary, is, as I read the law, you went from essentially a pilot project to saying that all HHS-funded grantees could deny services to people on the basis of sex or religion.

I think that is a horrendous precedent for this department that is so important to people. And we are not going to get parents that we need for these foster care programs.

Let me ask you about one other thing, and that is, as you know, I have felt very strongly that we are in the middle of an enormous transformation in the Medicare program. Back when I was director of the Gray Panthers, it was about acute care. Now it is about chronic disease—cancer, and diabetes, and heart disease, and strokes. And here in this committee—Senator Daines will certainly remember this—we passed, on a bipartisan basis, the CHRONIC Care Act, which took a number of constructive steps.

It helped the Medicare Advantage programs. It helped technology, telehelp programs. And you could have programs, for example Medicare Advantage programs, be able to pay for safety bars in a bathroom for those at risk of a fall.

My question to you—because time is so short—is, what can you tell us is being done to make sure that this program gets extended to traditional Medicare? Because as you know, that has been an area where we said, look, there is a lot more to do. But the future of Medicare is not what I was dealing with when I was director of the Gray Panthers: broken ankles. The future of Medicare is cancer, diabetes, heart disease, strokes, and people who have two or more of these conditions.

So what is being done to address traditional Medicare and expand services there?

Secretary AZAR. Absolutely. So with the CHRONIC Care Act that you led, it is a really important advance in thinking about Medicare for chronic care and also thinking about telehealth as part of that.

I would say, actually longer-term in traditional Medicare, this is where I would encourage you to look at what we are doing at the Center for Medicare and Medicaid Innovation around direct contracting for total cost of care.

If we can get providers, whether integrated systems or primary care providers—and the applications are due very soon—if we can get them to actually assume total cost of care, we can get out of micro-managing them on the procedures, the individual procedures. Instead, paying for that longer-term outcome and them having the financial upside of effective, long-term management, I believe long-term that is what causes the investments in real chronic care management like what you are talking about.

They may decide—because they will have skin in the game—to put the bar in the bathroom, for instance, or the ramp at the house, or the air conditioner to lead to a better long-term chronic care outcome, because they will actually have skin in the game.

Senator WYDEN. Let us do this. What you are talking about sounds constructive to me. If you could, for the record, give us a brief report about what the Department has done since you all took office there, and what are the projects that you plan to do in the next year, I think that would give us a little something to point at.

You have always taken my calls to discuss this, and I look forward to working with you. Thank you, Mr. Chairman.

Senator DAINES. Senator Wyden, that was a very uplifting finish to the hearing.

Senator WYDEN. There we are.

Senator DAINES. That is good. Thank you, Secretary Azar, for your attendance and participation today. I ask that any member who wishes to submit questions for the record please do so by close of business Thursday, February 27th.

With that, the hearing is adjourned.

[Whereupon, at 11:43 a.m., the hearing was concluded.]

A P P E N D I X

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF HON. ALEX M. AZAR II, SECRETARY,
DEPARTMENT OF HEALTH AND HUMAN SERVICES

The President's Fiscal Year (FY) 2021 Budget is built around a vision for HHS and a vision for American health care. We are building toward a future where HHS's programs work better for the people we serve; where America's health-care system is affordable, personalized, and puts patients in control; and where our human services programs put people at the center.

The budget reflects the administration's commitments to delivering on this vision and other important themes of HHS's work: advancing a patient-centered health-care system, protecting the lives of the American people, promoting independence, and making HHS the healthiest organization it can be.

Over the past year, under President Trump's leadership, the men and women of HHS have delivered remarkable results. Beginning in 2018 and through 2019, the number of drug overdose deaths in America began to decline for the first time in nearly 2 decades, thanks to huge expansions, assisted by HHS, in access to evidence-based addiction treatment. The Food and Drug Administration (FDA) approved a record number of generic drugs and biosimilars in FY 2019. We launched new payment models in Medicare that pay for health and outcomes, rather than sickness and procedures. We finalized a requirement, effective January 2021, that hospitals provide patients with useful price information, and proposed measures to give patients control over their own health data through interoperability. We launched President Trump's initiative to end the HIV epidemic in America within 10 years, and worked with Congress to secure funding for it. The Department played a vital role in responding to an Ebola outbreak in the eastern Democratic Republic of the Congo and the humanitarian crisis in Latin America. We took unprecedented steps to expand access to treatment for Americans with serious mental illness and worked to help seniors remain in their homes. The latest data from the Administration for Children and Families shows a record number of adoptions with child welfare agency involvement, and reductions in the number of children entering foster care. The budget proposes to continue work on these priorities, while also identifying new areas for action, such as maternal and rural health.

The budget proposes \$94.5 billion in discretionary budget authority and \$1.3 trillion in mandatory funding. Within our discretionary programs, it prioritizes funding for programs that have demonstrated effectiveness, proposes to end programs that have not, and focuses on direct services provided to the American people. On mandatory spending, the budget proposes commonsense reforms that will pave a path to fiscal sustainability and make these important programs work better for the people they serve.

FACILITATE PATIENT-CENTERED CARE

Providing Price and Quality Transparency

President Trump's executive order on *Improving Price and Quality Transparency in American Healthcare to Put Patients First* directs HHS to make health-care prices transparent, laying the foundation for a patient-driven and value-based health system. HHS has acted swiftly to require hospitals to publish the prices they negotiate with insurers and is working to do the same for issuers, so patients can understand their own out-of-pocket costs. CMS has also required Part D prescription drug plans to develop tools that allow beneficiaries to determine plan benefits and formularies.

The executive order calls for the development of a Health Quality Roadmap that aligns and improves reporting on data and quality measures across Medicare, Medicaid, the Children's Health Insurance Program, and other Federal health programs. The Roadmap will include a strategy for establishing, adopting, and publishing common quality measures; aligning hospital inpatient and hospital outpatient measures; and eliminating low-value or counterproductive measures.

HHS legislative proposals increase price and quality transparency in Medicare. For instance, the budget would eliminate coinsurance or copayments for a screening colonoscopy when a polyp is found, saving lives and supporting the President's policy to reduce out-of-pocket costs for this common procedure.

The budget also invests funding in programs that promote transparency. The budget requests \$51 million for the Office of the National Coordinator for Health IT, which includes funding to develop, promote, and adopt common standards to integrate health information and product transparency while protecting privacy. In addition, the new National Institute for Research on Safety and Quality within the National Institutes of Health (NIH) supports the administration's efforts to move health-care organizations from volume to value by focusing on improving outcomes, reducing cost, and expanding choices for consumers. Research investments will focus on developing knowledge, tools, and data needed to improve the health-care system.

Lowering the Cost of Prescription Drugs

The United States is first in the world in biopharmaceutical investment and innovation. But too often, this system has not put American patients first. We have access to the greatest medicines in the world, but access is meaningless without affordability. The budget supports quick congressional action to pass comprehensive legislation to address these flaws in our current drug pricing system and provide needed relief to the American people.

The budget delivers on President Trump's promise to bring down the high cost of drugs and reduce out-of-pocket costs for American consumers by pursuing policies that align with the four pillars of the President's *American Patients First Blueprint*: increased competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs.

The budget includes an allowance for bipartisan drug pricing proposals. The administration supports legislative efforts to improve the Medicare Part D benefit by establishing an out-of-pocket maximum and reducing out-of-pocket costs for seniors. The administration also supports changes to bring lower cost generic and biosimilar drugs to patients. These efforts would increase competition, reduce drug prices, and lower out of pocket costs for patients at the pharmacy counter.

The budget includes an allowance for savings of \$135 billion over 10 years to support the President's commitment to lower the cost of prescription drugs.

Protecting and Improving Medicare for Our Nation's Seniors

Over 60 million American seniors are in the Medicare program, and they are overwhelmingly satisfied with the care they receive through traditional Medicare and Medicare Advantage. The President is continuing to strengthen and improve these programs.

The budget continues to implement the President's executive order on *Protecting and Improving Medicare for Our Nation's Seniors*, building on those aspects of the program that work well, while also introducing market-based approaches to Medicare reimbursement. The administration seeks to protect and reform Medicare with proposals that strengthen fiscal sustainability and deliver value to patients. To drive reform, the Centers for Medicare and Medicaid Services (CMS) is modernizing the Medicare Advantage program, unleashing innovation, expanding telehealth options, and driving competition to improve quality among private Medicare health and drug plans. The administration is expanding flexibility for these Medicare Advantage plans to maximize choices for seniors, and taking action to ensure fee-for-service Medicare is not promoted over Medicare Advantage.

President's Health Reform Vision Allowance

While Americans have the best health-care options in the world, rising health-care costs continue to be a top financial concern for many Americans. President Trump's Health Reform Vision will protect the most vulnerable, especially those with pre-existing conditions, and provide the affordability, choice, and control Americans want and the high-quality care that all Americans deserve.

The President's Health Reform Vision would build on efforts outlined in the executive order, *Improving Price and Quality Transparency in American Healthcare to Put Patients First* to provide greater transparency of health-care costs and enshrine the right of a patient to know the cost of care before it is delivered. It focuses on lowering the price of medicine, ending surprise medical bills, breaking down barriers to choice and competition, and reducing unnecessary regulatory burdens. The Health Reform Vision will also prioritize Federal resources for the most vulnerable and provide assistance for low-income individuals. Medicaid reform will restore balance, flexibility, integrity, and accountability to the State-Federal partnership. Medicaid spending will grow at a more sustainable rate by ending the financial bias that currently favors able-bodied working-age adults over the truly vulnerable.

The budget includes savings of \$844 billion over 10 years for the President's Health Reform Vision Allowance.

Paying for Outcomes

The administration is committed to advancing a personalized and affordable health-care system that puts the patient at the center by ensuring Federal health programs produce quality outcomes and results at the lowest possible cost.

In part, this will be achieved by our continued focus on paying for outcomes rather than procedures. For instance, the budget seeks to improve Medicare primary care services by ensuring payments more accurately reflect clinician time, resources, and outcomes. The budget also implements a value-based purchasing program for hospital outpatient departments, ambulatory surgical centers, and post-acute care facilities, offering incentives to improve quality and health outcomes. Finally, the budget proposes a set of reforms that improve the physician experience and participation in the Quality Payment Program by eliminating reporting burdens for clinicians participating in the Merit-Based Incentive Payment System, CMS's largest value-based care payment program.

The administration issued proposed rules to modernize key regulations that advance the movement to value-based care and paying for outcomes. Specifically, the administration proposed reforms to the Anti-Kickback Statute, the Physician Self-Referral regulations (Stark Law), and 42 CFR Part 2. These proposed rules are part of HHS's Regulatory Sprint to Coordinated Care, which aims to reduce regulatory barriers and accelerate the transformation of the health-care system into one that better pays for value and promotes care coordination. These proposed rules reduce unnecessary regulatory burden on physicians and other health-care providers while reinforcing their statutory intents of protecting patients from unnecessary services, and limiting fraud waste and abuse. This includes adding flexibilities with respect to outcomes-based payments and part-time arrangements. These rules would allow physicians and other health-care providers and suppliers to design and enter into value-based arrangements that improve quality outcomes, produce health system efficiencies, and lower costs.

The CMS Center for Medicare and Medicaid Innovation (Innovation Center) launched a number of innovative payment and service delivery models to test ideas to shift our health-care system toward payment for outcomes and health rather than sickness and procedures. This effort includes Direct Contracting and Primary Care First, a new suite of payment model options that will transform primary care to deliver better value for patients throughout the health-care system. In addition, the Emergency Triage, Treat, and Transport Model provides greater flexibility to ambulance care teams to address emergency health care needs of Medicare beneficiaries following a 911 call, rather than delivering them to the hospital or emergency department for an unnecessary and expensive visit.

PROTECT LIFE AND LIVES

Combating the Opioid and Methamphetamine Crisis

In 2018, drug overdose deaths declined for the first time since 1990. A reduction in deaths from prescription opioid painkillers is almost entirely responsible for this decline. To maintain and build on this progress, HHS continues to advance the Department's five-point strategy to:

- Improve access to prevention, treatment, and recovery services, including the full range of medication-assisted treatments;
- Better target the availability of overdose-reversing drugs;
- Strengthen our understanding of the crisis through better public health data and reporting;
- Provide support for cutting edge research on pain and addiction; and

- Improve pain management practices.

The budget requests \$5.2 billion to address the opioid overdose epidemic and methamphetamine use, including \$169 million in new resources. Funding expands State Opioid Response grants in the Substance Abuse and Mental Health Services Administration (SAMHSA) to provide treatment, recovery support services, and relapse prevention. The budget provides funding to the Health Resources and Services Administration (HRSA) for Addiction Medicine Fellowships to support approximately 60 fellows annually in underserved, community-based settings that integrate primary care with mental health and substance use disorder prevention and treatment services.

While opioids have been at the forefront of the drug landscape, the crisis continues to evolve, and many public health experts believe we are entering into the fourth wave of the crisis, which is underscored by increases in overdose deaths involving cocaine and methamphetamine.

HHS is leveraging current efforts to address the opioid epidemic to combat the rising mortality and morbidity associated with methamphetamines and other stimulants. To allow flexibility to most effectively combat substance use in whatever form it takes, SAMHSA's State Opioid Response grant program has the flexibility to also address stimulants. HHS would direct \$50 million within NIH for research to develop medication-assisted treatment and evidence-based psychosocial treatment for methamphetamines and other stimulants.

Ending the HIV Epidemic: A Plan for America

In the 2019 State of the Union address, President Trump announced a bold new initiative to reduce new HIV infections by 75 percent in the next 5 years and by 90 percent in the next 10 years, averting more than 400,000 HIV infections in that time period. This initiative focuses on four key strategies:

- Diagnose all individuals with HIV as early as possible after infection;
- Treat the infection rapidly and effectively after diagnosis, achieving sustained viral suppression;
- Protect individuals at risk for HIV using proven prevention approaches; and
- Respond rapidly to detect and respond to growing HIV clusters and prevent new HIV infections.

The budget invests \$716 million in dedicated funding for the second year of the *Ending the HIV Epidemic: A Plan for America* initiative, an increase of \$450 million from FY 2020. This funding expands activities in the 57 target jurisdictions to increase HIV testing and access to prevention and treatment services.

With \$371 million, the Centers for Disease Control and Prevention (CDC) transitions from planning to implementation and intensifies work begun in FY 2020 in the 57 target jurisdictions. CDC grants to affected communities will drive additional testing with the goal in the second year of doubling the number of new HIV diagnoses rapidly treated with antiretroviral therapy to maintain health and prevent additional HIV transmissions. Funded jurisdictions will use pharmacy data, telehealth, mobile testing, and new science-based networks to ensure individuals enter and adhere to care.

With \$302 million, HRSA expands HIV prevention services to all community health centers in the targeted initiative areas and serves 28,000 additional HIV positive people through the Ryan White Program. HHS also requests \$27 million for the Indian Health Service (IHS) to enhance HIV testing and linkages to care for American Indians and Alaska Natives.

NIH directs \$16 million to leverage pilot data from 17 Centers for AIDS Research to design and evaluate effective, sustainable systems to implement HIV prevention and treatment interventions and rapidly implement strategies at scale that will be most effective.

These investments build on ongoing HIV activities supported across the Department and an announcement in 2019 to make pre-exposure prophylaxis medication available free of charge for up to 200,000 uninsured individuals each year for up to 11 years. The donation by Gilead Sciences, in partnership with HHS, will help reduce the risk of HIV infections, particularly for individuals that may be at the highest risk.

Improving Maternal Health

Approximately 700 women die each year in the United States from pregnancy-related complications, and more than 60 percent of these deaths are preventable.

In fact, women in the United States have higher rates of maternal mortality and morbidity than in any other industrialized nation—and the rates are rising. In addition to rising mortality rates, severe maternal morbidity affects more than 50,000 women and adds significant costs to the health-care system.

Cardiovascular disease is now the leading cause of death in pregnancy and the postpartum period, constituting nearly 30 percent of pregnancy-related deaths. Chronic hypertension—which is diagnosed or present before pregnancy or before 20 weeks gestation—may result in significant maternal, fetal, and neonatal morbidity and mortality. The rate of chronic hypertension increased by 67 percent from 2000 to 2009, with the largest increase (87 percent) among African American women. CDC points to hypertensive disorders, cerebrovascular accidents, and other cardiovascular conditions as some of the leading causes of maternal deaths, all potentially preventable conditions. It is imperative to identify risk factors prior to pregnancy in order to prevent poor pregnancy and postpartum outcomes.

HHS's *Improving Maternal Health in America* initiative is addressing this significant public health problem. This initiative focuses on four strategic goals:

- Achieve healthy outcomes for all women of reproductive age by improving prevention and treatment;
- Achieve healthy pregnancies and births by prioritizing quality improvement;
- Achieve healthy futures by optimizing postpartum health; and
- Improve data and bolster research to inform future interventions.

The budget provides a total of \$116 million for this initiative across the National Institute for Research on Safety and Quality (NIRSQ), CDC, HRSA, and IHS. This includes \$7 million for NIRSQ to improve service data, advance data evaluation, and expand medical expenditure surveys to ensure policy makers have timely and accurate data. The budget also invests \$24 million in CDC to expand the Maternal Mortality Review Committees to all 50 States and DC to ensure every case of pregnancy-related death is examined. The budget provides \$80 million in HRSA to improve the quality of maternal health services, expand access to care, and reduce disparities in care. The budget invests \$5 million in IHS to help improve health outcomes by standardizing care, increasing cultural awareness, and improving care for pregnant women.

Advancing American Kidney Health

Today's status quo in kidney care carries a tremendous financial cost. In 2016, Medicare fee-for-service spent approximately \$114 billion to cover people with kidney disease, representing more than one in five dollars spent by the traditional Medicare program. In July 2019, the President signed an executive order launching an initiative to transform care for the estimated 37 million Americans with kidney disease. The *Advancing American Kidney Health* initiative tackles the challenges people living with kidney disease face across the stages of kidney disease, while also improving the lives of patients, their caregivers, and family members.

The budget includes \$39 million across multiple HHS agencies and requests new legislative authority in support of the initiative's three goals:

- Reduce the number of Americans developing End-Stage Renal Disease (ESRD) by 25 percent by 2030.
- Have 80 percent of new ESRD patients in 2025 receive dialysis at home or a transplant.
- Double the number of kidneys available for transplant by 2030.

This funding also supports transplantation activities for other organs.

To achieve these goals, HHS is scaling programs nationwide to optimize screening for kidney disease and educate patients on care options. HHS is also supporting innovation and groundbreaking research to inform the next generation of targeted therapies and accelerate development of innovative products such as an artificial kidney. New and pioneering payment models are also being developed to increase both value and quality of care for the patient.

The budget also targets new funding towards HRSA's Organ Transplantation Program to remove financial disincentives for living organ donors. The budget invests \$31 million in HRSA for the Organ Transplantation program, including \$18.3 million for the Organ Procurement Transplantation Network, Scientific Registry of Transplant Recipients, and public and professional education efforts to increase public awareness about the need for organ donation. In addition, the proposed rule to increase accountability and availability of the organ supply—announced in December 2019—would improve the donation and transplantation rate measures, incenti-

vize Organ Procurement Organizations (OPOs) to ensure all viable organs are transplanted, and hold OPOs to greater oversight, transparency, and accountability while driving higher OPO performance.

HHS is working to accelerate innovation in the prevention, diagnosis, and treatment of kidney disease through the Kidney Innovation Accelerator (KidneyX), a public-private partnership between HHS and the American Society of Nephrology. The HHS Office of the Chief Technology Officer will continue the KidneyX competition in FY 2021 by challenging individuals, teams, and companies to build and test prototype solutions, or components of solutions, that can replicate normal kidney functions or improve dialysis access.

The budget proposes to establish a new program within the Office of the Assistant Secretary for Preparedness and Response (ASPR) that will advance kidney health. The Preparedness and Response Innovation program will support advanced research and development, prototyping and procurement of revolutionary health security products, technologies and other innovations. The program's first project will focus on portable dialysis equipment for emergency response. This will ensure that individuals with kidney failure have access to dialysis during a disaster.

The budget also advances legislative proposals to revolutionize the way patients with chronic kidney disease and kidney failure are diagnosed, treated, and supported. This effort includes extensions of both the NIH Special Diabetes Program and IHS Special Diabetes Program for Indians to address chronic conditions, such as diabetes, that can lead to kidney disease.

For patients who lose Medicare coverage at 36 months post-transplant and who do not have another source of health-care coverage, the costs of continuing immunosuppressive drug therapy may be prohibitive. Without these drugs, the patient's body rejects the transplant, reverts to kidney failure, and requires dialysis. To prevent transplant rejection and reversion to dialysis, the budget proposes to establish a new Federal program that provides lifetime coverage of immunosuppressive drugs for certain kidney transplant recipients until they are otherwise eligible for Medicare coverage. The budget also proposes to increase competition among, and oversight over, Organ Procurement Organizations to improve performance and increase the supply of organs for transplant. In addition, the budget advances new innovative kidney care payment models to encourage home dialysis, increase access to kidney transplants, and incentivize clinicians to better manage care for patients with kidney disease.

Transforming Rural Health

There are 57 million Americans living in rural communities. Rural Americans face many unique health challenges, including hospitals that are closing or in danger of closing; difficulty recruiting and retaining physicians, nurses, and other providers; and increased likelihood of dying from many leading causes of avoidable death such as cancer and heart disease.

HHS's *4-Point Strategy to Transform Rural Health* builds on current HHS initiatives in the following areas:

- Build a Sustainable Health Model for Rural Communities;
- Leverage Technology and Innovation;
- Focus on Preventing Disease and Mortality; and
- Increase Rural Access to Health Care.

The budget supports rural communities through programs such as the Rural Communities Opioids Response Program and the Telehealth Network Grant Program at HRSA, which supports substance use prevention, treatment, and recovery services, and promotes telehealth technologies for health-care delivery in rural communities. Project AWARE (Advancing Wellness and Resiliency in Education) will increase mental health awareness training in rural communities. In response to American Indian and Alaska Native communities' demand for telebehavioral services, IHS expands the Telebehavioral Health Center of Excellence with funding for new space, updated equipment, and additional behavioral health providers.

Telehealth services strive to make rural health programs more effective, increase the quality of health care, and improve health outcomes. The budget seeks to remove barriers to telehealth services in rural and underserved areas through a proposal to expand telehealth services in Medicare fee-for-service advanced payments models with more than nominal financial risk. This proposal broadens beneficiary access to Medicare telehealth services and addresses longstanding stakeholder concerns that the current statutory restrictions hinder beneficiary access. The proposal

expands the telehealth benefit in Medicare Fee-for-Service and provides authority for Rural Health Clinics and Federally Qualified Health Centers to be distant site providers for Medicare telehealth services. It also permits IHS and tribal facilities to be originating and distant site providers, even if the facility does not meet the requirements for being located in certain rural or shortage areas, and allows for coverage across State lines. The budget also proposes to modernize payments to Rural Health Clinics to ensure equitable payment for these health clinics and help rural communities maintain access to these crucial services. Finally, the budget proposes to allow Critical Access Hospitals to voluntarily convert to an emergency hospital that does not maintain inpatient beds.

Addressing Tick-borne Diseases

Tick-borne diseases, of which Lyme Disease is the most common, account for 80 percent of all reported vector-borne disease cases each year and represent an important emerging public health threat in the United States. With 59,349 reported cases in 2017, the annual number of reported cases has more than tripled over the last 20 years; due to under-reporting, this number substantially under-represents actual disease occurrence. The geographic ranges of ticks are also expanding, which leads to increased risk for human exposure to the bites of infected ticks. Most humans are infected through bites from very small young ticks, hosted by deer or mice.

To address critical gaps in knowledge, diagnostics, and preventive measures for tick-borne diseases, HHS is proposing an action plan that will prioritize and advance the most promising candidates and technologies for diagnosing and preventing Lyme and other tick-borne diseases. This plan, led by the Office of the Assistant Secretary for Health in partnership with NIH, CDC, and FDA, will address four primary areas: innovations in diagnosis and advanced detection, developing vaccine-based prevention, ensuring robust domestic surveillance of vector borne diseases, and providing additional knowledge to advance the best treatment and prevention options. These efforts will improve outcomes for those affected by Lyme Disease symptoms. This plan builds on the Kay Hagan Tick Act, enacted through the Consolidated Appropriations Act for 2020, to improve research, prevention, diagnostics, and treatment for tick-borne diseases.

The budget requests \$189 million, an increase of \$58 million, to address tick-borne diseases. This amount includes \$115 million for NIH to expand its research on of tick-borne disease, including in the prevention, diagnosis, and treatment; and \$66 million for CDC to address vector-borne diseases, focusing on tick-borne diseases, including tick surveillance, insecticide resistance activities, and development of improved diagnostics. FDA will ensure the safety and efficacy of products developed to prevent, diagnose, and treat vector-borne diseases.

Focusing on Influenza

Influenza is a serious disease that can lead to hospitalization and sometimes death, even among healthy people. In the United States, millions of people are sickened, hundreds of thousands are hospitalized, and tens of thousands die from influenza every year. In September 2019, the President signed Executive Order 13887, *Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health*. The executive order recognized influenza as a public health threat and national security priority, and directed HHS to prepare and protect the Nation.

The budget invests \$998 million to continue on-going influenza activities as well as targeted increases to support this directive. This amount includes \$306 million for ASPR to modernize influenza vaccine manufacturing infrastructure and advance medical countermeasure research and development. Activities include additional clinical studies on licensure of pre-pandemic recombinant-based influenza vaccine and the advanced development of novel diagnostics, respiratory protective devices, and alternative vaccine delivery technology. The budget also funds the Office of Global Affairs to support U.S. leadership of international efforts on pandemic influenza preparedness.

The budget requests \$216 million for CDC's Influenza program, an increase of \$40 million. CDC will expand influenza vaccine effectiveness monitoring systems and develop and characterize candidate vaccine viruses for vaccine manufacturers, and efforts to improve the evidence-base on non-egg-based vaccines. CDC will support whole genome characterization of more than 10,000 influenza viruses. All of these activities help build domestic capacity. CDC will also increase influenza vaccine use by removing barriers to vaccination and enhance communication to health-care providers about the performance of influenza vaccines.

The executive order also calls for the development of novel technologies to speed seed vaccine development, targeted development of vaccines that protect against multiple types of virus for multiple years, and to improve adjuvants. In support of this goal, the budget includes \$49 million for FDA to support regulatory science research and clinical assessments to promote development and access to safe and effective influenza vaccines, and \$423 million for NIH to accelerate influenza research, including universal flu vaccine development.

EMERGENCY PREPAREDNESS

HHS plays a key role in supporting domestic and international preparedness and response to ensure our Nation's safety. The budget invests \$2.6 billion in ASPR to expand efforts to prevent, prepare for, respond to, and recover from, the adverse health effects of public health emergencies. This amount includes \$562 million for the Biomedical Advanced Research and Development Authority to maintain a robust pipeline of innovative medical countermeasures that mitigate health effects of infectious diseases and chemical, biological, radiological, and nuclear agents. It also includes \$535 million for Project BioShield to support procurement of medical countermeasures against these threats, and \$705 million for the Strategic National Stockpile to sustain and increase inventory of high-priority countermeasures such as antibiotics to treat anthrax exposure and vaccine to prevent smallpox. These investments will help HHS advance progress towards national preparedness goals.

NIH supports a robust research portfolio to develop vaccines and therapeutics that enable rapid response to public health threats including emerging microbial threats, such as extensively drug-resistant tuberculosis, emerging viral strains such as Zika, and viral hemorrhagic fevers such as Ebola. The budget continues investments in NIH in scientific research on these new threats, and invests \$120 million in FDA to facilitate medical countermeasure development and availability to respond in the event of a microbial or other public health threat.

Strengthening the Indian Health Service

The administration is committed to improving the health and well-being of American Indians and Alaska Natives. This population continues to experience significant health disparities, and the budget includes key investments to ensure quality of care. The budget invests \$6.2 billion in IHS, which includes \$125 million for electronic health record modernization, provides funding to support IHS Services, Ending the HIV Epidemic, and Maternal Health, and includes \$125 million for high-priority health-care facilities construction projects. The budget proposes a new, indefinite discretionary appropriation and reforms for IHS to address Indian Self-Determination and Education Assistance Act section 105(1) lease costs.

Reforming Oversight of Tobacco Products

The budget proposes to move the Center for Tobacco Products out of FDA and create a new agency within HHS to focus on tobacco regulation. A new agency with a mission focused on tobacco and its impact on public health would have greater capacity to respond rapidly to the growing complexity of new tobacco products. Additionally, this reorganization will allow the FDA Commissioner to focus on its traditional mission of ensuring the safety of our Nation's drug, food, and medical products supply.

Providing Shelter and Services for Unaccompanied Alien Children

The Administration for Children and Families (ACF) provides shelter, care, and support for unaccompanied alien children apprehended by the Department of Homeland Security or other Federal Government department or agency. The number of unaccompanied alien children requiring care is inherently unpredictable. In FY 2019, ACF cared for 69,488 children, the highest number in the program's history. To ensure adequate shelter capacity and care in FY 2021, the budget requests a total of \$2 billion in discretionary funds to support capacity of 16,000 licensed permanent beds, depending on operational needs, and includes a mandatory contingency fund to provide up to \$2 billion in additional resources if needed.

PROMOTE INDEPENDENCE

Promoting Upward Mobility

In the human services work at HHS, the overarching goal is to promote personal responsibility, independence, and self-sufficiency—to help Americans lead flourishing, fulfilling, independent lives. HHS programs for low-income Americans achieve this goal by supporting work, marriage, and family life. HHS seeks to better

align our social safety net programs with the booming economy, and focus on work as the means to lift families out of poverty.

Many Americans are joining the workforce as the administration's policies continue to strengthen the economy and produce historically low unemployment rates. The administration supports working families by investing in child care, an important work support that helps families achieve independence and self-sufficiency. The administration is working to implement policies that increase access to high-quality, affordable child care.

The budget proposes to improve the Temporary Assistance for Needy Families (TANF) program by restoring its focus on employment and work preparation, and by targeting funds to low-income families. The proposal fundamentally changes the way the program measures success by moving to measures that focus on employment outcomes, phasing out the ineffective work participation rate. In addition, the budget establishes Opportunity and Economic Mobility Demonstrations that allow for the streamlining of funding from multiple safety net programs to deliver coordinated and effective services. The budget also seeks to improve consistency between work requirements in TANF and Medicaid by requiring that able-bodied individuals participate in work activities at least 20 hours per week in order to receive welfare benefits.

Supporting Child Care

Child care is an investment in both present and future generations of the workforce. However, it is also one of the biggest expenses for families and can be a barrier to work. Funding plays a critical role in helping families achieve self-sufficiency by providing parents access to a range of child care options. In FY 2018, the most recent year for which preliminary data are available, over 1.3 million children from about 813,000 low-income families received a monthly child care subsidy from the Child Care and Development Fund. The budget provides \$5.8 billion for the Child Care and Development Block Grant and \$4.2 billion in mandatory child care funding for a total investment of \$10.0 billion in child care. The mandatory funding includes a one-time \$1 billion fund for competitive grants to States to increase child care services for underserved populations and stimulate employer investment in child care. The budget will serve 1.9 million children.

Promoting Adoption

Adoption gives children stability and love during their childhood, and also a safe and stable environment in which to grow into responsible adults who flourish. Approximately 20,000 youth exit or "age out" of foster care each year without the safety net of a forever family, and their outcomes are often concerning. A longitudinal study found that only 58 percent graduated from high school, and only half found employment by age 24. More than a third of youth in one study had experienced homelessness at least once by age 26. Children and young adults in foster care cannot be expected to achieve the independence they need to thrive and flourish on their own—but finding them a loving forever family could change all that.

According to ACF, the number of children adopted with help from public child welfare agencies rose from 59,000 in FY 2017 to more than 63,000 in FY 2018. To sustain this momentum, ACF has launched a Call to Action for States and other stakeholders, which aims to develop and sustain key partnerships across public and private groups, including faith-based groups, with the goal of reducing the number of children in foster care and increasing the number of children who find a forever family, through adoption or otherwise.

The Adoption Assistance and Guardianship Assistance programs will provide \$4.1 billion in FY 2021 in mandatory funding to provide monthly support payments to families adopting sibling groups or other children with special needs. Under existing law, Adoption Assistance funding will keep pace with the number of qualifying children adopted each year.

HHS promotes adoption through administrative actions and funding incentives to promote adoption, and to identify and address barriers to adoption. Initiatives include family-finding programs, focusing on identifying the barriers that exist in the recruitment and development of foster and adoptive families, and the development and dissemination of court-related practice improvements addressing barriers to timely adoptions.

Supporting Families and Preventing the Need for Foster Care

Helping families receive the care and services they need before the involvement of a child welfare agency can help prevent a child from entering foster care. The

administration has focused on primary prevention, as well as adoption, and we are starting to see better results. HHS is implementing the Family First Prevention Services Act (Family First Act), which supports services to prevent child maltreatment and the need for foster care. This groundbreaking new legislation provides the opportunity for substantial improvements in outcomes for children and families. The budget proposes to streamline the process for evaluating evidence-based prevention services programs under the Family First Act to give States and tribes access to more programs that help prevent the need for foster care and assist kinship caregivers.

The budget invests \$510 million for discretionary child welfare activities in ACF, including services that allow children to remain safely with their families and education and training vouchers for youth aging out of foster care. In collaboration with CMS, the budget proposes that Qualified Residential Treatment Programs (QRTPs) be exempted from the institution for mental diseases (IMD) payment exclusion allowing children in foster care to have Medicaid coverage in these placements even if a QRTP qualifies as an IMD.

The budget provides \$197 million to ACF for child abuse prevention grants. These grants support increased use of evidence-based prevention programs, allowing States to explore new research opportunities and to adapt more rigorous evaluations of existing programs; demonstration projects to test the effectiveness of partnerships that strengthen family capacity and prevent child abuse through the co-location of services; and State plans for safe care of infants affected by substance use disorders.

The budget also proposes to expand the Regional Partnership Grant program by \$40 million each year, which will increase funding for grants that help courts, child welfare agencies, and other government and community entities work together and improve practices to address the impact of substance abuse, including opioids, on child welfare. The budget proposes an increase of \$30 million each year for the Court Improvement Program to help courts improve practices and comply with new mandates in the Family First Act.

Strengthening Efforts to Treat Serious Mental Illness and Serious Emotional Disturbances

In 2018, more than 11 million adults in the U.S. were living with a serious mental illness. More than 7 million children and youth experienced a serious emotional disturbance. They faced a greater risk of suicide and life expectancy 10 years shorter than the general population.

The budget provides \$1.1 billion to SAMHSA for serious mental illness and serious emotional disturbances, which includes funding to support Assertive Community Treatment for Individuals with Serious Mental Illness, Community Mental Health Services Block Grant, and Children's Mental Health Services. These programs provide comprehensive and coordinated mental health services for some of the Nation's most vulnerable populations and increases access to mental health services in schools. The budget will also provide targeted flexibility for States to provide inpatient mental health services to Medicaid beneficiaries with serious mental illness.

The budget also invests in programs that address the Nation's alarming rates of suicide. Suicide is the 10th leading cause of death in the United States—responsible for more than 47,000 deaths in 2017—and suicide rates have increased steadily for individuals of all ages. The budget provides \$93 million for suicide prevention activities, including additional funding to expand Zero Suicide initiatives to focus on adult suicide prevention and allow communities and States to tailor strategies to prevent suicide in their local jurisdictions.

Supporting Independence for Older Adults and People With Disabilities

The administration prioritizes community living for older adults and people with disabilities to ensure that they can maintain independence and live fully integrated in their communities. The budget invests \$1.5 billion in the Administration for Community Living for critical direct services that enable seniors and people with disabilities to live independently, such as senior meals, in-home chore assistance, independent living skills training, employment training, and information and referral services. These programs empower older adults and people with disabilities to live independently and make critical choices about their own lives.

PROMOTE EFFECTIVE AND EFFICIENT MANAGEMENT AND STEWARDSHIP

HHS is responsible for more than one-quarter of total Federal outlays. The Department administers more grant dollars than all other Federal agencies combined.

HHS is committed to responsible stewardship of taxpayer dollars, and the budget continues to support key reforms that improve the efficiency of Departmental operations.

Advancing Fiscal Stewardship

The administration recognizes its immense responsibility to manage taxpayer dollars wisely. HHS ensures the integrity of all its financial transactions by leveraging financial management expertise, implementing strong business processes, and effectively managing risk.

As the Department overseeing Medicare and Medicaid, HHS is committed to exercising proper oversight of these programs to protect the millions of impacted beneficiaries and the taxpayers in general. In accordance with the direction in the executive order on *Improving and Protecting Medicare*, HHS is investing in the newest technological advancements, such as Artificial Intelligence, to enhance our ability to detect and prevent fraud, waste, and abuse.

The Department is committed to reducing improper payments in Medicare, Medicaid, and Children's Health Insurance Program (CHIP). HHS continues to enhance existing program integrity tools to address improper payments and prevent fraud, including provider screening, prior authorization, and auditing providers and plans. New methods and technologies will allow HHS oversight to reduce improper payments and adapt to the changes in health care as we shift from a fee-for-service to a value-based health care payment system.

The budget advances new legislative and administrative proposals to strengthen the Department's ability to address weaknesses in Medicaid beneficiary eligibility determination processes, while providing tools to facilitate the recovery of overpayments made by States. HHS also continues to support updates to Medicaid information systems that offer critical support to program integrity efforts, including the Transformed Medicaid Statistical Information System (T-MSIS) and a new Medicaid drug rebate system. In addition, HHS includes proposals that enhance oversight of Medicare Advantage and Part D plans, increase the period of enhanced oversight on new providers, and expand Medicare fee-for-service prior authorization.

IMPLEMENTING REIMAGINE HHS

HHS supports the President's Management Agenda through ReImagine HHS, the Department's robust reform and transformation effort, organized around core goals to streamline processes, reduce burden, and realize cost savings. The effort takes an enterprise approach, affecting activities across the Department. For example, the Buy Smarter initiative plans to use new and emerging technologies to leverage the enormous purchasing power of HHS and streamline the end-to-end procurement process. The Maximize Talent initiative addresses modern-day human capital management and human resources operational challenges, resulting in key achievements: HHS's simplified recruitment process resulted in a significant increase in the number of new hires on-boarded since implementation, and HHS was rated the "Best Place to Work in the Federal Government" out of all executive departments in 2019. As part of the Bring Common Sense to Food Regulation initiative, FDA is working to increase collaboration between food regulatory programs to minimize dual jurisdiction and improve State product safety. As a result, 48 States and territories participate in the Produce Safety Implementation Cooperative Agreement Program, which increased State large farm inspections over 400 percent in FY 2019.

ReImagine HHS efforts are also making HHS more innovative and responsive. Under the Optimizing Regional Performance initiative, HHS developed a Regional Facilities Utilization Model with \$150 million in potential savings and a footprint reduction of more than 62 percent within 10 years. For the first time since 1974, HHS completed a comprehensive assessment of regions to better align with administration priorities and improve HHS's ability to serve Americans across the country. In addition, under the Optimize Coordination Across HHS initiative, HHS configured a new cloud environment for an administrative data hub to provide dashboarding capabilities for Operating Divisions, bringing together human resources, travel, and facilities data to inform better decision-making across the enterprise.

In FY 2021, all ReImagine HHS projects will reside in their permanent offices within HHS. This ensures that their work can sustainably continue going forward.

Grants Management

HHS continues to drive change for grants management government-wide. Leveraging the efforts and success of the HHS ReImagine Grants Management initia-

tive. The Office of Management and Budget pre-designated HHS as the Grants Quality Services Management Office (QSMO) to create and manage a marketplace of solutions for grants management; govern its long-term sustainability; institute a customer engagement model; and drive the implementation of standards and solutions to modernize grants management processes and systems. Guided by a government-wide governance board, QSMOs are tasked with offering solutions that, over time, will improve quality of service and customer satisfaction; modernize and automate processes and supporting technology; standardize processes and data; and achieve efficiencies in government-wide operations and maintenance.

In FY 2018, the government awarded over \$750 billion in grants to approximately 40,000 recipients across more than 1,500 programs.

Full designation as the Grants QSMO is contingent upon approval of a 5-year implementation plan and budget estimate in alignment with the published QSMO Long-term Designation Criteria. HHS is developing a vision and strategy to inform the Grants QSMO 5-year implementation plan, with significant engagement with stakeholders to ensure the Grants QSMO can meet their diverse needs.

Regulatory Reduction

HHS is committed to streamlining the regulatory process and evaluating necessary steps to eliminate or change regulations that impose unnecessary burden. Burdensome regulations can drive up costs of health care, while poorly designed regulations can come between doctors and patients, reducing the quality of care and the essential trust to that relationship. From FY 2017 to FY 2019, HHS succeeded in cutting the economic burden of its regulations by \$25.7 billion through 46 deregulatory actions. HHS had the largest deregulatory impact of any Cabinet agency during this time period.

HHS is using the power of new cognitive technologies for greater operational effectiveness and research insights, including regulatory reduction. HHS used an artificial intelligence-driven regulation analysis tool and expert insight to analyze the Code of Federal Regulations, seeking potential opportunities to modernize regulations. HHS since launched a Department-wide Regulatory Clean-Up Initiative to implement changes based on these findings, by reviewing and—where a change is warranted—addressing incorrect citations and eliminating the submission of triplicate or quadruplicate of the same citation.

HHS is working to implement the provisions of the executive order on *Promoting the Rule of Law through Improved Agency Guidance Documents*. This executive order will accomplish important policy goals that will improve HHS guidance practices in the long term. Prior to the issuance of this executive order, several Federal agencies issued internal memoranda regarding the appropriate use of guidance. The executive order requires agencies to now go a step further and codify certain good guidance practices and policies into Federal regulations. By August 27, 2020, each agency must finalize regulations to set forth processes and procedures for issuing guidance documents. In addition, by February 28, 2020, Federal agencies must establish a single, searchable database on its website that contains, or links to, all of the agency's guidance documents currently in effect. Any guidance document not included in the guidance website is deemed rescinded. HHS is committed to meeting the President's timelines.

QUESTIONS SUBMITTED FOR THE RECORD TO HON. ALEX M. AZAR II

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. Are there any proposals in the President's budget to change how Medicare benefit determination formulae, or to change how Social Security retirement of disability benefits are calculated?

Do proposals in the President's budget aimed at programmatic budget savings, relative to the budget baseline, through program integrity measures, for example, lead to absolute cuts in Medicare or Social Security benefit payments? Or, rather, including projected effects of the budget proposals, are Medicare and Social Security benefits projected to continue to rise relative to the budget baseline?

Regarding so-called cuts to Medicare, consider the views of the nonpartisan Committee for a Responsible Federal Budget. That nonpartisan group says that claims that the President's budget cuts Medicare benefits are false and misleading. They also say:

The President's Medicare proposals would improve the value of each Medicare dollar, reduce the unsustainable growth of the program, and lower costs for seniors and other households. These policies would not represent reductions in benefits, but instead reductions in cost for roughly the same level of benefits. Indeed, the policies would actually *reduce* costs for individuals by lowering premiums and out-of-pocket costs.

Reducing costs for individuals is also at the heart of my drug-pricing bill with Ranking Member Wyden. And I don't view our approach as benefit cuts either, and if we all focus on the intent and substance of proposals, rather than whether we can make statements for political purposes, I think we will all be better off. Do you agree that the President's budget proposals would lead to reductions in costs for roughly the same level of benefits for Medicare, and not "cuts to Medicare benefits"?

Answer. Under President Trump's leadership, the administration has taken significant steps to improve health-care markets and streamline insurance rules. The President's vision for health-care reform will further strengthen and protect Medicare, including through proposals that extend the solvency of the Medicare Hospital Insurance Trust Fund for at least the next 25 years.

President Trump's 2019 executive order, *Protecting and Improving Medicare for Our Nation's Seniors*, builds on those aspects of the Medicare program that work well, including market-based approaches in the current system. The budget furthers these goals for the Medicare program and saves proposes approximately \$756 billion in gross Medicare savings over 10 years.

Question. I've heard some people say that the President's budget involves "cuts" to Social Security. There are program integrity measures in the budget and proposals to test new approaches to increase labor force participation, but there are no proposals to change how Social Security retirement or disability benefits are calculated, as far as I can tell.

Several of the program integrity proposals in the President's budget were also proposed in budgets from President Obama. Things like using death data to prevent improper payments. The only things to cut there are improper payments.

President Obama's budgets claimed budget savings from those types of provisions, on the order of tens of billions of dollars. Yet, during hearings on President Obama's budgets, I didn't hear anyone from either side calling them cuts, or claiming that President Obama was out to cut Social Security or destroy its programs.

Instead, I heard that the proposals were designed for program integrity. For example, in a hearing before the Senate Finance Committee President Obama's fiscal year 2015 budget, which included some of the same proposals on Social Security that are in President Trump's fiscal year 2021 budget, then-Treasury Secretary Lew said:

What our budget does is, it lays out a program of program integrity to make sure that people who apply for disability are eligible for it, and we would work together with the kinds of changes we need to protect that critically important program.

I disagree with people calling things cuts now that they didn't call out as cuts when a Democrat was in the White House.

Are there Social Security program-integrity proposals in President Trump's Fiscal Year 2021 budget that are the same or substantively similar to any proposed in past budgets by President Obama?

Do any of the proposals in President Trump's Fiscal Year 2021 budget entail any changes in how Social Security retirement or disability benefits for eligible beneficiaries are calculated that lead to cuts in those benefits that are determined by statutory formulae?

Answer. HHS defers to the Social Security Administration.

QUESTIONS SUBMITTED BY HON. JOHN CORNYN

MFAR

Question. In November, CMS proposed the Medicaid Fiscal Accountability Rule that is supposed to bring greater transparency and accountability to the Medicaid program. As you may know, Texas is subject to extensive Medicaid reporting re-

quirements under its 1115 waiver, and the additional reporting requirements in the rule will ensure we are protecting taxpayer dollars. But many providers have expressed concern that the rule, as proposed, could lead to hospital closures, problems with access to care, and threaten the safety net.

Given stakeholder responses, how is HHS planning to balance the need for additional reporting of supplemental payments with timelines that prevent undue State burden or access issues for beneficiaries?

If you move forward with finalization and implementation of the rule, what assurances can you provide to make sure substantive concerns are addressed?

Answer. The Medicaid Fiscal Accountability Regulation (MFAR), CMS-2393-P, was published in the November 18, 2019, issue of the Federal Register, with a 60-day comment period that closed on January 17, 2020, which was subsequently extended by 15 days and closed on February 1, 2020. During this time, CMS also conducted numerous calls with States and other stakeholders to receive substantive feedback to help us understand the potential impact of the proposed rule.

The policies proposed within the rule are intended to ensure accountability of State financing, transparency of payments, and the fiscal integrity of the Medicaid program, including through numerous clarifications to Medicaid financing and oversight rules. Specifically, this proposed rule would impact States' reporting on payment methods and procedures to assure consistency with efficiency, economy, and quality of care as required by section 1902(a)(30)(A) of the act. CMS, and other Federal oversight entities, have found that current regulations and guidance do not adequately ensure that States are complying with the efficiency, economy and quality of care requirements of section 1902(a)(30)(A) of the act, and this proposed rule is intended to address those deficiencies. However, we have listened closely to concerns that have been raised by our State and provider partners about potential unintended consequences of the proposed rule, which require further study. Therefore, CMS has withdrawn the rule from the regulatory agenda.

BIOSIMILARS

Question. There has been bipartisan, bicameral legislation advanced this Congress to implement an access measure to incentivize Medicare Advantage and Part D plans to improve access to biosimilars on their formularies and therefore increase utilization of these lower-cost products.

Has HHS considered pursuing this on its own? If not, would you be able to look into that and get back to this committee?

Answer. The administration supports changes to bring lower cost generic and biosimilar drugs to patients. Since the administration issued American Patients First, its blueprint to lower drug-pricing costs, FDA has promoted competition in drugs and biologics, advanced a strong framework for biosimilars, and modernized regulatory oversight of generic drugs. The administration finalized a policy in which each biosimilar for a given biologic gets its own billing and payment code under Medicare Part B, to incentivize development of additional lower-cost biosimilars. Prior approaches to biosimilar coding and payment would have created a race to the bottom of biosimilar pricing, while leaving the branded product untouched, making it an unviable market that few would want to enter.

Question. Secretary Azar, I appreciate your focus on improving access to generics and biosimilars. You previously stated, "I am very much aware of these rebate walls that can prevent competition and new entrants into the system. . . . I don't like that practice. I think it's using their market power in ways that is not appropriate."

Can you explain what you're referencing in this quote—why aren't biosimilars penetrating the market?

Answer. There are a number of reasons why biosimilars have not taken off here in the United States. In so many cases, today's rebate system not only distorts pricing signals—it also discourages the introduction of new competition. Pharmacy benefit managers and payers are happy to continue receiving a big rebate on a biologic, rather than go to the trouble of covering a biosimilar competitor with not just a lower net price, but a lower list price too. What is standing in the way of that competition is sometimes referred to as the "rebate wall." It is only a good deal for defenders of the status quo, whether that's manufacturers selling certain drugs or pharmacy benefit managers negotiating big rebates.

Question. There are proposals in both the House and Senate to increase the add-on payments for biosimilars.

Have you considered a similar approach through CMMI? Or implementing a shared savings program where Medicare savings associated with prescribing a biosimilar would be shared with providers and more importantly patients through reduced co-pays?

Answer. We are focused on a long-term solution that increases the competitiveness of biosimilar drugs in the Medicare program. One action CMS has provided MA plans is the option of applying step therapy for physician-administered and other Part B drugs.

RADIATION ONCOLOGY ALTERNATIVE PAYMENT MODEL

Question. Last year, CMMI proposed a mandatory Radiation Oncology Alternative Payment (RO-APM) Model to include 40 percent of Medicare episodes across 17 cancer types with a bundled payment. The radiation oncology stakeholder community is very supportive of value based care and worked hard to submit a proposal to CMS before the CMMI proposal was released although the community's proposal seems to have been largely ignored. I am concerned that the RO-APM proposed by CMMI will disrupt patient care and so are radiation oncologists. A paper soon to be published in the *Radiation Oncology* journal, "Impact of Patient Stage and Disease Characteristics on the proposed Radiation Oncology Alternative Payment Model (RO-APM) at a Large Academic Cancer Center" found that the RO Model will be detrimental to the care of vulnerable populations with complicated cancers that were caught late and therefore require care that costs more than the model was designed for.

Would you be open to amending the proposed RO-APM to ensure that the disruption predicted to radiation oncology for our Nation's seniors does not happen?

Has HHS considered a smaller, targeted model to test out the bundled payment in radiation oncology to ensure patient care is enhanced?

Answer. CMS is committed to promoting higher quality of care and improving outcomes for Medicare beneficiaries while reducing costs, including among beneficiaries with cancer. We have undertaken a number of initiatives to improve cancer treatment, most notably with our Oncology Care Model. We believe that a model in radiation oncology would further these efforts to test ways to improve cancer care for Medicare beneficiaries and reduce Medicare expenditures. On September 29, 2020, CMS finalized a new Innovation Center model, the Radiation Oncology (RO) Model. The RO Model is expected to improve the quality of care for cancer patients receiving radiotherapy and reduce Medicare expenditures through bundled payments that allow providers to focus on delivering high-quality treatments. The new model creates simpler, more predictable payments that incentivize cost-efficient and clinically effective treatments to improve quality and outcomes. On October 21, 2020, in response to feedback from stakeholders, CMS announced that it would delay the start of the model to July 1, 2021.

In response to comments received during the public comment period, CMS made the following key changes to the final RO Model design:

- Delayed the start date until July 1, 2021 (from the proposed start of January 1st or April 1, 2020).
- Reduced required participation from 40 percent to 30 percent of eligible RO episodes annually that are furnished by RT providers and RT suppliers located in a random sample of CBSAs. This is the smallest possible model size that CMMI could test in order to demonstrate statistically significant savings.
- Reduced the discount from 4 percent for the Professional Component (PC) of the RO Model payment to 3.75 percent, reduced the discount from 5 percent for the Technical Component (TC) of the RO Model payment to 4.75 percent; and reduced the incorrect payment withhold from 2 percent to 1 percent.
- Reduced the 17 included cancer types in the RO Model to 16 included cancer types; as kidney cancer is not commonly treated with radiotherapy, it does not meet the criteria for inclusion in this model.
- Changed to allow the second half of the RO Model payment to be made when radiation treatment has ended before the end of the 90-day RO episode, but no earlier than 28 days after the initial treatment planning service was furnished.
- Revised to allow MIPS adjustments for the professional component of the RO Model payment.

- Added an annual opt-out option for low-volume entities, which allows any physician group practice, freestanding RT center, or HOPD that furnishes less than 20 episodes within one or more of the randomly selected CBSAs in the most recent year with available claims data to opt-out of the RO Model.
- Added a stop-loss limit of 20 percent for RO participants that do not qualify to receive an historical experience adjustment and that were furnishing included RT services at the time of the effective date of the final rule in a CBSA selected for participation.

CMS will continue to work with stakeholders to ensure that beneficiaries continue to have adequate access to these important services, and that providers have the tools and resources they need to implement the changes required by the RO Model.

STRATEGIC NATIONAL STOCKPILE

Question. The Strategic National Stockpile (SNS) can make purchases, as needed via Indefinite Delivery/Indefinite Quantity (IDIQ) contracts and SNS maintains IDIQ contracts for emergency purchases, such as pandemic preparation and response. It is my understanding that the Biomedical Advanced Research and Development Authority (BARDA) is not currently buying any syringes and has not received any funds to procure syringes at this time.

In light of the COVID-19 outbreak and the concerns from CDC of a possible spread, do you believe it is necessary for the SNS to begin purchasing necessary supplies like syringes?

Answer. Operation Warp Speed is taking a holistic view of vaccine administration supplies (vaccine, vials, syringes, etc.) to ensure we have ample quantities to meet demand. We are working closely with needle and syringe manufacturers to ensure sufficient supply remains available throughout the duration of the vaccine administration campaign.

Specifically, BARDA, in coordination with the SNS, FEMA, and DoD, has initiated procurement contracts with ancillary manufacturers to acquire stockpiles of ancillary supplies such as needle and syringes. BARDA is supporting ASPR/SNS efforts to place additional ancillary manufacturers under contract to bolster the manufacturing base. Finally, BARDA is working with FEMA and the DoD using DPA Title III to incentivize ancillary manufacturing capacity increases at multiple locations as well as recently awarded projects funding vial manufacturing in two locations. BARDA and its partners will continue to identify worthy projects as we acquire more information about the state of manufacturing in the health care sector. BARDA is currently collecting information on production capacity, including the availability of materials needed for fill/finish (e.g., vials) and administration (e.g., needles, syringes). BARDA assesses the need for COVID-19-related ancillary supplies above what is needed to administer other life-saving medications, with the intention that the administration of a COVID-19 MCM will not burden the regular demand of other critical domestic health-care needs.

Question. Given the uncertainty in supply chain, should the SNS diversify their sources of these necessary products?

Answer. Please see answer above.

Question. In existing IDIQ contracts SNS has set minimum purchasing amounts with suppliers. Does SNS take into account the production capability of manufacturers in setting these minimum purchase amounts?

Answer. Please see the response above. BARDA is leading these efforts, in coordination with DoD and other Federal partners.

Question. What appropriations account (identified by Treasury Account Symbol) are the IDIQ contracts funded out of?

Answer. Please see the response above. BARDA is leading these efforts, in coordination with DoD and other Federal partners.

QUESTIONS SUBMITTED BY HON. JOHN THUNE

Question. As you know, quality and access issues continue at Indian Health Service (IHS) facilities in South Dakota. The President's budget request includes \$12 million for recruitment and retention strategies and also references legislative pro-

posals to help build and support a competent and caring IHS workforce. What are the legislative proposals the administration is seeking?

Answer. The administration is seeking the following legislative proposals:

- To provide the Indian Health Service discretionary use of all title 38 personnel authorities.
- To provide half-time basis service obligation option for the Indian Health Service scholarship and loan repayment program.
- To seek an income tax exclusion for the Indian Health Service scholarship and loan repayment programs.
- To seek a waiver of Indian preference when there is an urgent staffing issue and specific conditions are met.
- To seek a withholding annuity and retiree pay for retired civil service employees convicted of moral turpitude.

IHS Congressional Justifications can be viewed and downloaded here: <https://www.ihs.gov/budgetformulation/congressionaljustifications/>.

Question. Former IHS pediatrician, Stanley Weber, has been convicted and sentenced for multiple sexual abuse charges. I understand the Department awarded a contract last year to an outside company to investigate whether IHS protocol had been followed in handling these allegations, so I'd like to inquire if that investigation has concluded and what information will be shared with Congress?

Answer. On May 10, 2019, IHS awarded a contract to an external contractor to conduct a medical quality assurance (MQA) review to examine whether laws, policies, and procedures have been followed with regard to protecting patients from sexual abuse. The report included a retrospective MQA review to evaluate actions taken from 1986 (when former IHS pediatrician Stanley Weber began working at IHS) to the present. The report by the external contractor was submitted to IHS in January 2020. Congress established specific restrictions regarding confidentiality and privilege of MQA records, pursuant to 25 U.S.C. 1675(e)(2). IHS made the redacted report available to certain congressional staff, including representatives from the South Dakota congressional delegation, at HHS headquarters on February 28, 2020 and March 2, 2020. The Government Accountability Office (GAO) received a redacted copy from IHS on March 16, 2020. The information that was redacted was in accordance with provisions of the Privacy Act, the Indian Healthcare Improvement Act, the Health Insurance Portability and Accountability Act, and applicable law regarding attorney-client privilege.

Question. In your response for the record last year, you stated that IHS implemented a new credentialing and privileging system for new applicants and re-applicants at IHS, and that privileging and performance evaluations would eventually also be tracked there. Have the performance evaluations been fully integrated into the new system? How does the system work to identify issues with existing providers, and not just providers in the application process?

Answer. In response to your first question, the IHS centralized credentialing and privileging software (ASM/MD-Staff) is being utilized in all facilities. The credentialing system implementation began in the IHS Phoenix Area in May 2017. The system automates aspects of the credentialing process, including the completion of initial and regular monthly verification of provider credentials, flagging any negatively changed items. This is an improved process that now provides real time situational awareness to governing boards on provider's status. In addition, while the system does provide a good resource for provider performance evaluation information, these evaluations are not created solely by, or stored within, the ASM/MD-Staff system.

In response to your second question, performance management and evaluations are completed in accordance with IHS and Department policies and procedures. Performance management requirements are coordinated by human resources (HR) and evaluations are stored within the HR systems. IHS is working with the Department to establish an HHS enterprise-wide electronic performance evaluation system to manage and track provider performance throughout the year. IHS Medical staff peer evaluation (OPPE/FPPE) requirements are guided by CMS and accreditation organizations, and these records are maintained in accordance with CMS regulations and accreditation standards within the Medical Staff files at each facility.

Question. Another former IHS provider, Pedro Ibarra-Perocier, was recently indicted on charges of sexual abuse. I understand he was placed on administrative leave while IHS investigated, but had been allowed to work at the local area office.

It has also been reported that he had previously been accused of workplace harassment by other employees. These repeat problems with staff are unacceptable. As head of the Department that oversees IHS, what more can you do to drive major change there?

Answer. As the administration continues to prioritize the health and well-being of American Indians and Alaska Natives, I am pleased to report that the IHS has made important strides to address and prevent sexual abuse in health-care facilities and strengthen policies on patient protections and staff reporting. Patients and employees should never face sexual harassment or abuse, and that includes our IHS providers. IHS continues to institute necessary reforms to create the high quality care environment that patients and employees should expect in IHS clinics and hospitals.

IHS issued new policies that address the types of protections set forth by nationally recognized professional organizations and has made significant progress on implementation. IHS is committed to protecting patients from sexual abuse and is determined to hold anyone accountable who has abused patients or failed to protect them. IHS requires annual mandatory training to strengthen protections against the sexual abuse and exploitation of children. The training reinforces IHS policy and is designed to help employees identify and immediately respond to suspected child maltreatment. IHS has also implemented a centralized credentialing system,¹ allowing credentialing staff now to access provider credentialing information in a single electronic database for all Federal IHS facilities. In addition, IHS recently announced the expansion of specialty care services, including behavioral health through telemedicine² as recommended by the White House Task Force to Protect Native American Children in the Indian Health Service System.³ Several of the recommendations in the Task Force's report would require congressional action. As indicated in response to your first question, the IHS has already made legislative proposals in the agency's Fiscal Year 2021 Congressional Justification of Estimates for Appropriations Committees⁴ that would address several recommendations. The link to the congressional justifications can be found here: <https://www.ihs.gov/budgetformulation/congressionaljustifications/>.

Question. As you know, I've been interested in the IHS electronic health record modernization since VA announced it would be transitioning its system in 2017. I appreciate that you provided a 2019 timeline in responses to questions for the record last year, and thanks for the specific mention of this issue in the 2021 budget. While the budget provides a roadmap for additional steps to be taken, I'd like to know if there is a targeted end date for completion of this modernization project?

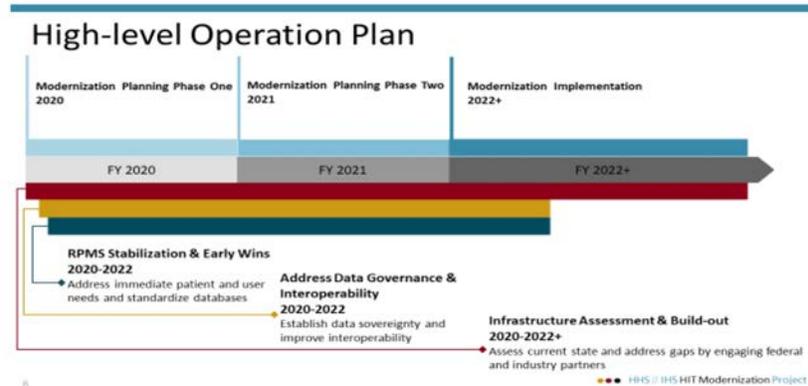
Answer. The Health IT Modernization project will take 7–10 years to complete, including a nationwide rollout to over 400 sites. Please see the following timeline below.

¹ <https://www.ihs.gov/budgetformulation/congressionaljustifications/>.

² <https://www.ihs.gov/newsroom/pressreleases/2020-press-releases/indian-health-service-announces-expansion-of-specialty-care-in-billings-area/>.

³ <https://www.whitehouse.gov/wp-content/uploads/2020/07/Task-Force-Report-Protecting-Native-American-Children-in-the-Indian-Health-Service-System-April-2020.pdf>.

⁴ https://www.ihs.gov/sites/budgetformulation/themes/responsive2017/display—objects/documents/FY_2021_Final_CJ-IHS.pdf.



Question. In 2018, CMS issued a much anticipated interim final rule that offered relief to durable medical equipment providers in some of the most rural areas, and CMS further extended that policy through subsequent regulation. This relief is scheduled to conclude at the end of 2020. Do you anticipate that CMS will further extend or expand this relief to ensure beneficiaries do not experience a disruption in access to needed equipment? Will you commit to continuing to work with my office on this?

Answer. In November 2018, CMS published a final rule finalizing a fee schedule adjustment methodology for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items and services furnished from January 1, 2019 through December 31, 2020 in areas that are not Competitive Bidding Areas and are either rural areas or non-contiguous areas.⁵ In accordance with section 3712(a) of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, CMS will continue to adjust the fee schedule amounts for items and services furnished in rural and non-contiguous non-competitive bidding areas within the U.S. based on a 50/50 blend of adjusted and unadjusted rates for the remainder of 2020 and through the remainder of the public health emergency, which could mean that this fee schedule adjustment methodology continues into 2021 if the public health emergency is still in effect after December 31, 2020. Also, as required by section 3712(b) of the CARES Act, CMS will provide higher payments for certain DMEPOS items and services furnished in non-rural, non-competitive bidding areas within the contiguous U.S. with dates of service on or after March 6, 2020, through the remainder of the public health emergency.

We are available to work with your office to provide technical assistance on draft legislation.

Question. Last year, several Finance Committee members sent a letter to the Department urging you to take administrative action to address the issue of retroactive DIR fees that pharmacists in all of our States find extremely challenging. Can you provide any insight as to what the Department's plans are in this area?

Answer. The administration is committed to putting American patients first by addressing the rising cost of prescription drugs for the American consumer. We value the critical role pharmacies play in health-care delivery and recognize that we cannot serve our beneficiaries effectively without addressing the needs of pharmacies. We appreciate the feedback of the committee as we evaluate ways to address the high cost of prescription drugs.

Question. As a proponent of value-based insurance design, I am hoping you would elaborate further on the demonstration referenced in the budget that aims to reduce the utilization of low-value care in Medicare. How do you plan to go about testing these options and what sort of options are you considering?

⁵ Final rule available at: <https://www.federalregister.gov/documents/2018/11/14/2018-24238/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-for-renal-dialysis>.

Answer. Under this budget proposal, CMS will explore options within their current demonstration authority to test prior authorization of low-value services. The demonstrations or models may include, but are not limited to, testing prior authorization on spinal injections for low back pain, carotid artery disease screening in asymptomatic adults, and vertebroplasty. When implementing this proposal CMS will consider patient access and other quality concerns, in an effort to reduce burden on patients while ensuring appropriate provision of health care.

QUESTIONS SUBMITTED BY HON. TIM SCOTT

ON ANTIMICROBIAL RESISTANCE (AMR)

Question. One of the most significant health and security threats facing Americans today is the rise of antimicrobial resistance, or “AMR.” We have an urgent need for new antibiotics to combat growing resistance, but there has been a significant decline in the number of companies investing in antibiotic R&D. With more than 10 million deaths projected each year beginning in 2050, AMR requires action now. In South Carolina, when I speak with providers, patient advocates, public health groups, academics, innovative manufacturers, and those invested in our national defense, all agree that the present and future challenges posed by AMR demand proactive, nonpartisan public policy solutions.

The fact is, investment in novel antibiotics has lagged, the pipeline is slim, and the threat is growing exponentially. We cannot afford to be reactive.

What steps has the Federal Government taken, and what further steps is it considering taking, to encourage more industry investment on this front and to stabilize long-term development in novel antibiotics?

Answer. HHS supports the implementation of the U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), which is a multifaceted strategy to improve how the United States addresses the threat of antibiotic resistance (AR) including the development of new antibiotics.

CDC’s AR Solutions Initiative invests in national infrastructure to detect, respond, contain, and prevent resistant infections across health-care settings, food, and communities. Data from CDC’s AR surveillance systems and laboratory infrastructure is critical to highlighting national and international challenges related to resistance and informing areas of greatest need for research and development. Additionally, the CDC and FDA AR Isolate Bank supports therapeutic, vaccine and diagnostic development by sharing curated AR isolates with the private sector and academic researchers and makes CDC’s sequencing data from AR pathogens publicly available to spur industry innovation. CDC will continue to encourage investment in antibiotic innovation through the next iteration of the U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB 2.0) by working with partners across all sectors to further strengthen the collection of AR data, provide isolates, evaluate new agents, and update guidelines.

Question. Do we have a sense, at this point, of how many Americans with coronavirus infections or seasonal influenza will contract a serious secondary infection from drug-resistant bacteria? Do we have the antibiotics needed to solve this problem?

Answer. Preliminary CDC data show that bacterial and fungal infections in COVID-19 patients from 2020 do not appear to be more common than infections in patients with influenza-like illness (ILI) from 2019. The currently available data indicate that bacterial and fungal infections occur at about the same frequency overall in patients with COVID-19 as they do in patients with ILI. However, when analyzed by where the infection occurs based on onset, the data indicate that hospital-onset, secondary bacterial and fungal infections occur more frequently in COVID patients than ILI, emphasizing the importance of health-care infection control practices, while community onset infections occur less frequently. COVID-19 creates a perfect storm for AR infections in health-care settings with multiple issues likely driving their increased frequency: longer length of stay, crowding, severely ill patients, common antibiotic use, and infection control challenges like shortages of PPE.

CDC is actively evaluating data related to bacterial and fungal infections in COVID patients and will be assessing if and how the type of patients impacted differs significantly from previous trends. Data from these analyses came during a pe-

riod of decreased hospital utilization for non-COVID patient care and could shift with a return to elective procedures and other patient care. CDC is also working with States to respond to outbreaks of drug resistant infections in COVID units that appear to be related to lapses in infection control practices. To date, CDC and its AR Lab Network have identified at least 10 outbreaks in COVID units around the country and is reaching out to health departments and health-care facilities to identify others. The pathogens identified in the outbreaks include pathogens listed as Urgent Threats in CDC's 2019 AR Threats Report, including multi-drug resistant Enterobacteriaceae such as Carbapenem-resistant Enterobacteriaceae, *Candida auris*, and multi-drug resistant *Acinetobacter* such as Carbapenem-resistant *Acinetobacter* (CRAB).

CDC recently presented data on antibiotic use and secondary bacterial infections related to COVID-19 at the virtual meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), on September 9 and 10, 2020. This Council meeting also included multiple other presentations from Federal, industry, and academic partners on the intersection between COVID-19 and antibiotic resistance. Presentations from this meeting are archived on the PACCARB website (<https://www.hhs.gov/ash/advisory-committees/paccarb/meetings/index.html>).

Question. An emerging consensus among diverse stakeholders points towards a robust pull incentive as a means of incentivizing the investment and innovative research and development necessary to ensure a sustainable pipeline of products that can adequately address both the short- and longer-term effects of AMR?

Answer. HHS convened a workgroup in March 2019 to analyze existing incentives, potential proposals for new incentives as raised by non-governmental, industry, and international groups, and other options to develop a strategic framework to further incentivize the development of new treatments for antibiotic-resistant infections. This analysis has included consideration of the current and future burden of AMR on both public health and the economy, as well as the dynamics of drug development that specifically impact relevant antibacterial and related products. This work is ongoing.

ON VALUE-BASED ARRANGEMENTS FOR INNOVATIVE THERAPIES

Question. We have discussed at length some of the various challenges facing innovative therapies, even after they receive FDA approval. Gene therapies, cell-based therapies, and a host of other diverse treatment options hold tremendous promise for patients, but traditional payment models lack the tools and flexibilities needed to ensure sustainable access to these novel products, injecting uncertainty into long-term investment forecasts and inhibiting patients' ability to benefit from them.

In the case of sickle cell disease, for instance, despite nearly 20 novel therapies on the horizon, which could save millions in the long term and enhance quality of life for many of the estimated 100,000 American patients currently suffering from the condition, conventional payment structures would likely be a poor fit, whereas innovative frameworks that allow for payment over time, conditioned on the attainment of key clinical endpoints, would better reward value while sustainably absorbing costs.

Unfortunately, outdated statutory and regulatory provisions create disincentives and barriers for these types of value-based arrangements, particularly with regards to price reporting and the Anti-Kickback Statute.

Secretary Azar, in what ways might current price reporting rules, such as for Medicaid AMP and Best Price, create obstacles for robust value-based arrangements, both commercially and in our public health programs?

I was encouraged by your Department's decision to move forward with new safe harbor protections for certain value-based contracts under the OIG rulemaking regarding AKS and Stark, but, as the rule explicitly explains, novel therapeutics and devices were excluded. What plans does your agency have for providing the regulatory protections necessary for robust VBAs for innovative therapies and other products not included in the recent rulemaking?

Answer. Gene therapies are innovative new treatments that repair defects in a patient's genetic code. While the life-saving impact of these often curative therapies are profound, their costs are unprecedented. To ensure access to gene therapies and other groundbreaking medicines—the list price for which can approach or exceed a million dollars for one course of therapy—it is critical to shift the Nation's payment systems to reward value.

Value-based payment in health care involves basing payment on improvements in patient outcomes. Hospital reimbursement and clinician reimbursement are moving from systems of payment based on the volume of care provided to payment based on value or outcomes. However, value-based payment for prescription drugs is still in its infancy. Current CMS regulations do not readily accommodate value-based payment arrangements. For example, when reporting Medicaid Best Price, which is the lowest net price a manufacturer offers in the U.S. after factoring in all rebates and discounts, manufacturers face challenges accounting for rebates and discounts offered for these value-based payment arrangements under current regulations, which may inhibit wider use of such agreements.

In June, as part of President Trump's longstanding commitment to lowering drug prices, HHS issued a proposed rule that would start to remove barriers to the development of payment models based on value for innovative new therapies. The proposed rule includes provisions that would support the health-care system's move to paying on the basis of value instead of volume and increasing accountability for outcomes, as payers (commercial and government) would be able to better negotiate discounts based on a drug's effectiveness. For example, the specific proposals in CMS's proposed rule would provide payers and manufacturers the flexibility to consider new value-based purchasing options while ensuring that Medicaid always gets the best deal, and would ensure that Best Price accurately captures both the prices that are paid in new types of payment models and the circumstances in which those prices are paid. In addition, more widespread adoption of payment arrangements based on value could lead to the collection of more evidence on clinical outcomes for a given therapy. This type of real-world, real-time evidence could help providers use new medications and treatments in a more targeted fashion. Increasing the link between reimbursement and drug effectiveness will also encourage payers to facilitate patients' access to new therapies by easing more traditional utilization management practices.

By offering more flexibility for payers and manufacturers to enter into value-based agreements while still ensuring that Medicaid always gets the best deal, HHS is continuing its efforts to foster innovation, increase access to the latest technologies, and ensure that the Medicaid program is sustainable and can continue to serve our most vulnerable populations.

As part of the Department's Regulatory Sprint to Coordinated Care, which aims to reduce regulatory barriers imposed on health care industry stakeholders to advance the transition to value-based care and promote care coordination, both CMS and the Office of Inspector General (OIG) published proposed rules in October 2019 that would create new flexibilities for value-based arrangements under the physician self-referral law and Federal anti-kickback statute, respectively, to account for the ongoing evolution of the health care delivery system, and in the case of the CMS rule, modernize the interpretation of the physician self-referral law.

On November 20, 2020, CMS announced the final rule, "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations," which was published in the Federal Register on December 2nd (<https://www.federalregister.gov/documents/2020/12/02/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations>). The final rule includes a comprehensive package of reforms to modernize the regulations that interpret the Stark Law while continuing to protect the Medicare program and patients from bad actors. This includes finalizing policies that advance the transition to a value-based health-care delivery and payment system that improves the coordination of care among physicians and other health-care providers in both the Federal and commercial sectors.

In OIG's notice of proposed rulemaking, OIG indicated that value-based contracting and outcomes-based contracting arrangements for pharmaceutical products raise unique program integrity issues from the arrangements that are addressed in the proposed rule. As a result, OIG has considered and continues to consider the development of future rulemaking to provide specifically tailored safe harbor protection for value-based contracting and outcomes-based contracting for the purchase of pharmaceutical products (and potentially other types of products).

ON VIRTUAL PROVIDERS IN MDP

Question. Since coming to Congress, combating diabetes has been one of my top priorities. More than 576,000 South Carolinians have diabetes, comprising 14.1 percent of our adult population, and more than 1.3 million people across the State have prediabetes. We unfortunately have the eighth highest diabetes rate in the country.

From a quality of life perspective and a cost perspective, diabetes is devastating. People who have it face medical expenses roughly 2.3 times higher than folks who do not. I applaud your agency for moving forward with the Medicare Diabetes Prevention Program model, which strikes me as a meaningful and cost-effective way to empower Americans to take the steps necessary to reduce their own risk of diabetes, along with some of the other conditions that too often come along with it.

That said, I know the uptake for MDPP has been lower than expected, which is why I partnered with Senator Warner and a bipartisan group of our colleagues to send a letter to CMMI requesting that CDC-recognized virtual providers be included. This would present an ideal avenue for expanding access through high-quality, innovative programming.

What role do you see virtual providers—and innovative technology more broadly—playing as we work to more effectively prevent and combat diabetes?

Would you be willing to consider implementing an MDPP model that integrates and assesses the work of virtual health technology?

In your department's budget request, there was a reference to "Innovative Alternatives to Durable Medical Equipment for Treatment and Management of Diabetes." Could you elaborate on how this might look in practice and what efforts your agency might be undertaking along these lines? To what extent might this area involve virtual health technology?

Answer. During the COVID-19 Public Health Emergency (PHE), the Department, through an Interim Final Rule with comment (IFC), amended the Medicare Diabetes Prevention Program (MDPP) expanded model to modify certain MDPP policies during the PHE. Specifically, this IFC will permit certain beneficiaries to obtain the set of MDPP services more than once per lifetime, increase the number of virtual make-up sessions, and allow certain MDPP suppliers to deliver virtual MDPP sessions on a temporary basis. Our goal is to align MDPP model-specific changes as much as possible to what the Centers for Disease Control and Prevention (CDC) has released for the duration of the PHE.

Regarding the budget request you mentioned, allowing coverage of non-durable medical equipment would provide beneficiaries innovative options for their health care not currently available in the Medicare benefit for DME. These alternatives may not meet the lifetime or repeatable use standard, but could improve beneficiary lifestyle and health outcomes, while not increasing costs to Medicare. Non-durable medical equipment may be more compact and not tethered to electrical cords, which increases patient mobility, and thus, may improve patient compliance with device use. Further, the non-durable medical equipment items may be safer for some beneficiaries than the covered DME item, for example: lower risk of infection due to disposable nature; non-electrical so avoids electrical malfunction; and uses of safe alternative materials to avoid beneficiary allergic reaction.

Additionally, it is possible that such features could improve patient compliance and clinical outcomes. Also, the benefit could allow potential coverage of additional treatment options for the patient that may offer a therapeutic advantage over durable alternatives (e.g., reduced treatment times).

ON MFAR

Question. In South Carolina, we have a supplemental payment program that is used to help offset the cost of providing medical education at our teaching hospitals. Our State Medicaid agency projected that the MFAR rule would cut those payments by about 60 percent, with the cuts targeting hospitals that serve children and those with complex needs.

For the past several years, CMS has talked about aligning Medicaid with the commercial market. Why is CMS now proposing to replace average commercial rates as the limit for Medicaid supplemental payments with arbitrary new limits that are tied to Medicaid base payments?

South Carolina spends less money for each Medicaid beneficiary than nearly any other State in the country. I've seen reports showing that some other States spend nearly three times as much per-member as we do. I am concerned that MFAR disproportionately impacts SC, one of our most efficient States, by targeting its children's and teaching hospitals.

I am also concerned about the procedural aspects of MFAR. In South Carolina, we have had Medicaid State plan amendments that were pending for 6 years before

CMS approved them. MFAR would require that CMS immediately re-approve all supplemental payment programs and then approve them again every 3 years thereafter, whether States proposed to amend them or not. I support CMS's focus on cutting red tape, but all of these re-approvals would inevitably mean more paperwork.

In light of ongoing backlogs and other labor-intensive approval processes, why would CMS add another expansive re-approval process into the mix, creating additional paperwork, particularly in the case of States not even making changes?

Answer. The Medicaid Fiscal Accountability Regulation (MFAR), CMS-2393-P, was published in the November 18, 2019, issue of the Federal Register, with a 60-day comment period that closed on January 17, 2020, which was subsequently extended by 15 days and closed on February 1, 2020. During this time, CMS also conducted numerous calls with States and other stakeholders to receive substantive feedback to help us understand the potential impact of the proposed rule.

The policies proposed within the rule are intended to ensure accountability of State financing, transparency of payments, and the fiscal integrity of the Medicaid program, including through numerous clarifications to Medicaid financing and oversight rules. Specifically, this proposed rule would impact States' reporting on payment methods and procedures to assure consistency with efficiency, economy, and quality of care as required by section 1902(a)(30)(A) of the Act. CMS, and other Federal oversight entities, have found that current regulations and guidance do not adequately ensure that States are complying with the efficiency, economy and quality of care requirements of section 1902(a)(30)(A) of the Act, and this proposed rule is intended to address those deficiencies. Please know that we have listened closely to concerns that have been raised by our State and provider partners about potential unintended consequences of the proposed rule, which require further study. Therefore, CMS has withdrawn the rule from the regulatory agenda.

ON OPIOID CO-PRESCRIPTION

Question. On April 5, 2018, the Surgeon General released an advisory statement, emphasizing the importance of expanding access to naloxone. In December 2018, an FDA joint advisory panel recommended the co-prescribing of naloxone with opioids. Shortly thereafter, HHS released naloxone co-prescription guidelines, calling for "co-prescribing naloxone when a patient is considered to be at high risk of an overdose," as "an essential element of our national effort to reduce overdose deaths" that "should be practiced widely."

In April 2019, CMS released the final 2020 Medicare Advantage and Part D Advance Notice Part II and Draft Call Letter, encouraging insurance plans to implement co-prescribing for beneficiaries at an increased risk for an opioid overdose. South Carolina is actively considering legislation in its House of Representatives to join 9 other States in implementing naloxone co-prescription policies. In short, the Surgeon General, HHS, CDC, CMS, SAMSHA, the AMA, AAFP, ASAM, a growing number of States including hopefully South Carolina, and FDA's advisory committee all support increasing access to naloxone through co-prescription.

Our current understanding is that, to date, no FDA action has been taken in response to the recommendation of its joint advisory committee or the growing consensus outlined above. Could you please provide an update on FDA consideration of recommending co-prescribing of naloxone with opioids for populations at elevated risk of opioid overdose?

Answer. On July 23, 2020, FDA announced it is requiring that labeling for opioid pain medicine and medicine to treat opioid use disorder (OUD) be updated to recommend that as a routine part of prescribing these medicines, health care professionals should discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment.

The required labeling changes, announced in a Drug Safety Communication, also recommend that health-care professionals consider prescribing naloxone when they prescribe medicines to treat OUD. Additionally, the labeling changes recommend that health care professionals consider prescribing naloxone to patients being prescribed opioid pain medicines who are at increased risk of opioid overdose, including those who are also taking benzodiazepines or other medicines that depress the central nervous system; those who have a history of OUD; and those who have experienced a prior opioid overdose. A naloxone prescription should also be considered for patients prescribed opioids who have household members, including children, or other close contacts at risk for accidental ingestion or opioid overdose.

The FDA is requiring that these recommendations be added to the prescribing information for opioid pain medicines and medicines to treat OUD, including buprenorphine, methadone, and naltrexone and for patients who may be at high risk of an opioid overdose like those with a prescription for sedatives like benzodiazepines.

The FDA is working with other Federal, State, and local officials as well as health-care professionals, patients, and communities nationwide to help increase availability of naloxone and combat opioid overdoses. Patients should talk to their health-care professional about how to obtain naloxone according to their State's requirements or guidelines. The U.S. Department of Health and Human Services has ongoing efforts to fight the opioid crisis and expand the use of naloxone. This includes: better targeting of overdose reversing drugs as part of a 5-Point Strategy to Combat the Opioids Crisis.

Planning is also underway within CDER's Office of Communications to promote additional naloxone communication and outreach among health-care providers, including a webinar that may be eligible for a continuing education credit.

QUESTIONS SUBMITTED BY HON. BILL CASSIDY

CMMI DIRECT CONTRACTING MODEL

Question. My office has heard some concerns from providers in Louisiana that under the current structure of the Direct Contracting option, physicians will not be successful in the model. The benchmark calculation methodology penalizes providers who have been participating in coordinated care of their population, such as the Medicare Shared Savings Program or Next Generation ACO, by basing the payment amount on the cost of care over the previous 3 years, but weighted at 50 percent for the last year. The benchmark will be lower compared to newly entered entities with no previous care coordination of their population, thus skewing benchmarks to a higher value, giving them the chance to capture greater shared savings. If the Direct Contracting Model is going to be successful, CMS needs to attract both high performing groups and new entrants interested in taking on risk.

What are some ways that CMS could take this into account to ensure the model offers opportunities for success for all varieties of physicians?

Answer. Direct Contracting is a set of two voluntary participation options aimed at reducing expenditures and preserving or enhancing quality of care for beneficiaries in Medicare fee-for-service (FFS). The participation options available under Direct Contracting create opportunities for a broad range of organizations to participate with the Centers for Medicare and Medicaid Services (CMS) in testing the next evolution of risk-sharing arrangements to produce value and high quality health care. Building on lessons learned from initiatives involving Medicare Accountable Care Organizations (ACOs), such as the Medicare Shared Savings Program and the Next Generation ACO Model, the participation options available under Direct Contracting also leverage innovative approaches from Medicare Advantage (MA) and private sector risk-sharing arrangements.

The participation options are anticipated to appeal to a broad range of physician practices and other organizations because they are expected to reduce burden, support a focus on beneficiaries with complex, chronic conditions, and encourage participation from organizations that have not typically participated in Medicare FFS or CMS Innovation Center models.

A key aspect of Direct Contracting is providing new opportunities for a variety of different organizations (Direct Contracting Entities or DCEs) to participate in value-based care arrangements in Medicare FFS. Under Direct Contracting, there will be three types of DCEs with different characteristics and operational parameters. These three types of DCEs are:

- Standard DCEs—DCEs comprised of organizations that generally have experience serving Medicare FFS beneficiaries, including Medicare-only and also dually eligible beneficiaries, who are aligned to a DCE through voluntary alignment or claims-based alignment. These organizations may have previously participated in section 1115A shared savings models (*e.g.*, Next Generation ACO Model and Pioneer ACO Model) and/or the Shared Savings Program. Alternatively, new organizations, composed of existing Medicare FFS providers and suppliers, may be created in order to participate in this DCE type. In either case, CMS expects that clinicians participating within these

organizations would have substantial experience serving Medicare FFS beneficiaries.

- New Entrant DCEs—DCEs comprised of organizations that have not traditionally provided services to a Medicare FFS population and who will primarily rely on voluntary alignment, at least in the first few performance years of the model. Claims-based alignment will also be utilized.
- High Needs Population DCEs—DCEs that serve Medicare FFS beneficiaries with complex needs, including dually eligible beneficiaries, who are aligned to the DCE through voluntary alignment or claims-based alignment. These DCEs are expected to use a model of care designed to serve individuals with complex needs, such as the one employed by the Programs of All-Inclusive Care for the Elderly (PACE), to coordinate care for their aligned beneficiaries.

CMS recently issued the financial methodology and rate books for the Direct Contracting model, and has held numerous webinars and office hours for interested stakeholders. More information can be found on the Direct Contracting website at: <https://innovation.cms.gov/innovation-models/direct-contracting-model-options>.

NEXT GEN ACO

Question. There are also concerns by primary care providers about the deductions and withholds built into this model. A 2-percent retention withhold to protect against early withdrawal seems excessive when applied to an experienced ACO that has a proven track records in value-based care.

Can CMS forgo the 2-percent retention withhold for those Next Gen ACO's that have proven experience in shared risk contracting with Medicare?

I have heard concerns from providers in my State regarding the continuation of the CMS Next Generation ACO Model. There have been reports that CMS may discontinue the model and require participants to transition to other risk-based models. Cumulatively over 2016–2017, Next Gen ACOs saved Medicare \$123 million, however no savings once factoring in shared savings. However, changing policy with an intended budget neutral effect can have tremendous impacts on behavioral economics, and save the system money. The NGACO Model seems to be successfully aligning incentives around the patient, and changing the way doctors and systems care for Medicare beneficiaries. It may be shortsighted to discontinue the model just because it showed modest savings.

Is CMS planning on making changes to the NextGen ACO Model, and if so, why?

Answer. In response to the COVID–19 Public Health Emergency (PHE), CMS made adjustments to some Innovation Center models. This included extending the Next Generation ACO Model through December 2021. In addition to this extension, CMS reduced participants' downside risk by proportionally reducing shared losses based on the number of months that fall within the PHE and also removed certain episodes of care for the treatment of COVID–19 from the calculation of shared savings or shared losses.

ACA AND MAGI ELIGIBILITY STANDARD

Question. The ACA greatly exacerbated improper payments and eligibility issues—the Modified Adjusted Gross Income (MAGI) eligibility rules prohibit States from conducting asset verification tests for the expansion population. Asset verification meanwhile is required for the traditional aged, blind, and disabled population. This creates an incentive to enroll able-bodied adults over truly needy populations. The budget provides States the option to apply asset tests to populations determined financially eligible by the MAGI standard, so States can refocus resources on the truly needy.

How would allowing States to consider held assets in the MAGI determination process ensure the Medicaid program is serving the truly needy, and not some folks sitting on a relative fortune?

Answer. Asset tests allow States to prioritize receipt of Medicaid for lower-income individuals by screening for assets and resources, such as savings accounts or vehicles. The ACA's Modified Adjusted Gross Income (MAGI) eligibility rules eliminated asset tests for most children and able-bodied adults, leaving asset tests only for aged, blind, and disabled Medicaid beneficiaries. The budget proposes to allow States the option to apply asset tests to populations determined financially eligible by the MAGI standard, such as able-bodied adults, so States can refocus Medicaid on the truly needy. This proposal also provides States with the option to apply asset

tests to individuals eligible through the MAGI standard who are receiving long-term care.

Greater flexibility to expand asset tests to MAGI populations could allow States to refocus Medicaid on the most vulnerable individuals by screening out individuals who have financial and other assets due to a windfall or savings and may be able to afford to pay for private insurance or medical expenses.

QUESTIONS SUBMITTED BY HON. TODD YOUNG

ORGAN DONATION—OPO COMPETITION

Question. In your testimony, you mention how the administration is proposing to increase competition among Organ Procurement Organizations (OPOs) to improve performance and increase the supply of organs for transplant.

Can you elaborate on your plans to increase competition?

How do you plan to do this when these 58 OPOs are regional monopolies?

ORGAN DONATION—UNOS OVERSIGHT

I joined Chairman Grassley, Ranking Member Wyden and Senator Cardin in a letter to the United Network for Organ Sharing (UNOS) questioning the adequacy of their oversight over our 58 OPOs. As the government contractor for nearly 40 years, UNOS is responsible for abiding by this vision of safety, transparency, and public trust which includes the close monitoring of OPOs. But, sadly, under their watch, numerous The HHS Office of the Inspector General (OIG) audits and news reports have found serious lapses in patient safety, misuse of taxpayer dollars, and tens of thousands of organs going unrecovered or not transplanted by various OPOs.

What sort of oversight is HHS providing over UNOS to ensure they're living up to the requirements set out in statute?

ORGAN DONATION—OPO USE OF TAXPAYER DOLLARS

The OIG and others have identified numerous inappropriate uses of Medicare funds by OPOs. This includes some OPOs using taxpayer dollars to buy sports tickets, charter private planes, and throw lavish parties. In one case, an OPO based in southern California used taxpayer dollars to throw a lavish New Year's Eve party, buy Rose Bowl tickets, and transport their executives in limousines. While OPOs spend taxpayer dollars on entertainment, lobbying, and gifts, patients are left waiting on a transplant list. This is simply unacceptable.

How is it that our government contractors are allowing these types of expenses to be reimbursed by taxpayers?

What does HHS plan to do about oversight of these types of reimbursements?

ORGAN DONATION—OPO PERFORMANCE

HHS's own data suggests that the vast majority of OPOs are failing, and as a result, 1,000 patients die every month for lack of an organ transplant. This is simply unacceptable given research cited by the President showing that OPOs fail to recover up to 28,000 organs every year.

The Centers for Medicare and Medicaid Services (CMS) has not decertified any OPO in decades. I applaud your leadership in changing regulations so that OPOs can be held accountable—noting that according to proposed rules, the majority of the country's OPOs are failing key performance metrics—that includes OPOs in Indiana, Iowa, Oregon, South Carolina, Idaho and so many other parts of the country. In the past, corrective action plans for OPOs have not worked.

So what steps are HHS taking now to prepare to actually hold OPOs accountable?

Answer. Several agencies regulate aspects of the U.S. organ transplant system. The Department's oversight of organ procurement organizations (OPOs) is provided by both the Health Resources and Services Administration (HRSA) and by the Centers for Medicare and Medicaid Services (CMS). The Organ Procurement and Transplantation Network (OPTN) is operated by contract between HRSA and the United Network for Organ Sharing (UNOS). Through the OPTN contract, HRSA requires the OPTN contractor to monitor and evaluate OPTN member compliance and identify potential patient safety threats.

All OPOs are required to comply with the OPTN final rule (42 CFR part 121). OPOs are mandated members of the OPTN and must comply with the rules and requirements of the OPTN approved by the Secretary. The OPTN maintains bylaws and policies consistent with its authority through the National Organ Transplant Act of 1984, the OPTN final rule, and the OPTN contract, which includes maintaining a national list of individuals who need organs, establishing membership criteria, policymaking for allocating organs, and reviewing and evaluating OPTN member organizations. The authority of the OPTN does not extend to the financial management of OPTN members, but does include oversight of member procurement and allocation activities and member compliance. Through the OPTN contract, HRSA requires the OPTN contractor to monitor and evaluate OPTN member compliance and identify potential patient safety threats. Under Federal law, CMS is charged with conducting surveys of OPOs to determine whether they meet the Conditions for Coverage, including outcome and process measures. Facilities must correct any problems cited in surveys in order to be certified and continue receiving payment for services from Medicare and Medicaid for at least 4 years. If an OPO is decertified, the OPO's donation service area (DSA) is opened to competition from other OPOs. CMS then assigns one or more other OPOs to serve all or part of the decertified OPO's DSA. Existing regulations ensure a DSA is never without an OPO or access to organ procurement services, especially donated organs.

On November 20, 2020, the Department issued a final rule that updates the OPO Conditions for Coverage to change the way OPOs are held accountable for their performance (<https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>). The final rule improves the current measures by using objective and reliable data, incentivizes OPOs to ensure all viable organs are transplanted, and holds OPOs to greater oversight while driving higher OPO performance.

The rule is a directive of President Trump's executive order on Advancing American Kidney Health and would apply to procurement of all organs from deceased donors. As a key goal, the President's executive order and this final rule seek to help the more than 113,000 people in the United States currently on the wait list for a lifesaving organ transplant, which far exceeds the number of transplantable organs available.

Under the final rule, all OPOs are encouraged to meet at least the donation and transplantation rates of the top 25 percent of OPOs, a ranking that will be publicly available. OPOs with performance rates that are below the top 25 percent will be required to take action to improve their rates through a quality assurance and performance improvement (QAPI) program, which CMS will assess at least every 12 months.

At the end of each re-certification cycle, each OPO will be assigned a tier ranking based on its performance for both the donation rate and transplantation rate measures and its performance on the re-certification survey. The highest performing OPOs that are ranked in the top 25 percent will be assigned to Tier 1 and automatically recertified for another 4 years. Tier 2 OPOs are the next highest performing OPOs, where performance on both measures exceed the median but do not reach Tier 1. Tier 2 OPOs will not automatically be recertified and will have to compete to retain their donation service areas (DSAs). Tier 3 OPOs are the lowest performing OPOs that have one or both measures below the median. Tier 3 OPOs will be decertified and will not be able to compete for any other open DSA.

These changes will hold OPOs to greater oversight, transparency, and accountability while driving higher OPO performance across the board to increase patients' access to needed organ transplants no matter where they live.

SOCIAL DETERMINANTS OF HEALTH

Question. A person's health should not be dependent on where they live or the economic challenges they face. But, these economic and social conditions, such as access to reliable transportation and stable housing, do have a profound effect on an individual's health and well-being. Addressing these factors can have a meaningful impact on the prevention and management of chronic diseases in our communities.

How does the administration plan on addressing these social determinants of health?

Answer. An individual's health is influenced by many factors, including socioeconomic factors, physical environment, and their health behaviors. Addressing the social determinants of health at play can have significant implications on a person's well-being and their ability to access comprehensive health care. This has been of paramount importance to the administration, and is reflected throughout the countless programs aimed at bridging the gap so that Americans can access the health care that they need. The administration is actively engaged in addressing and promoting health for all; HHS is committed to addressing the social determinants of health in all of its programs and initiatives and to eliminating barriers to health care.

DRUG SHORTAGES

Question. Drug shortages continue to be a problem for hospitals, physicians, and patients—most of whom are left with few alternatives. Last October, the Food and Drug Administration (FDA) released its Drug Shortage report that included a number of recommendations on how to prevent and reduce the impact of drug shortages. I noticed, however, that there was nothing specifically outlined in the President's budget that addressed this issue.

Could you outline for us how FDA plans to work with CMS and industry to advance the policies outlined in that report?

Do you believe FDA or CMS require any additional authorities in order to implement any of these goals?

Answer. The U.S. Food and Drug Administration (FDA) continues to work to find ways to mitigate drug shortages and does everything within our authority to help prevent and alleviate shortages, for both adult and pediatric products. We have asked manufacturers to evaluate their entire supply chain, including active pharmaceutical ingredients, finished dose forms, and any components that may be impacted in any area of the supply chain due to the COVID-19 outbreak.

Our public drug shortages lists are up-to-date with human and animal drugs and biological products that we have determined to be in shortage. These shortages are not all results of COVID-19, with many existing prior to the pandemic as results of market changes and supply challenges. We are updating these lists regularly and communicating in real-time so that patients and health-care providers have the most current information on product shortages in the U.S.

When potential shortages or disruptions of medical products are identified by FDA, we use all available tools to react swiftly to help mitigate the impact to U.S. patients and health care professionals. We will quickly share that information with the public, as appropriate, in close coordination with our Nation's response partners. FDA is working closely with manufacturers to make sure that they notify the agency of any permanent discontinuance or interruption of drug and biological product manufacturing in a timely manner. On March 27, 2020, FDA published guidance about the importance of these notifications, the timelines that drug and biologic manufacturers should follow when notifying the FDA, and the details manufacturers should provide about the discontinuance or interruption in manufacturing.

The FDA issued a report in October, 2019⁶ entitled, "Drug Shortages: Root Causes and Proposed Solutions." The report was the work of an inter-agency Drug Shortages Task Force of senior officials drawn from FDA's own ranks and several partner Federal agencies, including the Centers for Medicare and Medicaid Services (CMS). The agency invited public participation through a public meeting on November 27, 2018 with a docket to receive comments, and invited stakeholders to a series of listening sessions.

The report included three broad recommendations: (1) create a shared understanding of the impact of drug shortages and the contracting practices that may contribute to them, (2) create a rating system to incentivize drug manufacturers to invest in achieving quality management system maturity, and (3) promote sustainable private sector contracts. The report also proposed several legislative proposals and planned FDA initiatives that focus primarily on enabling FDA to help prevent supply disruptions from leading to shortages and mitigating shortages when they occur. FDA is implementing policies to prevent and mitigate shortages, including:

- Developing a pilot for a quality management maturity rating system.

⁶The report was subsequently updated in February 2020.

- Working with international bodies to reduce regulatory barriers to making manufacturing changes with a view toward increasing production.
- Preparing to implement a requirement added by the CARES Act under which drug manufacturers will report annually to FDA on the amount of each drug, including finished dosage forms and active pharmaceutical ingredients, that they manufacture, prepare, propagate, compound, or process for commercial distribution. Under this new reporting requirement, that took effect in September 2020, FDA expects it will have more insight into the volume of product coming into the U.S. market and where supply chains are vulnerable.
- Issuing guidances on information FDA will be collecting as part of the “notification” process and on risk management plans.
- Supporting advanced manufacturing, which is generally less vulnerable to quality problems leading to supply disruptions and shortages.

FDA continues to work with relevant stakeholders (*e.g.*, other Federal agencies and drug manufacturers) to facilitate the adoption of advanced manufacturing technologies as one of the proactive approaches to prevent drug shortages and ensure continuous supply of critical drugs in the U.S. Advanced manufacturing technology, which can be more cost-effective and environmentally friendly than traditional manufacturing technology, may enable the United States to play a larger role in pharmaceutical manufacturing. These include initiatives to enhance the efficiency of drug manufacturing by utilizing technology (such as through the use of 3D printing, miniaturization, continuous manufacturing and other techniques). By supporting education for a domestic workforce trained in these areas, skilled U.S. workers would be able to be part of this emerging trend in drug manufacturing. By moving from batch-to-batch production to continuous manufacturing, drugs can be produced much more quickly, and the quality is much more uniform. As part of the COVID-19 response, the Department has engaged companies to help promote domestic manufacturing and additional sources of medical products.

“Drug Shortages: Root Causes and Proposed Solutions” responds to the request from Congress to convene a task force to study the problem, prepare a report on the root causes of drug shortages, and make recommendations for enduring solutions. FDA, working in concert with the Task Force, fulfilled those objectives. As noted in the report, implementing the types of enduring solutions proposed will require multi-stakeholder efforts and rethinking of business practices throughout the health care system.

In Appendix D of the report (pages 84–88), CMS raises policy issues related to each of their programs.

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. Please provide the basis for the estimates in the President’s budget for each of the Medicaid legislative proposals including those contained in his “health reform vision,” to include baseline enrollment, baseline per member per month spending, and baseline trend rates, as well as projected changes in enrollment, projected per member per month spending, and projected year-to-year trend rates, along with all relevant assumptions.

Answer. In general, estimating the impacts of proposals requires various data sources (Medicaid and non-Medicaid), input from health-care and policy experts on the practical effects of changes to the programs, and informed assumptions about their impacts. The exact information needed depends heavily on the nature and specifics of the proposal. The attached file contains our projected expenditures, enrollment, and per enrollee expenditures from the President’s FY 2021 budget. This is the most recent set of projections we have completed, and it is important to note that it does not account for any impacts or legislation related to COVID-19. We have provided some notes along with these figures as well.

Question. On page 117, the HHS Fiscal Year 2021 Budget in Brief states that Proposed Rule (CMS-2421-P) “will allow States the option to conduct more frequent eligibility redeterminations, amongst other reforms to improve the integrity of State eligibility determination and renewal processes.”

Will such more frequent redeterminations apply to all populations determined financially eligible by the Modified Adjusted Gross Income (MAGI) standard, including children and individuals with disabilities?

Under the proposed rule (CMS–2421–P), how frequently would States be allowed to conduct eligibility redeterminations?

Are there limits or requirements around how States would be able to conduct eligibility redeterminations?

What are the proposed “other reforms” in the area of eligibility determination and renewal processes referenced in the budget in brief?

Answer. Current regulations generally prohibit States from conducting Medicaid eligibility redeterminations more than once every 12 months for individuals eligible based on financial criteria. The FY 2021 budget includes an administrative proposal to remove the regulatory restriction limiting a State’s ability to determine beneficiary eligibility to no more than once every 12 months for certain MAGI-eligible groups, absent information about a change in the beneficiary’s circumstances that may affect eligibility. Such changes would allow States the option to more frequently determine whether an individual remains eligible for Medicaid or if their income has exceeded the income limits.

HHS has not released the proposed rule “Strengthening the Program Integrity of the Medicaid Eligibility Determination Process” (CMS–2421–P). If the Department moves forward with a proposal, we will follow standard rulemaking procedure, which includes an extensive comment period for public feedback. We welcome input from all of our stakeholders as we make important policy decisions to improve our programs.

Question. On page 64, the Fiscal Year 2021 Analytical Perspectives budget document States that the President’s budget “proposes to allow States flexibility to more frequently assess beneficiary eligibility, while clarifying data matching requirements to ensure taxpayer resources are not supporting ineligible beneficiaries. This administrative proposal saves \$17.1 billion over 10 years.”

What are the clarifying of data matching requirements that you refer to?

What is the year-by-year enrollment decline that is the basis of the spending reductions under this proposal, including breakout by eligibility group?

Answer. Current regulations generally prohibit States from conducting Medicaid eligibility redeterminations more than once every 12 months for individuals eligible based on financial criteria. The FY 2021 budget includes an administrative proposal to remove the regulatory restriction limiting a State’s ability to determine beneficiary eligibility to no more than once per year, absent information about a change in the beneficiary’s circumstances that may affect eligibility. Such changes would allow States to more frequently determine whether an individual remains eligible for Medicaid or if their income has exceeded the income limits.

QUESTIONS SUBMITTED BY HON. MARIA CANTWELL

NOVEL CORONAVIRUS OUTBREAK

Question. In January, the first U.S. case of COVID was found in Washington State. Our health department has been working tirelessly to protect Washingtonians and prevent further outbreaks. However, Washington State has already spent over \$1.6 million on response and expects significant costs going forward. In early February, CDC sent the Washington State Department of Health diagnostic test kits to begin testing our own patients for COVID. But the test kits reported inconsistent results, requiring the State to use more resources *and* request additional assistance from the CDC. This virus is not only affecting the health of people in America and globally—it is taking a toll on the economy. In January 2020 alone, Washington State experienced a 25-percent drop in Chinese tourism in the Seattle area. At this time, we need to ensure that the CDC, our frontline defense, is adequately funded.

The budget includes over \$145 million in cuts to CDC programs that have been directly responding to the coronavirus outbreak and the diagnostic test kit development. Do you think these cuts are in the best interest of the American people, who expect an effective response to this outbreak and any future infectious disease outbreaks?

Answer. The President’s initial FY 2021 request was formulated with consideration to overall budget caps for discretionary spending and thus included cuts for many discretionary programs.

On March 17, 2020, the administration transmitted an FY 2021 budget amendment to Congress to increase funding for CDC to ensure that the agency had the resources beginning October 1, 2020, to continue its critical public health mission. This amendment requested a total FY 2021 funding level of \$8,329,102,000 for CDC, which is \$1,328,196,000 above the FY 2021 budget request. The additional funding would support priority CDC activities, including preparedness and response.

The administration worked closely with Congress to ensure that State and local public health departments had necessary resources to respond to COVID-19.

Question. The President has asked you to lead a Coronavirus Task Force. However, the Task Force does not include anyone from the Department of Defense, USAID, or the Department of Agriculture. Why are these agencies not a part of the task force? Do you believe the U.S. can properly respond to the COVID outbreak without their participation?

Answer. The President announced the formation of the Coronavirus Task Force on January 29th to help lead the administration's efforts to monitor, contain and mitigate the spread of the virus. The Task Force is led by Vice President Mike Pence and is coordinated through the National Security Council. It is composed of subject matter experts from the White House and several other United State Government agencies chosen by the White House to lead the overall, whole-of-government response. Throughout the pandemic, the White House has added new members to the Task Force as our response to the pandemic evolved. For example, on May 15th, the White House announced new individuals to the White House Coronavirus Task Force, including Secretary of Agriculture Sonny Perdue.

The President has a team of experts advising him and overseeing the response that is without parallel anywhere in the world, and with the leadership of the task force we were able to take early, bold action to help stop the spread of the virus and launch Operation Warp Speed.

Question. The budget proposes to cut over \$900 billion in Medicaid funding over the next decade including through block grants and caps. The administration also continues to attack the Medicaid program through State waivers for work requirements. Medicaid plays an important role in assisting States and localities in responding to public health emergencies, like the COVID outbreak.

Your new block grant guidance would cap Medicaid funding saying that States would have to ask CMS for permission for additional funding for a response to a public health emergency with no guarantee that they will receive it or that the request will be approved on a timely basis. Is it your view that States should have to ask for CMS permission before they can respond to a public health crisis like the coronavirus or risk being on the hook under this block grant system?

Assuming CMS approves the additional funding for a public health emergency under the Healthy Adult Opportunity waiver, what formula will be used to determine the amount of funding States will receive?

Answer. Federal statute allows, at the request of the Governor of an affected State, the President to declare a major disaster or emergency if an event is beyond the combined response capabilities of the State and affected local governments. Federal law also allows the Secretary of Health and Human Services (HHS) to declare that a public health emergency exists in the affected State, and authorize waiver or modification of certain Medicare (including EMTALA), Medicaid, and CHIP requirements under section 1135 of the Social Security Act.

With a public health emergency and a Presidential declaration in effect, there are many things CMS can do to help. For example, the Section 1135 waiver determination enables CMS to waive or modify certain Medicare, Medicaid, CHIP, Stark Law, and EMTALA requirements, including certain deadlines, quality reporting requirements, conditions of participation, and certification requirements. During an emergency, CMS moves quickly to use the full breadth of the waiver authority to maintain access to care for Medicare and Medicaid beneficiaries. In addition to waivers, CMS works closely with States, providers, and other stakeholders to provide guidance, technical assistance, toolkits, and other resources to make sure the people served by our programs continue to receive high quality health care even in the face of an emergency. As stated in our guidance and recognizing the dynamic health-care landscape in which State Medicaid programs are operating, CMS will provide States with the opportunity to propose updates to an approved HAO demonstration to account for any changes to projected expenditures or enrollment in the current demonstration year due to unforeseen circumstances out of the State's control, such as

a public health crisis or major economic event. This ability to modify waivers provides CMS with an opportunity to engage States in training, technical assistance, and guidance to maximize outcomes, and can help CMS and States identify potential new improvements to the unprecedented flexibility offered through an HAO waiver.

Question. Do you disagree with State Medicaid directors, who have said that no amount of flexibility you want to give can compensate for the magnitude of cuts proposed in the Healthy Adult Opportunity waivers?

Answer. HHS's proposed budget will have Medicaid spending grow at a more sustainable rate by ending the financial bias that currently favors able-bodied working-age adults over the truly vulnerable.

The Healthy Adult Opportunity (HAO) is not a mandatory change in the Medicaid program's structure or financing—this is an optional demonstration opportunity, and no State is under any obligation to participate. It is also not permission for States to strip benefits or limit eligibility—under HAO, participating States must still meet minimum benefit requirements and cannot cap or limit adult enrollment while still receiving enhanced Federal funding.

A number of States have already publicly expressed interest in HAO, and are supportive that the demonstration represents an innovative and historic approach to surmounting Medicaid's structural challenges while still providing rigorous protections for all Medicaid beneficiaries.

INDIAN HEALTH SERVICES (IHS)

Question. In Washington State, the Indian Health Service is a vital health-care provider to tribal and non-tribal communities throughout the State. Whether it is one of the six Indian Health Service facilities or a self-governance contract with one of our tribes, IHS-supported health care can be the only health-care option for hundreds of miles. It is imperative these providers are funded and the facilities can effectively serve patients. Unfortunately, there is significant work to do to meet this mission. For example, the IHS Omak clinic is situated in a converted modular office building that was always intended to be temporary. The current space has limited exam room space and severely constrains the number of health providers the tribe can offer. The tribe is in need of a new clinic so it can double the current number of doctors, dentists, and health providers. A new clinic is incredibly important to the tribe and the surrounding community because the nearest level 3 emergency room is more than 100 miles away. However, Washington State has not benefited from IHS facility construction programs like the rest of the country. The northwest Portland area IHS has had only one joint venture project since 1988. I am encouraged that the Colville Confederated Tribes in north central Washington are one of 10 finalists nationwide to be in the current round of joint venture applications.

Does HHS have a long-term plan to address IHS facility needs outside of the Priority Construction list?

Answer. IHS understands the health needs of the AI/AN population in Washington. The area has had many successes, such as:

- The Yakama facility has been renovated over the last few years using Medicaid and Medicare funding.
- The joint venture program is an opportunity for tribes and tribal organizations to receive funding to staff and operate a facility constructed or acquired by the tribe or tribal organization. Specifically, the Coleville application was awarded an opportunity to participate. We are looking forward to working with the Coleville Confederated Tribes in Omak, WA as they utilize this program.
- Smaller tribes and tribal organizations are able to get partial funding through the Small Ambulatory Program (SAP). This program selection process is also based on need and small populations have struggled with this program. IHS has amended the program to give more opportunities for smaller tribes to get awards. These changes will begin with the 2020 SAP offering.
- The Portland area IHS is working diligently to determine the ability to place an area-wide referral center near Seattle.

The Indian Health Service (IHS) Health Care Facilities Construction program is funded based on an IHS-wide list of priorities for construction projects. In the 1990s, the Health Facilities Construction Priority System (HFCPS) established one national list that prioritizes funding for the top ten inpatient and the top ten out-

patient facilities. The Indian Health Care Improvement Act (IHCIA) requires that “any project established under the construction priority system in effect on March 23, 2010, shall not be affected by any change in the construction priority system taking place after that date” (25 U.S.C. §§ 1631(c)(1)(D), (g)). The IHCIA “grandfathered” the HFCPS list, and the methodology used to add projects to the list is no longer in use. Appropriations for health care facility construction are allocated only to facilities on the HFCPS list until the grandfathered priority list completely funded. The 2019 facilities appropriation allowed IHS to partially fund all of the remaining projects on the grandfathered priority list.

Pursuant to a congressional request in 2000, the IHS, working with tribes, advisory committees, and the Department of Health and Human Services, completed a new methodology for a construction project list that will go into effect when the grandfathered HFCPS list is completed. When the current priority list is completely funded, IHS will generate a new list under the new system. One of the aspects of the new priority selection process is that it would include an option to allocate funds to area offices to address high-priority needs.

URBAN INDIAN HEALTH CENTERS

Question. There are 29 federally recognized tribes in Washington State and countless members of tribes from around the country. It is our Federal obligation to ensure all Washington State tribes and all tribal members have access to health care, no matter where they reside. To do this, it is critical tribal health-care providers have the recognition and resources they need to serve American Indians and Alaska Natives. This includes our urban Indian health-care providers.

The Seattle Indian Health Board in Washington State is a critical health-care provider for urban Native Americans and Alaska Natives throughout the Pacific Northwest. The Seattle Indian Health Board provides health-care services for about 6,000 patients annually, two thirds of whom identify as Native Americans or Alaska Natives from more than 250 different tribes. However, urban Indian health programs are currently reimbursed at a lower Federal rate for Medicaid patients than other federally and tribally operated Indian Health Service facilities. This sets critical urban Indian organizations like the Seattle Indian Health Board at a financial disadvantage even though they serve a population that continues to increase in numbers. That’s why I joined several of my colleagues in introducing the bicameral Urban Indian Health Parity Act to help expand services and improve the quality of care for Native Americans and Alaska Natives living in urban areas. This legislation gives Urban Indian health-care providers an equal voice.

Are you aware that Urban Indian Health organizations that provide a significant amount of health-care services to our tribes in urban centers are reimbursed at a lower rate?

Answer. Although Federal legislation, such as the Social Security Act and the Indian Health Care Improvement Act, authorizes urban Indian organization (UIOs) to bill and receive payment for the services they deliver, only two UIOs have obtained the All-Inclusive Rate (AIR) of \$479 due to their unique status as Service Units.

Question. Would you support our Urban Indian Health Organizations in receiving parity?

Answer. IHS continuously assesses options to improve care delivery for UIOs.

MEDICAID BLOCK GRANTS

Question. As you know, managed care is the primary manner that benefits are delivered in the Medicaid program. Federal rules require that payments to plans be made in a way that is sufficient to guarantee the plans can pay doctors and hospitals adequately to deliver benefits to plan enrollees. CMS’s Healthy Adult Opportunity (HAO) program would effectively negate those payment rules by eliminating CMS oversight of the rates to ensure they are actuarially sound. A Government Accountability Office (GAO) report found that some States were not complying with Federal actuarial soundness rules and actually recommended that CMS increase its oversight of State managed care rate setting.

How do you justify reducing CMS review of actuarially sound rate setting in the HAO waivers when GAO has already identified States that are not using actuarially fair rates?

Answer. States utilizing a managed care delivery system to serve populations under an HAO demonstration generally will be expected to meet the statutory re-

quirements that managed care rates be actuarially sound, as well as the regulatory requirements pertaining to the development of capitation rates. States will also be expected to certify that their managed care plans have the capacity to meet the State's standards for access to care and availability of services. However, States will have the opportunity under this demonstration to adopt alternative approaches to ensuring actuarially sound rates, network adequacy, access to care, and availability of services to those required under 42 CFR 438.68.

Regardless of the approach elected, all States implementing an HAO demonstration will be required to submit routine data reports to CMS. States seeking to implement managed care in a manner that differs from the statutory and regulatory requirements also may propose to exercise additional flexibilities in the administration of their managed care plan contracts, particularly for contract amendments, during the demonstration period for an HAO demonstration. A State would be expected to submit its initial managed care contracts to CMS for review and approval, and to submit subsequent amendments to CMS. Any amendments would be expected to be consistent with the terms of the HAO demonstration, as well as statutory and regulatory requirements that otherwise would apply to Medicaid coverage. CMS will monitor managed care contract amendments to ensure compliance with the terms of the demonstration and legal requirements. If the monitoring finds that a State's managed care contracts are not consistent with the terms of the demonstration, CMS would work with the State to bring it into compliance before initiating corrective action, which could include deferral or disallowance of costs, or termination of the demonstration. For States that would prefer the certainty that comes with approval, CMS also would allow States to seek formal approval for contract changes. Consistent with current requirements, States would be expected to incorporate the potential impact of substantive contract amendments into the capitation rates paid to managed care plans.

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

COVID-19

Question. In 2018, the administration reduced the global health section at the Centers for Disease Control and Prevention (CDC). What impact did this have on the ability of the CDC to respond to the COVID-19 outbreak?

Answer. Reductions to CDC's global activities that were reported by the press in 2018 were inaccurate. CDC's global health funding in FY 2018 and FY 2019 was \$488.6 million, an increase of \$54.5 million over the FY 2017 level, including \$50 million each year for global health security. For over 60 years, CDC has used its scientific expertise to help people across the world live healthier, safer, and longer lives. CDC works 24/7 to protect Americans and save lives around the world by detecting and controlling outbreaks at their source. In addition, CDC helps other countries increase their ability to prevent, detect, and respond to health threats on their own. CDC's global health appropriations include funding for programs in global HIV/AIDS, global immunization, parasitic diseases and malaria, and global health protection—which includes global health security activities to prevent, detect, and respond to infectious disease outbreaks.

Funds received for global health security in FY 2018 and FY 2019 were available for multiple years and helped to transition CDC's Global Health Security Agenda activities from the original FY 2015 Ebola emergency supplemental funding to more stable, annual appropriations. In FY 2019, Congress also established the Infectious Diseases Rapid Response Reserve Fund with \$50 million, and this funding was available to prevent, prepare for, or respond to an infectious disease emergency, domestic or international. In FY 2020, CDC received an increase of \$75 million to support global health security and an additional \$85 million for the Infectious Diseases Rapid Response Reserve Fund.

These investments have enabled CDC to build a stronger foundation to help selected partners build core public health capacity across the world in disease detection and response. CDC's strong partnerships with ministries of health and international partners, have enabled us to quickly respond to the outbreak through technical assistance, funding in emergency response, laboratory, surveillance, and epidemiology, border health and mitigation, infection prevention and control, and pandemic and vaccine preparedness planning. With the recent COVID-19 outbreak, Congress appropriated CDC supplemental funding for global disease detection and emergency response: \$300 million in Coronavirus Preparedness and Response Sup-

plemental Appropriations Act (available through September 2022), and \$500 million in the CARES Act (available through September 2024).

Question. Are there plans in place to address the existing gaps in the administration's global health security teams?

Answer. As the United States continues to support global health security as a priority for national and economic security, the U.S. government has been able to demonstrate strong leadership globally to advance health security priorities through a collaborative and multisectoral approach. Using the Global Health Security Agenda (GHSA) as a premier model of global health security engagement, these efforts, as outlined in the U.S. Global Health Security Strategy, focus on strengthening partner country capacities to prevent, detect, and respond to infectious disease threats, increasing international support for global health security, and ensuring a homeland prepared for, and resilient against, health threats.

The U.S. Government approach to advance global health security priorities involves a truly government-wide approach that draws on the unique roles and strengths of many departments and agencies both at headquarters and in-country, including the Departments of Health and Human Services, State, Defense, and Agriculture, the Centers for Disease Control and Prevention, and the U.S. Agency for International Development, among others. Globally, this whole-of-government approach supports GHSA through U.S. leadership in the multilateral GHSA 2024 initiative, which galvanizes commitment and action by other countries and advances priorities such as sustainable financing, and through bilateral technical collaborations with key GHSA partner countries, which addresses critical gaps and builds valuable partnerships.

The GHSA Annual Report for 2020 (https://www.state.gov/wp-content/uploads/2020/09/GHSA_ProgressImpactFY19_final.pdf) provides many concrete examples of what U.S. Government technical and financial support has done to help countries and partners achieve progress and the evidence of impact. Although this report covers progress prior to the COVID-19 pandemic, we do highlight in it the strong linkages between GHSA progress and COVID-19 response. Pre-COVID-19 capacity-building efforts supported by the U.S. Government have been leveraged extensively by our partner countries to support their response efforts. We will continue to publish these annual reports on progress that highlight examples of life-saving capacity-building work and related progress to strengthen national, regional, and global health security.

Question. Do you believe the FY 2021 budget's cuts to the CDC, in particular to the Public Health Emergency Preparedness Cooperative Agreement, CDC Preparedness and Response, Public Health Workforce are shortsighted in light of the ongoing global health threats that continue to emerge?

Answer. The President's initial FY 2021 request was formulated with consideration to overall budget caps for discretionary spending and thus included cuts for many discretionary programs. In March of this year, the administration submitted a revised request for CDC that would have provided an additional \$1.329 billion for the agency, an amount exceeding CDC's FY 2020 annual appropriation.

Question. What additional investments must the United States make in public health infrastructure to address gaps in our response capabilities?

Answer. The COVID-19 pandemic put a spotlight on the needs and disparities in public health infrastructure and highlighted the importance of public health-care capabilities across the country and throughout the world. These core capabilities form the backbone of CDC's capacity to protect America's health. A strong public health system includes robust data and analytics, laboratory capacity, a top-tier workforce, rapid response capabilities and a broad global footprint to stop disease at its source. The administration worked closely with Congress to ensure that State and local public health departments had necessary resources to respond to COVID-19. The investments supported with COVID-19 Supplemental funds will help improve public health infrastructure at all levels across the country, including: (1) improvements to national health data infrastructure to allow for rapid bi-directional exchange of critical information between local, State, and Federal public health systems and health care systems; (2) lab capacity expansion to enable increased testing by State and local health departments, the frontline for detection for the public health system in the United States; (3) supporting a robust, deployable, and flexible workforce to trace and monitor contacts of infected people, support the quarantine of contacts, and use tools to expand the reach and efficacy of contact tracers; and (4) the creation of a national preparedness and response culture in which public health enti-

ties learn and continuously optimize practices with direct staff bidirectional engagement and assistance.

Question. You recently stated there are 20 drugs made in China that have no substitutes, what can be done going forward to better secure our supply chain against reliance on foreign sole-source suppliers?

Answer. By supporting the growth of advanced manufacturing in the United States, we can reduce our dependence on China and other overseas manufacturers for APIs (Active Pharmaceutical Ingredients) as well as improve the resilience and responsiveness of our manufacturing base and reduce drug shortages.

Advanced manufacturing offers many advantages over traditional pharmaceutical manufacturing, and if the United States invests in this technology, it can be used to reduce the Nation's dependence on foreign sources of APIs, increase the resilience of our domestic manufacturing base, and reduce quality issues that trigger drug shortages or recalls. For example:

- Product quality can be precisely controlled with modern automation and control systems and can be closely monitored during production by using high-resolution analytics.
- High technology, computer-controlled production facilities are better able to rapidly respond to changes in demand because they typically do not have the equipment scale-up issues associated with traditional methods and can be capable of seamlessly producing a variety of dosages and even dosage forms.
- Advanced manufacturing platforms also have a much smaller footprint than traditional manufacturing platforms, and the equipment can be made portable so that it can be moved closer to markets, reducing the need for trans-continental shipping of components.
- Medicines can be produced at lower cost than by traditional methods.
- Environmental impact of manufacturing is significantly reduced.

Restricting the supply chain of pharmaceutical products from a specific country or region may have the unintended consequence of reducing redundancy in the supply chain and creating significant shortages of critical drug products. It may overlook other issues impacting supply chain availability, such as sole-source drugs manufactured in other regions. For these reasons, as a matter of course, the agency's primary focus is on instilling redundancy in the supply chain of pharmaceuticals by diversifying the supply chain and looking for opportunities to encourage domestic manufacturing.

We note that investments in advanced manufacturing technology and in strengthening the approach by which manufacturers assure the quality of their products can provide a safer and more secure drug supply chain and may promote domestic pharmaceutical manufacturing. Advanced manufacturing can be more cost-effective and environmentally friendly than traditional manufacturing technology and help prevent many quality problems from occurring in the first place.

As part of the COVID-19 response, the Department has engaged companies to help promote domestic manufacturing and additional sources of medical products.

In October 2019, the Drug Shortages Task Force released a report to Congress, *Drug Shortages: Root Causes and Potential Solutions*. The report found that in the United States, economic factors are the primary drivers of drug shortages. These factors relate to: limited incentives for drug manufacturers to produce certain drugs, *i.e.*, those with low profitability; market does not recognize and reward mature quality management systems used to ensure supply reliability; and logistical and regulatory factors that make it expensive and time consuming for manufacturers to increase supply of a drug after a disruption occurs.

GUN SAFETY

Question. The CDC considers its own data on non-fatal firearm injuries “unstable and potentially unreliable.” This makes it impossible to propose or study various programs and policies aimed at preventing gun deaths and injuries, including those among children. Recent budget allocations have increased support to improve upon the National Violent Death Reporting System (NVDRS), but how, specifically, will the CDC work to improve nonfatal firearm injury surveillance and reporting in 2020?

Answer. CDC strives to provide the most timely, accurate data available—including data related to firearm injuries. A number of data systems exist that researchers have used to examine firearm injuries. CDC provides information on non-fatal

injuries, including those related to firearms, on its publicly facing Web-based Injury Statistics Query and Reporting System (WISQARS). The underlying data WISQARS uses to provide this information comes from the National Electronic Injury Surveillance System—All Injury Program (NEISS–AIP). A key strength of using NEISS–AIP for WISQARS is that it captures emergency department visits for all injuries (such as falls or self-harm), and it is not specific to firearm-related visits. Additionally, it is usually more timely data than many other existing data sources, captures key narrative information on factors such as intent directly from the medical record, and is not dependent on administrative codes which often results in loss of more granular, contextual information. WISQARS will no longer show nonfatal national estimates that fail to meet strict quality standards. The suppression criteria are (1) fewer than 20 cases (unweighted data), (2) national estimates less than 1,200 (weighted data), or (3) when the estimate’s coefficient of variation (CV) is greater than 30 percent.

NEISS–AIP data are collected through an inter-agency agreement with the Consumer Product Safety Commission (CPSC) and represent a sub-sample of about ⅓ of the National Electronic Injury Surveillance System (NEISS). The data collected from selected hospitals are used to estimate national numbers. CDC is currently working with CPSC to look at the number and types of hospitals participating in NEISS and NEISS–AIP. CPSC is utilizing an independent contractor to evaluate sampling methods, methods for re-sampling if hospitals drop out, and how to best address the variance of the estimates, including increasing the size of the NEISS–AIP sample. Understanding these factors will help identify strategies that may improve the stability of estimates in the future. The final report from the contractor is anticipated at the end of September 2020. Once complete, CPSC staff will review the assessment and work with CDC and other Federal partners to determine next steps.

CDC is also undertaking efforts to strengthen nonfatal firearm injury data at the local and State level through the Firearm Injury Surveillance Through Emergency Rooms (FASTER) NOFO. CDC is funding 10 State health departments as part of the competitively funded FASTER NOFO to provide surveillance data in near-real time on emergency department visits for nonfatal firearm injuries. Syndromic surveillance has the potential to address two key gaps in nonfatal firearm injury data: first, it can provide data in near-real time on nonfatal firearm injury that is currently not available from other data systems, which typically have a 2–3 year lag time before information is available. Second, it can provide local data on nonfatal firearm injuries that is currently not widely available.

The first year of FASTER is funded with FY2020 money appropriated to CDC for firearm injury and mortality prevention research. CDC intends to fund 10 recipients. FASTER recipients were recently announced. Information about FASTER and the recipients are posted on CDC’s website: <https://www.cdc.gov/violence-prevention/firearms/funded-surveillance.html>.

Question. You correctly tweeted that “suicide is one of the leading causes of death in the United States and is on the rise.” Firearm suicide makes up half of all suicide, claiming the lives of nearly 23,000 Americans every year, including over 1,100 children and teens.

The data shows that the choice of means for suicide matters. Firearms have a fatality rate of approximately 90 percent. Conversely, only 4 percent of people who attempt suicide using other methods will die.

There are proven, effective methods to address access to lethal means and reduce suicide, including practicing secure gun storage and utilizing extreme risk laws that provide a method for families and law enforcement to temporarily prevent access to guns for someone who is in crisis.

Please describe what the Substance Abuse and Mental Health Services Administration (SAMHSA), Centers for Disease Control (CDC), and National Institutes of Health (NIH) are doing to confront the firearm suicide crisis, including: how is lethal means counseling about firearm access integrated into programs supported by SAMHSA, including the National Suicide Prevention Hotline?

Answer. The National Suicide Prevention Lifeline incorporates lethal means assessment and counseling into its expectations for participating crisis centers in the Lifeline network. All Lifeline centers sign a network agreement and agree to the Lifeline’s Standards for Suicide Risk Assessment and Guidelines for Callers at Imminent Risk. The Standards for Suicide Risk Assessment includes, as one of its components, assessing for available means to die by suicide, including firearms. In addi-

tion, when responding to callers at imminent risk, crisis centers are expected to try to work collaboratively on a variety of potential ways to reduce the risk, including taking steps to minimize the availability of lethal means. The Lifeline also provides a simulation training that incorporates assessing and counseling on accessibility of lethal means. The SAMHSA funded Suicide Prevention Resource Center has created an online course, Counseling on Access to Lethal Means, which has been widely used across SAMHSA's suicide prevention grant program. In addition, SAMHSA's Zero Suicide grants also require engagement of those with identified suicide risk in collaborative safety planning including reducing access to lethal means.

With FY2020 funds appropriated by Congress, CDC is supporting scientific research to understand and prevent firearm-related injuries, deaths and crime. Two research funding opportunities will be awarded by September 30, 2020. The first opportunity is Research Grants to Prevent Firearm-Related Violence and Injuries (R01): RFA-CE-20-006. The second research funding opportunity is Grants to Support New Investigators in Conducting Research Related to Preventing Interpersonal Violence Impacting Children and Youth (K01): RFA-CE-20-002.

CDC will make information on this research publicly available through the NIH Reporter (<https://projectreporter.nih.gov/reporter.cfm>). Descriptions of each funded study will also be available on CDC's website at <https://www.cdc.gov/violenceprevention/firearms/funded-research.html>.

CDC is also funding eight States and one university to implement and evaluate a comprehensive public health approach to suicide prevention with a focus on vulnerable populations. To support this program, CDC is committing approximately \$7 million in FY 2020. The purpose of this program is to implement and evaluate a public health approach to suicide prevention, with attention to vulnerable populations that account for a significant proportion of the suicide burden and have suicide rates greater than the general population.

Question. How does SAMHSA educate families about the need for secure gun storage to ensure children and teens cannot access a family firearm?

Answer. SAMHSA helped develop and supports the National Strategy for Suicide Prevention. Goal 6 of the National Strategy is to "promote efforts to reduce access to lethal means of suicide among people with identified suicide risk." SAMHSA's National Strategy for Suicide Prevention grants also include in the Funding Opportunity Announcement a requirement to "incorporate efforts to reduce access to lethal means among individuals with identified suicide risk." This effort will be done consistently with all applicable Federal, State, and local laws. SAMHSA's Zero Suicide grants also require engagement of those with identified suicide risk in collaborative safety planning including reducing access to lethal means. SAMHSA suicide prevention grantees have also worked collaboratively with firearm retailers in a program called the "Gun Shop Project."

Question. Does the administration supports extreme risk laws as a way to prevent suicide?

Answer. Yes, the administration supports these laws as it relates to the health and safety of Americans in mental health crisis. An examination of the use of these laws as a best practice in mitigating self-harm or harm to others was a key component/recommendation of the administration's Federal Commission on School Safety report. This Commission was implemented by President Trump following the tragic school shooting in Parkland, FL.

As a component of this report, both the Department of Health and Human Services and the Department of Justice reviewed extreme risk protective orders as a means of mitigating gun violence. These laws should have in place procedures to clearly report a concern to the authorities regarding access to lethal means by someone who may be having a mental health crisis.

Question. How SAMSHA makes families and law enforcement aware of extreme risk laws in the 17 States and District of Columbia that have these laws on the books?

Answer. SAMHSA suicide prevention grantees have the option of using funds to increase awareness of extreme risk protective orders.

Question. What research is being conducted by the CDC and NIH on firearm suicide and prevention?

Answer. With FY2020 funds appropriated by Congress, CDC is supporting scientific research to understand and prevent firearm-related injuries, deaths and

crime. Two research funding opportunities will be awarded by September 30, 2020. The first opportunity is Research Grants to Prevent Firearm-Related Violence and Injuries (R01): RFA-CE-20-006. The second research funding opportunity is Grants to Support New Investigators in Conducting Research Related to Preventing Interpersonal Violence Impacting Children and Youth (K01): RFA-CE-20-002.

CDC will make information on this research publicly available through the NIH Reporter (<https://projectreporter.nih.gov/reporter.cfm>) after the estimated start date, September 30, 2020. Descriptions of each funded study will also be available on CDC's website at <https://www.cdc.gov/violenceprevention/firearms/funded-research.html>.

CDC is also funding eight States and one university to implement and evaluate a comprehensive public health approach to suicide prevention with a focus on vulnerable populations. To support this program, CDC is committing approximately \$7 million per year for 5 years. The purpose of this program is to implement and evaluate a public health approach to suicide prevention, with attention to vulnerable populations that account for a significant proportion of the suicide burden and have suicide rates greater than the general population.

GRADUATE MEDICAL EDUCATION

Question. The budget proposes to consolidate Medicare GME, Medicaid GME, and CHGME into a single capitated program. Can you please provide more information on the justification for this change?

How will this consolidation into a single GME program, combined with a \$52 billion reduction in support for teaching hospitals, address the growing physician shortage?

Answer. Current graduate medical education funding is outdated, overly broad, and not sustainable in the long term due to its fragmented nature across multiple funding streams and lack of transparency and accountability. Effective in FY 2021, this proposal would consolidate Federal graduate medical education spending from Medicare, Medicaid, and the Children's Hospital Graduate Medical Education Program into a single grant program for teaching hospitals. Total funds available for distribution in FY 2021 would equal the sum of Medicare and Medicaid's 2017 payments for graduate medical education, plus 2017 spending on Children's Hospital Graduate Medical Education, adjusted for inflation. This amount would then grow at the CPI-U minus one percentage point each year. Payments will be distributed to hospitals based on the number of residents at a hospital (up to its existing cap) and the portion of the hospital's inpatient days accounted for by Medicare and Medicaid patients. The new grant program will be jointly operated by the Administrators of CMS and the Health Resources and Services Administration.

This grant program would be funded out of the general fund of the Treasury. The Secretary would have authority to modify the amounts distributed based on the proportion of residents training in priority specialties or programs (*e.g.*, primary care, geriatrics) and based on other criteria identified by the Secretary, including addressing health-care professional shortages and educational priorities. These changes would modernize graduate medical education funding, making it better targeted, transparent, accountable, and more sustainable.

REMAIN IN MEXICO POLICY

Question. Does the Department of Homeland Security (DHS) affirmatively provide the Office of Refugee Resettlement (ORR) with information that a child's parent or other relative is in Migrant Protection Protocols (MPP), as well as that person's identifying information, when transferring the child from DHS to HHS custody?

What information would ORR like to have from DHS if a child has been affected by MPP?

Answer. In some instances the Department of Homeland Security (DHS) provides information regarding an unaccompanied alien child's (UAC) previous enrollment in the Migrant Protection Protocols (MPP) at the time of the UAC's referral. In other cases, ORR may discover that a UAC or the UAC's parents were previously processed under MPP during the UAC's admission into an ORR care provider through interviews with the child or the child's family, or while the child undergoes assessments at a later point. ORR seeks the following information from DHS after determining a child may have been enrolled in MPP: UAC and parent(s) biographical information; UAC and parent(s) country of origin; alien number; location of the UAC

and parent(s) at the time they were classified as MPP cases; Notice to Appear (NTA); and, immigration court date, if applicable.

Question. What mechanism is ORR using to identify and track children affected by MPP? How many children does ORR believe are currently in its custody who have a parent or family member in MPP?

Answer. ORR has procedures to track and coordinate the care of children in the UAC program who are subject to MPP. Once ORR discovers that a UAC is subject to MPP, either through the intakes process or during the child's assessment, the ORR/Division of Unaccompanied Children's Operations (ORR/DUCO) case management team works with both the ORR/DUCO intakes team and ORR care providers to compile a list of all identified MPP cases. Every week, the ORR case management team sends the compiled master tracker list to DHS Immigration and Customs Enforcement (ICE) Juvenile and Family Residential Management Unit for further verification and additional information. Additionally, information regarding MPP cases are also entered as a Significant Incident Report (SIR) in the UAC Portal, ORR's UAC database.

Question. How many children does ORR believe have ever been in its custody who have a parent or family member in MPP?

Answer. As of August 31, 2020, there have been 624 UAC in ORR care whose parent(s) or legal guardian(s) were previously processed under MPP.

Question. How many of those children are under age 12? How many are infants, if any?

Answer. There were a total of 237 children under the age of 12. Specifically, a total of seven UAC were under 24 months of age; of those, only two children were under the age of 1. As of August 31, 2020, 30 UAC whose parents were processed under the MPP remain in ORR care.

Question. There are a number of reports documenting that children with serious health conditions are being subjected to MPP and that the discretionary medical exemption is not being used. Does HHS have a role in advising DHS decisions to grant medical exemptions to MPP?

Answer. The processing of MPP cases is under the sole purview of DHS's Customs and Border Protection. ORR respectfully defers to DHS for the response to this question.

Question. How many children with a parent or family member in MPP are currently in ORR care with a disability or serious health condition?

Answer. Seven UAC with a parent or family member enrolled in MPP who are currently in ORR care (as of September 10, 2020) have significant health concerns or disabilities. These are medical conditions that fall under the spectrum of chronic medical issues or disabilities as opposed to acute serious medical concerns.

Question. How many children total does ORR believe have been in its custody with a disability or serious health condition with a parent or family member in MPP?

Answer. ORR collects information about significant health conditions or disabilities in narrative form in individual UAC case files. Compiling this information for close to 600 cases will take significant time. HHS can work with committee staff on the most expeditious way to provide this information or provide it on a rolling basis.

Question. What changes has ORR made to its regular practices to facilitate communication between a child and his or her parent in MPP who likely have limited access to phones and/or electricity while in Mexico?

Answer. ORR policy requires that UAC be provided the opportunity to make a minimum of two telephone calls per week (10 minutes each) to family members in a private setting. For more information on this policy and other policies regarding communication please see ORR Policy Guide, section 3.3.10 Telephone Calls, Visitation, and Mail, available here: <https://www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied-section-3#3.3.10>. ORR care providers exhaust all the necessary avenues to facilitate UAC communication with their parents/relatives, including contacting shelters in Mexico, the Red Cross, and relatives in their home country, in Mexico, and in the United States.

Question. Does HHS assess children with a parent in MPP with the same health and education screenings it would provide to any other unaccompanied child?

Answer. Yes. Each UAC that enters ORR custody receives an initial medical examination (IME) conducted by a licensed primary care provider (*e.g.*, physician, physician assistant, or nurse practitioner) within two business days of arrival to an ORR shelter. The IME is based on a well-child examination, adapted for the unaccompanied alien children population with consideration of screening recommendations from the American Academy of Pediatrics, the Centers for Disease Control and Prevention, and the U.S. Preventive Services Task Force. Furthermore, ORR complies with all minimum standards set forth by the *Flores* settlement agreement. ORR provides educational services appropriate to the UAC's level of development and communication skills. For more information on services provided to UAC in ORR custody please refer to the ORR Policy Guide, section 3.3 Care Provider Required Services available at: <https://www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied-section-3#3.3>; and section 3.4 Medical Services available at: <https://www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied-section-3#3.4>.

Question. At what point is a child identified as having a parent in MPP returned to Mexico? What is the process for returning the child to Mexico?

Answer. The majority of UAC who have been processed under MPP by DHS have been released to their vetted sponsors in the United States. In cases where repatriation to Mexico occurred, ORR coordinated with DHS on the repatriation efforts. Each case is unique and ORR coordinates extensively with DHS to determine the best approach for reuniting a child with a parent or legal guardian in these types of circumstances. In some cases, a UAC may request voluntary departure to return to their home country and be reunited with a parent, if the parent opted to return to their home country instead of remaining in Mexico. In other cases, DHS can cancel the NTA and allow reunification with a parent to occur at the border.

Question. Has HHS made any determinations that it was not safe for a child to be returned to his or her family in Mexico? If so, please provide the details of that assessment.

Answer. HHS does not make determinations on the safety of immigration cases, HHS respectfully defers this question to DHS or to the U.S. Department of Justice/ Executive Office for Immigration Review (EOIR), the agency responsible for overseeing the U.S. immigration courts.

FAMILY SEPARATION

Question. What further improvements have been made to the UAC system to improve the tracking of children who have been separated from his or her parents and the basis for separation? How is that information communicated to legal service providers and child advocates?

Answer. ORR has several mechanisms for tracking UAC separated from an adult by DHS. ORR added a checkbox to the UAC Portal that is marked for any UAC separated from a parent or legal guardian, and can be used as means to quickly identify known separations for data reporting purposes. In addition, for children transferred to ORR custody subsequent to their separation from a parent or legal guardian, documentation of that separation is entered in the UAC Portal upon ORR learning of the separation (*e.g.*, through the creation of an SIR). This information is included in the UAC's case file as part of recording the UAC's experiences during their journey to the United States and placement in an ORR care provider facility. On a weekly basis, ORR communicates with Customs and Border Protection (CBP) as well as ICE staff to jointly reconcile a running list of children from their parents/ legal guardians.

On a weekly basis, ORR communicates with ICE staff to jointly reconcile a running list of children separated from their parents or legal guardians. On a monthly basis, the list is further reconciled through consultation with CBP at the operator level and vetted for release to plaintiffs' counsel in ongoing litigation. These lists include information relating to reasons for the separation as provided by DHS. However, this information often requires reconciliation and vetting through communication between HHS and DHS. Through these mechanisms, ORR continues to monitor children separated from their parent or legal guardian and document when separations from their parents are brought to ORR's attention.

All UAC in ORR custody meet with legal service providers (LSP) shortly after their placement in ORR custody. ORR notifies the LSP of a UAC separated from their parent after initial assessments are conducted and when possible, prior to the child's legal screening provided by the LSP. Child advocates are notified upon request or when appointed to a specific UAC in accordance with section 2.3.4 of the ORR Policy Guide available here: <https://www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied-section-2#2.3.4>.

Question. Does DHS always inform HHS of a family separation at the time of the child's referral to HHS custody? Does HHS receive specific details from DHS about reasons for separation at the time a child is transferred?

Answer. HHS is not always informed of a family separation at the time of the UAC's referral. However, in some cases, DHS indicates that a child has been separated from a parent or legal guardian and includes that information in the referral note. Once HHS finds out about a separation, it requests further information from DHS about the specific details related to the separation such as the separated parent(s)' name, alien number, and reason for separation. As noted in the previous question, ORR communicates with DHS on a weekly and monthly basis to jointly reconcile a running list of children separated from their parents or legal guardians. These lists include information relating to reasons for the separation as provided by DHS. However, this information often requires reconciliation and vetting through communication between HHS and DHS.

For any UAC, including those separated from an adult that is not child's parent or legal guardian, the ORR care provider includes information of that separation in the UAC's case file as part of recording the child's experiences during their journey to the United States and placement in an ORR care provider facility. ORR recognizes the oversight responsibilities of Congress and submits, as required by law, a monthly report to Congress on children separated from their parents or legal guardians by DHS and referred to ORR custody. This report includes, for example, the demographics of separated children as outlined in Senate Report 115–289. Each monthly report on separated children is available on HHS's website here: <https://www.hhs.gov/programs/social-services/unaccompanied-alien-children/index.html>.

FIREFIGHTER CANCER REGISTRY

Question. Can you provide an update on the implementation of the Firefighter Cancer Registry? In particular, does the program have sufficient funding to meet the program's goals?

Answer. The National Institute for Occupational Safety and Health (NIOSH) National Firefighter Registry team met with and presented to over 30 fire departments, fire service organizations, incident record management companies, State cancer registries, and researchers to receive input and fully understand research gaps and needs. A website for the National Firefighter Registry was also established (www.cdc.gov/NFR). A prototype for the registration web portal was developed to focus on optimizing user experience prior to implementation. The NIOSH team prepared an application for an Assurance of Confidentiality (AoC), which is the highest level of protection available for identifiable data and includes a secure mechanism for sharing de-identified data with external researchers. The approval process is expected to begin in FY 2021.

The NIOSH National Firefighter Registry team created an overall plan for the National Firefighter Registry (NFR), called a protocol, which included recruitment plans, the voluntary consent form, and enrollment questionnaire. It laid the foundation for how the registry would function and operate.

In addition, the National Firefighter Registry Subcommittee (NFRS) was formed. This group of 13 experts comprised of active and former firefighters, emergency response associates, public health experts, epidemiologists, scientific advisors, clinicians and State departments of homeland security met twice and reviewed the draft protocol (https://www.cdc.gov/niosh/bsc/nfrs/pdfs/DFSE_NI_NFR_Protocol_Draft-CLEARED-508.pdf). After a careful review of the protocol, the NFRS published a report with advice and recommendations (see <https://www.cdc.gov/niosh/bsc/nfrs>). The NFRS discussed and finalized the report with CDC/NIOSH's Board of Scientific Counselors (BSC).

Based on this report, and additional input from fire service and research stakeholders, the NIOSH team made further enhancements to the NFR protocol, questionnaire, and supporting materials. To add to the team, a full-time health communication specialist was hired and a communications plan for firefighters has been

drafted. This plan is currently being tested with a variety of firefighters in virtual focus groups.

Question. What steps are the Centers for Disease Control and Prevention taking to ensure that the registry reflects the diversity of the firefighting profession, including women, minorities and volunteers?

Answer. The NIOSH team established partnerships with key stakeholder groups, which included meeting with Women in Fire, the National Association of Hispanic Firefighters, and the National Volunteer Fire Council (NVFC) to raise awareness and seek input on the NFR. Additionally, a presentation on the NFR is scheduled for Women in Fire's November virtual conference. Focus groups have been scheduled with panels of female and Hispanic firefighters to discuss the communications plan and materials as they relate to reaching female and minority populations.

A promotional campaign contract was recently awarded to focus on communication and recruitment of a diverse sample of firefighters. The NIOSH team published an article in NVFC's publication "Firefighter Strong," which is mailed to all U.S. fire departments (<https://www.nvfc.org/latest-issue-of-firefighter-strong-now-available/>). A sampling design was also included in the NFR protocol that includes a focused component specifically targeting fire departments with large female, minority, and volunteer workforces.

QUESTIONS SUBMITTED BY HON. THOMAS R. CARPER

Question. The President's budget cuts more than \$1 trillion from Medicaid and other safety net programs that support millions of low-income Americans with food, heating, community and social services over the next decade. Since Medicaid is the largest payer for substance abuse treatment and covers roughly one in two pregnancies, these cuts to safety net programs far exceed any additional investments the budget outlines for addressing the opioid epidemic, mental health needs, or maternal health. What do you project to be the change in Medicaid enrollment as a result of these cuts? What do your department's analyses show about the effect of the Medicaid cuts on access to substance abuse treatment, mental health care, and maternal health care?

Answer. Medicaid plays a pivotal role in ensuring access to quality, affordable health care for the most vulnerable Americans. The FY 2021 budget does not propose cutting Medicaid, but rather maintains funding to at least FY 2020 levels and slows annual growth of the program from 5.4 percent to 3.1 percent. HHS's proposed budget will have Medicaid spending grow at a more sustainable rate by ending the financial bias that currently favors able-bodied working-age adults over the truly vulnerable. This administration is committed to providing States with additional program financing options that will create opportunities for States to invest in their health-care infrastructure.

Question. The United States and a growing number of countries have identified increasing cases of the coronavirus. What statutory changes are needed to increase CDC and public labs' capability and speed to test potential patients for the coronavirus?

Answer. It is important to note that commercial diagnostic labs have primary responsibility for large scale diagnostic testing after the initial phase of the response to a large-scale outbreak involving a novel pathogen. Early in a response, CDC plays a key role in aiding and equipping State public health laboratories to gain the independent capacity to conduct diagnostic testing for the pathogen. However, commercial diagnostic manufacturers are necessary to provide large-scale diagnostic testing for clinical purposes and to meet the needs of the entire health-care system. Ideally, public health laboratory testing capacity ramps up quickly and in parallel with large-scale commercial capacity, so that both the public health and health-care systems have the diagnostic capabilities needed.

The administration worked closely with Congress to ensure that State and local public health departments had necessary resources to respond to COVID-19. The investments supported with COVID-19 Supplemental funds will help improve public health infrastructure at all levels across the country, including lab capacity expansion to enable increased testing by State and local health departments, the frontline for detection for the public health system in the United States.

Question. As much as 80 percent of one's health outcomes are effected by social determinants of health, such as access to clean water or having an air filter to help

asthma. This is particularly true with Medicaid beneficiaries who are low-income. We know that addressing the root causes of unmet health care needs can improve overall health outcomes and, ultimately, lower costs for patients and providers, including the government. Medicare Advantage plans already have the flexibility to cover services to address social determinants of health. Is CMS collecting information from Medicare Advantage plans on the clinical and cost effectiveness of these services? What are your recommendations for providing seniors in fee-for-service Medicare with similar access to services that address social determinants of health?

Answer. Social determinants of health can include housing, transportation, education, social isolation, and more. These factors affect access to care and health care utilization as well as outcomes. As we seek to foster innovation, rethink rural health, find solutions to the opioid epidemic, and continue to put patients first, we need to take into account social determinants of health and recognize their importance.

Addressing the social determinants of health begins with identifying a patient's socioeconomic and environmental conditions and measuring the impact of those conditions on individual and community health. Organizations may measure these factors using a number of existing tools that can help in the identification process, including:

- Z codes from in the International Classification of Diseases (ICD–10–CM), which are a group of codes within the ICD–10 (diagnostic) codes that help clinicians capture a patient's socioeconomic and/or psychosocial needs (examples of Z-codes in table below),
- Accountable Health Communities (AHC) Health-Related Social Needs Screening Tool, which is used by organizations participating in the CMS AHC model to identify health-related social needs.
- PRAPARE tool (Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences), developed by the National Association of Community Health Centers for providers to collect the data needed to better understand and act on their patients' social determinants of health, and
- Health Leads Screening Toolkit, which is intended to be used by clinicians as a comprehensive way to assess patients for adverse social determinants.

Data collection will help us strengthen our understanding of the relationship between social determinants of health and health-care use across diverse populations, allowing us to develop solutions and better connect patients to much needed services. CMS has begun this effort in several post-acute care provider settings this year by requiring that some data elements be collected on standardized patient assessment instruments. Some of the data elements are derived from questions from the Accountable Health Communities and PRAPARE tools mentioned above.

In an effort to reduce expenditures and improve health outcomes, CMS is testing the Accountable Health Communities Model, which is the first model to include social determinants of health. The model is based on emerging evidence that shows addressing health-related social needs through enhanced clinical-community links can improve health outcomes and reduce costs.

Medicare Advantage plans can offer expanded types of supplemental benefits to chronically ill enrollees, Special Supplemental Benefits for the Chronically Ill (SSBCI). Medicare Advantage plans can provide SSBCI which may include non-primarily health related supplemental benefits that address chronically ill enrollees' social determinants of health so long as the benefits have a reasonable expectation of maintaining or improving the health or overall function of that chronically ill enrollee. Medicare Advantage plans may consider social determinants of health as a factor to help identify chronically ill enrollees whose health or overall function could be improved or maintained with SSBCI. CMS is also testing the Medicare Advantage Value-Based Insurance Design model, which allows participants to vary supplemental based on chronic condition or socioeconomic status or a combination of the two.

Adequately and appropriately addressing social determinants of health will require the efforts of all stakeholders including beneficiaries, community groups, and health care providers. The CMS Office of Minority Health collaborated with the Health Resources and Services Administration Office of Health Equity on an event focused on social determinants of health. Participants heard from renowned speakers on how social determinants influence health outcomes, such as physical and mental health, and major chronic conditions that have high prevalence among several racial and ethnic minority groups.

Question. According to a GAO report published late last year, administrative costs associated with implementing work requirements in Medicaid cost over \$400 million across just five States, and the Federal Government covered over 80 percent (\$331 million) of those administrative costs. By no means is this an efficient use of taxpayer dollars. Has the Department of Health and Human Services estimated the administrative costs of implementing work requirements across all Medicaid programs in the country? If so, what is it? And, what would be the Federal Government's share of the cost?

Answer. Numerous States requested flexibility offered through community engagement demonstrations, and HHS supports them in their efforts to tailor their Medicaid programs to make them more efficient and sustainable for the enrollees who depend on them. While the program costs of the demonstration are subject to 1115 demonstration budget neutrality requirements, these demonstrations are not aimed at short-term budget savings. HHS has encouraged States to leverage existing infrastructure in place for SNAP and TANF, but—as with any reform—States will have to make some investments in updating their IT systems and training their staff.

This administration's goal is to support State programs that help create a pathway out of poverty and a bridge to self-sufficiency. If an able-bodied, working age adult is purposefully remaining unemployed so that they can remain eligible for Medicaid, then we need to work together to address these perverse incentives and provide these individuals with an alternative way to access coverage that does not threaten the sustainability of a program that was never intended to provide coverage for that population.

Question. The 2020 Medicare Physician Fee Schedule (PFS) Final Rule includes a policy to increase Medicare payments to primary care providers while also decreasing payments to providers that bill mostly for services. This policy could have a significant effect on patient access to health-care providers. What policies has CMS considered to ensure patient access to health-care providers such as physical therapists that bill mostly or entirely for services?

Answer. This administration is committed to strengthening Medicare, and this requires making changes that will lower costs while ultimately improving health outcomes for beneficiaries. We know it is critical that beneficiaries have access to the services they need, and HHS is dedicated to ensuring our policies promote this goal. The 2020 Medicare Physician Fee Schedule was finalized after undergoing the standard rulemaking process, which includes an extensive period for the public to provide comments.⁷ HHS greatly relies upon the input we receive from the health-care community as we make final policy decisions, and we look forward to continuing our work to improve the program while ensuring beneficiaries have access to the care they need, including services provided by clinicians such as physical therapists.

The 2020 Physician Fee Schedule (PFS) final rule adjusted the relative value units (RVUs) for office and outpatient evaluation and management (E/M) visit codes effective beginning in 2021. The Department finalized the proposal to establish values based on recommendations by the American Medical Association Specialty Society Relative Value Scale Update Committee (RUC), which were based upon a survey of more than 50 specialty societies. We generally believe that the RUC-recommended values for these codes accurately reflect the resources involved in furnishing office and outpatient E/M visits and used them, with minor modifications, to establish values for these E/M visits.

The Department received public comments on the 2020 PFS proposed rule in support of revaluing certain services relative to the new office/outpatient E/M visit values. In the 2021 PFS proposed rule, we are proposing to revalue the following services that include, rely upon or are analogous to the office/outpatient E/M visits commensurate with the increases in values finalized for office/outpatient E/M visits beginning in 2021: end stage renal disease monthly capitation payment services, transitional care management services, maternity packages, cognitive impairment assessment and care planning, the initial preventive physical examination and initial and subsequent annual wellness visits, emergency department visits, therapy evaluations (including services furnished by physical therapists, occupational therapists, and speech language pathologists), and psychiatric diagnostic evaluations and psy-

⁷ Final Rule available at: <https://www.federalregister.gov/documents/2019/11/15/2019-24086/medicare-program-cy-2020-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other>.

chotherapy services. The proposed adjustments help to ensure that CMS is appropriately recognizing the kind of care where clinicians need to spend more face-to-face time with patients, like primary care and complex or chronic disease management. We are currently reviewing public comments on these proposals.

Question. How will patients benefit from the administration's recent proposal in the annual Notice of Benefit and Payment Parameters Rule for 2021 to allow insurers to redirect manufacturer coupons from patients to the plan, particularly in instances when there are no generic or alternative medications available for that patient's condition?

Answer. The Patient Protection and Affordable Care Act places an annual limit on the amount of cost sharing that can be incurred by an individual enrolled in a non-grandfathered health insurance plan or group health plan. In May 2020, CMS finalized a policy in the final Notice of Benefit and Payment Parameters Rule for 2021 that allows issuers to decide whether direct support given to enrollees by drug manufacturers—including through coupons—accrues toward an enrollee's annual limitation on cost sharing.⁸ The direct support provided by drug manufacturers reduces the amount that the enrollee is required to pay in order to obtain coverage for the drug. Under the policy, issuers have the flexibility to determine that the value of the coupon would not be considered a cost incurred by the enrollee, and will therefore not be required to be applied toward the annual limitation on cost sharing.

HHS recognizes that copayment support may help enrollees in the short term by encouraging adherence to existing medication regimens, particularly when copayments may be unaffordable to many patients; however, the availability of a coupon or other direct support may cause physicians and enrollees to choose an expensive drug when a less expensive and equally effective alternative drug is available.

The flexibility afforded under this policy gives plans and issuers the ability to address the cost of specific prescription drugs and lower the cost of health insurance overall. This final rule ensures that issuers and group health plans need not make changes to how they have historically handled direct drug manufacturer support amounts. HHS does not expect any significant increases in patient costs or non-adherence to medications if issuers choose to continue their current behavior.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

NIH BUDGET CUTS

Question. Sufficiently funding the National Institutes of Health is one area where Congress has consistently reached bipartisan agreement. Robust funding is essential because of the scientific breakthroughs that NIH's exceptional American researchers have managed to create over the years.

The President's FY 2021 budget request proposes devastating effects: slashing \$30 million from minority health research, \$190 million from diabetes and kidney disease research, and \$31 million from Drug Abuse programs—despite acknowledgment of the opioid crisis facing America and the increase in alcohol-related deaths in our country.

The budget proposes to cut \$440 million from biomedical research at the National Institute of Allergy and Infectious Diseases, which has been leading the research into potential new treatments and vaccines to address the novel coronavirus outbreak. The budget seems to miss the fact that it is impossible to cut funding for basic research and still make the kind of strides that our research community is known for.

Secretary Azar, what was the reasoning behind cutting a significant amount of funding to the National Institute of Allergy and Infectious Diseases, which is tasked with combating deadly infectious diseases like the novel coronavirus?

Answer. The budget continues to support biomedical research within NIH. Following the release of the President's budget, the NIH budget was amended to fund NIAID at a level that would be flat with the FY 2020 enacted level and surpassing

⁸ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans, available at: <https://www.federalregister.gov/documents/2020/05/14/2020-10045/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2021>.

the FY 2021 budget over \$400 million. Within this total for NIAID, the budget would maintain the FY 2020 enacted level for NIAID's universal influenza vaccine research. These activities include innovative research regarding investigational products for the diagnosis, treatment, and prevention of influenza infection, and to protect against future pandemics. This research informs new and improved therapies, diagnostics, and vaccines which is conducted through NIAID.

In addition, the administration's budget invests nearly \$1 billion in influenza detection and surveillance, prevention research, and collaboration efforts across HHS to enhance pandemic preparedness. This large investment accounts for supporting activities across HHS, which includes ASPR modernizing influenza vaccine manufacturing infrastructure and advance medical countermeasure research and development, supporting CDC's Influenza Program which will expand influenza vaccine effectiveness monitoring systems and develop and characterize candidate vaccine viruses for vaccine manufacturers, and efforts to improve the evidence-base on non-egg-based vaccine, and for FDA to support regulatory science research and clinical assessments to promote development and access to safe and effective influenza vaccines.

Question. Why does the budget not reflect additional funding for NIH, CDC, and other HHS agencies to address the novel coronavirus?

Answer. The budget continues to support a wide range of preparedness and response activities across NIH, CDC, ASPR, and other HHS agencies. The President's budget was formulated in advance of the full scale COVID pandemic. The budget continued to propose funding for the Infectious Diseases Rapid Response Reserve Fund at CDC, which provided resources to fund critical and urgent activities at the earliest stages of the COVID outbreak. The scale and magnitude of the COVID response was closely monitored and led to various COVID supplemental appropriations that provided significant funding to address the outbreak.

Question. How did the President determine which of these NIH programs merited such drastic decreases in funding? Was any medical researcher, scientist, or NIH personnel consulted in making these decisions?

Answer. The FY 2021 President's budget reflects the administration's commitments to advance a patient-centered health care system, protect the American people from public health threats, promote independence, and streamline Federal programs. NIH is constantly engaged with the budget formulation.

ESRD MEDICARE ADVANTAGE PROPOSED RULE

Question. Medicare Advantage is known to support very ill patients through care coordination and supplemental benefits not found in Medicare. As you know, individuals with ESRD have historically been unable to enroll in Medicare Advantage (MA) plans. In 2016, I led the effort to allow ESRD patients to have access to MA plans beginning in 2021 and was thrilled that it passed as part of the 21st Century Cures Act.

The Department of Health and Human Services released a proposed rule to implement this policy, though many patient groups and others in the kidney care community have raised concerns. For example, stakeholders have raised concerns that MA plans taking on high cost ESRD beneficiaries may increase costs, reduce supplemental benefits, or limit service areas—not just for ESRD patients, but for all MA enrollees. Weakening network adequacy requirements could allow insurers to structure plans that do not provide adequate providers and services for these ESRD and chronic kidney patients.

Can you describe how the administration plans to ensure dialysis patients have a meaningful and real choice when selecting MA plans?

Answer. The FY 2021 budget continues to implement the President's executive order on *Protecting and Improving Medicare for Our Nation's Seniors*, building on those aspects of the program that work well, while also introducing market-based approaches to Medicare reimbursement. The administration seeks to protect and reform Medicare with proposals that strengthen fiscal sustainability and deliver value to patients. To drive reform, the Centers for Medicare and Medicaid Services (CMS) is modernizing the Medicare Advantage program and expanding flexibility for Medicare Advantage plans to maximize choices for seniors. In CY 2021, CMS data confirm 99 percent of Medicare beneficiaries had access to at least one Medicare Advantage plan in CY 2020, and there were an average 39 plan options in each county, an 18 percent increase from 33 average plan options available in 2019.

Through policies included in the Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program final rule issued in June 2020, CMS strengthened network adequacy rules for Medicare Advantage plans. The rule codified our existing network adequacy methodology and finalized new policies to provide support for more plan options in rural areas and encourage the use of telehealth in all areas. In rural areas, CMS reduced the required percentage of beneficiaries that must reside within the maximum time and distance standards from 90 percent to 85 percent. This may expand Medicare Advantage plan options for beneficiaries by helping Medicare Advantage organizations to build networks in these areas. To encourage and account for telehealth providers in contracted networks, we provided Medicare Advantage plans a 10-percent credit towards the percentage of beneficiaries that must reside within required time and distance standards when the plan contracts with telehealth providers for Dermatology, Psychiatry, Cardiology, Otolaryngology, Neurology, Ophthalmology, Allergy and Immunology, Nephrology, Primary Care, Gynecology/OB/GYN, Endocrinology, and Infectious Diseases. To take into account the adverse effects that Certificate of Need (CON) laws have on access, we codified that Medicare Advantage organizations may receive a 10-percent credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in States that have CON laws, or other State imposed anticompetitive restrictions, that limit the number of providers or facilities in a county or State. To recognize greater competition and greater use of other dialysis treatment modalities in different communities, CMS provided for a more flexible approach to meeting network adequacy standards for Outpatient Dialysis than the current rigid time and distance requirements.

Beneficiary choice is important and beneficiaries with ESRD—like all other beneficiaries—should carefully consider their enrollment options when they become eligible for Medicare and during subsequent annual election periods. All beneficiaries who join a Medicare Advantage plan have opportunities to change plans or return to the original Medicare fee-for-service program during the annual election period (October 15th through December 7th) or the Medicare Advantage Open Enrollment Period (January 1st through March 31st for beneficiaries enrolled as of January 1st, and during the first 3 months of Medicare Part A entitlement and Part B enrollment for newly eligible beneficiaries). In some cases, such as when a beneficiary moves out of the service area or is in a plan that does not renew its contract, a special election period is available. Beneficiaries may also use special election periods for exceptional conditions,⁹ as appropriate, including the special election period for individuals with ESRD whose entitlement determination was made retroactively to enroll in an MA plan. Further, to the extent that there is an exceptional situation for an individual that is not addressed by our existing special election periods, we will have the ability to respond to the exceptional situation.¹⁰ Finally, there are special election periods available in situations where the MA plan fails to provide medically necessary services or the plan (or its agents) materially misrepresented the plan's provisions in marketing materials.

ORAL HEALTH TRAINING PROGRAMS

Question. In 2000, then-Surgeon General David Satcher reminded the Nation that oral health is essential to general human health. Since 2000, we have made some huge strides in ensuring access to affordable dental care. Medicaid and CHIP have come together to provide dental benefits to 43 million children from economically vulnerable families. These kids are the most likely to have tooth decay, but now they are able to have the dental check-ups to help stop minor oral health issues from becoming something life altering.

Key to the success of this program is having sufficient dentists in all communities across America. Unfortunately, 51 million Americans currently live in a designated dental health professional shortage area according to the Health Resources and Services Administration (HRSA).

HRSA's Oral Health Training programs have trained thousands of primary care dental residents and oral health-care providers, many of whom choose to stay working in underserved communities. The President's budget proposes to cut the entire \$41 million budget of these Oral Health Training Programs for 2020. While the FY 2021 budget makes a commitment to the National Health Service Corps, which pro-

⁹Newly codified in § 422.62(b)(4) through (25) and described in section 30.4.4 of Chapter 2, Medicare Managed Care Manual.

¹⁰Pursuant to § 422.62(b)(26)

vides scholarships and loan repayment to improve primary care, dental, and behavioral health in rural and underserved areas, it does not provide additional funding.

If the Oral Health Training program was eliminated, do you believe we would still be able to attract oral health-care providers to these rural and underserved communities?

Answer. The Oral Health Training Programs seeks to increase access to high-quality dental health services in rural and other underserved communities by increasing the number of oral health-care providers working in underserved areas and improving training programs for these providers. The FY 2021 President's budget prioritizes funding for health workforce activities that provide scholarships and loan repayment to eligible clinicians, including dentists and dental hygienists, in exchange for their service in areas of the United States where there is a shortage of health professionals.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN
AND HON. ROBERT P. CASEY, JR.

CHGME

Question. The budget proposes to merge several existing graduate medical education programs into a single capped grant program—combining Medicare, Medicaid, and the Children's Hospital Graduate Medical Education program (CHGME), while cutting overall funding for GME at the same time. Pennsylvania and Ohio have nine children's hospitals with CHGME programs. We are concerned that a "one size fits all" program will not serve the unique needs of children. The health-care needs of children are different than those of adults and the training needed to produce the pediatricians and other providers who provide that care are also different. CHGME is dedicated to supporting this training. In particular, CHGME plays a huge role in supporting the very specialized training that only occurs in many of our children's hospitals.

We face national shortages of pediatric specialists and regional shortages of primary care pediatricians; going forward, how will HHS ensure that the needs of children will be met?

Answer. Current graduate medical education funding is outdated, overly broad, and not sustainable long-term due to its fragmented nature across multiple funding streams and lack of transparency and accountability. Effective in FY 2021, this proposal would consolidate Federal graduate medical education spending from Medicare, Medicaid, and the Children's Hospital Graduate Medical Education Program into a single grant program for teaching hospitals. Total funds available for distribution in FY 2021 would equal the sum of Medicare and Medicaid's 2017 payments for graduate medical education, plus 2017 spending on Children's Hospital Graduate Medical Education, adjusted for inflation. This amount would then grow at the CPI-U minus one percentage point each year. Payments would be distributed to hospitals based on the number of residents at a hospital (up to its existing cap) and the portion of the hospital's inpatient days accounted for by Medicare and Medicaid patients. The new grant program would be jointly operated by the Administrators of CMS and the Health Resources and Services Administration.

This grant program would be funded out of the general fund of the Treasury. The Secretary would have authority to modify the amounts distributed based on the proportion of residents training in priority specialties or programs (*e.g.*, primary care, geriatrics) and based on other criteria identified by the Secretary, including addressing health-care professional shortages and educational priorities. These changes would modernize graduate medical education funding, making it better targeted, transparent, accountable, and more sustainable.

SOCIAL SERVICES BLOCK GRANT

Question. The Social Services Block Grant (SSBG) has been a significant and important funding source for child welfare services. In Ohio, counties use SSBG to fill gaps in funding including child protection, adoption services, foster care and services to prevent child abuse. While communities grapple with the long-term impact of the opioid crisis, they face high rates of child maltreatment, foster care admissions, and child poverty. SSBG remains a critical resource for children and families, yet again the President's budget calls for the elimination of the \$1.7 billion provided to States in the Social Services Block Grant.

Child safety and well-being depends on significant investments in both child care and child protection. We do not make children safer by slashing funds from one program to boost another.

Could you explain the rationale behind the elimination of SSBG to help offset an increase in the child care entitlement to States?

Answer. Quality and affordable child care is important for both the health of the economy as well as the well-being of our Nation's children. We know the need for quality child care options is greater than the current supply and this budget reflects our commitment to working with States to increase the amount of affordable child care and ensure that children are cared for in safe settings that support their development.

This budget proposes to maintain large increases to the Child Care and Development Block Grant (CCDBG) that were included in the FY 2019 and FY 2020 appropriations. States are using these funds to increase supply, improve payment rates, and meet other new requirements of the Child Care and Development Fund (CCDF) program. Maintaining this increase will ensure that States can continue making key changes to improve their CCDF programs.

This budget proposal also includes a significant increase to Child Care Entitlement (CCE), which, when combined with CCDBG funding, is estimated to serve approximately 1.8 million children and continue the progress made since reauthorization to improve the supply and quality of care and provide transparent information to both providers and parents. The CCE increase offsets changes made in other parts of the budget, including the Social Services Block Grant funding elimination and TANF program changes, to maintain investments in child care.

There is also a proposed one-time investment of \$1 billion in CCE funding for a competitive fund aimed at building the supply of care for underserved populations and to stimulate employer investment in child care. The funding, available for obligation for 5 years, will be awarded to States with the goal of building the supply of care by helping certain categories/types of providers enter and stay in the market. This would include home-based providers, providers serving student parents, and providers offering care during non-traditional hours.

HHS is committed to helping low-income working families meet their child care needs, and this budget reflects this priority by supporting the tremendous work that States are already doing while also moving the field forward by increasing supply to better meet the needs of working parents and their children.

Question. Have you or your office assessed how SSBG's elimination would impact children in Ohio and across the country, especially those in the child welfare system?

Answer. The Social Service Block Grant (SSBG) provides funding that is duplicative of resources available through other Federal programs. In a 2011 Government Accountability Office duplicative program report, SSBG was identified as a duplicative program. In addition, the program has not demonstrated its effectiveness at achieving the main purposes of the program, which include reducing or eliminative dependency on public benefits and supporting self-sufficiency.

The President's FY 2020 budget for the Administration for Children and Families (ACF) focuses on facilitating participation in American society through promoting work, shifting resources to prevention in child welfare, and maintaining support for early childhood education and care. The proposal to not include funding for SSBG is the same as the FY 2019 President's budget. However, the underlying authorization under title XX of the Social Security Act would remain to allow SSBG to be funded as a mechanism for rapid response in case of disasters and to receive Temporary Assistance for Needy Families transfer funding.

According to a 2017 Congressional Research Service report entitled, *Child Welfare: An Overview of Federal Programs and Their Current Funding*, Federal child welfare support is provided via multiple programs, the largest of which are included in the Social Security Act. Title IV-B of the Social Security Act primarily authorizes funding to States, territories, and tribes to support their provision of a broad range of child welfare-related services to children and their families. Funding for child welfare programs are primarily administered by ACF's Children's Bureau. In addition, there are competitive grant programs (authorized by the Victims of Child Abuse Act) administered by the Office of Justice Programs within the Department of Justice.

TOBACCO AND E-CIGARETTES

Question. While I appreciate your stated shared goal of preventing a new generation of children from becoming addicted to nicotine through e-cigarettes and your responses to my questions during the budget hearing on February 13, 2020, I remain frustrated by the lack of leadership from this administration on addressing youth tobacco and e-cigarette use.

The administration's final policy, issued in January 2020, has left thousands of flavored e-cigarette products on the market in vape shops, convenience stores, and gas stations across the country. According to the Campaign for Tobacco Free Kids, more than 100,000 locations across the country continue to sell flavored disposable e-cigarettes, e-liquids, and refillable devices.

What specifics is the administration taking to eliminate all flavored e-cig products, including disposable e-cigarette and vape products, from the market?

Answer. Protecting our Nation's youth from the dangers of tobacco products is among FDA's most important responsibilities, and HHS and the agency will continue to take aggressive steps to make sure tobacco products are not being marketed or sold to kids. Ensuring that tobacco products are not marketed, sold to, or used by youth and educating youth on the dangers of tobacco is a cornerstone of our comprehensive approach for the regulation of tobacco and are also the focus of FDA's Youth Tobacco Prevention Plan, which demonstrates the agency's commitment to protecting our children.

On September 9, 2020, the FDA and the Centers for Disease Control and Prevention released new data from the 2020 National Youth Tobacco Survey (NYTS),¹¹ which show 1.8 million fewer U.S. youth are currently using e-cigarettes compared to 2019. After 2 years of disturbing increases in youth e-cigarette use, HHS is encouraged by the overall significant decline reported in 2020. This is good news; however, the FDA remains very concerned about the 3.6 million U.S. youth who currently use e-cigarettes and we acknowledge there is work that still needs to be done to curb youth use.

As stated in your question, in January 2020, FDA issued a guidance ("the January 2020 guidance") outlining the agency's enforcement priorities for Electronic Nicotine Delivery Systems (ENDS) products that lack marketing authorization (subsequently revised in April 2020). [1] Beginning February 6, 2020, FDA began to prioritize enforcement against the following groups of illegally marketed ENDS products that do not have premarket authorization: any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored product); all other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.

FDA is actively investigating the illegal sale of these groups of products, and hundreds of warning letters have already been issued to violative entities. In addition, FDA is now prioritizing enforcement for any ENDS product that is offered for sale in the United States, and for which the manufacturer has not submitted a premarket application by the court-ordered September 9, 2020 deadline (or after a negative action by FDA on a timely submitted application).

The September 9, 2020 deadline for submission of premarket applications for deemed, new tobacco products on the market as of August 8, 2016, was a milestone to ensure these products undergo a robust scientific evaluation by FDA. Scientific review of new products is a critical part of how FDA carries out its mission to protect public health from the harms associated with tobacco use.

FDA's compliance and enforcement efforts include: conducting establishment inspections and online investigations to determine whether firms are continuing to distribute or sell deemed new tobacco products without premarket authorization; conducting compliance check inspections of retailers to ensure they are complying with the law, including not selling unauthorized tobacco products; checking online retailers; and performing other types of surveillance, including surveillance of imported products, to enforce the premarket authorization requirements informed by the agency's enforcement priorities. Please note that some of these activities have been temporarily postponed due to COVID-19, but they will resume when possible, guided by health and safety considerations.

¹¹ https://www.cdc.gov/mmwr/volumes/69/wr/mm6937e1.htm?s_cid=mm6937e1_w.

Generally, where FDA observes violations of the premarket requirements, the agency initially issues a warning letter. If companies fail to take corrective measures after receiving a warning letter, the Center for Tobacco Products (CTP) may pursue enforcement actions including civil money penalties, injunctions, no tobacco sale orders, or seizures.

The agency is committed to addressing the public health crisis of youth e-cigarette use by, among other things, focusing product review and enforcement on youth-appealing products and investing in campaigns to educate youth¹² about the dangers of e-cigarette use. FDA will remain vigilant in monitoring the marketplace, expanding our public education efforts and using our regulatory authority—changing course as necessary—to further ensure all tobacco products, and e-cigarettes in particular, are not marketed to, sold to, or used by kids.

In line with FDA's enforcement priorities stated in the January 2020 guidance, on September 9, 2020, FDA issued warning letters¹³ notifying three companies who sell or distribute unauthorized ENDS products that their products are illegally marketed. FDA issued a warning letter to XL Vape, LLC (doing business as Stig Inc.), a popular disposable e-cigarette brand among youth, warning the company to remove their disposable e-cigarettes from the market because they do not have the required premarket authorization. Additional warning letters were issued to Flavour Warehouse LTD (doing business as Vampire Vape) and Pretty Women UK LTD (T/A Coil2oil and Mad Kingdom Liquids) for illegally marketing unauthorized menthol-flavored e-liquids. The labeling and/or advertising of these products also features cartoon images, such as vampires and kings, that are commonly marketed and/or appeal to youth.

These warning letters are just the latest in the series of actions FDA has taken in the past weeks and months to ensure that youth do not begin using any tobacco product. In late July, the agency issued warning letters¹⁴ to 10 companies, including Puff Bar, warning the companies that their products are illegally marketed because they lack the required premarket authorization. The agency is working to ensure these illegally marketed products are no longer sold, and that the products will not be reintroduced on the market until the companies have applied for and received marketing authorization from FDA.

HHS and FDA remain fully committed to protecting the public health of America's youth as demonstrated through the agency's efforts in compliance and enforcement, public education, regulatory science research, premarket review, and regulatory policy.

[1] Final Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (revised), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market>.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH (NIOSH)

Question. You have spoken before about how you believe the Centers for Disease Control and Prevention (CDC) is the envy of the world when it comes to public health. As you know, the CDC is currently working to update and replace two NIOSH facilities in Cincinnati, OH. The agency is currently undergoing site acquisition activities and, according to a meeting Senator Portman and I participated in with representatives from the CDC and General Services Administration (GSA) at the end of 2019, CDC is on track to award a contract for design services for the project this spring.

This project is not just about updating the NIOSH buildings—this is about improving government efficiency and creating jobs in Southwest Ohio. Last year you committed to continuing to move this project forward. I again ask for your commit-

¹² <https://www.fda.gov/tobacco-products/public-health-education/real-cost-campaign#1>.

¹³ <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters>.

¹⁴ <https://www.fda.gov/news-events/press-announcements/fda-notifies-companies-including-puff-bar-remove-flavored-disposable-e-cigarettes-and-youth>.

ment to making this project a priority for the administration and keeping this project on schedule, despite the FY 2021 budget's proposed cuts to CDC.

Will you renew your commit to working with Senator Portman and me to keep this project moving forward under your leadership at HHS?

Answer. CDC's National Institute for Occupational Safety and Health remains committed to construction and development of the Consolidated Cincinnati Research Facility. In August of 2020, the contract for the architectural and engineering design of the campus facilities was awarded. The facility will consist of 235,000 gross square feet (GSF) for office and laboratory building(s), surface parking lots for employees, a parking deck for visitors and employees, security infrastructure, landscaping, and other additional work at the new CDC/NIOSH campus site. CDC expects the design phase to be complete in fall 2021, with construction beginning in early 2022 and completion in 2024. As the project continues to accelerate, we are committed to working with you and Senator Portman to keep this project moving forward.

PHYSICIAN FEE SCHEDULE

Question. My office has received a number of meeting requests and comments from Ohio constituents regarding the 2020 Physician Fee Schedule Final Rule and proposals that may be included in the 2021 Physician Fee Schedule Proposed Rule (yet to come out). While each stakeholder organization has its own priorities, many of them are frustrated by the Centers for Medicare and Medicaid (CMS) approach to gathering information and engaging with stakeholders throughout the rule-making process.

What will you do to ensure CMS provides stakeholders with sufficient opportunity to engage on proposals related to the 2021 Physician Fee Schedule rule leading up to the CMS proposed rule and then, once proposed, during both the official comment period?

What steps are you planning to take to ensure sufficient information and data is gathered to inform future policy changes?

Answer. This administration is committed to working closely with a variety of stakeholders, including providers on the front lines of care, to ensure our policies are improving the health-care system. The Department follows standard rulemaking procedure, which includes an extensive comment period for public feedback, and engages in numerous efforts to obtain stakeholder input. This can include regular calls with States, provider, patient advocacy organizations, industry groups, and other experts to discuss potential changes and to explain new policy decisions. The best innovation comes from the front lines, and this administration relies greatly on the feedback we receive to inform our work.

Each year CMS develops adjustments to the relative value units under the Physician Fee Schedule (PFS) based on our review of information that generally includes, but is not limited to, recommendations received from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Health Care Professionals Advisory Committee, the Medicare Payment Advisory Commission, and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the Federal Government. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations.

CMS proposes to establish relative value units for each calendar year for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. CMS accepts comments from the public for 60 days following the publication of the proposed rule, which are used to inform our final policies. Following the publication of final rules for the PFS, we encourage stakeholders to submit information such as invoices or other information to improve the accuracy of pricing to CMS by February 10th of the following year for consideration in future rulemaking, similar our process for consideration of RUC recommendations. We also continue to engage with stakeholders outside of rulemaking to receive feedback to inform future policies.

MFAR

Question. The recently proposed Medicaid Fiscal Accountability Regulation (MFAR) contains several provisions that would significantly impact the financing of

Ohio's Medicaid program. If finalized, the rule would have a chilling effect on Ohio's program—potentially impacting enrollees and services offered.

What plans does CMS have to engage in additional impact analysis related to the proposed rule?

What engagement has CMS had with States that would be impacted by the proposed rule?

Answer. The Medicaid Fiscal Accountability Regulation (MFAR), CMS-2393-P, was published in the November 18, 2019, issue of the Federal Register, with a 60-day comment period that closed on January 17, 2020, which was subsequently extended by 15 days and closed on February 1, 2020. During this time, CMS also conducted numerous calls with States and other stakeholders to receive substantive feedback to help us understand the potential impact of the proposed rule.

The policies proposed within the rule are intended to ensure accountability of State financing, transparency of payments, and the fiscal integrity of the Medicaid program, including through numerous clarifications to Medicaid financing and oversight rules. However, please know that we have listened closely to concerns that have been raised by our State and provider partners about potential unintended consequences of the proposed rule, which require further study. Therefore, CMS has withdrawn the rule from the regulatory agenda.

MATERNAL MORTALITY

Question. Each year, an estimated 700 women in the U.S. lose their lives due to pregnancy-related complications, with African American mothers dying at 2–4 times the rate of white mothers. Data from the Centers for Disease Control and Prevention (CDC) shows that more than 60 percent of pregnancy-related deaths occur in the days between delivery and one year postpartum and research demonstrates that up to half of all maternal deaths may be preventable. Because Medicaid is our Nation's primary source of insurance for expecting moms and childbirth, experts agree that extending Medicaid coverage for new moms for a full year postpartum will help improve health outcomes for both moms and babies.

The President's budget includes a proposal to extend Medicaid coverage for postpartum women with a substance use disorder for up to a full year after the birth of a baby. What more is your Department doing to help strengthen coverage and access to high-quality, comprehensive care for *all* mothers through Medicaid?

Answer. As the single largest payer for maternity care in the United States, Medicaid plays an important role in perinatal and maternal health. In 2014, CMS launched its Maternal and Infant Health Initiative (MIHI) to explore program and policy opportunities to improve outcomes and reduce the cost of care for women and infants in Medicaid and CHIP. Since then, much work has been done, such as the Postpartum Care Action Learning Series, a learning collaborative of States to drive quality improvement around postpartum care.

CMS is currently evaluating activities over the past 5 years, which includes publishing three issue briefs on March 9, 2020, to describe initiatives undertaken in the first phase of MIHI. These issue briefs are:

- Lessons Learned About Payment Strategies to Improve Postpartum Care in Medicaid and CHIP: This brief outlines the lessons learned about payment strategies to improve postpartum care visit rates and summarizes the changes three States made related to paying for maternity care in order to improve postpartum care under the Postpartum Care Action Learning Series.¹⁵
- The Maternal and Infant Health Initiative Grant to Support Development and Testing of Medicaid Contraceptive Care Measures: The CMS MIHI grant program supported development and testing of Medicaid contraceptive care measures. This analytic brief discusses the MIHI grant program, describes the contraceptive care measures developed as part of this effort, summarizes data reported by the MIHI grantees, highlights uses of the data, and identifies lessons learned.¹⁶

¹⁵ Available at: <https://www.medicaid.gov/medicaid/quality-of-care/downloads/postpartum-payment-strategies.pdf>.

¹⁶ Available at: <https://www.medicaid.gov/medicaid/quality-of-care/downloads/mihi-contraceptive-measures.pdf>.

- **Improving Postpartum Care: State Projects Conducted through the Postpartum Care Action Learning Series and Adult Medicaid Quality Grant Program:** This issue brief describes the quality improvement teams in the 10 States, their aims, the interventions they tested, their results, and lessons learned. In addition, this fact sheet provides summaries of the postpartum care-related projects that four States undertook as Adult Medicaid Quality grantees.¹⁷

In 2018, CMS announced the Maternal Opioid Misuse (MOM) model, which addresses the need to better align and coordinate care of pregnant and postpartum Medicaid beneficiaries with opioid use disorder (OUD) through State-driven transformation of the delivery system surrounding this vulnerable population. By supporting the coordination of clinical care and the integration of other services critical for health, well-being, and recovery, the MOM model has the potential to improve quality of care and reduce expenditures for mothers and infants. In December 2019, CMS announced the following 10 States were awarded MOM Model funding: Colorado, Indiana, Louisiana, Maine, Maryland, Missouri, New Hampshire, Tennessee, Texas, and West Virginia.

Additionally, CMS is reconvening an expert workgroup to help chart a course for the future of maternal infant health quality measurement and improvement. The workgroup will represent a wide variety of key stakeholders and Federal agencies and will provide updated recommendations for measurement, quality improvement and technical assistance opportunities.

In Medicaid and CHIP, the measures in the voluntary Child and Adult Core Sets assess the quality of care women receive at each step in their lifecycle and include quality measures associated with major drivers of pregnancy-related mortality and severe maternal morbidity. CMS has identified a subset of 11 Child and Adult Core Set measures for 2020 that comprise a Core Set of Maternal and Perinatal Health Measures for Medicaid and CHIP (Maternity Core Set).¹⁸ The Maternity Core Set includes a measure of early elective delivery, along with measures that examine prenatal and postpartum care, low birth weight babies and well-baby care. Since the core sets were established in 2010 and 2012, States have made significant progress reporting these measures. With the passing of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), State reporting of the Child Core Set, including maternal and infant health measures, will become mandatory beginning in 2024.

The Medicaid and CHIP Scorecard is a central component of CMS's commitment to increase public transparency and accountability about the programs' administration and outcomes.¹⁹ The Scorecard currently includes one maternal health measure (Postpartum Care), as well as two other measures from the Maternity Core Set, Well-Child Visits in the First 15 Months of Life and Live Births Weighing Less Than 2,500 Grams. Over time, the Scorecard will evolve to include health outcome metrics, and we are considering how the Scorecard can address maternal and infant health. CMS continues to work with States to encourage greater reporting to improve consistency across States.

MAXIMIZING OUR HEALTH-CARE WORKFORCE

Question. The President's FY 2021 proposed budget includes some language around supporting health-care professionals so that they may practice at the top of their license.

Can you please clarify what non-physician health-care professionals you plan on including in this effort?

Answer. The Fiscal Year 2021 Congressional Justification includes a description of the National Health Service Corps State Loan Repayment Program (SLRP) on pages 82 and 83. Specifically, the description says "States receiving funding from SRLP are encouraged to allow health professionals to practice to the full extent of their license." Apart from physicians, the health professional disciplines and specialties eligible to participate in SLRP, as referenced in this language include:

- Nurse Practitioners (specializing in adult, family, pediatrics, psychiatry/mental health, geriatrics, women's health, and certified nurse-midwives).

¹⁷ Available at: <https://www.medicaid.gov/medicaid/quality-of-care/downloads/postpartum-als-state-projects.pdf>.

¹⁸ Available at: <https://www.medicaid.gov/medicaid/quality-of-care/downloads/performance-measurement/2020-maternity-core-set.pdf>.

¹⁹ Available at: <https://www.medicaid.gov/state-overviews/scorecard/index.html>.

- Physician Assistants (specializing in adult, family, pediatrics, psychiatry/mental health, geriatrics, or women's health).
- Dental professionals (general, pediatric, registered dental hygienists).
- Mental health professionals (health service psychologists, licensed clinical social workers, psychiatric nurse specialists, licensed professional counselors, marriage and family therapists).
- Registered Nurses.
- Pharmacists.
- Substance use disorder counselors (licensed/credentialed/certified by their state of practice that meet educational requirements and master's degree requirement).

QUESTIONS SUBMITTED BY HON. MICHAEL F. BENNET

Question. I have been working with Senators Cassidy and Hassan to end surprise medical bills at the Federal level. It is outrageous that Americans can't easily identify which providers are in their network. Even when they do their research, they can still receive financially devastating bills, sometimes weeks or months later. Last year, Colorado took a strong step forward to protect patients from this predatory practice at the State level, but it doesn't protect all patients, so it's time for the Federal Government to do the same. The President also mentioned this issue in his budget.

How is the administration directing resources to help address this problem and protect patients from surprise medical bills?

Is the administration committed to our approach that includes an automatic payment with an option for providers to go to arbitration but only holds patients responsible for their in-network copay?

Answer. For too long, surprise medical billing has left some patients with unexpected and unjustified charges for services they did not know were out of network. The Trump administration believes it is past time to put an end to these deceptive medical billing practices. In May 2019, the administration released its principles on surprise billing which are: patients receiving emergency care should not be forced to shoulder extra costs billed by a care provider but not covered by their insurer; patients receiving scheduled care should have information about whether providers are in or out of their network and what costs they may face; patients should not receive surprise bills from out-of-network providers they did not choose; and Federal health-care expenditures should not increase.

Since then, the administration has taken regulatory action that will increase price transparency by hospitals and insurers, making health care prices more accessible to patients and the general public. In addition, the administration used its authority to prohibit providers receiving reimbursement for COVID-19 services from the Provider Relief Fund from balance billing patients during the current public health emergency. This administrative action helps protect patients from surprise bills for COVID treatment as well as for non COVID-related services. However, the administration currently does not have the statutory authority to implement a more permanent and comprehensive solution to surprise billing; congressional action is needed. This is why the administration has repeatedly called on Congress to act to eliminate the burden of surprise medical bills for patients across the country. We look forward to continuing to work with Congress to end this practice for good and to protect American families.

Question. Suicide is now the leading cause of death for teenagers in Colorado, and the State has the 11th worst suicide rate in the country. Some of the largest behavioral health providers in our State have also closed, which means that many families need to go out of State just to receive adequate mental health treatment. This can be due to a lack of beds or specialty care available. Medicaid covers about 40 percent of all children and youth in Colorado and we know that the barriers to care for children who live in poverty are even higher.

How would the budget's nearly \$1-trillion cut in Medicaid affect mental and behavioral health services for children who receive care through the program?

Although the budget contains some new investments, they amount to less than 1.5 percent of the funds we stand to lose if the administration repeals Medicaid expansion, a crucial program for Coloradans. One particularly troubling story belongs

to a mother in Colorado and her young daughter, who at 6 years old attempted suicide.

Will a \$1-trillion cut to Medicaid help families and children in America like this mother and her daughter?

Answer. Suicide is the 10th leading cause of death in the United States—responsible for more than 47,000 deaths in 2017—and suicide rates have increased steadily for individuals of all ages. HHS is committed to addressing this major health issue through public health surveillance, research, State and community based funding for mental health services, and supporting treatment. That’s why the FY 2021 budget proposes \$93 million for suicide prevention activities, including additional funding to expand Zero Suicide initiatives to focus on adult suicide prevention and allow communities and States to tailor strategies to prevent suicide in their local jurisdictions. In addition, the FY 2021 budget does not propose cutting Medicaid, but rather maintains funding to at least FY 2020 levels and slows annual growth of the program from 5.4 percent to 3.1 percent.

The FY 2021 budget will also provide targeted flexibility for States to provide inpatient mental health services to Medicaid beneficiaries with serious mental illness. Americans with serious mental illness face significant challenges getting the care they need. In 2018, 47.6 million adults had a mental illness, of whom 11.3 million suffered from serious mental illness, meaning their mental illness substantially interfered with or limited major life activities. More than one out of every three individuals with serious mental illness do not receive mental health care, and those who receive care often encounter a fragmented mental health system that is difficult to navigate.

Longstanding Federal law has prohibited States from receiving Federal matching funds for providing services to Medicaid beneficiaries while residing in an institution for mental disease (IMD). In November 2018, CMS announced a new Medicaid demonstration opportunity for States to receive authority to pay for short-term residential treatment services in an IMD for adults with serious mental illness and children with serious emotional disturbance. These demonstrations are allowing States to broaden access to treatment for individuals across the entire behavioral health spectrum. The FY 2021 budget includes a proposal that would build upon these efforts by allowing States the option of receiving Medicaid reimbursement for covered services in institutions for mental disease for adults with serious mental illness without a waiver, subject to meeting certain criteria.

Question. I am hearing significant concerns about a potential loss of Medicaid access in rural counties of Colorado under the cap on supplemental payments that CMS proposed in the Medicaid Fiscal Accountability Rule (MFAR).

Can you quantify the loss in coverage you expect if CMS implements this cap as proposed?

Can you explain how CMS would mitigate this reduction in access?

Answer. The Medicaid Fiscal Accountability Regulation (MFAR), CMS–2393–P, was published in the November 18, 2019, issue of the Federal Register, with a 60-day comment period that closed on January 17, 2020, which was subsequently extended by 15 days and closed on February 1, 2020. During this time, CMS also conducted numerous calls with States and other stakeholders to receive substantive feedback to help us understand the potential impact of the proposed rule.

The policies proposed within the rule are intended to ensure accountability of State financing, transparency of payments, and the fiscal integrity of the Medicaid program, including through numerous clarifications to Medicaid financing and oversight rules. However, please know that we have listened closely to concerns that have been raised by our State and provider partners about potential unintended consequences of the proposed rule, which require further study. Therefore, CMS has withdrawn the rule from the regulatory agenda.

HHS is committed to ensuring State compliance with section 1902(a)(30)(A) of the Social Security Act, which requires Medicaid provider payments to be “consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers” to provide access to care and services at least to the extent available to the general population in the geographic area. We will continue to monitor access to care and services for Medicaid beneficiaries, and have announced a new comprehensive strategy for monitoring access to care in Medicaid on July 11, 2019. That strategy may be accessed here: <https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/CIB071119.pdf>.

Question. To justify the 50-percent cap on supplemental payments to practitioners in the MFAR, CMS cites concerns about oversight of the Average Commercial Rate (ACR).

Why did CMS choose to propose elimination of the ACR that has been used in supplemental payment State Plan Amendments since at least 2005?

Why didn't CMS instead propose providing better oversight of ACR calculations?

If neither of these explain the 50-percent cap, then how did CMS choose the cap on supplemental payments?

Answer. The Medicaid Fiscal Accountability Regulation (MFAR), CMS-2393-P, was published in the November 18, 2019, issue of the Federal Register, with a 60-day comment period that closed on January 17, 2020, which was subsequently extended by 15 days and closed on February 1, 2020. During this time, CMS also conducted numerous calls with States and other stakeholders to receive substantive feedback to help us understand the potential impact of the proposed rule.

The policies proposed within the rule are intended to ensure accountability of State financing, transparency of payments, and the fiscal integrity of the Medicaid program, including through numerous clarifications to Medicaid financing and oversight rules. However, please know that we have listened closely to concerns that have been raised by our State and provider partners about potential unintended consequences of the proposed rule, which require further study. Therefore, CMS has withdrawn the rule from the regulatory agenda.

Question. According to CDC data, overdoses involving opioids killed more than 47,000 people in 2017, and 36 percent of those deaths involved prescription opioids. Congress passed into law several initiatives to treat patients facing opioid addiction but also to prevent addiction from occurring in the first place. We are still far from "solving" the opioid crisis or other addiction crises like meth and alcohol, so we need to explore more options while also ensuring the initiatives we have passed into law are implemented in a timely manner.

The SUPPORT for Patients and Communities Act (Pub. L. No: 115-271), which Congress passed and the President signed into law in October 2018, included a broadly bipartisan provision requiring the use of e-prescribing for all controlled substances under Medicare Part D by January 1, 2021, with reasonable exceptions based on similar State laws. Half of all States have already required e-prescribing, or will soon require it like Colorado, to combat the opioid epidemic.

We see that several States have already implemented their laws without significant interruptions to care. Can you work with CMS Administrator Verma to engage with my office to update me in the next few weeks on your plan to fully implement e-prescribing for prescription opioids, as required by statute, by January 1, 2021?

Answer. Section 2003 of the SUPPORT Act requires prescriptions for controlled substances covered under Medicare Part D to be submitted electronically by prescribers, unless a waiver applies, by January 1, 2021. We recognize the importance of electronic prescribing of controlled substances (EPCS) and the statutory mandate. CMS is working hard to make sure plans have the resources and support they need to implement these new requirements and we encourage all prescribers to conduct EPCS as soon as is feasible for them. We understand that implementing EPCS takes additional time and resources for prescribers. We also recognize that the current public health emergency for the COVID-19 pandemic presents additional EPCS challenges for some prescribers. As part of the CY 2021 Physician Fee Schedule proposed rule (CMS-1734-P) issued on August 3, 2020, we proposed to require all prescribers to conduct electronic prescribing of Schedule II, III, IV, and V controlled substances under Medicare Part D using the NCPDP SCRIPT 2017071 standard by January 1, 2022, except in circumstances in which the Secretary waives the requirement. Based on comments received, CMS finalized the provision with an effective date of January 1, 2021 and a compliance date of January 1, 2022 to encourage prescribers to implement EPCS as soon as possible, while helping ensure that our compliance process is conducted thoughtfully. We believe that this phased approach strikes a balance of adhering to the timeframe set forth in the SUPPORT Act, supporting more rapid implementation of EPCS, and giving prescribers adequate time to comply with the EPCS implementation requirement.

In addition, on July 30, 2020, we issued a Request for Information (RFI) soliciting input from stakeholders around implementation of Section 2003—in particular, whether CMS should include exceptions to the EPCS and under what circumstances, and whether CMS should impose penalties for noncompliance with this

mandate in its rulemaking, and what those penalties should be. The RFI sought input from stakeholders, including prescribers that CMS does not directly regulate under MA, and/or Part D, and who are not enrolled in Medicare or Medicaid. Responses to this RFI were due on October 5, 2020. The SUPPORT Act requires that CMS use rulemaking to determine any processes for enforcement, including on any prescriber waivers, penalties and appeals. CMS will continue to consider comments and recommendations received in response to both the proposed rule and the RFI and will propose any such processes in a future rule, to be effective no earlier than January 1, 2022.

Question. The growing coronavirus outbreak is a stark reminder of the central role infectious disease (ID) physicians play in responding to emerging infectious diseases and other public health emergencies. Despite the vital contribution ID physicians make to patient care, research, and public health, their work continues to be undervalued. While 90 percent of ID physicians' care falls under evaluation and management (E/M), the current E/M codes do not reflect the increasing complexity of E/M work. The current reimbursement is driving fewer physicians to enter the field of ID at a time when we need these experts to respond to a host of threats including coronavirus. I was pleased that CMS significantly modified its payment for E/M services in the CY 2020 Medicare Physician Fee Schedule (PFS), but I don't believe the modifications address the underlying undervaluation of existing E/M services.

To address this concern, would you be willing to establishing a Technical Expert Panel (TEP) at CMS to generate expert stakeholder input to refine E/M payment and policies? This could include outlining the specifications and objectives for conducting research regarding E/M codes.

Answer. The calendar year (CY) 2020 Physician Fee Schedule (PFS) final rule issued on November 1, 2019, adjusted the relative value units (RVUs) for office and outpatient evaluation and management (E/M) visit codes effective beginning in CY 2021. The Department finalized the proposal to establish values based on recommendations by the American Medical Association Specialty Society Relative Value Scale Update Committee (RUC), which were based upon a survey of more than 50 specialty societies. We generally believe that the RUC-recommended values for these codes accurately reflect the resources involved in furnishing office and outpatient E/M visits and used them, with minor modifications, to establish values for these E/M visits.

Although we believe that the RUC-recommended values for the revised office/outpatient E/M visit codes will more accurately reflect the resources involved in furnishing a typical office/outpatient E/M visit, we continue to believe that the typical visit described by the revised and revalued office/outpatient E/M visit code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits. Therefore, in the CY 2020 PFS final rule (84 FR 62856), we finalized the HCPCS add-on code GPC1X which describes the "visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex condition." We stated that we were not restricting billing based on specialty, but that we did assume that certain specialties, including infectious disease, furnished these types of visits more than others.

QUESTIONS SUBMITTED BY HON. ROBERT P. CASEY, JR.

MEDICAID

Question. The NPRM announced on December 20, 2019 entitled "Strengthening the Program Integrity of the Medicaid Eligibility Determination Process" (CMS-2421-P) received a "no" designation when reviewed for economic significance. This is inconsistent with public statements by Administrator Verma (*e.g.*, CMS.gov blog, June 25, 2019 where the director States over \$9.63 billion has been recovered through oversight efforts in just one State) or your own statements in response to my letters. Likewise, the President's budget calls for economically significant oversight through program integrity efforts in the amount of \$34.2 billion in savings over 10 years.

Explain how the proposals in the Strengthening the Program Integrity of the Medicaid Eligibility Determination Process are economically insignificant while the

opposite is claimed in the FY 2021 budget, comments from you and comments from Administrator Verma claim enormous fiscal cuts to the Medicaid program.

Answer. HHS has not released the Proposed Rule “Strengthening the Program Integrity of the Medicaid Eligibility Determination Process” (CMS-2421-P). If the Department moves forward with a proposal, we will follow standard rulemaking procedure, which includes an extensive comment period for public feedback. We welcome input from all of our stakeholders as we make important policy decisions to improve our programs.

PANDEMIC/CORONAVIRUS

Question. The past few weeks have seen a significant increase in the threat of COVID-19 worldwide. The threat to the public health of Americans is significant, particularly for at-risk populations, like people with disabilities and older adults. Epidemics and pandemics are unpredictable and we need to be ready to respond quickly and to respond on a global level. As COVID-19 has shown, events 8,000 miles away can reach us overnight.

The President’s budget proposes to slash significant funds from CDC and HHS programs that prepare for and respond to public health emergencies such as COVID-19. One example is a proposed almost 20-percent reduction in the Public Health and Social Services Emergency Fund. You have also proposed significant cuts to the CDC programs that address public health preparedness and response, including a \$85 million cut to efforts to address emerging infectious disease. You propose to reduce the overall CDC budget by over \$1.2 billion or over 18 percent. In a time when preparation and response to unanticipated diseases and health emergencies are so important, please detail why you have proposed cutting funding to programs that make it possible for the United States to prepare for these unexpected events and to respond with our global neighbors to the events, as well as how these cuts may impact the ability of ensuring that at-risk populations will be protected from illness.

Answer. On March 17, 2020, the administration transmitted an FY 2021 budget amendment to Congress to increase funding for CDC in FY 2021 to ensure that the agency had the resources beginning October 1, 2020, to continue its critical public health mission. This amendment requested a total FY 2021 funding level of \$8,329,102,000 for CDC, which is \$1,328,196,000 above the FY 2021 budget request. The additional funding would support priority CDC activities, including preparedness and response and emerging and infectious diseases.

The PHSSEF FY 2021 President’s Budget proposed a decrease of approximately \$96 million relative to the FY 2020 enacted level (about -3.5 percent). The most significant reduction in the PHSSEF FY 2021 President’s Budget was to ASPR’s Project Bioshield, however the decrease reflected Congress’s forward funding of procurement of Ebola countermeasures through emergency supplemental funding in FY 2020.

ORGAN TRANSPLANTS

Question. There is a well-documented history of discrimination against people with disabilities in organ transplant programs. Despite the Americans with Disabilities Act (ADA) and section 504 of the Rehabilitation Act prohibiting discrimination on the basis of disability, a number of States have found it necessary to enact laws to address continued barriers to receiving this lifesaving care. These barriers are reported to include medical professionals and transplant centers refusing to approve organ transplants for people with disabilities who may need help in order to follow complicated post-transplant treatment plans, or deciding that people with disabilities should be given a lower priority on waiting lists to receive an organ transplant. Additional barriers include the lack of evaluation and referral to organ transplant specialist for people with disabilities.

What plans does HHS have to take action against disability discrimination in organ transplantation and other areas in which life-sustaining care is inappropriately withheld from people with disabilities?

In what ways does HHS ensure people with disabilities receive evaluations and referrals to organ transplant specialist? Do you anticipate guidance or regulation on this topic in the coming year?

Answer. The Office for Civil Rights (OCR) is concerned with discrimination against persons with disabilities and recognizes that this discrimination can extend to the organ transplant context and other areas in which life-sustaining care is in-

appropriately withheld. Specifically, OCR has reviewed the National Council of Disabilities (NCD) bioethics series and the reports on Organ Transplant Discrimination Against People With Disabilities: Part of the Bioethics and Disability Series (September 2019) and The Danger of Assisted Suicide Laws: Part of the Bioethics and Disability Series (October 2019).

The National Council on Disability underscored the following: discrimination continues to occur in the nine States that have enacted laws explicitly prohibiting such discrimination; that disabilities unrelated to a person's need for an organ transplant generally have little or no impact on the likelihood that the transplant will be successful; and that many organ transplant centers have policies that bar or caution against placing people with HIV, psychiatric disabilities, or intellectual and developmental disabilities (I/DD) on the waiting list to receive an organ transplant.

In the report on assisted suicide, the National Council on Disability explains that persons with disabilities are often coerced to end their lives when faced with life-threatening conditions, even if the conditions are treatable. OCR has also received letters from Congress and stakeholders concerned about invidious steering of persons with disabilities into assisted suicide instead of suicide prevention treatments or resources. Similarly, OCR is aware of examples where doctors unilaterally enter "do not resuscitate" orders for patients with disabilities but not for patients without disabilities.

In the organ transplant context, OCR favorably resolved a case in North Carolina last year, where a medical provider deemed an individual ineligible to be on a heart transplant wait list by citing the individual's autism even though the disability was irrelevant to the odds of success of the procedure. OCR has also received letters from Congress and met with stakeholders who have addressed disability discrimination.

To address these issues, OCR is exploring issuing guidance or developing a proposed rulemaking to address the rights to be free from discrimination on the basis of disability in these contexts.

ADVISORY COMMITTEE ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN

Question. I have been a consistent supporter of newborn screening, which can identify infants born with conditions like phenylketonuria (PKU); my father pushed for Pennsylvania's PKU newborn screening law when he was Governor, and it was one of the accomplishments of which he was most proud. State newborn screening programs are supported by the Federal law, the Newborn Screening Saves Lives Act, which authorizes the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC). The ACHDNC is tasked with providing recommendations to the Secretary of Health and Human Services regarding what conditions should be included in the "recommended uniform screening panel," which then informs State policy on what heritable disorders they test for. The ACHDNC has been in operation for almost 20 years, and provides valuable recommendations regarding technologies, guidelines and standards to improve infant health and prevent infant deaths. However, the ACHDNC's statutory authority lapsed in October 2019, and the committee has had to halt its activities, preventing the committee from completing work underway when its authority lapsed or from starting new work.

I understand that you, as Secretary, have the authority under the Public Health Service Act to immediately restart the committee's activities by renewing its charter. Will you take immediate steps to reconstitute the ACHDNC as soon as possible so it can continue its lifesaving work?

Answer. Thank you for your interest in the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC). The ACHDNC provides important advice, technical information and recommendations regarding genetic disorders, newborn screening, and childhood screening to the Secretary. HRSA is working with the Secretary's office to continue ACHDNC's activities as a discretionary committee.

PHYSICIAN FEE SCHEDULE

Question. I have heard concerns from constituents about payment changes in the 2020 Physician Fee Schedule (PFS) Final Rule that will have a negative impact on providers who do not regularly utilize Evaluation and Management (E&M) codes due to the nature of their specialty. In calculating these payment changes, did HHS take into account the negative impact on those specialties, and has it considered possible ways to ameliorate that impact?

Answer. This administration is committed to strengthening Medicare, and this requires making changes that will lower costs while ultimately improving health outcomes for beneficiaries. We know it is critical that beneficiaries have access to the services they need, and HHS is dedicated to ensuring our policies promote this goal. The 2020 Medicare Physician Fee Schedule was finalized after undergoing the standard rulemaking process, which includes an extensive period for the public to provide comments.²⁰ HHS greatly relies upon the input we receive from the health-care community as we make final policy decisions, and we look forward to continuing our work to improve the program while ensuring beneficiaries have access to the care they need, including services provided by clinicians such as physical therapists.

The 2020 Physician Fee Schedule (PFS) final rule adjusted the relative value units (RVUs) for office and outpatient evaluation and management (E/M) visit codes effective beginning in 2021. The Department finalized the proposal to establish values based on recommendations by the American Medical Association Specialty Society Relative Value Scale Update Committee (RUC), which were based upon a survey of more than 50 specialty societies. We generally believe that the RUC-recommended values for these codes accurately reflect the resources involved in furnishing office and outpatient E/M visits and used them, with minor modifications, to establish values for these E/M visits.

The Department received public comments on the 2020 PFS proposed rule in support of revaluing certain services relative to the new office/outpatient E/M visit values. In the 2021 PFS proposed rule, we are proposing to revalue the following services that include, rely upon or are analogous to the office/outpatient E/M visits commensurate with the increases in values finalized for office/outpatient E/M visits beginning in 2021: end stage renal disease monthly capitation payment services, transitional care management services, maternity packages, cognitive impairment assessment and care planning, the initial preventive physical examination and initial and subsequent annual wellness visits, emergency department visits, therapy evaluations (including services furnished by physical therapists, occupational therapists, and speech language pathologists), and psychiatric diagnostic evaluations and psychotherapy services. The proposed adjustments help to ensure that CMS is appropriately recognizing the kind of care where clinicians need to spend more face-to-face time with patients, like primary care and complex or chronic disease management. We are currently reviewing public comments on these proposals.

QUESTION SUBMITTED BY HON. ROBERT P. CASEY, JR.
AND HON. SHERROD BROWN

CHILDREN'S HOSPITAL GRADUATE MEDICAL EDUCATION FUNDING

Question. The budget proposes to merge several existing graduate medical education programs into a single capped grant program—combining Medicare, Medicaid, and the Children's Hospital Graduate Medical Education program (CHGME), while cutting overall funding for GME at the same time. Pennsylvania and Ohio have nine children's hospitals with CHGME programs. We are concerned that a "one size fits all" program will not serve the unique needs of children. The health care needs of children are different than those of adults and the training needed to produce the pediatricians and other providers who provide that care are also different. CHGME is dedicated to supporting this training. In particular, CHGME plays a huge role in supporting the very specialized training that only occurs in many of our children's hospitals. We face national shortages of pediatric specialists and regional shortages of primary care pediatricians; going forward, how will HHS ensure that the needs of children will be met?

Answer. Current graduate medical education funding is outdated, overly broad, and not sustainable long term due to its fragmented nature across multiple funding streams and lack of transparency and accountability. Effective in FY 2021, this proposal would consolidate Federal graduate medical education spending from Medicare, Medicaid, and the Children's Hospital Graduate Medical Education Program into a single grant program for teaching hospitals. Total funds available for distribution in FY 2021 would equal the sum of Medicare and Medicaid's 2017 payments

²⁰ Final Rule available at: <https://www.federalregister.gov/documents/2019/11/15/2019-24086/medicare-program-cy-2020-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other>.

for graduate medical education, plus 2017 spending on Children’s Hospital Graduate Medical Education, adjusted for inflation. This amount would then grow at the CPI-U minus one percentage point each year. Payments would be distributed to hospitals based on the number of residents at a hospital (up to its existing cap) and the portion of the hospital’s inpatient days accounted for by Medicare and Medicaid patients. The new grant program would be jointly operated by the Administrators of CMS and the Health Resources and Services Administration.

This grant program would be funded out of the general fund of the Treasury. The Secretary would have authority to modify the amounts distributed based on the proportion of residents training in priority specialties or programs (*e.g.*, primary care, geriatrics) and based on other criteria identified by the Secretary, including addressing health-care professional shortages and educational priorities. These changes would modernize graduate medical education funding, making it better targeted, transparent, accountable, and more sustainable.

QUESTIONS SUBMITTED BY HON. MAGGIE HASSAN

MEDICAID EXPANSION

Question. Your budget would end the enhanced Federal funding for Medicaid expansion. The Congressional Budget Office has concluded that this policy change would lead States to begin ending coverage for their expanded Medicaid population, which according to the Kaiser Family Foundation would put approximately 17 million Americans at risk of losing coverage, including 57,000 in New Hampshire.

You testified at the hearing that these estimates were based off the President’s Fiscal Year 2020 budget, rather than the FY 2021 budget, yet while the mechanics of the FY 2021 policy differ from what was proposed in FY 2020, analysis from groups such as the Center on Budget and Policy Priorities estimates that the impact on expanded Medicaid, and potential impact to beneficiaries currently receiving coverage through expanded Medicaid, remains the same.

Can you provide the analysis and data your Department relied on in order to conclude that ending enhanced Federal funding for Medicaid expansion in your FY 2021 budget would not lead States to eliminate the expanded Medicaid program and eliminate coverage for beneficiaries currently covered by expanded Medicaid in expansion States?

Answer. Medicaid plays a pivotal role in ensuring access to quality, affordable health care for the most vulnerable Americans. The Department seeks to provide States with additional program financing options that will create opportunities for States to invest in their health-care infrastructure. The Trump administration understands that reforming Medicaid requires giving States the opportunity to implement Medicaid financing reforms that spur change and innovation; this requires affording States the ability to design State-based solutions that prioritize Medicaid dollars for the most vulnerable and support innovation while eliminating inefficient Medicare spending.

Under the FY 2021 budget proposal, Medicaid spending would grow at a more sustainable rate by ending the financial bias that currently favors able-bodied working adults over the truly vulnerable and by permitting States to select between a per capita cap or a block grant. The budget reflects HHS’s commitment to protecting the fiscal health of Medicaid and ensuring it remains a safety net for generations to come.

SUBSTANCE USE DISORDER TREATMENT IN MEDICAID

Question. Your Department’s Medicaid website notes that “the evidence is strong that treatment in managing SUDs provides substantial cost savings.” Can you provide the data that your Department used to arrive at this conclusion, including the estimated savings per Medicaid beneficiary achieved through robust access to substance use disorder treatment through Medicaid?

Answer. The monetary costs and associated collateral impact to society resulting from substance use disorders (SUDs) are very high. In 2009, for example, health insurance payers spent \$24 billion for treating SUDs. Of the \$24 billion, Medicaid ac-

counted for 21 percent of the spending. The evidence is strong that treatment in managing SUDs provides substantial cost savings.^{21,22} For instance:

- Persons with untreated alcohol use disorders use twice as much health care and cost twice as much as those with treated alcohol use disorders; and medications treating substance use disorder in pregnant women resulted in significantly shorter hospital stays than pregnant women with opioid disorder not receiving medication-assisted treatment (MAT) (10.0 days vs. 17.5 days).
- For inpatients with alcohol dependence, MAT was associated with fewer inpatient readmissions. Total health-care costs were 30 percent less for individuals receiving MAT than for individuals who are not receiving MAT.
- Medical costs decreased by 30 percent on average between the year prior to MAT and the third year following treatment, and these cost trends reflect a decline in expenditures in all types of health-care settings including hospitals, emergency departments, and outpatient centers.
- Medication-assisted treatment using Methadone for opioid use disorder treatment has been found to generate \$4 to \$5 in returns on health-care expenditures for every \$1 invested.
- Early intervention for younger individuals with substance use disorders can bring costs down as they have lower pre-treatment costs than older adults with substance use disorders.

TRANSPARENCY WITHIN MEDICARE

Question. As we discussed at the hearing, the Department of Justice announced two concerning settlements in January of this year. The first was with Practice Fusion, Inc, an electronic health records vendor found to have taken money from Purdue Pharma to incorporate alerts into their electronic health record system that were intended to influence physician prescribing of Oxycontin. The second settlement was with Patient Services Inc, a copayment assistance program that was found to have taken money from Insys to provide Medicare copayment assistance for their fentanyl-based drug Subsys, including for off-label use.

What tools does your Department have in place to identify these financial relationships in real time, in order to assess whether they are being used to influence prescribing in ways that pose risk to patients or raise Medicare spending by steering utilization?

Answer. Under current law, HHS OIG has no authority to require private-sector businesses to report data on financial relationships involving the exchange of information between such parties in a manner that would permit OIG to do real time monitoring. Accordingly, HHS OIG has neither systems nor tools in place through which we would be able to regularly access, collect, and analyze real time information on financial relationships between drug manufacturers and their business partners in order to identify potentially inappropriate activity. Generally OIG gains access to such information through use of an IG subpoena or a search warrant pursuant to a particular law enforcement investigation, but this would not be “real time” data.

Question. Does your department collect any data on payments from drug companies to non-profit copayment assistance programs, or payments to electronic health records vendors, that studies increasingly show have been used to influence prescribing and spending within the Medicare program?

Answer. OIG does not routinely collect data on payments from drug companies to non-profit copayment assistance programs or payments to electronic health records vendors. While engaged in law enforcement activities, OIG may receive such information on an ad hoc basis in connection with an investigation.

Question. In order to ensure compliance with the Federal anti-kickback statute, does your department require patient assistance programs to annually disclose data on the funding received from drug manufacturers; the prescription drugs this funding is used to provide copayment assistance for; the patient population for which the funding is used? Given the number of settlements announced by Department of Justice with drug companies and patient assistance groups regarding violations of the anti-kickback statute, what improvements to HHS authority would allow the Office of Inspector General to collect annual data on patient assistance programs that

²¹ <https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/substance-use-disorders/index.html>.

²² <https://www.medicaid.gov/federal-policy-guidance/downloads/cib-07-11-2014.pdf>.

would allow for real-time analysis of whether these programs are not violating Federal law?

Answer. OIG does not have direct programmatic relationships with patient assistance programs and does not require annual reporting of the types of data outlined above. Even if OIG received this sort of data, data analysis alone is unlikely to permit the identification of instances of non-compliance with the Federal anti-kickback statute. The settlements referenced above resulted from extensive investigations into the details of the arrangements between the pharmaceutical manufacturer donors and the patient assistance programs and the intentions of the parties. OIG would be happy to speak further about these issues.

ELECTRONIC HEALTH RECORDS DISCLOSURE AND TRANSPARENCY

Question. Given the increasing influence electronic health record systems have on the provider to patient relationship, do you believe your Department has sufficient disclosure requirements in place to detect potentially problematic financial relationships between electronic health records vendors and other health care stakeholders?

What steps are currently in place within your Department, including at the Office of the National Coordinator for Health Information Technology, to ensure that the certification process for electronic health records includes safeguards that protect patients and providers from unknowingly using products that have been developed with input or financial influence from stakeholders such as drug companies? Do you believe adding electronic health records vendors to the Medicare Open Payments database would improve your ability to identify problematic relationships between vendors and drug companies and providers?

Answer. Lack of seamless data exchange in health care has historically detracted from patient care, leading to poor health outcomes, and higher costs. CMS's Interoperability and Patient Access final rule, published on March 9, 2020, establishes policies that break down barriers in the Nation's health system to enable better patient access to their health information, improve interoperability and unleash innovation, while reducing burden on payers and providers. Patients and their health-care providers will have the opportunity to be more informed, which can lead to better care and improved patient outcomes, while at the same time reducing burden.

In addition, this rule modified CMS conditions of participation to require those hospitals that are appropriately equipped, including psychiatric hospitals and critical access hospitals, to send electronic patient event notifications of a patient's admission, discharge, or transfer to another health-care facility or to another community provider or practitioner. We believe that the capability to send patient event notifications should be a fundamental feature of hospital medical record systems to support effective care transitions and promote patient safety during transitions. This will improve care coordination by allowing a receiving provider, facility, or practitioner to reach out to the patient and deliver appropriate follow-up care in a timely manner. This policy will be applicable beginning May 1, 2021.

MATERNAL MORTALITY AND MORBIDITY

Question. The President's Proposed Budget for Fiscal Year 2021 includes a commitment from this administration to address the maternal mortality and morbidity crisis in the United States. As you know, a large number of the maternal mortality and morbidity cases among Americans can be attributed to complications before, during, and after childbirth that can be prevented when patients have access to adequate, quality prenatal and postpartum health-care services.

Quality, affordable prenatal, and postpartum care for pregnant patients is the key to addressing the maternal mortality and morbidity rates in the United States. It is also critical that patients who may experience pregnancy in the future have access to quality primary care services throughout their lifetime to ensure the healthiest possible pregnancy and childbirth experience.

While the proposed budget includes several maternal health policies that could help address this crisis, this budget as a whole would cause far more damage in access to prenatal and postpartum health-care services.

How do you square this administration's commitment to improving maternal health outcomes when, at the same time, this administration is limiting access to reproductive health-care services through policies such as the title X gag rule and the proposed rule on Medicaid Block Grant program, that together would limit access to health care services for hundreds of thousands of individuals of reproductive age?

Answer. HHS is committed to improving maternal health outcomes for families across the Nation. The FY 2021 budget proposes a new *Improving Maternal Health in America* initiative to address this significant public health problem. This initiative focuses on four strategic goals: achieve healthy outcomes for all women of reproductive age by improving prevention and treatment; achieve healthy pregnancies and births by prioritizing quality improvement; achieve healthy futures by optimizing postpartum health; and improve data and bolster research to inform future interventions.

The budget proposes a total of \$116 million for this initiative across the National Institute for Research on Safety and Quality (NIRSQ), CDC, HRSA, and IHS. This includes \$7 million for NIRSQ to improve service data, advance data evaluation, and expand medical expenditure surveys to ensure policy makers have timely and accurate data. The budget also invests \$24 million in CDC to expand the Maternal Mortality Review Committees to all 50 States to ensure every case of pregnancy-related death is examined. The budget provides \$80 million in HRSA to improve the quality of maternal health services, expand access to care, and reduce disparities in care. The budget invests \$5 million in IHS to help improve health outcomes by standardizing care, increasing cultural awareness, and improving care for pregnant women.

Separate from the initiative, the FY 2021 budget maintains title X Family Planning funding flat with FY 2020 enacted at \$286 million.

PATIENT MATCHING

Question. As part of the fiscal year 2020 appropriations agreement, Congress required the Department of Health and Human Services to submit a report on how to improve patient matching—which is the ability to link medical records for the same person across multiple sites of care.

While there may be longer-term steps that can be taken, research has shown that the Department of Health and Human Services can take steps today to improve patient matching—specifically through the use of common standards and data elements. For example, if the Office of the National Coordinator required use of the US Postal Service standard for home addresses in electronic health record systems (EHRs), match rates could improve by several percentage points.²³

What steps is the Office of the National Coordinator taking to require greater standardization of data for matching, including through use of the U.S. Postal Service standard?

Answer. The HHS Office of the National Coordinator for Health Information Technology (ONC) is taking numerous steps to increase standardization of data. This includes incorporating the United States Core Data for Interoperability (USCDI), which is a standardized set of health data classes and consistent data elements for nationwide and interoperable health information. ONC develops and maintains USCDI as part of the ONC Health IT Certification Program. Within the demographics section of USCDI, ONC certified health IT requires a number of additional data elements to assist with patient matching, including an individual's address, previous address, phone number, phone number type (*e.g.*, mobile), and email address. This expanded set of demographic data elements is used to support more accurate patient matching.

Also, in the recent Cures Act Final Rule, ONC adopted the USCDI and required its use across a range of certification criteria adopted within the ONC Health IT Certification Program. This includes both document-based exchange and exchange through standardized application programming interfaces. The USCDI demographic data elements can be used to assist with patient matching across settings and service providers within the health care industry. ONC is currently collecting submissions to consider in the next version of the USCDI.

In our Final Rule, we encouraged health IT developers and standards development organizations to improve address data quality through standardization and validation and by other means. In addition, we will continue to work with standards development organizations to evaluate potential solutions to improve patient matching, including considering the potential adaptability of the U.S. Postal Service formats for health IT use cases. Please see ONC 21st Century Cures Act Final Rule for further information: https://www.healthit.gov/sites/default/files/cures/2020-03/ONC_Cures_Act_Final_Rule_03092020.pdf.

²³ <https://www.pewtrusts.org/en/research-and-analysis/articles/2019/03/22/standardized-demographic-data-aids-patient-matching-rates-study-shows>.

In December 2019, a Congressional Appropriations Agreement for 2020 directed ONC to provide a report to Congress, in coordination with other appropriate Federal agencies, studying and evaluating current technological and operational methods to improve identity and matching of patients. ONC conducted two public stakeholder sessions collecting input for consideration in the report. Presentation topics varied but several presentations addressed standards for matching within and between domains. ONC collected public input for incorporation into the report through Friday, September 4, 2020. In addition, ONC conducted three Federal working sessions to discuss Federal identity and record matching efforts. Participating agencies have been given an opportunity to provide input to be incorporated into the report. A list of ONC's recent patient identity and patient matching efforts can be found on *HealthIT.gov* at <https://www.healthit.gov/topic/patient-identity-and-patient-record-matching>.

ELECTRONIC HEALTH RECORD BEST SAFETY PRACTICES

Question. The Centers for Medicare and Medicaid Services recently released regulations with questions on how the agency can improve the safety of electronic health records. As you know, electronic health records are now ubiquitous, and research suggests that the design and implementation of these systems—often referred to as usability—can contribute to patient harm.

One study examining 9,000 medication safety events found that a third of them occurred, in part, due to the usability of electronic health records.²⁴ Research has identified best practices that hospitals can take to improve electronic health record safety, and the Centers for Medicare and Medicaid Services can encourage adoption of these practices through its programs.

What steps are being taken by the Centers for Medicare and Medicaid Services to prioritize adoption of electronic health record safety best practices by hospitals?

Answer. Lack of seamless data exchange in health care has historically detracted from patient care, leading to poor health outcomes, and higher costs. CMS's Interoperability and Patient Access final rule, published on March 9, 2020, establishes policies that break down barriers in the Nation's health system to enable better patient access to their health information, improve interoperability and unleash innovation, while reducing burden on payers and providers. Patients and their health-care providers will have the opportunity to be more informed, which can lead to better care and improved patient outcomes, while at the same time reducing burden.

In addition, CMS modified conditions of participation to require hospitals that are appropriately equipped, including psychiatric hospitals and critical access hospitals, to send electronic patient event notifications of a patient's admission, discharge, or transfer to another health-care facility or to another community provider or practitioner. We believe that the capability to send patient event notifications should be a fundamental feature of hospital medical record systems to support effective care transitions and promote patient safety during transitions. This will improve care coordination by allowing a receiving provider, facility, or practitioner to reach out to the patient and deliver appropriate follow-up care in a timely manner. This policy will be applicable 12 months after publication of this rule.

APPLICATION PROGRAMMING INTERFACES (APIS)

Question. Recent proposed regulations from the Office of the National Coordinator and the Centers for Medicare and Medicaid Services on interoperability have a common thread: patients have a right to their health data and should be able to obtain the information in their chosen format—including a smartphone application. The regulations successfully achieve this by proposing the use of standard application programming interfaces (APIs), which allow different systems to communicate.

When will the proposed rules be finalized?

Additionally, can you elaborate on why standardizing application programming interfaces is a priority for the administration and why patients can benefit from getting their full medical records as set forth in the regulations?

Answer. On March 9, 2020, the Department released these two transformative final rules to give patients unprecedented secure access to their health data. The two rules, issued by the Office of the National Coordinator for Health Information Technology (ONC) and Centers for Medicare & Medicaid Services (CMS), advance

²⁴ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.0699>.

interoperability and patient access consistent with the bipartisan 21st Century Cures Act (Cures Act) and support President Trump's MyHealthEDData initiative. This initiative is designed to empower patients around a common aim: giving every American access to their medical information so they can make better health-care decisions.

Ensuring the privacy and security of patient information is a top priority for HHS. Identifying the right standards can help data flow securely and efficiently. The Department has identified Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) Release 4.0.1 as the foundational standard to support data exchange via secure application programming interfaces (APIs). ONC's 21st Century Cures Act rule, at 45 CFR 170.215, finalized interoperability and security standards for FHIR-based APIs. CMS's rule applies those standards to patient-access APIs that CMS-regulated payers are required to implement.

CMS-regulated payers, specifically Medicare Advantage organizations, Medicaid fee-for-service (FFS) programs, Medicaid managed care plans, CHIP FFS programs, CHIP managed care entities, and qualified health plan (QHP) issuers on the Federally Facilitated Exchanges—excluding issuers offering only stand-alone dental plans (SADPs) and QHP issuers offering coverage in the Federally Facilitated Small Business Health Options Program (FF-SHOP)—are required to implement and maintain a secure, standards-based (HL7 FHIR Release 4.0.1) API that allows patients to easily access their claims and encounter information, including cost, as well as a defined sub-set of their clinical information through third-party applications of their choice. Claims data, used in conjunction with clinical data, can offer a broader and more holistic understanding of an individual's interactions with the health-care system, leading to better decision-making and better health outcomes. These payers are required to implement the Patient Access API beginning January 1, 2021 (for QHP issuers on the FFEs, plan years beginning on or after January 1, 2021).

When individuals have access to their health information, they can better coordinate their care and have greater control over their health and well-being. ONC's interoperability efforts focus on improving individuals' ability to control their health information so they can shop for and coordinate their own care.

While many patients can access their medical information through multiple provider portals, the current ecosystem is frustrating and cumbersome. The more providers they have, the more portals they need to visit, the more usernames and passwords they need to remember. In the end, these steps make it hard for patients to aggregate their information across care settings and prevent them from being empowered consumers.

API-based exchanges have become commonplace in our everyday life, from mobile banking to booking a plane ticket, from downloading media to shopping online. Naturally, as adoption of electronic health records (EHRs) continues to expand, it is essential for APIs to play an increasing role with respect to health-care interoperability.

The need is evident. We use technology in so many facets of life. We send email, buy airline tickets, keep up with friends and family on social media, and order food from the convenience of our smartphones. Yet, obstacles continue to be encountered by patients trying to access their own electronic health information (EHI). It is time to change that paradigm.

ONC thanks Congress for the passage of the Cures Act and we look forward to implementing the ONC final rule, which promotes patient access to their electronic health information, supports provider needs, advances innovation, and addresses industry-wide information blocking practices. Placing patients at the center of care is critical to all that we do at ONC and the final rule continues to advance that goal, including through provisions that support the ability of patients to securely and easily obtain their EHI at no additional cost when electronically accessed (*e.g.*, by using the smartphone application of their choice).

E-CIGARETTE FLAVOR BAN

Question. In the weeks since the administration's partial ban on flavored e-cigarettes went into effect, there have been news reports, as well as information provided to my office by pediatricians and teachers in New Hampshire, suggesting that a migration to flavored single-use e-cigarette cartridges has already occurred in response to the partial flavor ban.

How is your department evaluating this information on an ongoing basis to inform subsequent modifications to the flavor ban policy, given that the early reports from experts in the field suggest it is not achieving its intended result, which is to curb youth use of e-cigarettes, and how quickly after evaluating this information would FDA announce and implement a policy change?

Answer. On September 9, 2020, the U.S. Food and Drug Administration, in partnership with the Centers for Disease Control and Prevention, released new data from the 2020 National Youth Tobacco Survey (NYTS), which show 1.8 million fewer U.S. youth are currently using e-cigarettes compared to 2019. After 2 years of disturbing increases in youth e-cigarette use, HHS is encouraged by the overall significant decline reported in 2020. This is good news; however, the FDA remains very concerned about the 3.6 million U.S. youth who currently use e-cigarettes and we acknowledge there is work that still needs to be done to curb youth use.

As a science-based regulatory agency, FDA continuously monitors the tobacco product marketplace to identify emerging trends. The Center for Tobacco Products (CTP) also monitors the latest published research through multiple working groups that develop and maintain a comprehensive understanding of the science behind tobacco products, including ENDS. We will continue to monitor the scientific literature and emerging data from national surveys and adjust our enforcement efforts and regulatory approach as appropriate.

FDA will take appropriate action regarding tobacco products that are marketed without premarket authorization, including as warranted based on changed or new information, or to better address minors' use of those products. FDA's January 2020 ENDS guidance did not alter the fact that it is illegal to market any new tobacco product without premarket authorization. The agency has discretion to pursue enforcement action at any time against any deemed new tobacco product marketed without premarket authorization, regardless of whether it falls within one of the categories of enforcement priorities outlined in our January 2020 ENDS guidance.

As noted above, FDA will prioritize enforcement against any ENDS product that continues to be sold and for which the agency has not received a premarket application. Based on several factors—including the likelihood of youth use or initiation—FDA will make the best use of agency resources to enforce against any other deemed new tobacco product that does not have the required premarket authorization.

We are committed to addressing the public health crisis of youth e-cigarette use by, among other things, focusing product review and enforcement on youth-appealing products and also investments in youth education campaigns regarding the dangers of e-cigarette use. We will remain vigilant in monitoring the marketplace, expanding our public education efforts and using our regulatory authority to further ensure that all tobacco products, and e-cigarettes in particular, are not marketed to, sold to, or used by kids. If we see a product that is targeted to kids, we will not hesitate to target that product.

In addition, it is important to emphasize that FDA's Premarket Tobacco Product Application (PMTA) review process is grounded in science and law. In order for a product to receive market authorization, an application must demonstrate through studies, data, and thorough product details, that the marketing of the product meets the applicable standard in the law, "appropriate for the protection of the public health." FDA considers youth initiation and use of a tobacco product when reviewing premarket applications. During review of premarket applications for ENDS products, FDA considers information on youth appeal, youth use, and evaluates that information in determining whether a tobacco product meets the statutory standard. FDA then conducts a rigorous scientific review of the information contained in each applicant's PMTA. If, after this review, FDA finds the ENDS product meets the statutory standard for authorization, among other requirements, it will issue a marketing order.

FDA may require that an applicant restrict the sale and distribution of its product authorized via the PMTA pathway, to ensure that its marketing of the product does not result in youth use. The agency may also require that applicants apprise FDA of efforts to prevent youth access and exposure. FDA also continues to monitor products after they receive a marketing authorization, including assessing the potential for increased use among youth. Ultimately, FDA can withdraw a marketing order if, among other reasons, it determines that the continued marketing of a product is no longer appropriate for the protection of the public health.

BUPRENORPHINE WAIVER

Question. Bipartisan legislation in both the Senate and House would eliminate the buprenorphine waiver requirement that imposes lengthy training requirements that may limit the number of providers willing to obtain a waiver, which limits patient access to medication-assisted treatment, particularly in rural areas.

Given the public health benefit to expanded access to MAT as part of a comprehensive approach to treatment and recovery, and the known barriers created by this waiver requirement, is this administration supportive of efforts to eliminate the waiver requirement?

Answer. The administration is conceptually supportive of eliminating the DATA 2000 Waiver, but there are a number of issues that need to be addressed in order for all health practitioners who are not yet waived to begin to practice and at this time the bills congressional members have introduced do not sufficiently address the concerns of the Federal interagency. We, along with colleagues at ONDCP and DOJ are available to offer technical assistance or draft legislative language and we recommend coordinating this through ONDCP who can bring the right experts to the table from the three agencies on behalf of the White House.

TRANSPORTATION

Question. There is bipartisan agreement that difficulty accessing transportation in rural and underserved areas keeps people across the country from accessing needed medical care. In addition to difficulties securing rides to and from appointments, either by car or via public transportation, patients with mobility issues face additional transportation barriers and require assistance when trying to safely exit their home prior to accessing transportation, or enter an appointment after receiving transportation to care. What efforts are underway at your Department to provide support to those patients for whom the transportation barriers they face at the beginning and end of their trip may keep them from accessing more widely available assistance such as ride share services covered by their insurance plan, or discounted public transit programs?

Answer. Under Federal regulations, States must assure both emergency and non-emergency medical transportation to all Medicaid beneficiaries.

TELEHEALTH

Question. As providers work to expand access to telehealth services through investments in technology and improvements to provider reimbursement, what efforts are underway at your Department to ensure that patients, particularly seniors, will have access to the hardware they need, and the required training to operate that hardware, in order to facilitate uptake of telehealth services, particularly in rural and underserved communities?

Does your Department require additional support from Congress to ensure that Medicare patients for whom telehealth services may be beneficial have access to the equipment and training they need in order to utilize these services?

Answer. Ensuring access to health-care services in rural areas is a top priority for the Trump administration, and expanding the availability of telehealth services is an important part of this effort. On August 3, 2020, President Trump signed Executive Order 13941, *Executive Order on Improving Rural Health and Telehealth Access*, demonstrating this commitment.

During the COVID-19 public health emergency (PHE), we have seen a substantial increase in the use of telehealth services as access to in-person care was limited to prevent the potential spread of the disease. The Department's analysis shows a weekly jump in virtual visits for CMS beneficiaries, from approximately 14,000 pre-PHE to almost 1.7 million in the last week of April. Additionally, a recent report by the Department shows that nearly half (43.5 percent) of Medicare fee-for-service primary care visits were provided through telehealth in April, compared with far less than one percent (0.1 percent) in February before the PHE. Importantly, the report finds that telehealth visits continued to be frequent even after in-person primary care visits resumed in May, indicating that the expansion of telehealth services is likely to be a more permanent feature of the health-care delivery system.

As directed by President Trump's Executive Order on Improving Rural and Telehealth Access, through the calendar year 2021 Medicare Physician Fee Schedule proposed rule, CMS is taking steps to extend the availability of certain telehealth services after the PHE ends, giving Medicare beneficiaries more convenient ways to

access health care particularly in rural areas where access to health-care providers may otherwise be limited.

During the public health emergency, CMS added 135 services such as emergency department visits, initial inpatient and nursing facility visits, and discharge day management services, that could be paid when delivered by telehealth. CMS is proposing to permanently allow some of those services to be done by telehealth including home visits for the evaluation and management of a patient (in the case where the law allows telehealth services in the patient's home), and certain types of visits for patients with cognitive impairments. CMS is seeking public input on other services to permanently add to the telehealth list beyond the PHE in order to give clinicians and patients time as they get ready to provide in-person care again. CMS is also proposing to temporarily extend payment for other telehealth services such as emergency department visits, for a specific time period, through the calendar year in which the PHE ends. This will also give the community time to consider whether these services should be delivered permanently through telehealth outside of the PHE.

DEMENTIA SCREENING

Question. The Office of Disease Prevention and Health Promotion at HHS has stated that Alzheimer's and other forms of dementia are more frequently undiagnosed among patients living in rural and underserved communities. Access to dementia screening at no cost as part of the Medicare wellness visit would provide patients and caretakers with critical information that could allow them to begin making modifications to their homes or care plans in order to prepare for a change in health status. However, there is resistance to covering dementia screening as a diagnostic service for which there is no curative treatment.

Given the recent advances in efforts to find curative therapies for dementia and Alzheimer's, and the importance that an early diagnosis can play for patients, family members and caretakers who wish to proactively establish care plans in response to a diagnosis, do you support coverage for dementia screenings as part of annual wellness visits for seniors and at-risk patient populations?

Answer. "Detection of any cognitive impairment" is currently a statutorily required element of the Medicare annual wellness visit (AWV). CMS's Medicare Learning Network for the AWV directs physicians and other practitioners to the National Institute on Aging's Alzheimer's and dementia resources for professionals for information on structured, validated cognitive assessment tools.

CORONAVIRUS (COVID-19) RESPONSE

Question. As one of the administration officials tasked by the President with overseeing our Nation's coronavirus preparedness and response efforts, you are playing a role in a multi-agency effort to ensure the safety of Americans domestically and abroad.

According to recent reporting, there has been confusion and conflict between the Centers for Disease Control and Prevention (CDC), the State Department, and other government officials regarding the appropriateness of transporting patients who are at risk of, or have been diagnosed with, Coronavirus, from locations overseas back to the United States. Can you explain how those decisions are made, and how public health input from CDC is balanced with the need to get patients back to the United States? Additionally, given what little we know about Coronavirus transmission, what precautions are in place to ensure that individuals traveling with diagnosed or at-risk patients in airplanes or to and from quarantine locations are sufficiently protected?

Answer. Under U.S. law, the U.S. Department of State (DOS) may fund the repatriation of private, destitute U.S. citizens abroad to the United States on a reimbursable basis. Further under U.S. law, the Department of State may fund the evacuation, when their lives are endangered by war, civil unrest, or natural disaster, of private U.S. citizens or foreign nationals, on a reimbursable basis to the maximum extent practicable. CDC offers public health recommendations when appropriate. For additional questions, please contact DOS.

Question. In late January, CDC distributed several hundred Coronavirus test kits to domestic and international locations to be used by public health officials for more expedited testing. Two weeks after those kits were distributed, these test kits were recalled by CDC. What is the timeline for the distribution and validation of new test kits?

Answer. In early February, one of the three major components in CDC's test kits was problematic and the tests had to be recalled. In response, CDC validated the test's effectiveness without the problematic component; re-manufactured the test kits; obtained enforcement discretion from FDA to distribute the authorized test without the problematic component; and successfully distributed the new test kits on February 27th. The FDA reissued a revised EUA for this test on March 15th.

SUPPORT ACT IMPLEMENTATION

Question. Your department has yet to meet several of its statutory obligations under the SUPPORT Act, including provisions requiring the Centers for Medicare and Medicaid Services (CMS) to provide guidance to States seeking to promote innovative approaches to serving beneficiaries with substance use disorder. According to an article published by *Inside Health Policy* on February 24, 2020, CMS has produced only one of seven guidance documents that were due in calendar year 2019 regarding substance use disorder treatment and services for Medicaid beneficiaries. Specifically, these documents would provide States with guidance on topics such as:

- Reimbursement options for substance use disorder treatments—including medication-assisted treatment—that can be delivered via telehealth.
- Opportunities to finance and improve family-focused residential treatment programs.
- Recommendations for improving care for infants with neonatal abstinence syndrome and their families.
- Best practices for ensuring Medicaid coverage of former foster youth.
- Best practices for prescription drug monitoring programs and privacy protections for Medicaid beneficiaries.

Please provide an update on the status of these critical guidance documents, reasons for their delay, and the date by which you plan to provide this guidance to States as required by the SUPPORT Act.

Answer. Combating the opioid epidemic is a top priority for the Trump administration. To date, the Department has taken significant steps to carry out provisions in the SUPPORT Act while advancing the goals of our Five-Point Strategy. This comprehensive, evidence-based strategy aims to: improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with substance use disorders and to help individuals to achieve long-term recovery; strengthen public health data collection and reporting to improve the timeliness and specificity of data and to inform a real-time public health response as the epidemic evolves; advance the practice of pain management to enable access to high quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms; target the availability and distribution of overdose-reversing medications to ensure the broad provision of these drugs to people likely to experience or respond to an overdose, with a particular focus on targeting high-risk populations; and support cutting-edge research that advances our understanding of pain and addiction, leads to the development of new treatments, and identifies effective public health interventions to reduce drug-related health harms.

The SUPPORT Act has been an essential enabler of HHS efforts to confront the opioid crisis. Through new and expanded authorities granted by the SUPPORT Act, we have been able to expand the scope and effectiveness of our programs across nearly the entire Department in order to deliver meaningful results related to the substance use crisis.

The Department is continuing to implement provisions of the SUPPORT Act during the COVID-19 public health emergency (PHE). For example, CMS published the Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements proposed rule in the Federal Register (85 FR 37286) on June 19, 2020. This proposed rule would amend this section of the regulation to implement new opioid-related DUR standards that are required of States under section 1004 of the SUPPORT for Patients and Communities Act, as well as additional opioid-related DUR standards that CMS is proposing under the authority of section 1927 of the Social Security Act. Most recently, on September 4, 2020, CMS issued guidance to States regarding opportunities to improve care for infants with Neonatal Abstinence Syndrome (NAS) and their families, as required by section 1005(a) of the SUPPORT Act. In addition, this has included a CMS informational bulletin issued on April 2, 2020, that provided State Medicaid agencies and other interested stake-

holders information about options to facilitate access to services and treatment of substance use disorder through the use of telehealth delivery methods as outlined in section 1009(b) of the SUPPORT Act. The bulletin includes details and guidance on Medicaid coverage of assessment, medication-assisted treatment, counseling, and medication management using telehealth solutions.

QUESTIONS SUBMITTED BY HON. CATHERINE CORTEZ MASTO

Question. In 2018, the President signed into law the BOLD Infrastructure for Alzheimer's Act, and in December 2019, Congress funded BOLD Act grants. The budget proposes to discontinue CDC's work on chronic disease management and surveillance, and cut funding for Alzheimer's work conducted by CDC. How much less funding would this budget propose for such work? What activities that the CDC performs or funds would be discontinued as a result?

Answer. The President's budget proposes funding the Alzheimer's disease program at \$3,493,000, which is a reduction of \$12 million from the FY 2020 enacted level. At this level, CDC would continue to fund national organizations to implement the National Healthy Brain Initiative's *State and Local Public Health Partnerships to Address Dementia: The 2018–2023 Road Map*. Activities for implementation with specific population groups and at the national level would have to be scaled back. The surveillance and analysis of data about cognitive decline and caregiving through the Behavioral Risk Factor Surveillance System (BRFSS) and the National Health and Nutrition Examination Survey (NHANES) would not continue. In addition, the new awards to implement the BOLD Act would not continue, which includes funding for three Public Health Centers for Excellence (Risk Reduction, Early Diagnosis, and Caregiving) and funding for programmatic activities in 14 States, one large county, and one tribal organization. Programmatic recipients are focusing on changing systems, environments and policies to promote risk reduction, to improve early diagnosis, to prevent and manage comorbidities, and to avoid hospitalizations.

Question. Many of the entities who use title X in rural Nevada rely on registered nurses and public health nurses to serve patients. The recent rule excludes registered nurses from performing pregnancy counseling—a duty well within their scope of practice. As recently as December CMS wrote about the “burden” of Federal rules that “limit health professionals from practicing at the top of their license.”²⁵ Why is this case an exception to that principle?

Answer. The Office of Population Affairs (OPA) recognizes that the clinical site workforce varies greatly across the title X network and continues to show flexibility when working with individual grantees to ensure quality patient care as well as compliance with the statutes, legislative mandates, and regulations associated with title X funding.

Under the title X Final Rule, nondirective counseling may be provided by physicians and advanced practice providers. The final rule defines “advanced practice providers” as a medical professional who receives at least a graduate level degree in the relevant medical field and maintains a license to diagnose, treat, and counsel patients. The term Advanced Practice Provider includes physician assistants and advanced practice registered nurses (APRN). Examples of APRNs that are an Advanced Practice Provider include certified nurse practitioner (CNP), clinical nurse specialist (CNS), certified registered nurse anesthetist (CRNA), and certified nurse-midwife (CNM). These examples were selected as APPs due to their advanced medical degrees, licensing, and certification requirements.

Question. Among the proposed “major savings and reforms,” this budget calls for the elimination of “fourteen health professions training programs that provide funds to training institutions to improve the Nation's health workforce.” One of the programs targeted for elimination appears to be the State Offices of Rural Health program. Why did you cut funding for State Offices of Rural health?

What other programs do you envision would do the work that State Office of Rural Health is conducting?

Answer. HHS has a four-point strategy to transform rural health: build a sustainable health model for rural communities; leverage technology and innovation; focus on preventing disease and mortality; and increase rural access to health care.

²⁵ CMS.

The budget invests \$6.5 billion, an increase of +\$122 million or 2 percent, above FY 2020 to increase quality care to rural areas through programs in HRSA, SAMHSA, and IHS.

Question. Have you increased the programs that provide direct service delivery by the same amount?

Answer. The budget includes proposals that enhance access to SUD treatment and policies that will lead to better outcomes for new mothers. The budget invests \$1.1 billion in discretionary spending in FY 2021 in SAMHSA programs, a +\$42 million increase above FY 2020. The budget also request \$6.2 billion for the Indian Health Service (IHS). This investment is strategic to make the greatest impact on health outcomes across Indian Country.

Question. Mental health is a major stated policy priority for you and the President. Would you call mental health parity an essential provision of mental health services access?

Do you think insurance carriers are fulfilling their obligations to that end?

If not, what is this administration doing to ensure compliance and hold them accountable?

Answer. A key part of the administration's effort to improve access to mental health services is working with our partners across the Federal Government and, with States and the provider and plan community to make stakeholders aware of the requirements of the Mental Health Parity and Addiction Equity Act (MHPAEA), to promote compliance with and enforce the law and regulations. The Department provides technical assistance to States, issuers, and plans in response to numerous complex questions regarding Mental Health Parity requirements. The Department works closely with States both on a one-to-one basis and, with the Department of Labor, through participation in the National Association of Insurance Commissioners' Mental Health Parity and Addiction Equity Act (B) Working Group.

Since the enactment of MHPAEA, Federal agencies have released additional regulations and guidance to assist consumers and State regulators in understanding MHPAEA requirements. The Department, along with the Departments of Labor and the Treasury, and other Federal agencies have issued regulations to implement the law and continue to issue guidance and publications to address discrete issues raised by stakeholders. For example, the Departments have clarified in previous regulations and guidance the breadth of disclosure required, as well as which documents participants, beneficiaries, and their authorized representatives have a right to receive (and generally may find helpful) under MHPAEA, the Employee Retirement Income Security Act of 1974 (ERISA), and the PPACA. Moreover, in light of the ongoing opioid epidemic, FAQs also included clarifications related to commonly found non-quantitative treatment limits that reduce access to substance use disorder treatments in particular. Such guidance and publications also include documentation on State best practices to promote parity compliance, and tools for reporting parity violations. The Departments of Labor and HHS also released a document which identifies plan provisions and health insurance benefit design elements that are red flags for parity limitations that are potentially impermissible.

In addition, Federal agencies have been committed to enforcing the law, promoting compliance, assisting consumers, and conducting investigations. With respect to health insurance issuers selling health insurance products in the individual and group markets, States have primary enforcement authority with respect to title XXVII of the Public Health Service Act (PHS Act). HHS only enforces a provision of title XXVII of the PHS Act in a State if the State is not substantially enforcing the provision (PHS Act § 2723(a)(1) and (2)). Currently, HHS is responsible for the enforcement of MHPAEA with respect to issuers selling products in the individual and fully insured group markets in three States: Missouri, Texas, and Wyoming. The Department conducts market conduct examinations of health insurance issuers in these three States and in States that have a collaborative enforcement agreement with HHS if the State requests such an examination in order to obtain issuer compliance with a Federal requirement.²⁶ In addition, the Department and the Department of Labor conduct investigations of MHPAEA complaints for non-Federal gov-

²⁶ HHS will enter into a collaborative enforcement agreement with any State that is willing and able to perform regulatory functions but lacks enforcement authority. If the State finds a potential violation and is unable to obtain voluntary compliance from an issuer, it will refer the matter to HHS for possible enforcement action.

ernmental plans and ERISA plans, respectively.²⁷ The most recent report of the Department's and the Department of Labor's MHPAEA enforcement actions can be found at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/mhpaea-enforcement-2019.pdf>.

Question. Relaxed oversight of the managed care organizations that would deliver Medicaid coverage under the proposed Medicaid block grant would at best keep the status quo of mental health parity, and at worst give license to MCOs to fail to meet that objective without ramification. Does this concern you?

Answer. HHS's proposed budget will have Medicaid spending grow at a more sustainable rate by ending the financial bias that currently favors able-bodied working-age adults over the truly vulnerable.

The Healthy Adult Opportunity (HAO) is not a mandatory change in the Medicaid program's structure or financing—this is an optional demonstration opportunity, and no State is under any obligation to participate. It is also not permission for States to strip benefits or limit eligibility—under HAO, participating States must still meet minimum benefit requirements and cannot cap or limit adult enrollment while still receiving enhanced Federal funding.

Under the HAO demonstration, States will be given the opportunity to elect one of two options to measure and monitor access and availability of Medicaid services in a managed care delivery system. States generally will be expected to meet specified managed care statutory requirements that provide beneficiary protections, facilitate beneficiary decision making, support access to services, monitor program administration, and measure the quality of the delivery system. For example, States will be expected to certify that their managed care plans have the capacity to meet the State's standards for access to care and availability of services. However, States will have flexibility under this demonstration to propose alternative approaches to ensure network adequacy, access to care, and availability of services to those required in current Federal regulations. The State would need to develop and propose alternative standards subject to CMS approval and provide reasonable evidence of enrollee access to care and satisfaction. Regardless of the approach elected, all States participating in the HAO will be required to submit routine data reports described in the Monitoring and Evaluation section of the guidance.

A number of States have expressed interest in HAO and are supportive of the demonstration, which represents an innovative and historic approach to surmounting Medicaid's structural challenges while still providing rigorous protections for all Medicaid beneficiaries. At this time, Utah and Tennessee have submitted applications to amend their section 1115 waiver demonstrations to seek flexibilities to test innovative Medicaid financing models similar to the flexibilities offered under HAO.

Question. Section 208 of the Prescription Drug Pricing Reduction Act as approved by this committee allows States to enter into multi-year contracts with pharmaceutical manufacturers for the purchase of multimillion-dollar drugs for Medicaid beneficiaries. If a State took advantage of the flexibility to waive coverage of certain drugs in the Healthy Adult Opportunity block-grant proposal, would you expect that same State to go to the trouble of contracting with a drug company to pay millions of dollars over several years for a drug that it doesn't have to cover in the first place?

Answer. This budget endorses bipartisan, bicameral drug pricing legislation like the Prescription Drug Pricing Reduction Act (PDPRA). But it is difficult to opine on how the PDPRA would interact with the Healthy Adult Opportunity (HAO) until we would see more final bill text supported by both chambers of Congress.

Question. This budget would cut and consolidate the graduate medical education programs that train physicians and calls for \$50 billion in cuts without any corresponding reinvestment in health workforce training. It does not propose to redistribute physician slots to areas of need, instead opting to make payments based on the number of physicians an institution is currently training. What solution would you offer to States like Nevada, Montana, Idaho, Alaska, Wyoming, or South Da-

²⁷ Sponsors of self-funded, non-Federal governmental plans may opt out of certain requirements of title XXVII of the PHS Act, including MHPAEA. In all States, HHS has authority to initiate an investigation or a market conduct examination to determine whether a non-Federal governmental plan that has not filed a valid MHPAEA opt-out is out of compliance with MHPAEA.

kota, any of those States whose physician training programs are the smallest in the country? How do they build their programs?

Various members of Congress on both sides of the aisle and the capitol have written to you asking that you provide special exceptions to GME rules that would support workforce development in rural and underserved areas—you haven't elected to use that authority. Do you expect to do so in the future?

Answer. Current graduate medical education funding is outdated, overly broad, and not sustainable long term due to its fragmented nature across multiple funding streams and lack of transparency and accountability. Effective in FY 2021, this proposal would consolidate Federal graduate medical education spending from Medicare, Medicaid, and the Children's Hospital Graduate Medical Education Program into a single grant program for teaching hospitals. Total funds available for distribution in FY 2021 would equal the sum of Medicare and Medicaid's 2017 payments for graduate medical education, plus 2017 spending on Children's Hospital Graduate Medical Education, adjusted for inflation. This amount would then grow at the CPI-U minus one percentage point each year. Payments will be distributed to hospitals based on the number of residents at a hospital (up to its existing cap) and the portion of the hospital's inpatient days accounted for by Medicare and Medicaid patients. The new grant program would be jointly operated by the Administrators of CMS and the Health Resources and Services Administration.

This grant program would be funded out of the general fund of the Treasury. The Secretary would have authority to modify the amounts distributed based on the proportion of residents training in priority specialties or programs (*e.g.*, primary care, geriatrics) and based on other criteria identified by the Secretary, including addressing health-care professional shortages and educational priorities. These changes modernize graduate medical education funding, making it better targeted, transparent, accountable, and more sustainable.

Question. Do you believe that we can fully address care quality and abuse and neglect in nursing homes without paying more for the care that those facilities deliver?

Answer. Within the Department, the Centers for Medicare and Medicaid Services (CMS) sets and oversees minimum health and safety requirements that nursing homes must meet to participate in the Medicare and Medicaid programs, including requirements for infection control and prevention. State Survey Agencies, under agreements with the Secretary, conduct inspections, known as surveys, to observe and certify to CMS a facility's compliance with these requirements. CMS's commitment to improving and protecting nursing home residents' health and safety has never been stronger, and this focus is not new. In 2019, the agency announced a five-part strategy for ensuring safety and quality in Medicare and Medicaid participating nursing homes. This strategy outlined the steps the agency has taken and plans to take to keep nursing home residents safe: strengthening oversight, enhancing enforcement, increasing transparency, improving quality, and putting patients over paperwork. This framework serves as the agency's guide to making enhancements and improvements in ensuring nursing home safety and quality.

During the COVID-19 public health emergency, CMS has issued extensive guidance and tools for nursing homes to use to make sure they have the flexibilities they need to combat the COVID-19 pandemic while keeping residents safe. A chart listing all of CMS's guidance documents and updates for nursing homes during this pandemic can be accessed at: <https://www.cms.gov/files/document/covid-guidance-and-updates-nursing-homes-during-covid-19.pdf>.

In addition, CMS has also provided extensive individualized technical assistance to nursing homes in an effort to help reduce transmission and the risk of COVID-19 spread among residents. This has included work by the Quality Improvement Network-Quality Improvement Organizations (QIN-QIOs)—groups composed of health quality experts, clinicians, and consumers that CMS contracts with to improve the quality of care delivered to Medicare beneficiaries—that have directly contacted, visited and worked with nursing homes with a high number of infection control deficiencies. Beginning in July, the Department additionally deployed Federal Task Force Strike Teams to provide onsite technical assistance and education to nursing homes experiencing outbreaks. The Task Force Strike Teams were composed of clinicians and public health service officials from CMS, the Centers for Disease Control and Prevention, and the Office of the HHS Assistant Secretary for Health. HHS is coordinating the nursing home activities of QIN-QIOs and Task

Force Strike Teams to avoid duplication of efforts at facilities with infection control deficiencies that are also experiencing outbreaks.

Question. Can you say with certainty that seniors who rely on their State's Medicaid program for nursing home coverage will experience zero change in their coverage and benefit should their State adopt the Healthy Adult Opportunity plan?

Answer. The Healthy Adult Opportunity (HAO) emphasizes the concept of value-based care while granting States with extensive flexibility to administer and design their programs within a defined budget. This State opportunity will enhance the Medicaid program's integrity through its focus on accountability for results and quality improvement, making the Medicaid program stronger for States and beneficiaries.

HAO is available to all States, with a focus on a limited population—adults under age 65 who are not eligible for Medicaid on the basis of disability or their need for long term care services and supports, and who are not eligible under a State plan. Other very low-income parents, children, pregnant women, elderly adults, and people eligible on the basis of a disability will not be directly affected—except from the improvements that result from States reinvesting savings into strengthening their overall programs. Under HAO, beneficiaries will maintain all of the Federal due process and civil rights they have today, and HAO demonstrations will be expected to provide minimum benefit standards, eligibility protections, and limits on out-of-pocket expenses.

Question. Last fall GAO published a report touting the huge benefits of third party revenue to IHS. Those dollars help IHS facilities to make system improvements from hiring new providers all the way to keeping the heat on.²⁸ Would you agree with GAO's conclusion that expanded health insurance coverage is beneficial to IHS operations?

Answer. GAO reported that increased collections have allowed IHS to expand services and service complexity provided offsite through the Purchased/Referred Care (PRC) program.

Question. Do you think HHS could do more to increase enrollment among American Indians and Alaskan Natives in the health coverage for which they are eligible?

Answer. HHS/IHS does its best to ensure that American Indian and Alaska Natives (AI/AN) are enrolled in health coverage for which they may be eligible. For many AI/AN consumers as well as enrollment assisters, locating and reviewing current information related to enrollment specific to AI/ANs can be overwhelming. One idea that has been raised by the National Indian Health Board, one of IHS' partners and the recipient of a 3-year cooperative agreement under the IHS National Indian Health Outreach and Education initiative, is to develop a single website that gathers all of the information in one central place which will improve efficiency and ease the enrollment process.

Question. The coronavirus outbreak is a stark reminder of the need to be prepared for public health threats. I am concerned the administration is not heeding this lesson with regards to the growing crisis of antibiotic resistance. Without antibiotics, common medical procedures such as surgeries and cancer chemotherapy will carry significant risk of untreatable infections. However, the efficacy of current antibiotics and the volume of antibiotics in the development pipeline are not keeping up with current or future needs. In fact, two companies with a combined five antibiotics on the market filed for bankruptcy last year alone. The administration has yet to articulate a strategy for reversing this dangerous trend. Please describe your immediate shorter term plans to mitigate the effects of these bankruptcies and your longer-term plan to ensure a robust infrastructure to develop and commercialize antibiotics to meet urgent threats.

Answer. Antibacterial resistance remains an important public health crisis. BARDA has provided over \$1.2 billion in non-dilutive funding and technical support to early stage product developers, via our CARB-X project, and to clinical stage product developers under our Advanced Research and Development (ARD) portfolio. These resources have ensured product developers have access to the tools and support to bring innovative life-saving antibiotics from the bench to the market that overcome the evolving threat of antibiotic resistance. Importantly, with this funding, BARDA has established a robust portfolio composed of CARB-X, with over 30 candidates in development, and 16 advanced development public-private partnerships

²⁸ GAO.

focused on the development of 16 novel, small molecule candidates. Through Project BioShield (PBS), BARDA has entered into a partnership with Paratek Pharmaceuticals worth up to \$285 million to support the clinical development and approval of omadacycline for post-exposure prophylaxis and treatment of a bioterrorist. Under this agreement, the USG will procure and stockpile omadacycline in the Strategic National Stockpile. Omadacycline is also active against multidrug resistant bacteria, and is thus promising for providing additional protection against antibiotic resistant bacteria such as those diagnosed in COVID-19 patients. Funding the development of new, life-saving antibiotics and their procurement under PBS, affirms our commitment to support the antibiotic industry and fulfills the mission of Project BioShield: to enhance the biomedical preparedness of the Nation by providing a market incentive that rewards successful medical countermeasure development.

Medicaid Projections: President's FY 2021 Budget
(Office of the Actuary, CMS)

	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
1. Medical assistance payments (benefits)													
Expenditures (in billions)													
Total expenditures—HHS	588.2	608.6	657.2	679.2	716.4	761.9	801.2	848.3	910.1	964.8	1,023.7	1,097.0	1,166.5
Federal expenditures—HHS	368.9	386.0	410.2	425.4	448.4	476.5	500.7	529.8	567.4	601.1	637.3	682.1	724.6
Annual growth rates													
Total expenditures		3.5%	8.0%	3.4%	5.5%	6.4%	5.2%	5.9%	7.3%	6.0%	6.1%	7.2%	6.3%
Federal expenditures		4.6%	6.3%	3.7%	5.4%	6.3%	5.1%	5.8%	7.1%	5.9%	6.0%	7.0%	6.2%
2. Enrollment													
Enrollment (in millions of average annual enrollees)													
Eligibility category													
Aged enrollees	6.0	6.1	6.3	6.4	6.7	6.9	7.1	7.3	7.5	7.7	8.0	8.2	8.4
Enrollees with disabilities	10.3	10.2	10.2	10.3	10.4	10.5	10.5	10.6	10.7	10.8	10.9	11.0	11.1
Children	29.6	28.9	28.5	28.5	28.9	29.2	29.5	29.7	30.0	30.2	30.5	32.8	33.7
Adults	15.6	15.2	14.9	14.8	14.8	14.9	15.0	15.0	15.1	15.1	15.2	15.2	15.3
Expansion adults	12.2	12.1	12.3	12.6	12.6	12.7	12.7	12.8	12.8	12.9	12.9	13.0	13.0
Territory enrollees	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
Total	75.1	73.9	73.6	74.0	74.8	75.5	76.2	76.8	77.5	78.1	78.8	81.5	82.8
Annual growth rates													
Eligibility category													
Aged enrollees		1.7%	3.3%	1.6%	4.7%	3.0%	2.9%	2.8%	2.7%	2.7%	3.9%	2.5%	2.4%
Enrollees with disabilities		-1.0%	0.0%	1.0%	1.0%	1.0%	0.0%	1.0%	0.9%	0.9%	0.9%	0.9%	0.9%
Children		-2.4%	-1.4%	0.0%	1.4%	1.0%	1.0%	0.7%	1.0%	0.7%	1.0%	7.5%	2.7%
Adults		-2.6%	-2.0%	-0.7%	0.0%	0.7%	0.7%	0.0%	0.7%	0.0%	0.7%	0.0%	0.7%
Expansion adults		-0.8%	1.7%	2.4%	0.0%	0.8%	0.0%	0.8%	0.0%	0.8%	0.0%	0.8%	0.0%
Territory enrollees		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Total		-1.6%	-0.4%	0.5%	1.1%	0.9%	0.9%	0.8%	0.9%	0.8%	0.9%	3.4%	1.6%

3. Per enrollee spending													
Federal expenditures per enrollee													
(in dollars per enrollee)													
Eligibility category													
Aged enrollees	8,665	8,695	9,264	9,641	10,030	10,446	10,870	11,315	11,789	12,294	12,820	13,371	13,980
Enrollees with disabilities	12,329	12,717	13,805	14,425	15,100	15,847	16,657	17,514	18,425	19,393	20,411	21,481	22,621
Children	2,176	2,284	2,522	2,648	2,774	2,908	3,049	3,198	3,356	3,524	3,701	3,871	4,061
Adults	3,112	3,865	3,807	3,997	4,183	4,379	4,585	4,803	5,033	5,273	5,525	5,788	6,064
Expansion adults	5,673	6,199	6,510	6,763	7,070	7,394	7,737	8,098	8,480	8,882	9,304	9,745	10,206
Total	4,816	5,183	5,542	5,810	6,082	6,376	6,689	7,020	7,373	7,746	8,138	8,425	8,820
Annual growth rates													
Eligibility category													
Aged enrollees	0.3%	3.1%	6.5%	4.1%	4.0%	4.1%	4.1%	4.1%	4.2%	4.3%	4.3%	4.3%	4.6%
Enrollees with disabilities	3.1%	3.1%	8.6%	4.5%	4.7%	4.9%	5.1%	5.1%	5.2%	5.3%	5.2%	5.2%	5.3%
Children	5.0%	5.0%	10.4%	5.0%	4.8%	4.8%	4.8%	4.9%	4.9%	5.0%	5.0%	4.6%	4.9%
Adults	24.2%	24.2%	-1.5%	5.0%	4.7%	4.7%	4.7%	4.8%	4.8%	4.8%	4.8%	4.8%	4.8%
Expansion adults	9.3%	9.3%	5.0%	3.9%	4.5%	4.6%	4.6%	4.7%	4.7%	4.7%	4.8%	4.7%	4.7%
Total	7.6%	7.6%	6.9%	4.8%	4.7%	4.8%	4.9%	4.9%	5.0%	5.1%	5.1%	3.5%	4.7%

Notes:

1. Medical assistance payment expenditures exclude certain adjustments, such as claims incurred but not yet reported.
2. Expenditures per enrollee exclude the following expenditures: disproportionate share hospital (DSH) collections; other unallocated expenditures; and territory expenditures.
3. Expenditures per enrollee exclude the following enrollees: territory program enrollees.
4. Expenditures do not include administrative expenditures or other non-benefit expenditures.
5. Notes on trends:
 - i. Expenditures increase faster in 2029 due to the expiration of legislatively mandated DSH cuts.
 - ii. Children and total enrollment increase faster in 2029 (and per enrollee expenditure growth slower) due to exhaustion of CHIP allotments, and children in M-CHIP programs become eligible for CHIP.
 - iii. Adult per enrollee expenditures increase sharply in 2019 due to adjustments in reported expenditures related to expansion and non-expansion adults.

PREPARED STATEMENT OF HON. CHUCK GRASSLEY,
A U.S. SENATOR FROM IOWA

I appreciate Secretary Azar appearing before the committee to discuss President Trump's budget for fiscal year 2021. Secretary Azar oversees a sprawling department with programs that are crucial to the health and well-being of many Americans. The budget represents the administration's recommended funding for those programs, as well as its key policy proposals.

While Congress decides funding levels and program changes, we have a duty to review the administration's budget proposal. Secretary Azar is here to help us in that regard. As with any budget submission, I disagree with a number of proposals. But I do want to speak to a few issues where it reflects my priorities.

Ranking Member Wyden and I have made lowering prescription drug prices a top priority. President Trump's focus on the issue has been a game-changer. Secretary Azar has been the point person for the administration's efforts. The Secretary has also helped greatly with our legislative effort. He and his team have provided guidance and technical assistance as we developed and refined the bipartisan bill the committee reported out in July of last year.

I am pleased that the budget calls on Congress to quickly pass a bipartisan bill and includes a prescription drug place-holder for \$135 billion in reduced taxpayer subsidies to drug companies. I will ask the Secretary to expand on this when we move to questions. For now, I will say that I look forward to continuing to work with the Secretary, the ranking member, and other Senators to provide relief to patients.

The budget also contains a number of proposals to improve health care in rural communities. Ensuring access to health care in Iowa and other rural areas has long been a priority for me. Ranking Member Wyden and I continue to discuss how to help rural and other underserved areas. The administration's budget further bolsters our effort.

I'd like to also take a moment to highlight an effort to help HHS be more effective in executing its mission. I understand that the HHS Office of National Security (ONS) is forging new ground with the intelligence community to leverage technology in innovative ways to better streamline intelligence operating procedures and to mitigate counterintelligence threats. I encourage the intelligence community to provide even broader access to ONS as it relates to its products and databases and to allow HHS to access vital information that it needs to mitigate threats to the Department, its funded partners, and its interagency colleagues.

As you are aware, via my oversight efforts, I've worked to make sure that ONS receives access to certain intelligence community-related material and that it has gained access to some. However, more work needs to be done. Recently, I sent two classified letters to intelligence community components to help bridge the gap between ONS and its IC counterparts. As I've said before, the left hand and right hand must work together for the taxpayers.

I will conclude by noting that HHS has many important challenges. Some are longstanding, like the high cost of prescription drugs. Others appear with little notice, such as the novel coronavirus. While there is sure to be disagreement on many items in the budget, the issues I have highlighted are a reminder that we can work together in a bipartisan way to get things done for the American people.

PREPARED STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON

President Trump's health-care agenda rips scores of new holes in the safety net that vulnerable Americans are sure to fall through. The textbook example is Medicaid. Right now, the administration is attempting to do on its own what it failed to do through the Congress: block-grant the Medicaid program.

It's a policy the Finance Committee debated in this very room back in September 2017. It didn't make it out of the committee. It didn't get a vote on the floor. It didn't go anywhere—because it's a bad policy that hurts people.

That said, the Trump administration doesn't seem to mind. It's trying to pull an administrative end-run around the Congress to push the dirty work of Medicaid block grants onto the States. You hear a whole lot of Washington lingo about "flexi-

bility.” They even gave it a name that goes straight to the Orwellian Hall of Infamy: Healthy Adult Opportunity.

Make no mistake: the Trump administration’s proposal to block-grant Medicaid, led by CMS Administrator Seema Verma, would be the beginning of the end for the health-care safety net. It’s not about flexibility, it’s certainly not about opportunities for healthy adults—it’s about draconian cuts. And it comes in addition to the other cuts the Trump administration has proposed for Medicaid. So let’s talk about what slashing Medicaid really means for individual Americans.

Medicaid pays for two out of three nursing home beds in this country. That’s because in the United States, growing old is expensive. Before I was elected to Congress, I was the co-director of the Oregon Gray Panthers, a service organization for seniors. I spent a lot of time visiting with seniors in their homes, and the majority of them were folks who had to stretch every last penny to get by. So this issue goes way back for me.

Even when people do everything right—when they scrimp and save over decades, when they skip vacations, when they live modestly and do every last thing they can to prepare for retirement—people still run out of money in old age. All it takes is one surprise illness or injury for the bills to accumulate. Or a family emergency. Or damage to a home. Savings dry up. It’s a fact of life.

And that’s on top of all those who don’t have savings—the millions and millions of people who go through their lives walking an economic tightrope. Nearly half of all American adults would struggle to come up with \$400 in an emergency. That doesn’t mean they have no right to see a doctor or get long-term care in old age.

Protecting those people is what Medicaid and its nursing home guarantee is all about. Without that health-care safety net, what are seniors supposed to do when the savings dry up? How are nursing homes supposed to stay open without cutting their services down to frighteningly poor levels? How are low-income seniors who want to stay in their homes going to afford their health care?

So when you hear all the talk about “flexibility,” “innovative solutions,” and “holding States accountable,” it’s all a smokescreen for Medicaid cuts. The consequences are dangerous, and they are personal.

The Trump administration has also gone to court to have the entire Affordable Care Act thrown out. Protections for pre-existing conditions—gone. Tax credits for health care—gone. Rules banning the worst insurance company abuses—gone. You’re talking about tens of millions of people getting kicked off their health care.

It would be devastating for people like Jasper. He’s a young guy with a big heart and a lot of energy. But he was born with serious medical issues—cystic fibrosis, cardiac and pancreatic problems, hearing loss. He gets a lot of costly treatment, and his family relies on the Affordable Care Act for peace of mind that he will get the care he needs. Donald Trump has no backup plan for Jasper and his family if he successfully repeals the ACA.

That didn’t stop the President from saying during his State of the Union address that he had made an “ironclad pledge” to “always protect patients with pre-existing conditions.” Donald Trump protects pre-existing conditions like sea lions protect salmon on our mighty Columbia River. It’s the kind of protection that comes with an uptick in the mortality rate.

Let me turn to prescription drug prices. The President has held a whole lot of curtain-raising events for shiny new policies on prescription drugs. Let’s recap a few. He was going to force Big Pharma to list drug prices on television ads—that policy was blocked. He’s talked about requiring rebates to go directly to patients—didn’t follow through. He was going to tie drug prices in the U.S. to drug prices abroad—still nothing. He had a policy to speed approval of generics—no apparent effect.

So for all the Trump talk about drug prices over the last 3 years, patients are still getting mugged at the pharmacy counter. Drug prices are up again in 2020.

The Finance Committee has worked hard on the prescription drug issue, as has the House. Chairman Grassley has been a good partner on this, and I hope that we can find a way to move all this good work forward.

Bottom line, the President has been making promises about bringing down drug prices for 3 years, and he hasn’t gotten it done.

COMMUNICATIONS

AMERICAN ACADEMY OF AUDIOLOGY
11480 Commerce Park Drive, Suite 220
Reston, VA 20191
Contact: Susan Pilch, J.D.

The American Academy of Audiology appreciates the opportunity to provide these comments to the Committee as it seeks to gather information regarding the Administration's planned healthcare priorities from Health and Human Services Secretary Alex Azar. The Academy is the world's largest professional organization of, by and for audiologists. Representing the interests of approximately 14,000 audiologists nationwide, the Academy is dedicated to providing quality hearing care services through professional development, education, research, and increased public awareness of hearing and balance disorders.

President's Budget Proposes Additional Five Percent Reduction to Non-Primary Care/Services—Compounding Significant Reductions for Those Providers Planned for 2021

The Administration's budget proposal contemplates a monthly payment to providers who are eligible to bill for evaluation and management services (E/M) and who provide ongoing primary care to Medicare beneficiaries. To achieve budget neutrality, a five percent reduction to the valuations of all non-primary care services and procedures under the PFS would pay for these additional payments. While the Academy appreciates the importance of primary care services for Medicare beneficiaries, this five percent reduction would compound the already expected eight percent reduction contemplated for audiology in 2021. A combined thirteen percent reduction for audiology in Medicare would be unsustainable.

Expected 2021 Medicare Reimbursement Cuts to Providers that Do Not Bill E/M Codes Need Reevaluation to Ensure Equity Across Provider Types

In the 2020 Physician Fee Schedule (PFS) final rule, CMS accepted the AMA RUC recommendations for increased payment for the office/outpatient evaluation and management (E/M) codes. However, in an effort to maintain budget neutrality and offset the E/M increased payments, CMS also announced significant decreases in Medicare reimbursement in 2021 that will directly impact providers with low utilization of E/M services and providers who do not bill office/outpatient E/M codes. Given the existing disparities between the actual reimbursement rates prior to the application of any reductions and the access or lack thereof to particular billing codes among different providers, the actual impact of the expected reductions will not be uniform across all providers.

Audiology-Specific Distinctions That Compound Planned Reimbursement Reductions

With respect to audiology, we would like to highlight some of the unique circumstances and distinctions that will compound the effect of the planned reimbursement reductions:

- Current regulations prohibit audiologists from billing Medicare for E/M codes.
- Audiologists are not permitted to use the new G codes for E/M services.
- Audiologists do not have any dedicated E/M codes at this time. In contrast, some other non-physician providers have created their own dedicated E/M codes.
- The AMA drafted a listing of E/M services performed by HCPAC providers. However, this listing only identified the word "evaluation" in the code descriptor.

- Audiology codes identified are procedural services which have “evaluation” in the descriptor. This is an erroneous assumption as “evaluation” in these CPT codes defines cognitive work, not management.
- The closest approximation of audiology E/M codes may be based on payment for cognition within the RVU.

In light of the aforementioned considerations, the proposed 6% cut for budget neutrality and additional 2% sequestration cut will have a disproportionate effect on audiologists. Audiologists do not have access to E/M services to offset the expected 8% reimbursement reduction. We have concerns that these reductions will have an unfortunate impact on patient access to services and care. An **additional** 5% reimbursement reduction to audiologists, as proposed in the President’s Budget, is untenable.

We have highlighted these concerns to CMS in hopes that the Agency will consider an alternate approach with respect to achieving budget neutrality to offset the E/M increases in a way that takes into account the inherent differences between provider types.

Improving Access to Hearing Healthcare in Rural Areas—the Medicare Audiology Access and Services Act of 2019 (H.R. 4056/S. 2446).

The President’s budget proposal lists improving access to rural healthcare as an overarching priority. To that end, untreated hearing loss is a significant concern in rural areas. Approximately 20% of the U.S. population reside in rural areas and adults within these areas represent a vulnerable population with barriers to accessing hearing healthcare.¹ Untreated hearing loss can lead to depression, anxiety and social isolation and tends to be more prevalent in rural areas.² In addition, hearing impairment prevalence is positively associated with poverty, reduced educational attainment, and manual labor occupations³—characteristics that are more prominent in rural communities.⁴ Untreated hearing loss also has profound implications to overall health and can impose significant financial burdens to the healthcare system. Individuals with even mild hearing loss are three times more likely to experience a fall and falls are the leading cause of fatal injury for Americans over age 65.⁵ In addition, research is now emerging indicating that Seniors with hearing loss are more likely to develop cognitive decline up to 40% faster than those without hearing loss.⁶

Legislation has been introduced in both the House and Senate that would eliminate many of the current barriers to rural elderly patients being able to more efficiently access hearing healthcare. This legislation would reclassify audiologists under Medicare as “practitioners,” allow for direct access by Medicare patients to audiologists and allow audiologists to provide currently covered services beyond diagnostics.

Direct Access to Audiologist Services in Medicare Would Remove a Current Barrier to Rural Patient Screening and Treatment

Currently Medicare beneficiaries must first receive a physician referral to see an audiologist for hearing and balance diagnostic tests. The American Academy of Audiology strongly supports removing this barrier and favors giving beneficiaries the option to see either a physician or an audiologist first for hearing and balance-related health care. The Federal Employees Health Benefits Program (FEHBP), the Veterans Administration (VA) as well as many private health plans allow their enrollees direct access to audiologists without physician referral. The VA has had this policy in place since 1992. In a letter from VA Acting Deputy Under Secretary for Health, Michael Kussman, MD to Senator Grassley in 2004, he states that the VA direct access policy “provides high-quality, efficient and cost-effective hearing care.” Dr. Kussman goes on to state that requiring all veterans with hearing loss com-

¹ Chan S., Hixon B., Adkins M., Shinn J.B., and Bush M.L. (2017). Rurality and determinants of hearing healthcare in adult hearing aid recipients. *The Laryngoscope*, 127(10), 2362–2367.

² Brennan-Jones CG, et al. Self-reported hearing loss and manual audiometry: A rural versus urban comparison. *Aust J Rural Health*. 2015.

³ Chou C., et al. Association of socioeconomic position with sensory impairment among U.S. working-aged adults. *American Journal of Public Health*. 2015;105(6):1262–1268.

⁴ Chan S., Hixon B., Adkins M., Shinn J.B., and Bush M.L. (2017). Rurality and determinants of hearing healthcare in adult hearing aid recipients. *The Laryngoscope*, 127(10), 2362–2367.

⁵ Centers for Disease Control and Prevention. (May 2018) Deaths from Falls Among Persons Aged 65 Years—United States, 2007–2016. <https://www.cdc.gov/mmwr/volumes/67/wr/mm6718a1.htm>.

⁶ Lin, Frank and Yaffe, Kristine. *Journal of the American Medical Association: Hearing Loss and Cognitive Decline in Older Adults*. (February 2013) <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1558452>.

plaints to see ENT physicians would result in unnecessary medical care, inefficient use of VA resources, and longer waits for veterans who need the specialized care of ENT physicians. “The [direct access] policy is cost-effective because an unnecessary clinic visit is avoided.” In addition, Dr. Kussman states that “the VA has not experienced patient complaints or problems as a result of the direct access policy.”⁷

Rural Medicare beneficiaries in particular would benefit from being able to directly access the care of an audiologist. Given significant travel distances that exist in rural communities, removing an unnecessary physician visit would streamline access to care, provide needed interventions in a timely manner and save the patient and the Medicare program money.

The Department of Veterans Affairs Successfully Uses TeleAudiology to Reach Rural Patients; Medicare Should Follow Suit

Audiologists are currently classified as “suppliers” in Medicare and as such are not among the list of providers authorized to provide services via telehealth. However, if audiologists were to be reclassified as “practitioners”—similar to how clinical psychologists and clinical social workers are classified in Medicare, they would be authorized to provide and be reimbursed for audiology services provided via telehealth.

As a model, the Department of Veteran Affairs has recognized that providing audiology services via telehealth is an effective way to reach rural veterans.⁸ “Expanded use of innovative technology is increasing access points to hearing care in remote areas, enabling telehealth providers to expand their reach to patients and their families in satisfying and effective ways,” said Chad Gladden, audiology telehealth coordinator for the Audiology and Speech Pathology National Program Office.⁹

Conclusion

The American Academy of Audiology appreciates this opportunity to provide our thoughts and suggestions on the President’s 2021 budget proposal specifically as it relates to imminent Medicare reimbursement reductions for audiology, additional proposed reductions and ways in which to expand rural Medicare beneficiary access to hearing care services.

AMERICAN SPEECH-LANGUAGE-HEARING ASSOCIATION
2200 Research Boulevard
Rockville, MD 20850-3289
actioncenter@asha.org
301-296-5700
<https://www.asha.org/>

Chairman Grassley and Ranking Member Wyden: The American Speech-Language-Hearing Association (ASHA) thanks you for the opportunity to submit this statement to the Committee on the President’s Fiscal Year (FY) 2021 Budget. My name is Theresa H. Rodgers, MA, CCC-SLP, ASHA’s President for 2020.

ASHA is the national professional, scientific, and credentialing association for 211,000 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students.

Overview

Audiologists and speech-language pathologists (SLPs) are highly educated, trained, and certified health care professionals who are licensed in every state to provide diagnostic and treatment services. Audiologists and SLPs provide patient-centered care in the prevention, identification, diagnosis, and evidence-based treatment of hearing, balance, speech, language, cognitive-communication, and swallowing disorders in individuals of all ages. The dedicated individuals of both professions work tirelessly to help realize ASHA’s vision of making effective communication, a human right, accessible and achievable for all.

ASHA members, including the more than 1,400 in Iowa and nearly 2,200 in Oregon, work in health care settings to help people learn, maintain, or improve skills and functional abilities that have not developed normally (habilitation), and to regain

⁷ https://www.audiology.org/sites/default/files/advocacy_files/DeptofVeteranAffairs.pdf.

⁸ <https://www.blogs.va.gov/VAntage/62446/audiology-telehealth-helping-rural-veterans-access-hearing-evaluations/>.

⁹ <https://www.blogs.va.gov/VAntage/62446/audiology-telehealth-helping-rural-veterans-access-hearing-evaluations/>.

skills that have been impaired due to injury, illness, or condition(s) that have impacted normal functioning (rehabilitation).

Audiologists and SLPs provide services supporting the overall health and well-being of their patients to ensure that people of all ages—especially older Americans—can properly manage and/or avoid costly conditions or impairments that could impact their ability to effectively communicate and result in costly post-acute care (PAC).

The President’s FY 2021 Budget (Budget) request includes numerous provisions of interest and concern to ASHA that will impact the ability of audiologists and SLPs to provide essential hearing, balance, speech, language, and cognitive care, especially to individuals enrolled in Medicare and Medicaid. The following comments highlight several of these proposals and recommend improvements to ensure beneficiaries of these important programs have timely access to needed care provided by these licensed health care professionals.

Medicare

Medicare is the primary federal program seniors rely on for health care; therefore, ensuring that statute and regulations provide sufficient reimbursement and efficient administration to allow audiologists and SLPs to provide clinically appropriate care—at the proper time and in the right setting—is of paramount importance. ASHA is interested in the following Medicare proposals in the Budget and the impact on audiologists and SLPs to meet that mandate.

Lowering the Cost of Prescription Drugs

The budget includes an estimate of \$135 billion in savings over 10 years for enactment of comprehensive drug pricing reform. ASHA supports ensuring that Medicare beneficiaries have access to affordable prescription drugs and other benefits and services necessary to ensure their health and well-being. However, ASHA is disappointed that the budget proposal did not recommend reinvesting a portion of the savings from prescription drug reform to enhancing hearing benefits under the Medicare program.

ASHA supports Section 602 of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, which the House of Representatives passed on December 12, 2019. Section 602 would enable audiologists to be reimbursed by Medicare for covered diagnostic and treatment services that they are licensed to provide and would reclassify audiologists as practitioners under Medicare giving seniors better access to hearing and balance care provided by audiologists. The provision also mandates a study to examine beneficiary direct access to audiologists and clarifies that the U.S. Secretary of Health and Human Services (HHS) has the authority to authorize audiologists to furnish services for reimbursement without requiring beneficiaries to first obtain a physician order.

These changes are necessary because Medicare precludes seniors from accessing the full range of services provided by audiologists in a timely manner by requiring a clinically unnecessary physician order and limiting reimbursement to diagnostic services, although audiologists’ scope of practice includes auditory and vestibular treatment and neurological monitoring. Medicare currently covers these treatment services when furnished by clinicians, such as physicians or other nonphysician practitioners. In addition, most private health plans, Federal Employees Health Benefits (FEHB) Program plans, the U.S. Department of Veterans Affairs (VA), and some Medicare Advantage plans allow for direct access to audiology services, which is consistent with state laws.

The inability of most Medicare beneficiaries to receive both diagnostic and treatment services provided by an audiologist limits access to timely hearing health care and may increase health care costs. The National Academy of Sciences issued a report, “Hearing Health Care for Adults: Priorities for Improving Access and Affordability,” which recommends Medicare coverage of audiology treatment.¹ In addition, research conducted by the Johns Hopkins Bloomberg School of Public Health has found that “older adults with untreated hearing loss incur substantially higher total health care costs compared to those who don’t have hearing loss—an average of 46%, totaling \$22,434 per person over a decade.”² Since individuals with mild hearing

¹National Academies of Sciences, Engineering, and Medicine. (2016). *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*. Retrieved from <http://nationalacademies.org/hmd/reports/2016/Hearing-Health-Care-for-Adults.aspx>.

²Reed, Nicholas S., et al. (2018). *Trends in Healthcare Costs and Utilization Associated with Untreated Hearing Loss Over 10 Years*. Retrieved from <https://www.jhsph.edu/news/news-releases/2018/patients-with-untreated-hearing-loss-incur-higher-health-care-costs-over-time.html>.

loss are three times more likely to experience a fall, and falls are the leading cause of fatal injury for Americans over 65, early diagnosis and timely treatment of hearing and balance impairments by audiologists helps older Americans avoid more serious and costly health care problems that undermine their quality of life. Seniors with hearing loss develop cognitive problems and experience cognitive decline up to 40% faster than those with normal hearing.^{3, 4, 5} Furthermore, untreated hearing loss leads to depression, anxiety, and social isolation.⁶

To address these deficiencies, ASHA has endorsed bipartisan legislation, S. 2446, the Medicare Audiologist Access and Services Act, introduced by Senators Elizabeth Warren and Rand Paul, along with Senators Roger Wicker and Sherrod Brown. S. 2446 addresses this issue by enabling audiologists to provide both diagnostic and treatment services; thereby, allowing beneficiaries direct access to audiologists without a physician order, and reclassifying audiologists as practitioners under Medicare, which would allow these licensed health care professionals to provide telehealth services.

ASHA encourages the Committee to include provisions from S. 2446 in any prescription drug bill advanced in the Senate and/or reconciled with H.R.

3. Reinvesting a portion of savings from enactment of comprehensive drug pricing reform in new hearing benefits under Medicare will improve hearing and balance care for America's seniors while lowering health care costs resulting from injuries sustained as a result of untreated hearing and balance related falls.

Expand and Enhance Access to Medicare Telehealth Services

The Budget proposes several budget neutral provisions to expand and enhance access to telehealth services under Medicare. ASHA appreciates Executive Order 13813, "Protecting and Improving Medicare for Our Nation's Seniors" and supports corresponding efforts to enhance access to Medicare-covered services through telehealth.

Medicare does not reimburse audiologists or SLPs for telehealth services. However, both audiologists and SLPs are qualified providers of telehealth services and provide such services under many state laws and other payer policies, including Medicaid. Twenty states have included provisions in licensure laws that specifically authorize audiologists and SLPs to perform services via telehealth.⁷ Private insurers in 30 states have established policies that allow audiologists and SLPs to provide services via telehealth.⁸ In addition, 27 state Medicaid programs authorize these clinicians to perform services via telehealth.⁹

A growing body of research on the use of telepractice for communication disorders includes many studies demonstrating the comparability of telepractice and in-person services. For example, research conducted by the VA indicates that audiology services provided via telehealth are comparable to in-person delivery of care, while pub-

³ Lin, Frank and Ferrucci, Luigi. (2012). *Hearing Loss and Falls Among Older Adults in the United States*. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3518403/>.

⁴ Centers for Disease Control and Prevention. (2018). *Deaths from Falls Among Persons Aged 65 Years—United States, 2007–2016*. Retrieved from <https://www.cdc.gov/mmwr/volumes/67/wr/mm6718a1.htm>.

⁵ Lin, Frank and Yaffe, Kristine. (2013). *Journal of the American Medical Association: Hearing Loss and Cognitive Decline in Older Adults*. Retrieved from <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1558452>.

⁶ Oxford Academic. (2012). *Hearing-impaired adults are at increased risk of experiencing emotional distress and social engagement restrictions five years later*. Retrieved from <https://academic.oup.com/ageing/article/41/5/618/47025/Hearing-impaired-adults-are-at-increased-risk-of>.

⁷ American Speech-Language-Hearing Association. (n.d.). *Licensure Board Telepractice Requirements: Audiology and Speech-Language Pathology*. Retrieved from <https://www.asha.org/uploadedFiles/Telepractice-Requirements-and-Reimbursement.pdf>.

⁸ American Speech-Language-Hearing Association. (n.d.). *Private Insurance Laws and Regulations: Telepractice Reimbursement, Audiology and Speech-Language Pathology*. Retrieved from <https://www.asha.org/uploadedFiles/Telepractice-Requirements-and-Reimbursement.pdf>.

⁹ American Speech-Language-Hearing Association. (n.d.). *Medicaid Laws and Regulations: Telepractice Reimbursement, Audiology and Speech-Language Pathology*. Retrieved from <https://www.asha.org/uploadedFiles/Telepractice-Requirements-and-Reimbursement.pdf>.

lished studies also indicate that speech-language pathology services provided via telehealth are as effective as services provided in person.^{10, 11, 12}

ASHA supports enabling audiologists and SLPs to provide telehealth services to Medicare beneficiaries when clinically appropriate and the ability of the clinician to ensure that the quality of any services provided via telehealth matches the quality of services provided in-person. Medicare coverage of audiology and speech-language pathology services would increase outlays by less than \$2.5 million over five years and less than \$10 million over 10 years.¹³

ASHA supports bipartisan legislation, S. 2741, the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2019, introduced by Senators Brian Schatz, along with Senators Roger Wicker, Ben Cardin, John Thune, Mark Warner and Cindy Hyde-Smith, co-chairs of the Senate Telehealth Caucus, among others. The bill, which has 33 bipartisan cosponsors and was referred to the Finance Committee, eliminates several barriers in Medicare that inhibit the ability of licensed health care professionals to provide telehealth services.

Of specific interest to ASHA, Section 3 of S. 2741 authorizes the HHS Secretary to waive certain restrictions on telehealth services, including those related to the types of providers who can provide telehealth services. In addition, Section 14 would permit demonstration programs that could allow audiologists and SLPs—and other licensed health care professionals—to provide telehealth services to Medicare beneficiaries.

ASHA encourages the Committee to consider S. 2741 and/or include these low to minimal cost provisions in any health-related legislation the Committee may consider this year.

Reprioritize Primary and Preventive Care in Medicare

The Budget proposes a budget neutral provision to create a risk-adjusted monthly “Medicare Priority Care” payment for providers who are eligible to bill for outpatient evaluation and management (E/M) services and who provide ongoing primary care to Medicare beneficiaries. The proposal follows the release of the 2020 Medicare Physician Fee Schedule (MPFS) final rule, issued on November 15, 2019, in which the Centers for Medicare and Medicaid Services (CMS) proposed to increase reimbursement for office/outpatient E/M codes for 2021.

Unfortunately, CMS proposed steep and seemingly arbitrary reductions to services furnished by other physician and nonphysician professionals to ensure the budget neutrality of the MPFS as required by statute. CMS acknowledged the “magnitude of redistributive adjustment necessary to, budget neutralize the increased values,” while noting that future rulemaking would address the issue. The Budget proposal notes that a 5% annual reduction to the valuation of all non-primary care services and procedures, as determined by the Secretary under the MPFS, will achieve budget neutrality of the proposal.

ASHA supports coding and payment changes to office/outpatient E/M services and recognizes that CMS must meet statutory requirements to maintain budget neutrality by offsetting the E/M payment increases. However, ASHA is extremely concerned about the significant negative financial impact the budget neutrality requirement will have for many specialties—including audiology and speech-language pathology—that cannot report E/M services as part of their Medicare benefit category to help potentially offset the projected reductions in 2021.

On February 5, 2020, Representatives Buddy Carter and Lisa Blunt Rochester sent a letter to CMS that was signed by 99 members of the House of Representatives requesting additional information about the process CMS used to reduce the reimbursement for services furnished by the 37 specialty providers that would be negatively impacted by the proposed rule. On February 10, 2020, a group of 13 organizations representing providers of specialty services, including ASHA, submitted com-

¹⁰ Gladden, Chad. (2013). *The Current Status of VA Audiology*. Retrieved from https://www.ncrar.research.va.gov/Education/Conf_2013/Documents/Gladden.pdf.

¹¹ Hayman M., Skinner L., and Wales D. (2017). *The Efficacy of Telehealth-Delivered Speech and Language Intervention for Primary School-Age Children: A Systematic Review*. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5546562/>.

¹² Alvares, Robin, Grogan-Johnson, Sue, and Rowan, Lynne. (2010). *A pilot study comparing the effectiveness of speech language therapy provided by telemedicine with conventional on-site therapy*. Retrieved from <https://journals.sagepub.com/doi/abs/10.1258/jtt.2009.090608>.

¹³ Quantria Strategies. (2015). *ASHA Telehealth Cost Study. Analysis of a Proposal to Extend Telehealth to Audiology and Speech-Language Pathology Services*. P. 3–4.

ments to CMS ahead of the publication of the FY 2021 proposed rule and recommended several alternative options for mitigating the proposed reductions.

However, as evidenced by the Budget proposal, CMS will likely note in its FY 2021 proposed rule that it lacks sufficient regulatory authority to fully address the fee schedule's budget neutrality requirement absent legislative intervention. Therefore, **ASHA encourages the Committee to engage with CMS to better understand the impact such cuts would have on seniors' access to medically necessary services and explore legislative alternatives that could mitigate the negative impact of such reductions on audiologists, SLPs, and other specialty service providers.**

Address Excessive Payment for Post-Acute Care Providers by Establishing a Unified Payment System Based on Patients' Clinical Needs Rather than Site of Care

The Budget proposes to reduce annual payment updates for skilled nursing facilities (SNFs), home health agencies, and inpatient rehabilitation facilities from FY 2021 to FY 2025, and institute a budget neutral unified payment system that would span all four PAC settings, including long-term care hospitals, with payments based on episodes of care and patient characteristics rather than the site of service. The proposal also would require a unified quality reporting program across all four settings.

As part of the effort to ensure program integrity across PAC settings, CMS implemented the new prospective payment system for SNFs, the Patient-Driven Payment Model (PDPM), on October 1, 2019. PDPM bases payment on patient characteristics rather than on the type and volume of services provided. CMS developed PDPM to address concerns of therapy overutilization to maximize reimbursement rather than meet patient needs under the previous payment system. CMS implemented a similar program known as the Patient-Driven Groupings Model (PDGM) for home health settings on January 1, 2020.

ASHA supports improving payment accuracy by basing payments on individual patient characteristics rather than service volume. However, we are monitoring the impact of PDPM implementation to ensure Medicare beneficiaries in SNFs continue to receive clinically appropriate therapy services provided by SLPs.

ASHA is troubled by reports from its members—and those from other therapy professions—about staffing reductions and changes in terms of employment that were attributed to the new payment model. SLPs have also shared that they were told the system requires group and concurrent therapy, establishes productivity requirements, and specifies which therapy professionals may provide care based on payment categories. None of these actions have basis in statute or regulation.

ASHA encourages the Committee to monitor ongoing implementation of PDPM and to request relevant CMS data to determine PDPM's and PDGM's impact on utilization relative to the previous payment model. Data on outcomes and quality improvement, hospital readmission rates, falls, and avoidable health conditions would be useful to determine the impact of PDPM implementation on Medicare beneficiaries' access to clinically appropriate care.

Medicaid

The Budget assumes a net savings to Medicaid of \$920 billion over the next decade, which is realized through “reforms” designed to transform Medicaid financing. Unfortunately, the Budget assumes significant savings from several proposals focused on reducing Medicaid expenditures, rather than enhancing services or ensuring more robust provider networks. ASHA is especially interested in the following Medicaid proposal in the Budget and its impact on audiologists and SLPs to provide services to Medicaid beneficiaries.

Implement Medicaid Community Engagement Requirement

The Budget proposes to require certain Medicaid recipients to find employment, participate in work training programs, or volunteer at least 20 hours per week to receive statutorily mandated benefits.

This specific proposal is expected to reduce Medicaid spending by \$152 billion over the next decade, according to Budget documents.

CMS has also issued guidance to state Medicaid directors that allows states to shift some Medicaid program funding to block grants. Under the guidance, which CMS refers to as the Healthy Adult Opportunity program, the federal government would provide a set amount of funding to states for their Medicaid program and allow states to determine how the funding is used for different coverage groups. States

could institute additional conditions of eligibility, such as work requirements, without federal approval.

Several states have implemented work requirements as a condition for enrolling in Medicaid. However, inappropriate application of these administrative requirements can result in wrongful termination from the program forcing reapplication, avoidable gaps in coverage, and delayed or denied medically necessary treatment. Imposing work requirements can significantly harm children, elderly, and individuals with disabilities, particularly for vulnerable individuals who cannot meet those requirements due to underlying health conditions, disabilities, or other functional impairments.

The administrative costs of monitoring and enforcing work requirements may undermine the financial savings theoretically realized by reducing enrollment and restricting access to health care coverage for those with medically necessary needs. In addition, determining whether HHS has authority to condition Medicaid coverage on compliance with work requirements without congressional authorization is the subject of ongoing judicial review. For example, on February 14, 2020, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit unanimously agreed that the Secretary's authorization was indeed unlawful.¹⁴

ASHA is opposed to substantial reductions in Medicaid funding and to requiring program participants (especially children, the elderly, and those with disabilities) to comply with so-called community engagement requirements, both of which are solely designed to reduce program expenditures and not to improve the health and well-being of those who rely on this important social safety net program. **ASHA recommends that the Committee carefully consider how work requirements for Medicaid eligibility impact access to medically necessary care for low income American citizens in need of health care coverage.**

If work requirements remain in place or are expanded, **ASHA recommends that Congress require CMS to establish standards that avoid disenrollment of individuals without access to other health insurance coverage and ensure that the burden imposed on Medicaid beneficiaries and state Medicaid agencies for monitoring and enforcing work requirements do not ultimately reduce the availability of federal and state funds for providing medically necessary care to enrolled Medicaid beneficiaries.**

Conclusion

ASHA encourages the Committee to consider with care the impact of the Budget proposal on the ability of those who rely on Medicare and Medicaid to access necessary health care services mandated by law, especially the hearing and balance care provided by audiologists and the speech, language, swallowing, and cognitive care provided by SLPs.

Thank you for the opportunity to provide this statement for the record. ASHA appreciates the Committee's examination of the Budget and looks forward to working with the Committee to ensure audiologists and SLPs can provide timely, quality, and clinically appropriate services to individuals throughout their lifespan in the proper setting as efficiently and cost effectively as possible. For more information, contact Jerry White, ASHA's director of federal affairs, health care, at jwhite@asha.org.

CENTER FOR FISCAL EQUITY
14448 Parkvale Road, Suite 6
Rockville, MD 20853
fiscalequitycenter@yahoo.com

Statement of Michael G. Bindner

Chairman Grassley and Ranking Member Wyden, thank you for the opportunity to submit these comments for the record to the Committee on Finance on the HHS FY 2021 Budget Request.

As we all know, the appropriations process for the next fiscal year takes place within the context of the Bipartisan Budget Act of 2019. In an election year, staying within the current parameters is the best course. Early passage makes transition

¹⁴Gresham, et al. v. Azar et al., No. 19-5094 (D.C. Cir. 2020). Retrieved from https://www.courtlistener.com/pdf/2020/02/14/charles_gresham_v_alex_azar_ii.pdf.

easier for the next administration and Senate, regardless of electoral outcomes. Even if the President is reelected, staff turnover is to be expected in the Administration and the Committee. If changes are to be made due to changes in party, enactment before the election can always be supplemented with new legislation.

Health Insurance Reform is likely off the table, although a single-payer plan is inevitable, as we discuss in Attachment One. Until then, the status of the Affordable Care Act is still at issue. The Administration believes that the Act is failing. It was not, but it will soon with the end of mandates. Rates will soon start going up as incentives for the uninsured are not adequate in the light of pre-existing condition reform to make them less risk averse than investors in the private insurance market, the whole house of cards may collapse—leading to either single payer or the enactment of a subsidized public option (which, given the nature of capitalism, will evolve into single payer). While no one knows how the uninsured will react over-time, the investment markets will likely go south at the first sign of trouble.

It is likely that the Administration will have to deal with these issues next fiscal year, so whatever is budgeted for analytical support in the Department should likely be doubled. This is especially the case if a single-payer plan is sought by a new Administration. Please see Attachment One to see our previously submitted options for such a plan. The key to enacting any reform is funding, likely through tax reform Attachment Two discusses our most up to date treatment of this issue. The possibility of Wealth Taxes is discussed in Attachment Three. They are not a feasible option.

Retirement security for seniors and the disabled must always be addressed. Any cuts must be avoided. Indeed, they are dead on arrival. In the long-term, as we have stated recently as well debt will be a problem—but not within the next few years—as neither Europe nor China will enact the same kind of consolidated income tax, debt and monetary reserve system that allows us to be the world's currency securitization provider.

Debt reduction must not be an excuse to cut entitlements. As we state in our debt volume, *Squaring and Setting Accounts: Who Really Owns the National Debt? Who Owes It?*—December 2019, the debt assets owed to the bottom 40% are sacrosanct, as they paid for it with regressive payroll taxes while they were working or by having to shift from the Civil Service Retirement System to the Federal Employee Retirement System which required savings rather than a defined benefit. Forty years ago, the decision was made to advance fund the retirement of the baby boomers, rather than immediately begin subsidies from the general fund. Doing so would have required repealing the tax cuts on the rich enacted by President Reagan, the Senate and just enough conservative Democrats in the House to do damage. They also gave us the ill-advised 1986 tax reform.

Now that the wealthy have to pay what they owe to the trust fund (or rather, the children of the wealthy of the 1980s), people are talking about means testing Social Security and were talking about making it attractive to upper classes by investing it. The latter non-sense died in 2008. The former would again make asset holders fix the debt liability of the top 10%. It would also rob the bottom two quintiles of their most effective voice—higher income taxpayers who do receive benefits. As long as they get them, the program is safe.

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—Single-Payer, June 12, 2019

There is no logic in rewarding people with good genes and punishing those who were not so lucky (which, I suspect, is most of us). Nor is there logic in giving health insurance companies a subsidy in finding the healthy and denying coverage for the sick, except the logic of the bottom line. Another term for this is piracy. Insurance companies, on their own, resist community rating and voters resist mandates—especially the young and the lucky. As recent reforms are inadequate (aside from the fact of higher deductibles and the exclusion of undocumented workers), some form of single-payer is inevitable. There are three methods to get to single-payer.

The first is to set up a **public option** and 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.

The second option is Medicare for All, which I described in an attachment to yesterday's testimony and previously in hearings held May 8, 2019 (Finance) and May 8, 2018 (Ways and Means). Medicare for All is essentially Medicaid for All without the smell of welfare and with providers reimbursed at Medicare levels, with the difference funded by tax revenue.

Medicare for All is a really good slogan, at least to mobilize the base. One would think it would attract the support of even the Tea Partiers who held up signs saying "Don't let the government touch my Medicare!" Alas, it has not. This has been a conversation on the left and it has not gotten beyond shouting slogans either. We need to decide what we want and whether it really is Medicare for All. If we want to go to any doctor we wish, pay nothing and have no premiums, then that is not Medicare.

There are essentially two Medicares, a high option and a low one. One option has Part A at no cost (funded by the Hospital Insurance Payroll Tax and part of Obamacare's high unearned income tax as well as the general fund), Medicare Part B, with a 20% copay and a \$135 per month premium and Medicare Part D, which has both premiums and copays and is run through private providers. Parts A and B also are contracted out to insurance companies for case management. Much of this is now managed care, as is Medicare Advantage (Part C).

Obamacare has premiums with income-based supports and copays. It may have a high option, like the Federal Employee Health Benefits Program (which also covers Congress) on which it is modeled, a standard option that puts you into an HMO. The HMO drug copays for Obamacare are higher than for Medicare Part C, but the office visit prices are exactly the same.

What does it mean, then, to want Medicare for All? If it means we want everyone who can afford it to get Medicare Advantage Coverage, we already have that. It is Obamacare. The reality is that Senator Sanders wants to reduce Medicare copays and premiums to Medicaid levels and then slowly reduce eligibility levels until everyone is covered. Of course, this will still likely give us HMO coverage for everyone except the very rich, unless he adds a high-option PPO or reimbursable plan.

Either Medicare for All or a real single payer would require a very large payroll tax (and would eliminate the HI tax) or an employer paid subtraction value added tax (so it would not appear on receipts nor would it be zero rated at the border, since there would be no evading it), which we discuss below, because the Health Care Reform debate is ultimately a tax reform debate. Too much money is at stake for it to be otherwise, although we may do just as well to call Obamacare Medicare for All.

The third option is an **exclusion for employers**, especially employee-owned and cooperative firms, who provide medical care directly to their employees without third party insurance, with the employer making HMO-like arrangements with local hospitals and medical practices for inpatient and specialist care.

Employer-based taxes, such as a subtraction VAT or payroll tax, will provide an incentive to avoid these taxes by providing such care. Employers who fund catastrophic care or operate nursing care facilities would get an even higher benefit, with the proviso that any care so provided be superior to the care available through Medicaid or Medicare for All. Making employers responsible for most costs and for all cost savings allows them to use some market power to get lower rates.

This proposal is probably the most promising way to arrest health care costs from their current upward spiral—as employers who would be financially responsible for this care through taxes would have a real incentive to limit spending in a way that individual taxpayers simply do not have the means or incentive to exercise. The employee-ownership must ultimately expand to most of the economy as an alternative to capitalism, which is also unstable as income concentration becomes obvious to all.

The key to any single-payer option is securing a funding stream. While payroll taxes are the standard suggestion, there are problems with progressivity if such taxes are capped and because profit remains untaxed, which requires the difference

be subsidized through higher income taxes. For this reason, funding should come through some form of value-added tax.

Timelines are also concerns. Medicare for All be done gradually by expanding the pool of beneficiaries, regardless of condition. Relying on a Public Option will first serve the poorest and the sickest, but with the expectation that private insurance will enlarge the pool of those not covered until the remainder can safely be incorporated into a single-payer system through legislation or bankruptcy.

Attachment Two—Tax Reform, Center for Fiscal Equity, November 13, 2019

Individual payroll taxes. These are optional taxes for Old-Age and Survivors Insurance after age 60 (or 62). We say optional because the collection of these taxes occurs if an income sensitive retirement income is deemed necessary for program acceptance. Higher incomes for most seniors would result if an employer contribution funded by the Subtraction VAT described below were credited on an equal dollar basis to all workers. If retained, the ceiling should be lowered to \$75,000 to reduce benefits paid to wealthier individuals and a 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.

Income Surtaxes. Individual income taxes on salaries, which exclude business taxes, above an individual standard deduction of \$75,000 per year, will range from 6% to 36%. 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. Transferring OASDI employer funding from existing payroll taxes would increase the rate but would allow it to decline over time. So would peace.

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 and inherited assets will be reset, 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 24% rate is between the GOP 20% rate and the Democratic 28% rate. It's time to quit playing football with tax rates to attract side bets.

Subtraction Value-Added Tax (S-VAT). These are employer paid Net Business Receipts Taxes that allow multiple rates for higher incomes, rather than collection of income surtaxes. They are also used as a vehicle for tax expenditures including healthcare (if a private coverage option is maintained), veterans' health care for non-battlefield injuries, educational costs borne by employers in lieu of taxes as either contributors, for employee children or for workers (including ESL and remedial skills) and an expanded child tax credit.

The last allows ending 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). An inflation adjustable credit should reflect the cost of raising a child through the completion of junior college or technical training. 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 has 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 Value-Added Tax (C-VAT). 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-VAT 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.

Attachment Three—Wealth Taxes

Senators Warren and Sanders have proposed wealth taxes to get our financial house in order. As expected, wealthy donors are not liking the idea of a wealth tax, nor are those who felt that President Trump will still be in office by election day. They underestimate the desire by Senate Republicans for self-preservation. Even without Trump on the ballot, 2020 is more like 1974 than 1984.

The bigger danger to enacting a wealth tax is that, even though Senator Warren is taking only small dollar donations, congressional candidates have no such qualms.

Wealthy taxpayers must want to pay more or they will stop higher taxes cold. They won't pay more to fund a higher child tax credit, a Green New Deal or Medicare for All.

Senator Warren is getting a raw deal on Medicare for All. Her funding solution was meant to fund the Sanders proposal. Critics are decrying her plan for being less specific, but the reality is that her plan dovetails off of his bill. Her proposal is an attempt to add meat to the revenue side, which Senator Sanders leaves open.

Broad based social services must be funded by a broad-based tax, such as our proposed subtraction VAT in Attachment Two. The reason that the Affordable Care Act came under attack was not objections to mandates (which is a creature of the Heritage Foundation proposal), but because it was funded by a payroll surtax on unearned income from dividends and capital gains from taxpayers in the top 2% of filers.

High income investors exercise monopsony power over their workers, it is likely that everyone shared the pain. A broad-based consumption tax would be an easier sell (were it not for President Obama's promise not to increase taxes on the bottom 98%). The cynical view is that Obama knew that attacks in ACA funding would make the Republicans demonstrate their fealty for the rich. If so, this stunt cost his party the Congress.

A wealth tax can be considered an ex post facto income tax, also making it unconstitutional. It could be established by constitutional amendment, but it would be far easier to create salary surtax prepayment bonds. This plays to why the wealthy would want to pay more and would save us a bundle on net interest payments.

Getting the wealthy on board is essential to reform. Social Security was passed because FDR played Wall Street against the threat of socialism. It is now time to fund socialism by helping Wall Street get out of the debt bomb it has created for itself.

HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

310 Montgomery Street
 Alexandria, VA 22314-1516
 Phone: (703) 549-4432
 Fax: (703) 549-6495
<https://www.hida.org/>

The Honorable Chuck Grassley
 Chairman
 U.S. Senate
 Committee on Finance
 104 Hart Senate Office Building
 Washington, DC 20510

The Honorable Ron Wyden
 Ranking Member
 U.S. Senate
 Committee on Finance
 221 Dirksen Senate Office Building
 Washington, DC 20510

Dear Chairman Grassley and Ranking Member Wyden:

We are writing to express our support for full funding for the Public Health and Social Services Emergency Fund as part of the Fiscal Year 2021 Labor, Health and Human Services, Education, and Related Agencies bill. As the funding source for the Assistant Secretary of Preparedness and Response (ASPR), full funding is necessary to fully equip our country to prepare for and respond to global pandemics such as the Coronavirus. These funding levels are vital to ensuring the U.S. is prepared for the next global pandemic. Additionally, the Section 301 tariffs currently in place on certain medical product imports from China prevent our country from being fully prepared to address current and future public health challenges.

The reauthorization legislation included in the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAI), addressed for the first time, specific language regarding the security and capabilities of the healthcare supply chain. In order to ensure an elastic supply chain, capable of responding to all manners of public health emergencies including natural disasters, biological events, and pandemic diseases, adequate funding needs to be provided for the ASPR. Funding for these programs will help to strengthen public and private partnerships, as mandated by PAHPAI, before, during, and after public health emergencies. The provisions in PAHPAI supporting this initiative include:

- Sec. 302(a)
- Sec. 302(b)
- Sec. 403(a)(1)(B)(i)(II)
- Sec. 403(a)(4)(E)
- Sec. 319C-3(b)(1)(A)(ii)

Medical products are critical to any emergency or pandemic response. Just this year, our country was faced with a particularly severe influenza season while also managing the emerging Novel Coronavirus (COVID-19). These simultaneous events have placed a substantial increase in demand for vital supplies such as gloves and gowns which are essential to protecting the American people.

While coronavirus has been well contained domestically, the healthcare supply chain relies heavily on shipping containers from China to deliver safe, affordable and timely product to U.S. shores. As the world responds to coronavirus, it has become clear that the U.S. cannot rely so heavily on one foreign entity to meet its demand for healthcare supplies. It is essential that Congress fully fund programs, identified under PAHPAI, which support the partnership of government agencies with industry working toward the development of a domestic cushion of essential medical supplies as well as the diversification of their means of production.

Furthermore, the Section 301 tariffs on medical products such as gloves and gowns hinder our country's ability to fully prepare for and respond to global pandemics. Products such as gloves and gowns are essential to protect the American people as they prevent infection as medical professionals respond to infectious diseases such as flu and the Coronavirus, manmade terrorist incidents with biological pathogens, natural disaster responses such as hurricanes, earthquakes, and fires, and thousands of medical procedures every day. We have seen a substantial increase in demand for these supplies during infectious outbreaks, including the 2014 Ebola out-

break and the 2009 H1N1 epidemic, and we are seeing similar increases during the current Coronavirus event.

Adequate funding for the Agencies responsible for preparing for and responding to public health emergencies is vital to ensuring our country is prepared to respond to the next coronavirus, Ebola, or SARS. As such, we strongly urge you to support full funding for the Assistant Secretary of Preparedness and Response as part of the Fiscal Year 2021 Labor, Health and Human Services, Education, and Related Agencies bill. Furthermore, we appreciate your attention to the issue of Section 301 tariffs as applicable to imported health product and their impact on the U.S. response to coronavirus. Your continued support helps ensure the availability of safe and affordable healthcare products during pandemics and other public health events.

Sincerely,

Linda Rouse O'Neill
Vice President, Government Affairs
Health Industry Distributors Association

