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PRESIDENT'S FISCAL YEAR 2020 HEALTH CARE PROPOSALS

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED SIXTEENTH CONGRESS

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PRESIDENT'S FISCAL YEAR 2020 HEALTH CARE PROPOSALS

THURSDAY, MARCH 14, 2019

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

The hearing was convened, pursuant to notice, at 10:15 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Chuck Grassley (chairman of the committee) presiding.

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

Also present: Republican staff: Brett Baker, Health Policy Advisor; Erin Dempsey, Health Policy Advisor; Ryan Martin, Senior Human Services Advisor; Stuart Portman, Health-care Policy Advisor; and Karen Summar, Chief Health Policy Advisor. Democratic staff: Anne Dwyer, Senior Health Policy Counsel; Michael Evans, General Counsel; Peter Gartrell, Investigator; Matt Kazan, Senior Health Policy Advisor; and Arielle Woronoff, Senior Health Policy Counsel.

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

The CHAIRMAN. Good morning, everybody, including our witness and all the members of the committee.

So I welcome Mr. Azar, our Secretary for HHS. I appreciate his coming before the committee to talk about Health and Human Services proposals in the President's budget for fiscal year 2020.

Congress decides how much the government spends and how to allocate these resources. The President gets to have his say, and it is our duty to consider those recommendations, or another way I sometimes say it is that, a President proposes, but Congress disposes.

We are here to discuss the part of the President's budget and the recommendations in regard to programs in the Department of Health and Human Services. These programs impact the day-to-day lives of many people in Iowa and throughout the country, adding up to about 130 million people just on Medicare and Medicaid.

Human services programs administered by HHS help millions of families in need while promoting upward mobility. The programs this committee oversees spend over $1 trillion and take hundreds of millions of dollars to administer. The President's budget proposal aims to tackle a number of pressing challenges. It looks to get a

better handle on the opioid epidemic. And it looks to improve child welfare outcomes. This committee has been active on these issues and others, of course, and has a role in overseeing that HHS implements the laws that Congress has passed in these areas.

The budget of the President also strives to lower the high cost of prescription drugs, which I have not heard a person on this committee say is not important. It is always a necessity to be working in that direction, and we have not done enough. I share that goal with the President's budget and look forward to working with my colleagues on this committee to find ways to make medications more affordable in Medicare and Medicaid while protecting taxpayers who fund these programs.

We all know that last June, President Trump and Secretary Azar laid out something to help reduce drug costs for patients. And I think they deserve tremendous credit for taking that route. Their sustained efforts have helped to make big drug pricing policy changes possible that probably have not been done yet. This committee is working on it as well.

The budget serves as a reminder that Congress needs to act to make sure that Medicaid and Medicare are around for future generations. Putting these programs, then, on a sustainable financial path while ensuring patients can get the care they need is obviously hard work, and we do not tackle it enough, sometimes not at all.

And I have said many times, regardless of the issue, the legislative heavy lifting needs to be done in a bipartisan manner to achieve a lasting solution. This hearing, then, provides an opportunity to talk about issues important to our constituents and the entire Nation.

So whether you agree or disagree with the specific policy proposals in the budget, it is important that we engage with this Secretary on these issues. So we appreciate, Mr. Secretary, your being here to perform the time-honored tradition of testifying on the budget, which enables us to execute our duty to consider the President's proposals. I look forward to a robust discussion.

Senator Wyden?

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

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

Senator WYDEN. Thank you very much, Mr. Chairman. Mr. Chairman, you know I always want to try to find common ground on health-care issues, and you and I have been able to do that in the past.

Mr. Secretary, I wish it was not the case, but it does seem to me that the Trump administration has what amounts to an inexhaustible supply of destructive health-care ideas that harm the vulnerable. I am going to start with the Arkansas paperwork requirements. I describe it that way because, with the President's blessing, Arkansas went ahead with this right-wing experiment there.

They said it was all about work requirements, but it is really about paperwork and reducing coverage. Eighteen thousand people

in Arkansas have lost their health care. They are people who want to work, people who are working.

The administration was asked on Tuesday, Mr. Secretary, why so many people in Arkansas have lost coverage. The Trump administration has been basically clueless about all those people losing coverage. And now they are talking about making it mandatory in every State.

It does not make people healthier. It is not about promoting work. It is a back-door scheme to kick people off their Medicaid coverage by putting mountains of paper between patients and doctors. And it seems that there is one sort of far-right experiment after another.

You have these Governors and Attorneys General suing HHS to get the Affordable Care Act ruled unconstitutional. This legal argument would not wash virtually anywhere. But instead of defending the law, as is the long-standing bipartisan practice, the Trump Justice Department said, "We are on board." In fact, they focused their attack on unraveling pre-existing condition protections, want them ruled unconstitutional.

The brief is so absurd, colleagues, three career officials—career officials, people who do not do politics—said they would not put their names on it. One even resigned. After a political appointee agreed he would be the public face of this attack, he got a nomination to the Sixth Circuit Court of Appeals.

Now when you talk about pre-existing conditions—a number of my colleagues on our side have been very eloquent on this—you have to talk about junk insurance. The fight against junk insurance goes back decades. For me it was going back to the days when you had Medigap supplements—which were not worth the paper they were written on—targeting seniors.

More recently, there was a similar effort in the private insurance market. The Trump administration said, "We are not in the business of cracking down anymore. Let us bring the junk insurance back so scam artists are free to sell bargain-basement plans on the individual market that do not cover the care people need."

Next the Trump administration wants to fillet the Medicaid program by block-granting it and capping it. This idea, colleagues, is so bad, it harms so many people that nobody could even—on the other side—move such an approach in this committee room when we had a hearing on it.

Not only would it put essential care on the chopping block for millions—including kids, people with disabilities—in my view this block grant approach is a surefire way to create a nationwide crisis of nursing home closures, because Medicaid pays for something like two out of three nursing home visits.

Now the administration is reportedly exploring how to block-grant Medicaid by administrative fiat. The administration cut the open season for health insurance in half and a variety of other approaches that would make it harder for people to sign up for coverage. The budget takes away middle-class tax credits, and the list of sabotage just goes on and on.

So, as I touched on at the beginning, it is really stunning how creative the Trump administration has been in making health care worse in America.

I would like to take a brief look at the pharmaceutical checklist and compare the President's promises to what we have actually seen him deliver. On the campaign trail, the President went after the pharmaceutical companies all-in. And in 2017 he said, "Drug makers are getting away with murder." But 2 years in, he sure does not look like he is getting anything resembling a passing grade.

The President once said he wanted to let Medicare negotiate to bring down drug prices. Now, colleagues, those are his words; the President said we have to negotiate to bring down prices—nowhere to be found in the budget, nothing in the budget that forces the manufacturers to lower their prices. So there has not been any concrete action to back it up.

I am going to follow with just two last issues quickly. First, on the separation of migrant children from their parents, last year the Secretary came before the committee, told us that HHS was on the case, the kids were accounted for, and reunification would proceed smoothly. The Secretary said, "With just basic keystrokes, within seconds, they could find any child in their care." Based on available evidence, that is just not the case.

Reports suggest that the government cannot account for the whereabouts of potentially thousands of kids who are in its care. HHS documents that were recently released show that there were thousands of allegations of sexual abuse inflicted on kids in government custody.

So you have a trio of Secretaries in the Trump administration sending reassuring messages, but behind the scenes, these kids were just battered by chaos. And certainly these abuse allegations are very troubling. It is a horrifying scandal. And right now—and I am very pleased the chairman and I are working on this in a bipartisan way—I am concerned that the administration wants to intimidate and silence journalists trying to expose it.

The chairman has been the leader of the Whistleblower Caucus, and I appreciate him working with me on that.

Finally, an issue dealing with foster care: in January the Trump administration gave South Carolina a green light for religious discrimination in its foster care program. The announcement came with the assurance that it would only be one State, that this was a unique set of circumstances, that there was not going to be any discrimination, and that was how it was rolled out.

Then the President got up at the National Prayer Breakfast and said that he was looking at making this policy national. In my view, this road heads directly towards taxpayer-funded discrimination on religious grounds.

The first victims of the discrimination will be people who want to step up and provide safe and loving homes for foster kids, people who are Jewish, people who are Catholic, who are Muslim, who choose to practice no religion, LGBTQ Americans, potentially others. The next victims will be vulnerable youngsters, since the policy would limit the number of foster homes available to them.

There are also alarming questions about what this would mean for Jewish kids and Catholic kids who would wind up in settings that are hostile to their faiths. And we talked at the hearing—and there can be differences of opinion on this—but as a Jewish kid,

a first-generation Jewish kid, these questions are not an abstract kind of a matter for what I remember growing up Jewish was all about. And I certainly want to know what it would mean for LGBTQ kids.

So there is a lot to dig into, Mr. Chairman. And I look forward to pursuing these issues here in the committee and looking for bipartisan solutions.

The CHAIRMAN. Thank you very much.

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

The CHAIRMAN. Our witness, the Secretary, served as General Counsel of HHS from 2001 to 2005, and then turned to being Deputy Secretary of HHS from 2005 to 2007. He has earned a bachelor's degree from Dartmouth College and his law degree from Yale University.

Secretary Azar, we welcome you, and proceed with your statement.

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

Secretary AZAR. Thank you very much, Chairman Grassley and Ranking Member Wyden. Thank you for inviting me to discuss the President's budget for fiscal year 2020.

It is an honor to have led the Department of Health and Human Services over the roughly 14 months since I appeared before this committee as a nominee. The men and women of HHS have delivered remarkable results in that time, including record new and generic drug approvals, new affordable health insurance options, and signs that the trend in drug overdose death is beginning to flatten and decline.

The budget proposes $87.1 billion in fiscal year 2020 discretionary spending for HHS while moving toward our vision for a health-care system that puts American patients first. It is important to note that HHS had the largest discretionary budget of any nondefense department in 2018, which means that staying within the caps set by Congress has required difficult choices that I am sure many will find quite hard to countenance today.

Today I want to highlight how the President's budget supports a number of important goals for HHS. First, the budget proposes reforms to help deliver Americans truly patient-centered affordable health care. The budget would empower States to create personalized health-care options that put you, as the American patient, in control and ensure you are treated like a human being and not a number. Flexibilities in the budget would make this possible while promoting fiscal responsibility and maintaining protections for people with pre-existing conditions.

Second, the budget strengthens Medicare to help secure our promise to America's seniors. The budget extends the solvency of the Medicare Trust Fund for 8 years, while the program's budget will still grow at a 6.9-percent annual rate.

In three major ways, the budget lowers costs for seniors and tackles special interests that are currently taking advantage of the Medicare program. First, we propose changes to discourage hos-

pitals from acquiring smaller practices just to charge Medicare more.

Second, we address overpayments to post-acute providers.

Third, we will take on drug companies that are profiting off of seniors and Medicare. Through a historic modernization of Medicare Part D, we will lower seniors' out-of-pocket costs and create incentives for lower list prices. We also protect seniors by transferring funding for graduate medical education and uncompensated care from Medicare to the general Treasury fund, so all taxpayers, not just our seniors, share these important costs.

I want to acknowledge the substantial work of this committee on drug pricing in particular, including work to lower out-of-pocket drug costs. Thanks to legislation on pharmacy gag clauses that this committee sent to President Trump's desk, America's pharmacists can now always work with patients to get them the best deal on their medications.

I also want to note that today HHS is publishing voluminous new data on price increases taken from 2016 to 2017 on drugs paid for by Medicare and Medicaid. These data shed light on the kind of abusive behaviors we are addressing with the President's budget and his drug pricing blueprint.

Since the blueprint's release, we have seen results including significantly fewer price increases taken by brand drug companies and consumer price inflation for prescription drugs going negative in 2018. But there is more work to be done, and I believe there are many, many areas of common ground on drug pricing where we can work together to pass bipartisan legislation.

Finally, the budget supports HHS's five-point strategy for the opioid epidemic: better access to prevention, treatment and recovery services that are targeting the availability of overdose reversing drugs, better data on the epidemic, better research on pain and addiction, and better pain management practices.

The budget provides $4.8 billion toward these efforts, including the $1-billion State opioid response program, which we have focused on access to medication-assisted treatment, behavioral support, and recovery services.

The budget also invests in other public health priorities including fighting infectious disease at home and abroad. It proposes $291 million as the first year of funding for President Trump's plan to use the effective treatment and prevention tools we have today to end the HIV epidemic in America by 2030.

I want to conclude by saying that this year's budget will advance American health care and help deliver on the promises we have made to the American people. And I look forward to working with this committee, as we have always done on our shared priorities, and I look forward to your questions today.

Thank you very much, Mr. Chairman.

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

The CHAIRMAN. Can I remind my colleagues, since I have two hearings I have to chair today on the subject of the budget, we are going to have 5-minute rounds. But I hope people will not extend beyond the 5 minutes.

Mr. Secretary, the Family First Prevention Services Act, which is meant to keep people out of foster care—I have two questions. One, what is your agency doing to make sure States know about this new policy, as well as others that were part of Family First?

Secretary AZAR. Thank you, Mr. Chairman.

As you know, the Family First Act sets very aggressive timelines. And our efforts to educate the States include regional listening sessions with States and tribes, formal requests for public comment, site visits in many States to observe effective community-based prevention programs, national webinars, in-person discussions with our relevant grant clusters, participation in child welfare professional membership or association meetings, and individual meetings and calls with State and county child welfare leaders.

The CHAIRMAN. Do you know how many States are taking advantage of the new opportunity? And if you cannot give us that figure, would you please answer in writing?

Secretary AZAR. I do not have that at my fingertips, but we will get that to you in writing.

The CHAIRMAN. Okay.

Iowa has 38,000 people in small markets, 23,000 people in individual markets that have been called "grandmothered plans." These plans provide health insurance for small business owners, including farmers in my State. These people like their plans. The grandmothered plans have been extended four times, and the last extension expires at the end of the year.

So I am concerned about these 60,000 people and their health insurance. Will you consider extending the grandmothered plans for as long as possible, or even considering making the plans permanent?

Secretary AZAR. So, Chairman Grassley, we appreciate your continued advocacy on behalf of grandmothered plans, and I share your concerns. We certainly do not want to do anything that adds to the disruption that the Affordable Care Act has already caused, especially for the people of Iowa.

Iowa has been very hard hit by the changes in the individual market, especially its small business people and its farmers. The grandmothered plans have served a very important role for them.

That policy is currently under review as part of the annual cycle. But please rest assured in knowing that I personally, and the President, want to avoid any disruption to those individuals if we can do so.

The CHAIRMAN. Okay.

My last issue deals with the fact that, in the past several months, I have written to NIH, your OIG, and the Department of Justice regarding foreign threats to taxpayer-funded medical research and intellectual property.

Last month the Inspector General released a report on the National Institutes of Health's handling of U.S. genomic data. This data is extremely valuable for ongoing research. In addition to the value of the data, there is a risk that this data can fall into the wrong hands. The OIG report found that NIH did not consider national security risks when permitting and monitoring foreign principal investigators' access to United States citizens' genomic data.

The IG further noted that the National Institutes permitted access to genomic data to for-profit entities, including companies from China, even though the FBI has identified those companies as having ties to the Chinese government. The Inspector General also found that NIH did not verify that foreign researchers had completed information security training. I am very concerned about this OIG report. I, of course, hope you are as well.

Will you commit to working with my office and NIH as we continue to work on this issue to make sure privacy as well as national security concerns are addressed?

Secretary AZAR. We absolutely will. We share your concerns. And we are always working to safeguard intellectual property and sensitive data and other U.S. national interests, including by prioritizing the OIG recommendations to ensure that security policies keep current with our emerging threats and to make training and security plans a requirement.

The NIH recently did establish a working group to the advisory committee of the Director to address how to mitigate these concerns. And we look forward to continuing to work with you and the committee on these issues.

The CHAIRMAN. Okay. I will reserve my 16 seconds. Proceed.

Senator WYDEN. Mr. Chairman, first of all, thank you very much for bringing up Family First as your initial question.

Colleagues, this is a transformation in foster care. And you have people like Marian Wright Edelman of the Children's Defense Fund who said it has been her dream for 30 years. And she has colleagues who are very conservative who would probably echo her words.

So you are bringing that up with the Secretary, and I have talked with him as well. We have to accelerate the timetable, colleagues. That is what the chairman's question was all about. So I want to associate myself with your remarks, Mr. Chairman.

When we get this in place, colleagues, this is going to be a genuine transformation in foster care in America.

Mr. Secretary, I want to start my questions by quoting your boss. President Trump keeps promising better health care for more people. In September of 2015, for example, the President said, "I am going to take care of everybody. Everybody is going to be taken care of much better than they are taken care of now."

So I want to start by quoting the President of the United States. The fact is that coverage has gone down on his watch. It has gone down according to the survey data that I have in my hand.

Mr. Chairman, I would ask unanimous consent to make that survey data part of the record.

The CHAIRMAN. Without objection.

[The survey appears in the appendix on p. 181.]

Senator WYDEN. And the survey data indicates that 7 million fewer Americans have insurance today than before the President was elected. For the first time in a decade, the rate of uninsured children has actually gone up. So I have entered the polling data that I am citing into the record.

The President said he was going to take care of everybody and everybody was going to do better. Mr. Secretary, do you have any reaction to that? How is the President's promise being followed up

on? The survey data indicates 7 million fewer Americans have insurance coverage.

Secretary AZAR. I mean, is it not fascinating? I thought the Affordable Care Act was taking care of everything also.

Senator WYDEN. Well, it is kind of hard with all the sabotage. But if you would answer the question, 7 million fewer people have insurance coverage now than when the President started. And the President said everybody was going to get a better deal. So on his watch, coverage went down.

Secretary AZAR. Well, the President does want everyone to have access to affordable health care, and that is why we keep proposing reforms in our budget, as well as keep trying to make reforms under the Affordable Care Act, as long as it is there, to make more affordable options available.

You know, for instance, I have approved 7 waivers, 1332 waivers to States for reinsurance pools that have brought premiums down by 9 to 30 percent. Our marketing activities—by being more efficient and relying more on the insurance companies to do the marketing, we have actually reduced that expense which comes out of user fees that go into the premium base for our citizens.

And that actually has pulled premiums down for them as a result of our actions. We have stabilized the marketplace. The premiums actually went down this year for the first time ever. We had more plans enter the marketplace since 2015.

So I think we all share the goal of expanding affordable options for individuals as well as in the employer space, which now is at 178 million Americans getting their insurance through their employers.

Senator WYDEN. I just want the record to show, colleagues, that the President said everybody is going to be taken care of much better. I asked the Secretary to respond to the fact that there has been, on the President's watch, a net increase of about 7 million adults without coverage, and we have not gotten any response to that.

Now, Mr. Secretary, I want to ask you about these junk plans. And I think you and I have talked about this. For me this goes back to the days when people got junk sold to supplement Medicare. We finally got that changed.

We were trying to improve the coverage in the individual market. Now there have been changes in the rules where, for example, junk plans can discriminate against people with pre-existing conditions.

I have the text of the rule here. It says in the definition of short-term limited duration coverage, "It is not subject to requirements regarding guaranteed availability and guaranteed renewability."

Why would you want to turn back the clock and move us back to the days when we had junk insurance? That is in the final rule in my hand.

Secretary AZAR. So short-term limited duration plans, as you know, were expressly provided for under the Affordable Care Act and continued in the Obama administration. We simply restored them as a more viable option for people. People need to go in with their eyes open, and that is why we put those kinds of disclosures in there.

They do not have to have all the coverage. We are seeing, I believe, some short-term plans that do offer pre-existing coverage. Some do not.

So we are continuing to provide more options to people. It is a 50- to 70-percent lower price. Your junk could be to a farmer in Iowa, a lifeline to some form of coverage.

Senator WYDEN. I am over my time.

I only want to say that not only did we get rid of some of the junk insurance in the past, the Obama people did try to tighten up the rule. You are going in the other direction.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Cornyn?

Senator CORNYN. Thank you, Mr. Chairman.

Thank you, Mr. Secretary, for being here. I want to follow up a little bit on Chairman Grassley's question about security protocols at institutions that are doing taxpayer-funded research.

As you know, China in particular has been enormously aggressive, not only in terms of stealing intellectual property, but trying to exploit vulnerabilities in our country when it comes to foreign investment. We have reformed the CFIUS, the Committee on Foreign Investment in the United States, in a bipartisan way to try to address that.

But what I would like to hear a little bit more from you about is what sort of standards should Congress and the administration insist upon for institutions that are the recipients of taxpayer funding to do research? As you noted, it is not just intellectual property, it is data—and our adversaries are vacuuming up as much as they can get by any means available.

So is this something that you think Congress ought to look at and act on?

Secretary AZAR. We obviously would welcome any partnership with Congress, and, Senator, we would be happy to get you more detail than I am able to provide in a quick response. But we are taking this very seriously. It is an immense challenge.

And the NIH Director sent out information to grantees on a couple of issues; for instance, primary investigators or other investigators under R01 NIH-funded grants receiving duplicate payments, for instance, from other entities, which need to be disclosed and accounted for and considered as to whether they should be eligible. Individuals on peer review bodies receiving payments from foreign entities, for instance—similar guidance there to make sure they were enforcing the rules clearly.

I think some of these institutions have not been enforcing the rules, and we have been trying to get very clear with them about what is required if you are receiving Federal money in terms of foreign interference and foreign funding.

Senator CORNYN. Well, I know from experience that some of the institutions in my State, while the FBI does make counterintelligence briefings available, they are really not set up to try to provide, on a comprehensive basis, the information that these institutions need about how to protect themselves against the foreign and outside threat. And this is not just foreign countries. These are cyber-criminals and others as well.

But I have had more than one of my constituents in Texas at a major institution, basically, come to me and say, we have been exploited in ways that we never were prepared for or never really aware of. So I think it is a matter of grave concern, and we look forward to working with you and the administration and colleagues on both sides of the aisle to protect that data and that intellectual property and the privacy of the American people.

You were recently quoted—this is on the question of kidney innovation. We know that there are a lot of people who suffer from kidney disease, presumably because of high blood pressure, a lot of it associated with symptoms of their diabetes which is not adequately controlled. And of course, we know millions of people are on dialysis on a regular basis.

You said, "It is the epitome of a system that pays for sickness rather than health, and this administration is intent on shifting those priorities." I want to work with you on that. But if you can just maybe summarize here, quickly, sort of what your thoughts are about kidney innovation.

Secretary AZAR. Well, there has been very little kidney innovation, actually, in the last several decades. And that is quite disturbing. We have been entirely too content to place individuals on dialysis and to have that be actual facility dialysis, which is a brutalizing process for individuals. It is necessary, but 3/4 days a week going in, being sapped, essentially becoming disabled because the energy flow comes out of you from that process.

We have globally low rates of home dialysis. Whether peritoneal dialysis or otherwise, we should get our home dialysis rates up. But most importantly, we need to get people transplanted. We need more kidneys. We need to increase the flow, and we need to fix the financial incentives in our system.

Right now every financial incentive in our system is towards dialysis, not towards transplantation and long-term survivorship. And you get what you pay for.

Senator CORNYN. Well, I am really happy to see your focus on that. And again, I really would like to work with you, and I am confident this is something we could do together.

Finally, biosimilar competition—we have heard from CEOs a few weeks ago about the role of patents and limiting competition for certain drugs, including biologics. Can you talk to us a little bit about what we can do to encourage more competition for biosimilars?

Secretary AZAR. We are fully committed on biosimilar competition and creating a genuine biosimilar marketplace. And we are open to all ideas and working with Congress on that.

I am very concerned when it comes to biologic products about the evergreening of patents and expanding patent estates. I am not an expert in intellectual property, but it disturbs me. There is a deal, which is, you should have the exclusive right to practice your invention for a time period, but things are just going on and evergreening too long and preventing the entry of biosimilars into the marketplace. And I am concerned a great deal about that, as is the President.

Senator CORNYN. Thanks for your indulgence.

The CHAIRMAN. Senator Stabenow?

Senator STABENOW. Well, thank you, Mr. Chairman and Ranking Member.

And, Mr. Secretary, it is good to see you again. Let me first start out—and this is not where I want to spend the majority of my time.

But I do want to say that I am deeply concerned about maternal and child health programs. There are seven that have been eliminated. I had an extensive, robust conversation with the Acting OMB Director yesterday in a budget hearing about that, but also the attempts to cap, block-grant, cut the Medicaid program.

I certainly will rigorously oppose. We have more than 675,000 people in Michigan enrolled in Healthy Michigan who would lose their health care, and 1.2 million children getting coverage through Medicaid, which is about half of our kids. Two out of three seniors in nursing homes rely on Medicaid.

But what I want to talk about—because we have differences, but it is also our job to find common ground, and you mentioned common ground in your statement. So I want to actually spend my time talking about an area where we can move forward in a positive way and have common ground, and that is related to mental health and addiction.

When I leave this hearing, Senator Roy Blunt and I will be doing a press conference with law enforcement, community leaders, health leaders, to roll out the next step in expanding the Excellence in Mental Health and Addiction Treatment Act. One out of five people in our country will have a serious mental health issue during their lifetime, and we know the majority of deaths under age 50 are drug overdoses. This is incredibly serious, as you know.

And I want to just give a shout-out. Our current bill is cosponsored by Senators Wyden, Ernst, Schumer, Gardner, Whitehouse, Sullivan, Klobuchar, and Tillis, supported by Senators Menendez, Casey, and Cortez Masto on the committee. And we are adding people in pairs, Republican and Democrat. So I expect many more people to be added.

Basically, this is a transformative way to permanently address mental health and addiction services by indicating that we want this to be treated not in terms of grants—when the grant runs out, you no longer get care—but a permanent part of our health-care system, like we do community health centers. And so you and I have talked about this, but we created quality standards for behavioral health services in the community like we did for Federally Qualified Health Centers.

And now we have started the process of showing that this funding can work. I want to thank you. In your budget, you do have some funding related to this. We need to structurally take the next step: 24-hour crisis services and outpatient care coordination, care working with law enforcement, emergency rooms, veterans groups.

We have found that the eight-State demonstration project that we were able to get funding for has actually worked beyond what we had even hoped for. And we do not quite have 2 years' worth of data yet.

We have 11 more States that put together quality plans and want to now do this. And we know that if we can help them get this set up that they will be able to incorporate it into their own

plans as they move forward. So it is a matter of quality standards and helping them get going.

And I would just mention that we have an assistant police chief from Oklahoma who is joining us today at the press conference talking about how they used to spend hours in the emergency room at the local hospitals with somebody having a problem. And now they can go to the psychiatric 24-hour crisis center.

So I could go on further, but I want to just ask you, Secretary Azar, can you give us an update on the activities at HHS related to both the demonstration program and the grant awards?

Secretary AZAR. So, thank you very much for your questions, Senator Stabenow, and thank you for your personal leadership and championship on this issue.

The Excellence in Mental Health legislation that you discussed would extend CMS's demonstration for Certified Community Behavioral Health Clinics and permit additional States to participate. We support efforts to increase access to and improve quality of community behavioral health services through CCBHCs. These facilities provide a comprehensive, coordinated range of evidence-based behavioral health services certified by the State.

Our budget, as you mentioned, includes $150 million for SAMHSA to continue the Certified Community Behavioral Health Clinic's expansion grant program, which supports the CCBHCs in Michigan. And we look forward to working with you on the important legislative package that you discussed.

Senator STABENOW. Thank you.

And, Mr. Chairman, I am looking forward to working with you and other members of the committee. I would welcome other co-sponsors as well. This is a very important step in really showing that we are serious about community mental health and addictions.

Senator ROBERTS. Would the Senator yield?

Senator STABENOW. Yes, I would be happy to, for my distinguished chairman on the Agriculture Committee.

The CHAIRMAN. Do not take a lot of time, please.

Senator ROBERTS. I just want to be added as a co-sponsor. I thought I was, but I guess I was not, because you did not read my name.

Senator STABENOW. I am thrilled. Thank you.

The CHAIRMAN. You are added as a co-sponsor.

Senator Cantwell?

Senator CANTWELL. Well, I am happy to be added with Senator Roberts if that is the——

Senator STABENOW. Excellent. All right. Here we go.

All right. Mr. Chairman, we are on a roll. Could we continue? Thank you.

The CHAIRMAN. Can they not communicate it to you silently?

Senator CANTWELL. Thank you, Mr. Chairman.

Senator STABENOW. Thank you.

Senator CANTWELL. Secretary Azar, we have had a couple of chances in settings with our colleagues to discuss both drug pricing and health care at large in the context of the administration's interest in bringing market forces to the table. So you have said a couple of times at these meetings that you do believe in creating negotiations as a tool to help.

And I see in your budget you include a Medicaid prescription drug demonstration that is also empowering States to do that. Is that correct?

Secretary AZAR. Absolutely, to allow State Medicaid programs to figure out alternative approaches to negotiating formularies and securing discounts that may be superior to what we have even in our statutory rebate structure.

Senator CANTWELL. Great.

And so our State, the State of Washington, is looking at a Netflix model as it relates to the hep C drug. So that would be something that you would see as a like program in negotiating?

Secretary AZAR. We are very supportive of these alternative approaches. Louisiana and Washington are looking at approaches where you basically would do a subscription-type arrangement with one or more drug companies to basically provide access to patients who meet clinical criteria, but at a fixed, capitated amount so the State can have predictability in its budget.

I think it is very innovative. I am very excited about these kinds of developments. We are very supportive.

Senator CANTWELL. Great.

I do not know if you stayed up late at night to watch the replay of the drug manufacturers here before the Senate a week or two ago, but I am not sure they did themselves any favors.

When I asked them whether they were for market forces, they pretended that those are not market forces, and that they—well, they did not say that. They said those are their inflicted—I do not know their exact term, but they made it sound like they had no alternatives.

And obviously the alternative is, they do not have to participate. They do not have to participate. If they do not want to give a discount, if they do not want access to that market, they do not have to participate.

On that point, the basic health plan, I believe the administration has chosen to—at least as it relates to New York and Minnesota—continue to allow those programs. Does that not also represent an ability for States to negotiate, bringing together a market of interest that is harder to serve, and basically bundling them up, and then attracting insurers? Is that not a similar model?

Secretary AZAR. I apologize. I did not know about a change in view on the work of ours on the basic health plan. I know that is a passion of yours.

If we could talk offline about that, I would be very happy to do so.

Senator CANTWELL. Okay.

Secretary AZAR. I just am not as familiar on changes there.

Senator CANTWELL. Well, I do not think there is—I am not sure that there is a change. I am just asking you if you think that represents—just like the drug negotiation, in empowering States to negotiate on price—do you think that represents a similar model?

Secretary AZAR. As a general matter, we want to be empowering States to run programs in their jurisdiction as they see fit so that they can make the kind of value choices. You know, we have approved very innovative demonstrations, for instance in Maryland, that would be very different than what, perhaps, Washington

might do. And we want to respect different models, try different models.

Senator CANTWELL. Well, I think the distinction here I am trying to make is that when you block-grant something but you do not give the power to people—look, we see that the challenges of a baby boomer population reaching retirement and people living longer are going to cause a bigger demand in our budget.

So we want tools that are going to help us reduce those costs. And being able to negotiate or bundle people up and create that negotiating power and then allowing people to—if the manufacturers or the providers do not want to participate, they do not have to participate. But it at least gives us market forces.

And I just want to clarify that you are for those market forces.

Secretary AZAR. I generally am in favor as long as it is consistent with whatever the values of a State are in making choices to enhance market forces.

Senator CANTWELL. Right.

Secretary AZAR. Because like you said, we often talk about the drug market as if it is a free market and a competitive market. It does not function like a competitive market. Actually what I am trying to do is bring real market forces to bear, because it is not functioning that way.

Senator CANTWELL. I think the next thing that we have to do is that—it is very hard to get, you know, CBO scoring on these things, but I definitely think that we need to work harder at drawing some data and information about how these really would help from even a Federal perspective. And obviously they have been quite successful in the case of Minnesota and New York in driving down costs to the population.

So we look forward to working with you on that.

Thank you, Mr. Chairman.

The CHAIRMAN. The Senator from Delaware.

Senator CARPER. Thanks, Mr. Chairman.

Mr. Secretary, welcome. It is good to see you. Thank you for being here and for your leadership at the Department. And to the people who are with you, thank you. Welcome.

Several weeks ago at the table where you are sitting we had six or seven CEOs from drug companies, pharmaceutical companies in this country and from around the world. And they agreed—I asked them all to think about three principles with respect to trying to achieve more cost-effective drugs, a better value from those drugs that are being developed, and finally, steps that we need to take to make sure that we do not take away the incentives for investors to invest in pharmaceuticals.

I asked them all to give me their perspectives on three different factors, and I am going to just mention those to you again. I just wrote them down.

One of those was the idea of eliminating rebates to PBMs. That was one. Second was creating and implementing value-based arrangements. And the last one was increasing the transparency industry-wide with respect to how the industry sets prices.

Those were the three issues that I raised that day. And I asked them all to just think about them and to say whether or not they

thought those were ideas that they could agree on and would recommend that we try to agree on.

And they all did. They all said, "We agree," and we went right down the line, and they said, "We all agree with that." I would just ask the same question of you.

Secretary AZAR. So, of course, we have been pushing on all of those fronts. So on the rebate rule that I proposed—and I would love to get the support of and work with this committee on getting rid of rebates and having discounts go to patients when they show up at the pharmacy. Just for our seniors in Part D, that is $29 billion a year of rebates going to pharmacy benefit managers that could go to the patient starting January 1st when they show up at the pharmacy.

It is just an incredible change. And it would bring transparency, as you just mentioned, because then these discounts, these negotiations, would not be behind-the-scenes deals, they would be transparent. And I think we could actually see a virtuous cycle of price competition at the pharmacy counter, instead of right now these perverse incentives to higher list prices as the means of competing.

Senator CARPER. Okay.

Secretary AZAR. Second, on value-based arrangements, we are all in on that. We are working on how we can provide guidance and further pathways.

Senator Cantwell just mentioned one, which is that Netflix-type model that we have tried to open pathways for, but other value-based arrangements. We want to work with you on that.

And generally, transparency—we are in favor of that transparency around pricing practices. We are happy to work with you on efforts there.

Senator CARPER. Sometimes we need to be mindful of unintended consequences of the things that we do here. And would there be any unintended consequences that you can think of from implementing the policy with respect to rebates?

Secretary AZAR. So what we are doing right now with rebates is, the rebates go to these middlemen, and they are used to lower premiums for——

Senator CARPER. Do any of them go to middlewomen?

Secretary AZAR. Well I—fair question.

Senator CARPER. Perhaps.

Secretary AZAR. Pharmacy middlemen and women. Okay. [Laughter.]

They can be used to somewhat subsidize premiums for everybody. It is a very perverse notion of insurance, because what happens is, we are denying access to the discounts to these sick people who show up at the pharmacy and have drug expense, to subsidize lower premiums for the un-sick people, sort of the opposite of how insurance is meant to work.

Senator CARPER. I like that word, "un-sick."

Secretary AZAR. So under our proposal, we have been very transparent with the different estimates and said there could be as much of it as a $2 to $5 per-month increase in premiums as a result of that. But the average drug in Part D is $300. The average rebate is 26 to 30 percent.

That means that, for anyone using a drug with an average rebate on it, in the first fill of that drug they would save a hundred bucks, and that is almost twice what the maximum premium impact could be under even our actuaries' most extreme analysis.

So it is something we have to think about, and that is even if that happens, because I think these PBMs are going to actually work to keep their premium costs flat as they always do. It is a very price-sensitive market in terms of purchasing plans. They want to hit the benchmark and do not want to be beaten out by competition.

I think they will pull that out of pharma companies. I think that is where the money will come from to keep premiums flat.

Senator CARPER. You may have just answered this question, but I am going to ask it anyway. How much would Part D premiums and the burden on Federal taxpayers increase as a result of eliminating rebates to PBMs?

Secretary AZAR. So we put out three different actuarial analyses in our proposed rule; we wanted to be transparent. Actuaries can add and can do math. They are not really good at predicting human behavior or especially what companies do in an economic system. So the estimates range from, I believe, $100 billion of savings up to $200 billion of cost. That is a $300-billion wide margin.

We wanted to be transparent. I believe premiums will not go up, and as a result we will save money on this program. But we wanted to be transparent that there is the risk that other things could happen.

Senator CARPER. Okay. Thanks.

Do you also support the elimination of drug company rebates in the private health insurance market?

Secretary AZAR. I do because, if we can get rid of rebates, list prices will come down. We have very big classes of drugs right now where there are huge rebates, 50-, 60-, 70-, 80-percent rebates. And there will be no reason for these artificially inflated list prices if we get rid of rebates.

Senator CARPER. Okay.

Did you include this policy in your budget?

Secretary AZAR. That is not formally in the budget because, of course, we proposed the Part D rebate rule.

I think 30 States follow what we do on the anti-kickback statutes, so I think just our actions alone will dominate the commercial space because they will follow us.

Senator CARPER. Good.

Mr. Chairman, my time has expired.

I am going to follow up with a question for the record on increasing transparency, and another one about asking you to think out loud about the transparency laws that I think California has recently adopted and implemented—so, for the record.

Thank you.

The CHAIRMAN. Senator Daines?

Senator DAINES. Thank you, Mr. Chairman.

In Montana, we are facing a meth crisis. In fact, it is a Mexican meth crisis. And it is devastating our families and our communities. Unfortunately, it is our children who end up entering the child welfare system, and they are among the hardest hit.

Statewide, roughly one-third of our children in foster care in Montana are there because of meth use by their parents. In fact, last year my legislation—it was the Child Protection and Family Support Act. It was passed into law as part of the Family First Act to help children stay with their families as they receive substance abuse treatment.

I have seen firsthand the benefits, just a few weeks ago in Billings at the Rim Rock Treatment Center, where mothers seeking treatment are kept with their children under supervision, instead of being separated.

Secretary Azar, how is the Children's Bureau working with agencies like SAMHSA and CMS to coordinate implementation of Family First?

Secretary AZAR. So, thank you for your leadership on the Child Protection and Family Support Act. The Family First legislation, as Senator Wyden mentioned, is so important. It really gives us very valuable tools, instead of incentivizing the outplacement into foster care, to keep kids together if we can make a safe home for them. And it is such an aggressive, comprehensive package of legislation. It has really been a whole across-the-department effort of our Administration for Children and Families, as you said, working with SAMHSA, working with CMS to support all the very aggressive timelines in the statute.

Senator DAINES. I can tell you too, the feedback I am receiving on the ground back home is just remarkable. I was literally in a facility there where you had moms with little bassinets and cribs and little bunk beds there with their children under supervision, and just heard great feedback. This is the right path to take here to help these moms who are suffering addiction issues.

How is HHS prioritizing the meth crisis? Meth seizures in Montana doubled year-over-year. We just got the data here last month. We have a truly—it is a Mexican cartel meth crisis; high potencies, 90-plus percent on this meth. It is no longer the homegrown meth. It is cartel meth that is so potent.

How are they partnering together to fight the epidemic in places like Montana?

Secretary AZAR. So, obviously the $4.8 billion that we have for the opioid crisis, there are major elements of that that deal with just broad substance use disorder. So as we, for instance, open up the door to our institutions for mental disorders—the IMD waiver procedure to allow for more than 15 beds in an inpatient facility—that is broadly applicable to substance use disorder and serious mental illness. And so that is helpful.

So many of our other programs here go in that direction. Now a lot of the grants, the State opioid response grants, are, of course, by Congress set to focus on opioid use. But again, the capabilities there and just the national focus on addiction and treatment, I believe help with meth also, although it is not directly targeted.

Senator DAINES. Yes, and I tell you the linkage of what is going on right now with meth in Montana and violent crime, it is stressing our systems across the State.

I want to shift gears, Secretary Azar. I know you have heard of the recent scandal involving Stanley Weber. He was a former Indian Health Service pediatrician who sexually abused Native

American boys on multiple Indian reservations, including the Blackfeet Reservation in Montana. Mr. Weber has been convicted in Montana. He faces additional charges in South Dakota for his unspeakable crimes. He has destroyed the lives of children he has abused. And despite repeated warnings signs, report of suspicions, IHS chose instead to turn a blind eye while Mr. Weber continued his horrific behavior for decades. It is a clear systemic breakdown of the worst nature.

Moving forward, Mr. Secretary, how will you ensure that all allegations against Indian Health Service employees are thoroughly investigated so that monsters like Mr. Weber are handled appropriately?

Secretary AZAR. Thank you for raising that, Senator. This situation, the conduct of course is unacceptable and intolerable. But the failure to root that out and deal with it in a timely manner is also unacceptable.

So we have two investigative measures under way. I have asked the Office of the Inspector General to look at the processes, procedures, and personnel involved as well as a systemic approach.

How can we ensure this does not happen again and have open systems of reporting? What, if anything, in our culture at the IHS allowed that to happen and go on and not be dealt with the way it should have been?

In addition, IHS is going through a procurement now to have an independent outside government entity do the same type of audit and evaluation, because I agree with you: there are cultural dimensions when something like this happens that have to be fixed. And Admiral Weahkee has been determined that not only those directly responsible, but those who may have allowed it to happen should also——

Senator DAINES. Thank you, Mr. Secretary.

In closing, I am going to be introducing the Jobs Act with Ranking Member Brady today to make needed reforms to the Temporary Assistance for Needy Families, the TANF program. It will bolster work requirements and help more families move from poverty to prosperity.

We have seen in the President's budget proposal, the President agrees that stronger work requirements must be a priority of this Congress. I look forward to working with you, Mr. Secretary, on this important issue.

Secretary AZAR. Absolutely. Thank you.

The CHAIRMAN. Senator Whitehouse?

Senator WHITEHOUSE. Thank you, Mr. Chairman.

Secretary Azar, I have given your staff the map that I showed you before the hearing. I have a copy of it here, but I think you will probably do better looking at it there.

This is an area that you know, because you used to live right down here. You did some time in New Haven, as I understand it.

Secretary AZAR. I did 3 years of time.

Senator WHITEHOUSE. If you go right up the road, up 95 here to Norwich, New London, you get to a Connecticut hospital called Backus Hospital. And of course, in New Haven you have Yale New Haven Hospital. Those hospitals have a 1.25-plus wage index.

And here is Westerly Hospital in Rhode Island. The distance from Westerly Hospital in Rhode Island to Backus Hospital in Norwich is about 12 minutes according to Google.

Westerley gets reimbursed at 1.04. There is a 20-percent differential in how the Connecticut hospital, 12 minutes away, is compensated compared to Rhode Island Hospital across our borders.

And, if you go to the other side, here is Saint Anne's Hospital in Fall River. Saint Anne's hospital is compensated at 1.35. And Saint Anne's hospital is 5 minutes from the Rhode Island border. Well, maybe 6 or 7, but it is very close to the Rhode Island border.

This is a labor market. People go across State boundaries to work in different hospitals. They go across the State boundaries to get service in different hospitals. For some patients and emergencies, you are quicker from Rhode Island to Saint Anne's than you are to Rhode Island Hospital.

So it boggles my mind why your organization is imposing a 20-percent hit on Rhode Island Hospital compared to its Connecticut neighbor 12 minutes away, and a 30-percent hit on Rhode Island compared to our neighbors there 6 minutes from our border. Some of this is baked into the system.

But just a few years ago, we had an imputed rural floor index that at least kept us at 1.15, 1.14 basically on average. We were still the least reimbursed State in this area, and your organization decided to punch our hospitals in the face with a 10-percent cut that you did administratively, that you did without any means for us to repeal it; that is entirely within your organization's discretion. And I would really like to have it fixed, because I do not think you could defend why Saint Anne's should be paid 30 percent more than Rhode Island Hospital, why Backus should be paid 20 percent more than Westerly Hospital.

With differentials that big, it affects the survivability of these hospitals. It affects their ability to pay for nurses and get the best hires to come and work for them at that lower rate. And of course, it is ridiculous when you think that the service area is completely overlapping.

So please, can you take a look at this? We have gotten hammered, I think, unfairly, unjustifiably, and without recourse.

Secretary AZAR. Thank you. I appreciate your concern and your passion for Rhode Island providers. And I do appreciate that you recognize so much of the absurd——

Senator WHITEHOUSE. We were already the cheapest. Why kick us in the face?

Secretary AZAR. And I appreciate that you recognize that so much of the absurdity of the wage index is baked into statute. We are going through a process now that we have opened—asked for comment on a revision to the whole wage index system.

Unfortunately, by statute——

Senator WHITEHOUSE. For the record, I have no confidence in the process. I have no confidence that it will lead to a result. I have no confidence that it will be done timely. I have no confidence in it whatsoever.

And I do not know what you are being told by your people, but I have zero confidence in that process producing anything resem-

bling a solution to this problem. And I do not know how you can defend a 30-percent differential from like 10 minutes apart.

Let me ask one other thing. I just have a few seconds.

There are States that are working on improving the nature and experience of end-of-life care, called Advanced Care. They run into problems with the 2-night 3-day rule. For a dying patient, that makes no sense. They run into problems with the curative-palliative boundary; that makes no sense with a dying patient.

And they run into problems with respite care rules where the respite is, you take granny and you have to drag her off to a hospital rather than bring in a home care worker to help. It would be cheaper, less disruptive, less painful for the family.

So I will follow up on this.

Secretary AZAR. Please do.

Senator WHITEHOUSE. But there is an opportunity here to offer waivers and let States compete to take advantage of those waivers. And States that are working with this population will be able to prove that they save money and they make a more humane and better family experience out of this particularly intimate time of life.

Secretary AZAR. We would be very happy to work with you on that. That all seems to be very common-sense as far as I can tell.

Senator WHITEHOUSE. From as far as I can tell too. Yes, sir. Thank you.

The CHAIRMAN. Senator Brown?

Senator BROWN. Thank you, Mr. Chairman.

Mr. Secretary, thank you for the progress you have made on tobacco. Given the Commissioner's recent announcement that he will be leaving, I would like to get your commitment to continuing those efforts, and I would really appreciate "yes" or "no" answers to the following five or six questions.

Will you commit to reducing nicotine in cigarettes to non-addictive levels?

Secretary AZAR. Absolutely. That is the nicotine rule that we will be working on. The Commissioner laid out an agenda on nicotine reduction in tobacco products, yes.

Senator BROWN. Will you commit to continuing efforts to prohibit menthol cigarettes and flavored cigars?

Secretary AZAR. We just, actually yesterday, announced a ban on flavored cigars that will go into effect once the guidance is effective. And I think within 30 days after that we would end enforcement——

Senator BROWN. And menthol cigarettes?

Secretary AZAR. And on menthol cigarettes we have initiated a process with an advanced notice of proposed rulemaking. The legal issues on withdrawal of menthol from tobacco are more complex. We need to go through a very stringent evidence process on that.

I am deeply concerned about menthol in cigarettes, but it is a trickier issue. But I am very concerned about the addictive nature of it, especially some of the recent studies about the attractiveness of menthol to certain subpopulations.

Senator BROWN. Thank you, and I appreciate those substantive answers. I need them shorter if they can be.

Will you continue to raise the alarm about youth use of cigarettes?

Secretary AZAR. Absolutely.

Senator BROWN. Will you commit to moving forward with the effort to restrict flavors in cigarettes and issuing a final guidance in a timely manner?

Secretary AZAR. Yes, on the e-cigarettes, the flavoring in e-cigarettes, yes. We will be driving that forward with full vigor. And the Commissioner's agenda—just to be very clear, his agenda on tobacco and cigarettes is my agenda.

Senator BROWN. Okay; good to hear that.

Will you commit to taking more aggressive action to protect kids from flavored e-cigarettes if the current proposal fails to reduce youth use of e-cigs?

Secretary AZAR. I think we were very clear that even if we see data this summer—with the next round of data that we may have to take even more aggressive steps.

Senator BROWN. And you, of course, will hold the next FDA Commissioner accountable on these important priorities?

Secretary AZAR. Absolutely.

Senator BROWN. Good.

Now I have questions that will be a little more difficult for you.

You have a copy of the HHS budget and brief in front of you. If you would turn to page 100, halfway down the page you propose implementing mandatory work requirements in Medicaid for able-bodied working-age individuals—mandatory work requirements in Medicaid for able-bodied working-age individuals.

The term "able-bodied adult" in this paragraph—can you please define it for me?

Secretary AZAR. I think it is a common-sense definition. We have used that in some of the waivers that we have already implemented, that we have approved for States. I believe it would be consistent with that.

I do not know that our budget actually laid out a definition——

Senator BROWN. I'm sorry, Mr. Secretary, to interrupt. "Common-sense definition" does not work. We have asked you in a hearing to define "able-bodied." You have not given a definition.

We have asked in QFRs as a follow-up to your confirmation. You have proposed a policy requiring every State to implement work requirements on a population that you still have not precisely defined. We need that definition.

Secretary AZAR. I would point you to the waivers that we have approved in, I believe eight States, on the definition of the individuals who would be subject to those community engagement requirements. The budget does not define that. It calls for Congress to act. That would certainly be a subject that we would work with Congress on if that were to move in Congress.

Senator BROWN. Well, help me understand who these able-bodied adults are. Does your definition of able-bodied adult include an individual suffering from addiction?

Secretary AZAR. It should not—non-elderly, non-disabled, non-pregnant working-age adults. And I think in all of the eight waivers that we have approved, we have excluded individuals who would be unable to work because of substance use disorder.

I believe that is the case. I cannot speak to what is in the budget proposal in terms of—I do not know that we have specified in detail as opposed to just the broad thematic approach of work requirements, community engagement requirements, and harmonizing those across all public welfare programs.

Senator BROWN. How about an able-bodied woman who gave birth less than 3 months ago?

Secretary AZAR. I believe, I just, you know, I want to respond to you in writing, because I do not want to accidentally—I do not want to give you an accidental reassurance on some of these details that I am afraid I do not have with me at the moment. But we will be glad to get you information on that.

Senator BROWN. An able-bodied person who is disabled?

Secretary AZAR. Disabled should—I believe I just said that the individual has to be non-disabled, is my information.

Senator BROWN. So is the sheer definition——

Secretary AZAR. How one is able-bodied, I believe it is sort of inherent in the definition on the able-bodied aspect here that they would be non-disabled is my understanding.

Senator BROWN. Now does your definition of "able-bodied adult" include a full-time home care worker who makes minimum wage, she qualifies for Medicaid, but she does not have the time to refile complicated and burdensome paperwork to demonstrate proof of employment on a monthly basis? If she does not, she gets kicked off.

Is that a person who is able-bodied?

Secretary AZAR. Any individual receiving free health care certainly ought to be able to supply information about their compliance with community engagement. That seems very little to ask for someone receiving free health care.

I would refer you to the exemptions that we have in our State plans, including the exemptions in the Arkansas plan. So if a beneficiary lives at home with his or her minor dependent children, 17 or under, they are exempt. If they are caring for an incapacitated person, they are exempt. If they are pregnant or 60 days postpartum, exempt; substance abuse disorder, exempt; any mental condition——

Senator BROWN. I hear that. I have to wrap up.

I appreciate it, Mr. Chairman. We have seen how work requirements in Arkansas have ripped coverage away from tens of thousands of Americans without any reportable increase in employment.

You admitted during testimony this week you do not know why the 18,000 individuals in Arkansas lost coverage. I will tell you why. It is because this administration has made a conscious decision—the opposite of dignity of work—has made a conscious decision to kick hard-working "able-bodied Americans" off their insurance coverage when they are unable to meet the paperwork and bureaucratic requirements, not as a way to improve employment rates or promote health, but as a way, ultimately, which your department is all about, to pay for permanent tax cuts for the rich.

That is the outcome of your policy. You have seemed to fit this definition so that you can do that.

The CHAIRMAN. Senator Hassan?

Senator HASSAN. Well, thank you, Mr. Chairman. And I want to thank you and the ranking member for having this hearing. And thank you, Secretary Azar, for being here.

Look, I have some concerns about the HHS budget that I will get to in a minute, but I want to start with one area where we have some real common ground, which is ending surprise medical bills. Surprise medical bills happen, as you know, when patients receive unexpected and often massive bills, often for receiving care that they did not realize was considered out-of-network.

I have been working with a bipartisan group of Senators to end this practice, including Senators Cassidy, Bennet, Young, and Carper from this committee. I understand that HHS is also interested in working on surprise medical billing, and some of our staff have already met with members of your team to discuss solutions to this issue. We appreciate those conversations.

Will you commit to continue working with our bipartisan group of Senators to address surprise medical billing?

Secretary AZAR. Absolutely. We are deeply committed to solving this problem, and I appreciate your and Senator Cassidy's leadership.

Senator HASSAN. Thank you.

And can we also count on HHS to provide timely technical assistance as we finalize our legislative proposals?

Secretary AZAR. Yes, absolutely.

Senator HASSAN. Thank you for that commitment.

I know I speak for our full working group when I say we look forward to finding a bipartisan solution to this issue.

Now, let us move on to the budget. I appreciate that this budget extends access to Medicaid for new mothers suffering from opioid use disorder and maintains funding for State opioid response grants, although we could really use more of that funding. Experts have said that it will cost hundreds of billions of dollars in sustained investment to address this crisis.

How much do you think it will cost over the next 10 years?

Secretary AZAR. In terms of the consequences of the opioid crisis?

Senator HASSAN. Providing treatment and further prevention recovery services, the kids who are affected, grand-families?

Secretary AZAR. You know, Senator, I want to do justice to such an important question. I do not—I could not give you an estimate of that. We did propose the $4.8 billion, the continuation of our bipartisan work together in the budget.

Senator HASSAN. And I understand that. Right.

And I am going to move on. I do not mean to be rude, but time is limited.

Because the real question is, do you really think that the funding in this budget is adequate to address the problem?

Secretary AZAR. I do believe that we are making progress. On every measure, we are making progress. It is going to be a long fight.

Senator HASSAN. Well, and that gets me to my next point. We did not get here to this point with this epidemic overnight. You and I have talked about that.

It is going to take years of sustained investment to truly turn the tide of the epidemic. Moreover, while I appreciate—as I have just

said—that there is funding specifically targeted toward combating the opioid crisis in this budget, the budget would also slash programs that are absolutely critical to fighting this crisis, as well as undermining critical health-care services for millions of Americans and thus, harm our efforts to combat this crisis.

So here is what this budget would do. It would lead to millions more being uninsured. It would cut and cap the traditional Medicaid program.

And for people who are not as familiar with that, not only does that impact an awful lot of people in nursing homes, it impacts some of our most vulnerable people who depend on Medicaid. And as we have a larger population of people who are surviving longer, happily, with very complex medical conditions, but who cannot work, that is really a devastating cut for them.

And this budget would end Medicaid expansion, which experts on the front lines of the opioid crisis have said is the number one tool at our disposal to combat the opioid epidemic. It certainly is in my State.

In States that have expanded Medicaid, as we did on a bipartisan basis in New Hampshire when I was Governor, hardworking people have better access to health care, including substance use disorder treatment that they need to live healthy, productive lives.

In the last year, States across the country, including deeply conservative ones, have voted by referenda to authorize Medicaid expansion in their States. So, why does this budget say to the millions of Americans who support Medicaid expansion, whose lives have been changed by Medicaid expansion, who voted for Medicaid expansion at the ballot box—why does this budget say to them, "Your voices do not matter"?

Secretary AZAR. So we replace the Medicaid expansion with a new $1.2-trillion grant program to States to actually allow your State and others to custom-design an insurance approach here that we think could allow a real focus on those populations that most need it, whether it is the traditional Medicaid populations of aged and disabled, pregnant women and children, those suffering from substance use disorder, as opposed to more the blunderbuss, "give Medicaid to anybody who happens to meet the income threshold."

You could actually allow a much more targeted, focused approach.

Senator HASSAN. And I——

Secretary AZAR. That is our philosophy.

Senator HASSAN. Yes, and I have seen some examples of folks trying to do that that have not worked. Medicaid expansion is working.

And I just will finish up to Senator Brown's point. There are a lot of people who got Medicaid coverage who had lost their jobs, let us say lost their health insurance coverage during the recession, then got sick because they could not get their medicine or could not get their treatment, and they could not work. Medicaid expansion coverage got them healthy again, and they are back at work. And then they are moving off of Medicaid into the private insurance market, which is exactly the trajectory we want.

I can tell you instance after instance in New Hampshire where being eligible for health-care coverage when you are struggling and

at some of the worst, most difficult times of your life has actually helped people back into the job market.

The work requirements, and this ending of Medicaid expansion, are totally counterproductive to that.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Thune?

Senator THUNE. Thank you, Mr. Chairman.

Mr. Secretary, thanks for being here. And I would like to associate myself with the comments I understand were made by Senator Daines regarding the IHS and this recent story about a provider out there being involved with some very criminal activities. And so I hope that you will work very, very hard to get to the bottom of that, and make sure that appropriate actions are taken to ensure not only that these people are brought to justice, but that this sort of thing never happens again.

And then there is a broader issue I would just like to ask you about, because you and I have had this conversation several times about the ongoing concerns with the quality of care of South Dakota Indian Health Service facilities. And while it is not a problem that can be fixed overnight, it is one that I expect the administration to be working on to address.

And unfortunately, facilities in South Dakota continue to be a significant issue. So what I would like to know is—and maybe you can speak and reiterate what you did earlier about the issue I mentioned at the beginning. But could you also talk about specific steps that HHS, I guess I should say, is taking to improve care at IHS facilities and what investments the proposed HHS budget makes toward that goal?

Secretary AZAR. Absolutely, Senator. Thank you.

And I will not, in the interest of time, repeat about Dr. Weber, but just the disgust and dismay that that happened, continued to happen, was not dealt with. And we are working to ensure we change the culture, and it would bring outside voices in to make sure we learn how to make sure that could not happen again. So just absolutely horrific; should not have happened.

We have prioritized in a budget that makes very difficult choices—we actually prioritize the IHS budget. We prioritized direct care delivery to our Alaska Native and American Indian patients.

We invest $5.9 billion in discretionary funding for IHS, which is an increase of $391 million above the continuing resolution level and $140 million above fiscal year 2019 enacted. Admiral Weahkee created the first-ever quality and oversight office directly under him, and I am actually surprised that it was the first time we had this. We were running a hospital system. We should have had a quality and safety, constant quality improvement culture and office around that. We have created that.

We have dedicated $58 million towards certification remediation, really focused on the South Dakota facilities that you have mentioned, to ensure a collaborative relationship and preparedness for working with CMS to make sure they are always meeting accreditation standards, so that they could have a leg up.

I think we have $10 million in our budget focused on recruiting and retention, because, of course, it is about getting quality individ-

uals into these facilities. The people always are the centerpiece that make the difference in it.

I have asked for external reviews, and we are, of course, open to any ideas you have on how we can improve the quality and safety performance. We owe that to any patient in our facilities.

Senator THUNE. Well, we have legislation that we have introduced up here that we hope eventually gets acted on—it is in the Indian Affairs Committee—which makes a number of reforms to IHS. That is something we have been working on for a long time.

But it just strikes me that we have got to come up with some new models, some new way of dealing with this, because it is just—intergenerationally, these problems do not get any better and in fact, worsen over time. And we have had some specific examples in emergency facilities in the last few years we had to shut down, just because there have been so many violations and areas where care, when it is being provided, is actually putting people at risk, and we are losing people as a result of this.

The IHS in its current form, incarnation, has just been a complete failure. And when it comes to taking care of the people whom they are tasked with caring for in Indian country—and I, for one, am certainly willing to entertain new ideas. I know there are some thoughts about perhaps getting providers, hospitals who are willing to come and serve some of our reservation and tribal communities under contract, but whatever it takes to just get out of this rut we are in and come up, literally, with a new model, a new way of delivering services that does justice to the people who live in our reservation communities.

I am certainly open to those, and I hope that you and your staff will be willing to entertain and look at new ways of tackling and addressing this challenge as well, because we are doing a disservice to people in Indian country. And that has got to change.

So I have a couple of other questions, Mr. Chairman, I would like to perhaps submit for the record. I know my time is up, but I certainly wanted to make those points about the IHS.

Secretary AZAR. And, Mr. Chairman, could I just clarify? I believe it is $8 million for recruiting and retention, not 10. I think I said 10.

And I appreciate your concern about the particular facilities, but I would like to—I just do not want to say I have seen it personally. There are so many dedicated men and women of the Indian Health Service who, in Alaska and the lower 48, do deliver high-quality care for people.

We have our challenges. We have our issues. We want to fix them, but I do want to say that we are a vital part of Indian communities. And the people are so dedicated. And we need to fix the problems, but I do want to respect those who are really doing the job so well.

Senator THUNE. And I think there are—I do not dispute that at all. I think there are some really terrific people who care deeply, and are trying to do a good job.

It just seems that, in our part of the country in the northern plains, in our tribal communities, they seem to be the exception rather than the rule there. And we have a really hard time not only recruiting, but retaining people in these communities.

So we need professionals who can go out and serve. And it is important that we provide the incentives, the right incentives to do that. We have legislation that would do that, and I know that you all are focused on it as well, but it has got to change.

Thank you.

The CHAIRMAN. Senator Lankford?

Senator LANKFORD. Thank you, Mr. Chairman.

Mr. Secretary, thank you for being here. Thanks for all the work that went into this.

I need to ask a couple of questions. You and I have spoken multiple times about DIR fees and that retroactive clawback process that has been so painful for independent pharmacies around the country as they are trying to be able to provide pharmaceuticals to people who need them, especially in rural areas.

You have done a proposed rule. Myself and several others have come in and backed you on that one. Can you give us any update on that, or where things are going with that rule?

Secretary AZAR. So that rulemaking, of course, is pending. I believe the comment period is closed, and so we are working on the final on that.

What that would do in the proposal is ensure that the patient is getting the full benefit of whatever the lowest reimbursement level from a pharmacy benefit manager to the pharmacy would be. As a result, we think that would—and I have heard from pharmacists—effectively change this retrospective DIR approach that is hurting so many community pharmacists.

Senator LANKFORD. And the rebates are not getting to the patient——

Secretary AZAR. They are not.

Senator LANKFORD [continuing]. At the end of the day. And so that is part of the challenge as well.

Last year, you and I spoke at, actually, an Appropriations hearing, and I was on this same song at that point with you as well, about DIR fees. You had mentioned that the Office of Inspector General, you were going to talk to them about doing a study on that one.

Do you have any updates on that study or a knowledge of the timeline?

Secretary AZAR. Yes. So that study is underway, and I believe it is close to being wrapped up and getting out.

Senator LANKFORD. Okay. That would be terrific.

Let me shift subjects with you. In your budget, you mentioned some reforms on 340B, trying to be able to help get towards more targeted low-income patients.

But there are not a lot of details on it. Can you help fill in the blanks for me a little bit about what you are thinking on 340B and that program?

Secretary AZAR. You bet. So first, we have asked for plenary regulatory authority for HRSA within the 340B program. We just are not able to actually regulate in that program right now. And we need the ability to do that to conduct appropriate oversight and ensure and demand transparency.

We have asked for a user fee program from the beneficiaries of the hospitals and entities that could benefit from the 340B program

to actually fund our work in providing that type of oversight. We also have asked that those entities that are taking advantage of the 340B program live up to their commitment to deliver charity care to individuals. By not sharing with them the savings from our drug pricing program, we have reduced the reimbursement and the spread that hospitals are getting in the drug program.

We have reduced that and saved seniors $320 million a year. But we have to plow those savings back to all facilities, and we, in the budget, have proposed that those savings should only go to facilities that are dedicating 1 percent, minimum, to charity care.

Senator LANKFORD. So, 1 percent is an exceptionally low threshold. I have heard that number thrown around a lot. What percentage of providers do you think are out there that could not meet the 1-percent threshold of charity care right now? Let us say they do charity care, but how many could meet a 1-percent threshold?

Secretary AZAR. I do not have that data. I fear that it is not all of them, which is rather astounding.

Senator LANKFORD. Right.

Well, that would be a concern, obviously, long-term. If you are saying you are doing charity care and cannot handle a 1-percent number, then you are not doing significant charity care, and we need to be able to discuss that.

Let me shift one more time to the biosimilar area. And I know that Senator Cornyn brought up some of these things, but I want to be able to drill down a little bit more on this.

Between the biosimilar program and a recommendation that is out there that your budget includes—a zero dollar cost sharing on generics and biosimilars for low-income beneficiaries in Medicare Part D—would that make sense to actually expand in the part B area as well?

Secretary AZAR. I have not studied that question, but we want to incent the adoption of biosimilars. Figuring out whether it is cost sharing or is it around provider reimbursement on biosimilars in Part B, I am happy to work with you on that.

Whatever it takes, we want to ensure that we can create a viable, profitable biosimilar industry here that shifts share to it the way we have done with the generic industry.

Senator LANKFORD. So there have been some concerns that the incentives currently in place, especially in the Part B world, are not to use the biosimilars, to do the biologic, and that there is a higher reimbursement amount and a higher reimbursement percentage in Part B for the biologic.

How does that get balanced out long-term? Where do you think that needs to go?

Secretary AZAR. So right, with Part B, because you get paid ASP, average sales price, plus 6 percent, if you have a higher price—which would be the branded product—you, the physician, get reimbursed more for using that drug than if you use a lower-cost biosimilar.

It is perverse. And we need to solve—that is a part of what we are proposing with our foreign reference pricing, the international pricing index model.

That is part of what we changed in the reimbursement model that we did in Part B in this administration to actually make bio-

similars more price-competitive against the branded product, not discriminated against.

Senator LANKFORD. Right.

There are some concerns—and Scott Gottlieb had mentioned he had some concerns that there was just noise in the marketplace between biologics and biosimilars, saying biosimilars do not live up to the standard. Many companies have both, but there is an intentional effort to try to make it noisier and seem like they are not as safe, biosimilars and such.

Do you perceive that in the marketplace as well?

Secretary AZAR. I perceive that, although increasingly the big pharma companies are actually getting into biosimilars.

Senator LANKFORD. They are doing both.

Secretary AZAR. So I think that will get mitigated over time.

The CHAIRMAN. Senator Casey?

Senator CASEY. Thank you, Mr. Chairman.

Mr. Secretary, thank you for being here. I appreciate the time that we spent recently with members of the committee talking about lowering drug prices. And I appreciate the work that both branches of government are trying to do.

You are a native of my home State, a Johnstown native who went to great schools and did well and now is serving in government. We are always happy to see a Pennsylvanian do well, and I say that not just for reference, but for connection to a series of questions I have on Medicaid.

As you might know, in our State—I think this is generally true in most States—but in Pennsylvania Medicaid is roughly a 40, 50, 60 program. Forty percent of the kids, 50 percent of people with disabilities—about half of anyone with a disability is covered by Medicaid—and the 60 is actually a lower number. It is actually a little higher than that. Seniors who are in a nursing home get the benefit of Medicaid.

In the 40 percent of kids covered by Medicaid in Pennsylvania, the number is even higher if a child has a disability. It is 60 percent of children with disabilities. So obviously, it is a huge concern to Pennsylvanians whenever we are talking about cuts to Medicaid, or even changes to Medicaid. It can be beyond disruptive for a family with a child with a disability.

You know as well that we have a lot of rural communities in our State. Forty-eight of the 67 counties are rural. A lot of them have rural hospitals that would be not just compromised, but a lot of hospitals would close if there are massive cuts to Medicaid.

I think, generally, across the country we found out in 2017 that Medicaid is not a "them" program. It is an "us" program. It is our kids who have disabilities. It is our seniors, our families.

The opioid epidemic, I think, focused people's attention on solutions. One of the solutions to good treatment was Medicaid expansion. Unfortunately, the budget proposal seeks to cut, not just to cut it, but to eliminate Medicaid expansion.

To give you a sense of what that means in Pennsylvania, we have more than 80,000 people, almost 81,000 at last count, who get treatment for mental illness or a substance use disorder circumstance. And that happens to be the category where opioid treatment finds itself.

When you look at counties in our State, your home county of Cambria County where Johnstown is, just think about it this way: 65 percent of the people in Pennsylvania got health care after the Affordable Care Act, sixty-five percent under Medicaid expansion. In Cambria County, it is 72 percent.

So to say that I and many others will fight these cuts with an unyielding passion is an understatement. We are going to fight this battle. We will fight your department. We will fight the administration. We will fight anyone, and we are going to win this battle.

So I would urge you and the President and the budget meisters to reconsider eliminating Medicaid expansion, to reconsider block-granting. And that leads me to my question.

First question: is Health and Human Services right now in conversations with or negotiations with any State regarding block-granting of Medicaid or per capita caps on Medicaid, which are very similar?

Secretary AZAR. So we have discussions with States where they will come in and suggest ideas like—I do not know about any, perhaps per capita, but there may be States that have asked about block-granting, per capita, restructurings around, especially, expansion populations.

Senator CASEY. So let me just stop you there.

Secretary AZAR. It is at their instigation.

Senator CASEY. Yes, the answer is "yes," you are having those conversations. Do you know how many States?

Secretary AZAR. I do not know exactly how many.

Senator CASEY. Would you commit, and I think you should commit—a little hint there—to inform us about those negotiations or conversations, but also to make the documents that pertain to those conversations and negotiations public?

Secretary AZAR. I do not think it would be proper. I think it would actually—it violates our ability to work with a Governor and a State as they try to consider different approaches to allow those interactions to be——

Senator CASEY. Well, here is the problem if you do not disclose that you are having those conversations or are not making the documents public. People who have a concern about block-granting Medicaid—and they are in the tens and tens of millions—do not know what is happening. They will find out about it after the ink is dry.

We need to know what is happening in those conversations, even if it is out of Pennsylvania, and if it is not. But we need to make sure that the documents are made public, and that folks out there who care about this program know that those conversations are taking place.

The CHAIRMAN. Senator Cassidy?

Senator CASSIDY. Thank you.

As I open up, Secretary Azar, I am going to kind of touch on several things my colleagues across the aisle have said.

First, will you clarify, there has been this number tossed around about Arkansas's work requirement dis-enrolling 15,000 people. Will you clarify that, please?

Secretary AZAR. Thank you. I really appreciate that.

So we had in Arkansas—under their waiver program, 18,000 individuals, approximately, did not comply with the work requirements. That means they did not submit the required forms, or they did not do the work.

We see churn like this in State Medicaid programs all the time, people coming in and out of the Medicaid program. Here is a key fact: only 1,000 of those 18,000 people appealed their disqualification based on compliance with community enrollment—only 1,000. Only 1,452 of those 18,000 people even reapplied for Medicaid when the open enrollment period came again.

That seems a fairly strong indication that the individuals who left the program were doing so because they got a job. This booming economy provided opportunities, and they have insurance elsewhere and did not need the Medicaid program.

We see this in Medicaid all of the time, and it is why enrollment nationwide in Medicaid is down.

Thank you for asking about that.

Senator CASSIDY. Yes.

Well, I will also point out, when you have record-low unemployment for high school dropouts, and record-low unemployment for people of color and veterans and women, it may be that people are moving into something which provides benefits, which is our goal.

Secondly, let me just talk a little bit about Medicaid. My colleague from Pennsylvania just talked about the per-beneficiary payment or per-capita cap, which, by the way, is how the Federal Employees Health Benefits program works. The insurance company gets a certain amount of money per enrollee based upon certain factors, and then they live within that.

It is a reform used by almost every single major insurance company, but we do not use it for Medicaid. I guess the importance of that is that Medicaid, as we know, is cannibalizing State budgets.

The ranking member spoke of his concern regarding this. I will point out that Oregon just had to pass a 6-year tax on hospital insurance plans and others to raise $430 million because the Medicaid budget is so expansive. And the Governor is exploring taxes upon employers.

At some point, everybody has to say, "Let us have a reform." I am not entirely sure I agree with where you are going with it, but I applaud you for acknowledging that Medicaid is just chewing up State budgets and the Federal budget, and we are not going to be able to treat patients if the program is not sustainable.

I say that as a fellow who for 25 years treated the uninsured in Medicaid. If the program is not sustainable, that is false compassion. I will just say that once more.

Now, let me ask you this kind of more mundane thing, if you will. I really like what you are doing with price transparency. But one of the pushbacks has been that that may not be meaningful to a patient. They are just wondering what they are going to be on the hook for.

Now I understand that there is a blue-button or a real-time benefit analysis piece of software that people can put on their smartphone and tap it, and immediately know what they are on the hook for when a procedure is ordered. But it has just not yet been deployed.

What is CMS's role in the deployment of that? And any holdups, and why the holdup?

Secretary AZAR. So the blue-button 2.0 approach actually gets you access through an API environment where other web designers can provide you access to your Medicare claims information.

The exciting new tool is actually the electronic real-time benefit tool that we have put in the Part D program, where we have proposed that you would actually, as a patient, be able to know before you walk into the pharmacy, and actually when your doctor is writing a prescription, what you would pay out of pocket for that drug, that you would have the right to know that information across the board. We want people to have the right to know what you would pay out of pocket before you go in.

Senator CASSIDY. So that will be Part D. I applaud that. Oftentimes, a physician does not know that.

Secretary AZAR. Absolutely.

Senator CASSIDY. So what about moving beyond Part D, and to oh, I am going to have my colonoscopy at the general hospital versus my colonoscopy at the ambulatory surgical center, because it is a lot less at the ambulatory surgical center.

So what about extending that beyond just drugs?

Secretary AZAR. So I am very interested in looking at that, and the Office of the National Coordinator's Interoperability and Information Blocking regulation is part of the proposal there. We actually asked for feedback on that question of moving towards that type of negotiated discount price transparency, so you know what you will pay out of pocket before you receive a service.

Senator CASSIDY. And any time frame as to when that might be executed?

Secretary AZAR. That would be the regular rulemaking processes. So it will take some time. We are in the comment period right now, which would be a 60-day comment period.

Senator CASSIDY. Okay.

Thank you, sir.

The CHAIRMAN. Senator Menendez?

Senator MENENDEZ. Mr. Secretary, I want to join my colleague from Rhode Island who earlier approached you on the question of the rule floor. This is a critical issue to us. This is the first administration in which we have not gotten at least an extension as we try to figure out a long-term solution to the problem. And it is unacceptable.

And so at this point, you know, we have tried the nice way. At this point, you know, we are going to have to look at what our options are on nominations and other things. So I just hope we can get there, and get there quickly, because there is a real consequence to New Jersey hospitals and to the people who have to attend them.

Let me just ask you this. A Federal judge in California has ordered the administration to take responsibility for all children who were separated from their parents at the U.S.-Mexico border and placed with relatives or sponsors after July 1st of 2017.

The order comes on the heels of a January Inspector General report of the Department that found there were thousands more children separated from their parents than the 2,800 that are already

acknowledged by the administration. Independent of the IG report, were you aware of other children who may have been separated, outside of the 2,800 reported to the Federal court?

Secretary AZAR. So HHS's ORR program always receives children who are separated, because DHS will set first—they are separated——

Senator MENENDEZ. I am talking in this time period. I am talking about this specific set of circumstances. I am not talking about generic——

Secretary AZAR. No, but that would be subject to the court's order. There are always children who are separated and sent to us by DHS because the—DHS checks on the putative parents. They find them not to be parents. They find the parents to have committed felonies that are covered by the TVPRA, or there may be another child welfare——

Senator MENENDEZ. Thousands were not sent because of felonies. Let us not get into that.

Secretary AZAR. And again, the IG speculated that there may have been thousands, not that they found them.

But what we are working with the court on is the question—every child that was in our care as of June 26th, the date of the court's order, was in the original class and is accounted for in terms of where they are and where the parents are, and reconnected, except we have four who remain to be connected, and that is because——

Senator MENENDEZ. When were you aware of those cases?

Secretary AZAR. Of which cases?

Senator MENENDEZ. Outside of the 2,800.

Secretary AZAR. Probably in the context of the IG's report mentioning that. But also I became aware later, in the course of these controversies, that there had been some efforts in 2017——

Senator MENENDEZ. So, before the IG's report, you were not aware?

Secretary AZAR. No, I am not saying that. I cannot remember when there was public reporting or discussion about the fact that DHS had done a pilot or pilots of a zero-tolerance referral policy that also led to separations.

I was not aware of that at the time. I was not at the Department for some of it, and then was not aware of it at the time.

Senator MENENDEZ. I am talking about the time period that you were in the Department, Mr. Secretary. I am not talking about some other time.

Can you submit to me in writing what are the exact steps that HHS is taking to ensure that these families that have been separated are identified and reunified?

Secretary AZAR. Well, here is what is important to remember. Almost every child whom we put through a sponsorship program goes to a relative. So these children were not in our care as of June 26, 2017.

They were placed with family members. And we will work with the court on appropriate procedures. If by chance there is a parent who is not connected with their child—I am not aware of it—but if there is, we will absolutely work to ensure that they are connected.

These kids should be with relatives under every circumstance.

Senator MENENDEZ. I will reiterate to you my request. You are great as a lawyer. I happen to be a lawyer too. I am not going to let you burn all my time.

My request is very simple. Will you submit in writing the exact steps that you are taking to ensure these families are identified and reunited?

Secretary AZAR. I believe that is possible, because it would be consistent with our status reports to the court.

Senator MENENDEZ. In February 2018, when you appeared before the House, you told Representative Castor that you would instruct HHS agencies to conduct gun violence research. Last year, the fiscal year 2018 Omnibus included clarifying language that the Dickey Amendment does not bar the Centers for Disease Control and Prevention from studying gun violence.

Is the CDC conducting gun violence research?

Secretary AZAR. So that is not, I believe, an accurate representation of what I actually said last year. What I said was what you unnecessarily, I think, clarified in the statutory language. I made it very clear that I saw nothing in the Dickey Amendment that would prevent or ban CDC from conducting research on violence, including gun violence research, and the CDC Director confirmed that.

Senator MENENDEZ. Let me get to my question. My question is very simple. Is the CDC conducting gun violence research?

Secretary AZAR. We need Congress to fund that, if Congress wishes to fund that. CDC does not have a bucket of money like the NIH does for just general R01 peer review projects.

Senator MENENDEZ. So the answer is "no." And then you need money. Is that it?

Secretary AZAR. If Congress wishes to fund gun violence research, we will faithfully implement it if it is funded at CDC. That is——

Senator MENENDEZ. Thank you.

Secretary AZAR. I am sorry, Mr. Chairman.

When I referred to the date of the court's order, I said June 26, 2018. I think I should have said June 26, 2017. It was June 26, 2018. I just wanted to be very clear.

The CHAIRMAN. Senator Cortez Masto?

Senator CORTEZ MASTO. Thank you.

Mr. Secretary, let me follow up on that. According to internal agency documents, HHS has received more than 4,500 complaints of sexual abuse of unaccompanied minors from 2014 to 2018. And almost 200 of these are contractor staff on minor allegations of sexual assault.

Disturbingly, the reports like this are not new. Please tell me what you are doing, and what the agency is doing, to ensure the safety of these children.

Secretary AZAR. Absolutely.

Any sexual misconduct or sexual abuse involving these children is absolutely unacceptable. Let us be very clear about that. And we need policies, procedures, training, everything to ensure that does not happen.

Over the last 4 years, including the previous administration—we get about a thousand allegations a year of sexual misconduct. That is three categories. One would be inappropriate sexual behavior. That could be one child saying something, a bad word to another child, sexual harassment, and then, of course, the core category of sexual abuse.

And as you mentioned, over 4 years, with I think 182,000 children in our care, we have received 178 allegations of potential sexual abuse between a staff member of a grantee and one of the minor children. Many of those proved to be unsubstantiated once investigated. And we will be, I think, in the next several weeks hopefully, reporting out some more information about the levels of substantiation there.

But we have put in place a Sex Abuse Prevention National Coordinator at ORR. We have a committee around that person. Every report of sexual misconduct must be reported within 4 hours. Sexual abuse must be reported to, as relevant, Federal, State, local law enforcement, and Child Protective Services authorities.

Where we find a substantiated finding, we take action on that. You know, there was the one instance that you may have seen the video of, the pulling of the hair, the video. Before that ever became public, we had swooped in, investigated that, worked with the State.

We shut down that facility, removed the kids. We shut down another facility of that grantee and removed the kids. And we stopped placement at six others of those facilities, wound those down. And now for those facilities to come back online, they actually will have to go through relicensing by the State licensing authority.

So, if you have ideas of ways we can do it better, I am all open. We want to ensure—one case is too many. Absolutely.

Senator CORTEZ MASTO. Thank you.

And so, for that reason, please provide me with the policies and protocols——

Secretary AZAR. We will.

Senator CORTEZ MASTO [continuing]. And what you are doing to ensure the safety, particularly of the contractors that you are working with as well, and how they are identifying the individuals that work for them——

Secretary AZAR. I will be very glad to do that.

Senator CORTEZ MASTO. Thank you.

Secretary AZAR. Thank you for asking about it. I think we all share the views that, if we can do anything better, we are open to any approaches and ideas to ensure that——

Senator CORTEZ MASTO. Thank you. I look forward to working with you further on that.

Let me jump back to the budget itself, because I do have concerns about repealing the ACA and replacing it with the Graham-Cassidy bill.

In the State of Nevada, under a Republican Governor, the Affordable Care Act has been an incredible benefit. We had the Governor create a Silver State Health Care Exchange. He expanded Medicaid. And because of that, the ACA had a bigger impact in rural areas in Nevada than it did in some of our cities. In fact, the uninsured rate among low-income Nevadans dropped by 28 percent in

rural Nevada, compared to a 19-percent drop in the uninsured rate in our State's metro areas.

So what policies in this budget would make up for the more than 10-percent increase in the number of rural Nevadans without health insurance if the ACA is to be repealed as this budget requests?

Secretary AZAR. So our proposal, and of course Congress would have to adopt it—it is a proposal—would be that we would take away the Medicaid expansion and the Affordable Care Act individual exchange programs, and actually replace them with a $1.2-trillion State-based grant program that would give the States tremendous flexibility to come up with approaches.

They would have to protect against pre-existing conditions, for instance, invisible or visible risk pooling, common-sense mechanisms——

Senator CORTEZ MASTO. So let me ask you this, because I appreciate that. In my State, we had already looked at the Graham-Cassidy bill. It does not support it. It does not help the State of Nevada. It does not address this.

So what flexibility are you giving to any of the Governors who have concerns about this change and the impact it is going to have to their State and their individuals living there? Is there flexibility?

Secretary AZAR. Well, of course, Congress would have to pass all of this that is proposed in the budget for there to be any need for that discussion. At this point, we are working with Governors and States under 1332 to just make things work.

I have granted seven reinsurance waivers so far to States.

Senator CORTEZ MASTO. I appreciate that, and I have seen that. And I know that is something the Governors had requested.

But the concern is, in particular, this block-granting and the cuts that is going to make to Medicaid.

And I echo my colleague, his concerns about the block grant and the impact in the communities. And listening to the Governors, they know better. They know better the impacts that they are going to have.

And so, I look forward to working with you on this. I know it is a challenge, but I think we should be listening to the people in those States that are really impacted by this. And I appreciate you being here today. Thank you.

Secretary AZAR. Thank you.

The CHAIRMAN. Senator Young?

Senator YOUNG. Welcome to the committee, Secretary Azar. I am so grateful for your hard work and thoughtfulness, and for the work of your team. I have really enjoyed working with you. So thank you.

Last week at the National Kidney Foundation's Kidney Patient Summit, you spoke about the burden that kidney disease places on both patients and the Medicare program, and how the administration is "going to look at how we can deliver more organs for transplants."

In the President's budget, I saw the administration is requesting more funding for HRSA's organ transplant program, but I do not see much else on transplantation. So that does concern me. There

are over 113,000 Americans currently waiting for a transplant in the United States.

According to recent reports, if HHS implemented system-wide reforms to our organ donation system, there is a potential to recover up to 28,000 more organs per year, saving thousands of lives and billions in taxpayer funds.

So, Mr. Secretary, my question for you is, what is the administration planning on doing in terms of increasing transplantation?

Secretary AZAR. Well, Senator Young, thank you for your leadership on the issue of transplantation. It is a commitment shared by the President. He is deeply concerned about increasing organs available for transplantation. And if you have suggestions on ways, either through legislation or administrative practice, that we can improve the availability and supply of organs, we are glad to work with you on that.

One of the things that I announced that we want to work on in kidney transplantation in particular is ruling more kidneys in as available. You know, the last time the rules were set for acceptability of kidneys, it was in an era before, say, we had hep C treatments, just to give you one example.

Senator YOUNG. Yes.

Secretary AZAR. So we rule out organs, and we rule out donors, perhaps, all too fast. We need to update that, and we are going to update that.

We have also got to improve our living donor programs. We need to think about appropriate ways that we can support living donors who are giving into the system. So whether that is wages or health care or other benefits that are appropriate, we are looking at that and look forward to any ideas you have there.

Senator YOUNG. Well, I am glad you have ideas that you just volunteered to me. We do have some additional systemic ideas that we have pulled together from different stakeholders. I would like to dialogue in the future with you and your team about those. Perhaps some of them can be implemented.

Are there any additional tools that you need from Congress in order to implement the things you just mentioned to me, or to implement other reforms in this area?

Secretary AZAR. We might, especially around the issue of supporting donors, because of the valuable consideration requirements that were put in for the right reason, of course, to prevent the buying and selling of organs. But we do need to look and see whether any of our statutory provisions get in the way of good commonsense approaches to support individuals who are kind enough to basically do a living donation.

Senator YOUNG. Okay. Thank you, Mr. Secretary.

Earlier this year, CMS announced it had decided to recertify LiveOnNY, which is a federally certified organ procurement organization, despite persistent under-performance for decades. This decision comes after CMS had announced in June of last year that they would not recertify the Organ Procurement Organization for continued poor performance.

LiveOnNY's poor performance is nothing new. The organization was first faced with decertification by CMS in 2014 for failing to meet performance requirements, but was later recertified anyway.

So this goes back pre-Trump administration. It goes back a number of years. The organization's leadership and its trade association then admitted that the CMS performance measures were "self-reported and unaudited" and that the "accuracy and consistency of OPO data cannot be assured."

So the current OPO data and evaluation systems have allowed LiveOnNY and other OPOs around the country to evade any meaningful oversight or remediation, leaving patients waiting for life-saving organs that may never come. This has impacted me and some of my friends personally, Mr. Secretary.

So does HHS have the systems in place to objectively evaluate OPO performance or to enforce a decertification when appropriate? And to be clear, when I say it has impacted me, it has impacted people I know.

But do you have systems in place to objectively evaluate performance?

Secretary AZAR. So we do regularly survey our Organ Procurement Organizations to determine compliance with our regulations. We hold them accountable for failure. And where there is failure, they do need to come up with corrective action plans and bring themselves into compliance.

But if there are approaches that we can use to tighten up our oversight of OPOs and ensure higher-level performance, we would always be willing to work with you and have those or seek legislation that would give us the authority to impose those.

The CHAIRMAN. Senator——

Senator YOUNG. So just to close—and thank you, Mr. Chairman.

The CHAIRMAN. Please, go ahead quickly.

Senator YOUNG. I would recommend, respectfully, Mr. Secretary, that HHS consider changing CMS performance metrics by which OPOs are evaluated to make the criteria objective and verifiable.

Thank you.

The CHAIRMAN. Senator Scott?

Senator SCOTT. Thank you, Mr. Chairman.

And, Mr. Secretary, thank you for being here this morning, or this afternoon at this point.

I want to associate myself with Senator Young's comments as they relate to liver transplants and to recognize the important fact that both the southeast, as well as the Midwest, are places where the donation rate is very high, and the current system has provided for us to have the resources necessary, the organs necessary, to meet the needs in our regions.

And changing that system could be to the detriment of the very regions that produce the highest donation rate. So I want to associate myself with those comments.

I would also like to say "thank you" for the waiver for Miracle Hill Adoption. There is no doubt that, as the ranking member will have a chance to speak after I am finished, he may have a different opinion than I on this topic.

It is incredibly important. There is nothing more American than religious liberty. To allow for adoption agencies in every State to practice and to adhere to their core principles and to participate in the adoption space is critical. It is essential. And at the same time, we recognize that people of different faiths have adoption agencies

that will be able to take advantage of such a waiver, if the waiver is given to other States. This is a good thing.

I think what you all have done is reinforce the primary premise of what helped found this Nation of religious liberty. The important space in the adoption arena only makes it more valuable because of the number of kids who would be negatively impacted without the waiver that you have given to South Carolina, to Miracle Hill.

I am trying to create a little insulation as I finish my comments on this issue before my ranking member has a chance to try to dissect it and have a different take on this. But without any question, religious liberty in the adoption space is essential to placing more kids in good homes in this Nation.

So what you have done is help kids around this country, and specifically in South Carolina, and hopefully we become a model for other States who would seek such a waiver.

On the sickle cell disease front, I had a chance last week to meet with Dr. Collins, who had some exciting news. And he told me to do what I have not done in a very long time, watch more TV.

He suggested that on "60 Minutes" there was going to be an amazing report about new therapies coming forward in the sickle cell space, in the rare disease space. I think that the excitement in his voice and the optimism about the future as it relates to rare diseases, it was palpable. I hope that as we move forward, what we will see from HHS are the type of resources necessary for folks who are disproportionately on Medicaid—who have sickle cell—having access to the therapies.

And so my question is, does your agency have the tools and authorities needed to leverage new and innovative payment models for drugs that provide a cure for certain conditions, specifically conditions like sickle cell disease?

Secretary AZAR. You know, it is a very insightful question. We are all excited about that story we saw on "60 Minutes." We are excited about the research that we are seeing by the pioneers at NIH.

I think Dr. Collins and I are both convinced that, within the next 5 years, we may literally see a cure for sickle cell anemia.

Senator SCOTT. Fantastic.

Secretary AZAR. But—and for other gene therapies—it will come at a cost.

Senator SCOTT. Absolutely.

Secretary AZAR. And it will be a big cost. And I do not think our systems are well-adapted to, say, million-dollar curative therapies, or half-a-million-dollar curative therapies.

And I would love to work with Congress on approaches to deal with that. We have some authorities. We will certainly use them as best we can to deal with that, but this is a major challenge, these types of very expensive curative therapies that will come. And our system was not built for that.

Senator SCOTT. No, it was not.

I will say that, having had a relationship with the Medical University of South Carolina, which has done a really good job of treating patients, particularly youth with sickle cell, the lifetime expense of the disease would be reduced substantially if we could figure out a model for the disease up front, eliminating it.

I will close with my last seconds on the issue of DSH payments. I am sure you are aware that, with the new model coming out, the cuts in the DSH payment could have a catastrophic impact on States like South Carolina, where we could see a 34-percent cut in payments to our State.

I hope that you guys will take a closer look at the model that you will use to spread the cuts that will be seen around the country and that have a profound impact on our State.

Secretary AZAR. Thank you, Senator.

Senator SCOTT. Thank you, Mr. Secretary.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Cardin?

Senator CARDIN. Thank you, Mr. Chairman.

Secretary Azar, welcome. It is always good to have you here.

This is a hearing where we get a chance to, at least, understand and express our concerns in regards to the President's budget. And I do recognize Congress has a reputation for expressing its own views on the budget. We do not always follow the President, but I think the President's budget is extremely important, because it does express priorities of the administration.

So let me just raise a couple specific budget issues so you know my views. To me, the Medicaid cut is outrageous.

I have served in the State legislature. I know the pressures on State budgets. Turning this over to a block grant, removing the expansion of Medicaid under the ACA, it is going to have a major impact on health care among Marylanders who are the most vulnerable, our seniors, and it will nationwide.

So I do not want this hearing to go by without you understanding how deeply concerned I am about the Medicaid cuts.

I feel the same on the Medicare side. And you try to connect the Medicare cuts to some specific policies that I do not think are going to work, and I just really raise those issues.

On the Medicaid budget, for one moment, I just really want you to follow up on this, because I do believe we probably had the same view on this. And I think the budget may be inconsistent.

I am worried about the proposal running counter to the prudent layperson standard in regards to emergency health care. We have long established through law and through practice and Medicaid and Medicare that if you should go to the emergency room because of your symptoms, then you will be reimbursed under the private health insurance or government health insurance.

And yet, you are looking at waiver authority in regards to copayments for emergency room care that is not needed. I want to make sure that does not run afoul of the prudent layperson standards. And I would just urge you to make sure that is the case.

I think we have an agreement. I do not think we will be in disagreement there. But the way the rules can be interpreted—when someone has chest pain, sweating, et cetera, thinks he is having a heart attack, then ends up now having to pay a higher copay because he did not have a heart attack, and then realizes maybe he should have had a heart attack in order to get his bills paid.

So I have just hope that we could follow up on that issue.

Secretary AZAR. I am happy to. As you describe it, I suspect we would be in alignment in thinking about the common-sense approach and application there. But I am happy for us to follow up on that together.

Senator CARDIN. I appreciate that, because, again, some of the technicians can run afoul of some of our policies, so that is helpful.

I quite frankly do not understand the philosophy for the National Institutes of Health, NIH cut that is in this budget. The last time I checked, I think it was one out of 10 or one out of 11 worthwhile projects at NIH that are being funded. It is so exciting, the work that they are doing in regards to health-care outcomes and saving us money long-term, better quality life, et cetera.

It also leads to a lot of private-sector activity, which is good for our economy. What was the rationale for the NIH cut?

Secretary AZAR. So, as I said in my opening statement, the cuts here are difficult, and they are from an overarching budget environment of trying to achieve the caps deal that Congress and President Obama struck for the 2020 year's caps.

We, as a very large discretionary budget, as well as with NIH being the largest portion of our discretionary budget, we got a 12-percent cut across our department on discretionary. We applied that to NIH with 12 percent, tried to wall off opioids and opioid research as well as the pediatric cancer initiative.

But we all value NIH. We value the work. I am sure we can economize if Congress were to work with the administration on a change in overall caps or Congress takes a different approach. We are obviously going to work with you on that.

Senator CARDIN. And I accept that explanation, which means it is illogical, your cut, and you will work with us to make sure that we not only restore that, but provide some additional funding for NIH.

So I appreciate your honesty in that answer. And I will interpret it the way—— [Laughter.]

Secretary AZAR. That would not be my interpretation. I support the proposal that we have——

Senator CARDIN. I hear you. I think I will quit while I am ahead on that exchange, and I am going to declare victory.

In regards to one last issue, I raise the issue of restrictions on the title 10 grant programs as they relate to family planning and preventive health care.

There have been areas where we understand the administration's position in regards to restrictions on abortion. We do not necessarily agree with that, but I would hope that we could reach an accommodation on family planning and preventive health care where common-sense policies need to be in place at the Federal level in order to make sure women can get the health care that they need and deserve. And I look forward to working with you on this issue, and hope that we can reach some better accommodation.

Thank you, Mr. Chairman.

Senator SCOTT [presiding]. Thank you, sir.

Ranking Member Wyden, please.

Senator WYDEN. Thank you, Mr. Chairman.

Mr. Secretary, on the foster care front, I think we are working to really up our game on Family First, and your folks have reached out, and I appreciate that.

We have a problem on this other issue with respect to South Carolina. And I think anybody who is watching this knows that one of my favorites here in the United States Senate is Senator Scott. And he and I really like to find common ground, not spend our day shouting at each other.

I just want to make sure everybody understands what concerns me so much about what is going on in South Carolina. I think Senator Scott made an important point. He said, "Nothing is more American than religious liberty." I surely agree with that.

Nothing also is more un-American than religious discrimination. And that is what I believe is going on with this Miracle Hill program in South Carolina.

Now, the administration has initiated this effort by allowing taxpayer-funded faith-based foster care agencies in South Carolina to cite religious beliefs as justification for denying foster children placements in safe and loving homes.

Senator Scott, Mr. Chairman, if I could just place those documents in the record, that would be good.

Senator SCOTT. Yes.

[The documents appear in the appendix beginning on p. 183.]

Senator WYDEN. Great.

And so my question to you, Mr. Secretary, is, do you think placing a Jewish foster child in a Christian home that teaches the child everything he or she believes is wrong is the best placement for that child?

Secretary AZAR. Of course, we do not support any restriction on placement of children. But what we do support is, these children need to find homes, and we support as many providers as possible being engaged. And faith-based providers are the bedrock of some of our most difficult placements in terms of disabled, hard-to-place children.

They always historically have been, and that is why the Roman Catholic Diocese of Charleston as well as the Coalition for Jewish Values supported the accommodation that we provided at the request of the Governor of South Carolina. It was not at our initiation. It was at the Governor's request to provide this exemption, this waiver to allow them to continue to work with co-religionists.

It is not an animus towards any group or other entities or individuals. And in fact, they are required—if they cannot work with individuals who come forward, this Miracle Hill organization, they would be required to refer those individuals to the State placement foster care authority or two other foster care providers, of which there are many in the State of South Carolina, who would be willing to work with them.

Our focus is on the kids and child welfare. And we need more people as foster parents, not fewer, not excluding based on our views, but rather including.

But I appreciate your concern. This is about these balances.

Senator WYDEN. Well, that is not the experience, for example, of Jewish parents in South Carolina. We got a press story from a Ms. Beth Lesser saying that she was the only Jewish person at one of

these orientation sessions, and she said it was humiliating to essentially be told, Christian's over here, Jewish folks somewhere else.

And Senator Scott, when I am done, is going to make a good suggestion in my view, which is that nobody is shouting around here. And I have enormous respect for Senator Scott, and he and several of our colleagues would like to have thoughtful discussions about this and would be happy to include you.

I just will tell you, I am very troubled about this because I am a Jewish kid, first-generation Jewish kid. If my parents had been killed in an automobile accident, in South Carolina I might have been placed in one of these homes where everybody would tell me everything I learned was wrong. So we've got to do better here.

Let me just do something for the record really quickly. Then I think Senator Scott is going to make a suggestion that I very much like.

Last night we got, late in the evening, a response to a letter I sent you detailing potential conflicts of interest involving members of the federal pain task force. And I will just tell you I felt that the letter was very insufficient. I am concerned about individuals and organizations we are looking into having substantial financial ties to opioid manufacturers.

I would like you to tell me this morning—and I will put this in the record so you have a copy—that you will commit to giving me individual detailed answers to the nine questions within 10 days, because we just got something last night, and it was not even close to responsive to the questions.

Can I have that commitment that we will get answers in 10 days?

Secretary AZAR. I have not seen the incoming or the outgoing. I was aware of the issue, but I do not know the scope and breadth of the request. I can assure you I will talk to the team and see what we can get you and as quickly as we can.

I just cannot make that commitment, not knowing the incoming or the outgoing. We will get you as much as we can as quickly as we can.

Senator WYDEN. We share a bipartisan concern about opioids. It is going to be a lot harder to tackle the scourge of opioids if we just sit back and let rampant financial conflict drive so many of these decisions. So I need answers, and I hope—I understand that you are not up on the substance. I hope I will get them back within 10 days. We gave you all a lot of time originally.

Senator SCOTT. Thank you, sir.

Secretary AZAR. Mr. Chairman, could I beg your indulgence?

When one is giving these remarks—I want to make sure. There was an exchange with Senator Menendez, and I just wanted to make sure to clarify because——

Senator SCOTT. Certainly.

Secretary AZAR [continuing]. When one is speaking quickly or getting interrupted, and I just—on the *Ms. L* class expansion, which is the court proceeding in San Diego that we are subject to, the Joint Status Report that HHS filed with the court reports on children who were in our custody as of June 26, 2018. I think I said that, but I just want to be clear about that, that we are not at this

point gathering data on the expanded class because the court has not yet ordered a remedy.

While the court expanded the class, it has not ordered a remedy. And the court is considering what the appropriate remedy for that new class is because none of those children is currently in our custody.

I think I said that, but I've got a lot of people who watch just to make sure. I always want to be completely accurate and make sure the Senators are getting—that I do not accidentally misstate something.

So I appreciate your indulgence.

Senator SCOTT. Thank you.

One comment on Senator Wyden's comments. I think there is a chance for people of good conscience, be it Senator Lankford, myself, Senator Wyden, and others to sit down and have a conversation about religious liberty at the adoption space, and how we move forward.

I do think it is important for us to recognize the important truth in this country, that when it comes to religious liberty and government funding, whether it is Pell Grants going to private schools that have a religious affiliation or child-care programs that have a religious affiliation, or the workplace that has religious affiliation, the one thing that we have always done as a Nation is to protect folks and their worship and their ability to practice their faith and their principles as they see fit.

With 4,000 kids in South Carolina in foster care, we should not discriminate against a religious group because they want to adhere to their core convictions. I think that is incredibly important.

I will make a statement by Chairman Grassley that he wanted—I'm sorry?

Senator WYDEN. Could I just respond really quickly for a wrap-up on that?

Senator SCOTT. Certainly.

Senator WYDEN. Again, I very much welcome this idea of a discussion with Senator Scott, myself, Senator Lankford.

I want people to know, though, what Jews who want to be foster parents in South Carolina are facing at Miracle Hill. During the orientation, Ms. Beth Lesser was asked her religion. She was told she could not work with Miracle Hill because it placed children only with people who were Evangelical Christians.

Senator SCOTT. And, Senator Wyden, I do not want to go back and forth on this topic, but I will say that it is critically important for us to recognize that the Coalition of Jewish Values agreed with the exception, and this will be a conversation we will have to have on another day.

Let me just close with the comments from Chairman Grassley relating to unaccompanied children. This is from his written statement that I wanted to read before you left.

"A number of my colleagues have pointed out their concerns about recent reports that employees at HHS facilities have sexually and physically abused unaccompanied migrant children in their care.

"Let me be very clear, any sexual misconduct—any sexual misconduct—especially that involving vulnerable children at government facilities, is unacceptable and horrific.

"According to reports, this has gone on as far back as 2014. Regardless of the administration, Congress takes this issue seriously and will hold the government accountable.

"That is why I"—Senator Grassley—"along with Senator Feinstein have now sent two letters to HHS and the Inspector General calling for an immediate investigation. We sent our first letter in July, and just again last week.

"I expect answers and a full investigation. If the abuse has been perpetrated by contractors, they need to be fired immediately and their contracts terminated.

"Secretary Azar, I appreciate your attention to this issue, and I expect your agency's continued cooperation with our oversight efforts. 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, March 28th.

With that, this hearing is adjourned.

[Whereupon, at 12:32 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

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

The mission of the U.S. Department of Health and Human Services (HHS) is to enhance and protect the health and well-being of all Americans by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services. This work is organized into five strategic goals, and is unified by a vision of our health-care, human services, and public health systems working better for the Americans we serve. By undertaking these efforts in partnerships with States, territories, tribal governments, local communities, and the private sector, we will succeed at putting Americans' health first.

Since I testified before this committee in 2018, the HHS team has delivered impressive results. This past year saw HHS, the Department of Labor, and the Department of Treasury open up new affordable health coverage options, at the same time the Affordable Care Act (ACA) exchanges were stabilized, with the national average benchmark premium on *HealthCare.gov* dropping for the first time ever. According to a report by the Council of Economic Advisers, actions taken by the administration, along with the elimination of the individual mandate penalty, are estimated to provide a net benefit to Americans of $453 billion over the next decade.

Congress worked with the administration to deliver new resources for fighting the opioid crisis, allowing HHS to make more than $2 billion in opioid-related grants to States, territories, tribes, and local communities in 2018. Prescriptions for medication-assisted treatment options and naloxone are up, while legal opioid prescribing is down. HHS also worked to bring down prescription drug prices, including by setting another record for most generic drug approvals by FDA in a fiscal year and working with Congress to ensure pharmacists can inform Americans about the lowest-cost prescription drug options.

The President's fiscal year (FY) 2020 budget supports HHS's continued work on these important goals by prioritizing key investments that help advance the administration's commitments to improve American health care, address the opioid crisis, lower the cost of drugs, and streamline Federal programs, while reforming the Department's programs to better serve the American people.

The budget proposes $87.1 billion in discretionary budget authority and $1.2 trillion in mandatory funding for HHS. It reflects HHS's commitment to making the Federal Government more efficient and effective by focusing spending in areas with the highest impact.

HHS's fiscal year 2020 budget reflects decisions not just to be prudent with taxpayer dollars, but also to stay within the budget caps Congress created in the budget Control Act. With the largest non-defense discretionary appropriation of any cabinet agency in 2019, HHS must make large reductions in spending in order to stay within Congress's caps, set a prudent fiscal course, and provide for other national priorities. This budget demonstrates that HHS can prioritize its important work within these constraints, and proposes measures to reform HHS programs while putting Americans' health first.

REFORM, STRENGTHEN, AND MODERNIZE THE NATION'S HEALTH-CARE SYSTEM

Reforming the Individual Market for Insurance

The budget proposes bold reforms to empower States and consumers to improve American health care. These reforms return the management of health care to the States, which are more capable of tailoring programs to their unique markets, increasing options for patients and providers, and promoting financial stability and responsibility, while protecting people with pre-existing conditions and high health-care costs.

The budget includes proposals to make it easier to open and use Health Savings Accounts and reform the medical liability system to allow providers to focus on patients instead of lawsuits.

Lowering the Cost of Prescription Drugs

Putting America's health first includes improving access to safe, effective, and affordable prescription drugs. The budget proposes to expand the administration's work to lower prescription drug prices and reduce beneficiary out-of-pocket costs. The administration has proposed and, in many cases, made significant strides to implement bold regulatory reforms to increase competition, improve negotiation, create incentives to lower list prices, reduce out-of-pocket costs, improve transparency, and address foreign free-riding. Congress has already taken bipartisan action to end pharmacy gag clauses, so patients can work with pharmacists to lower their out-of-pocket costs. The budget proposes to:

- Stop regulatory tactics used by brand manufacturers to impede generic competition;
- Ensure Federal and State programs get their fair share of rebates, and enact penalties to prevent the growth of prescription drug prices beyond inflation;
- Improve the Medicare Part D program to lower seniors' out-of-pocket costs, create an out-of-pocket cap for the first time, and end the incentives that reward list price increases;
- Improve transparency and accuracy of payments under Medicare Part B, including imposing payment penalties to discourage pay-for-delay agreements; and
- Build on America's successful generic market with a robust biosimilars agenda, by improving the efficient approval of safe and effective biosimilars, ending anti-competitive practices that delay or restrict biosimilar market entry, and harnessing payment and cost-sharing incentives to increase biosimilar adoption.

Reforming Medicare and Medicaid

Medicare and Medicaid represent important promises made to older and vulnerable Americans, promises that President Trump and his administration take seriously. The budget supports reforms to make these programs work better for the people they serve and deliver better value for the investments we make. This includes a plan to modernize Medicare Part D to lower drug costs for the Medicare program and for Medicare beneficiaries, as well as proposals to drive Medicare toward a value-based payment system that puts patients in control. The budget also provides additional flexibility to States for their Medicaid program, putting Medicaid on a path to fiscal stability by restructuring its financing, reducing waste, and focusing the program on the low-income populations Medicaid was originally intended to serve: the elderly, people with disabilities, children, and pregnant women.

Paying for Value

The administration is focused on ensuring Federal health programs produce better care at the lowest possible cost for the American people. We believe that consumers, working with providers, are in the best position to determine value. The budget supports an expansion of value-based payments in Medicare with this strategy in mind. That expansion, along with implementation of a package of other reforms, will improve quality, promote competition, reduce the Federal burden on providers and patients, and focus payments on value instead of volume or site of service. Two of these reforms are: (1) a value-based purchasing program for hospital outpatient departments and ambulatory surgical centers; and (2) a consolidated hospital quality program in Medicare to reduce duplicative requirements and create a focus on driving improvements in patients' health outcomes. Advancing value in Medicare, along with the other reforms in the budget, will extend the life of the Medicare trust fund by 8 years, while also helping to drive value and innovation throughout America's entire health system. Furthermore, in December the administration released a report entitled *Reforming America's Healthcare System Through*

Choice and Competition, which contains a series of recommendations to improve the health-care system by better engaging consumers and unleashing competition across providers.

PROTECT THE HEALTH OF AMERICANS WHERE THEY LIVE, LEARN, WORK, AND PLAY

Combating the Opioid Crisis

The administration has made historic investments to address opioid misuse, abuse, and overdose, but significant work must still be done to fully turn the tide of this public health crisis. The budget supports HHS's five-part 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 provides $4.8 billion to combat the opioid overdose epidemic. The Substance Abuse and Mental Health Services Administration (SAMHSA) will continue all opioid activities at the same funding level as FY 2019, including the successful State Opioid Response Program and grants, which had a special focus on increasing access to medication-assisted treatment—the gold standard for treating opioid addiction. At this level, the budget also provides new funding for grants to accredited medical schools and teaching hospitals to develop substance use disorder treatment curricula.

In FY 2020, the Health Resources and Services Administration (HRSA) will continue to make investments to address substance use disorder, including opioid use disorder, through the Rural Communities Opioid Response Program, the National Health Service Corps, behavioral health workforce programs, and the Health Centers Program.

Medicare and Medicaid policies and funding will also play a critical role in combating the opioid crisis. The budget proposes allowing States to provide full Medicaid benefits for 1 year postpartum for pregnant women diagnosed with a substance use disorder. The budget also proposes to set minimum standards for Drug Utilization Review programs, allowing for better oversight of opioid dispensing in Medicaid. Additionally, it proposes a collaboration between the Centers for Medicare and Medicaid Services and the Drug Enforcement Administration to stop providers from inappropriate opioid prescribing.

The Ending HIV Epidemic Initiative

Recent advances in HIV prevention and treatment create the opportunity to not only control the spread of HIV, but to end this epidemic in America. By accelerating proven public health strategies, HHS will aim to reduce new infections by 90 percent within 10 years, ending the epidemic in America. The budget invests $291 million in FY 2020 for the first phase of this initiative, which will target areas with the highest infection rates with the goal of reducing the number of new diagnoses by 75 percent in 5 years.

This effort focuses on investing in existing, proven activities and strategies and putting new public health resources on the ground. The initiative includes a new $140-million investment in the Centers for Disease Control and Prevention (CDC) to test and diagnose new cases, rapidly link newly infected individuals to treatment, connect at-risk individuals to Pre-Exposure Prophylaxis (PrEP), expand HIV surveillance, and directly support States and localities in the fight against HIV.

Clients receiving medical care through the Ryan White HIV/AIDS Program (RWHAP) were virally suppressed at a record level of 85.9 percent in 2017. The budget includes $70 million in new funds for RWHAP within HRSA to increase direct health-care and support services, further increasing viral suppression among patients in the target areas. The budget includes $50 million in HRSA for expanded PrEP services, outreach, and care coordination in community health centers. Additionally, the budget also prioritizes the reauthorization of RWHAP to ensure Federal funds are allocated to address the changing landscape of HIV across the United States.

For the Indian Health Service (IHS), the budget includes $25 million in new funds to screen for HIV and prevent and treat hepatitis C, a significant burden among persons living with HIV/AIDS. The budget also includes $6 million for the National

Institutes of Health's regional Centers for AIDS Research to refine implementation strategies to assure effectiveness of prevention and treatment interventions.

In addition to this effort, the budget funds other activities that address HIV/AIDS including $54 million for the Minority HIV/AIDS Fund within the Office of the Secretary and $116 million for the Minority AIDS program in SAMHSA. These funds allow HHS to target funding to minority communities and individuals disproportionately impacted by HIV infection.

Prioritizing Biodefense and Preparedness

The administration prioritizes the Nation's safety, including its ability to respond to acts of bioterrorism, natural disasters, and emerging infectious diseases. HHS is at the forefront of the Nation's defense against public health threats. The budget provides approximately $2.7 billion to the Public Health and Social Services Emergency Fund within the Office of the Secretary to strengthen HHS's biodefense and emergency preparedness capacity. The budget also proposes a new transfer authority that will allow HHS to enhance its ability to respond more quickly to public health threats. Additionally, the budget supports the government-wide implementation of the President's National Biodefense Strategy.

The budget supports advanced research and development of medical countermeasures against chemical, biological, radiological, nuclear, and infectious disease threats, including pandemic influenza. The budget also funds late-stage development and procurement of medical countermeasures for the Strategic National Stockpile and emergency public health and medical assistance to State and local governments, protecting America against threats such as anthrax, botulism, Ebola, and chemical, radiological, and nuclear agents.

STRENGTHEN THE ECONOMIC AND SOCIAL WELL-BEING OF AMERICANS ACROSS THE LIFESPAN

Promoting Upward Mobility

The budget promotes independence and personal responsibility, supporting the proven notion that work empowers parents and lifts families out of poverty. To ensure Temporary Assistance for Needy Families (TANF) enables participants to work, the budget includes a proposal to ensure States will invest in creating opportunities for low-income families, and to simplify and improve the work participation rate States must meet under TANF. The budget also proposes to create Opportunity and Economic Mobility Demonstrations, allowing States to streamline certain welfare programs and tailor them to meet the specific needs of their populations.

The budget supports Medicaid reforms to empower individuals to reach self-sufficiency and financial independence, including a proposal to permit States to include asset tests in identifying an individual's economic need, allowing more targeted determinations than are possible with the use of a Modified Adjusted Gross Income standard alone.

Improving Outcomes in Child Welfare

The budget supports implementation of the Family First Prevention Services Act of 2018 and includes policies to further improve child welfare outcomes and prevent child maltreatment. The budget also expands the Regional Partnership Grants program, which addresses the considerable impact of substance use, including opioid use, on child welfare.

Strengthening the Indian Health Service

Reflecting HHS's commitment to the health and well-being of American Indians and Alaska Natives, the budget provides $5.9 billion for IHS, which is an additional $392 million above the FY 2019 Continuing Resolution. The increase supports direct health-care services across Indian Country, including hospitals and health clinics, Purchased/Referred Care, dental health, mental health, and alcohol and substance abuse services. The budget invests in new programs to improve patient care, quality, and oversight. The budget fully funds staffing for new and replacement facilities, new tribes, and Contract Support Costs, ensuring tribes have the necessary resources to successfully manage self-governance programs.

FOSTER SOUND, SUSTAINED ADVANCES IN THE SCIENCES

Promoting Research and Prevention

NIH is the leading biomedical research agency in the world, and its funding supports scientific breakthroughs that save lives. The budget supports strategic investments in biomedical research and activities with significant national impact.

NIH launched the Helping to End Addiction Long-term (HEAL) initiative in April 2018 to advance research on pain and addiction. Toward this goal, NIH announced funding opportunities for the historic HEALing Communities Study, which will select several communities to measure the impact of investing in the integration of evidence-based prevention, treatment, and recovery across multiple health and justice settings. The budget provides $500 million to continue the HEAL initiative in FY 2020.

The budget supports a targeted investment in the National Cancer Institute to accelerate pediatric cancer research. Cancer is the leading cause of death from disease among children in the United States. Approximately 16,000 children are diagnosed with cancer in the United States each year. While progress in treating some childhood cancers has been made, the science and treatment of childhood cancers remains challenging. Through this initiative, NIH will enhance drug discovery, better understand the biology of all pediatric cancers, and create a national data resource for pediatric cancer research. This initiative will develop safer and more effective treatments and provide a path for changing the course of cancer in children.

The new National Institute for Research on Safety and Quality (NIRSQ) proposed in the budget will continue key research activities currently led by the Agency for Health-care Research and Quality. These activities will support researchers by developing the knowledge, tools, and data needed to improve the health-care system.

Addressing Emerging Public Health Challenges

CDC is the Nation's leading public health agency, and the budget supports its work putting science into action.

Approximately 700 women die each year in the United States as a result of pregnancy or delivery complications or the aggravation of an unrelated condition by the physiologic effects of pregnancy. Findings from Maternal Mortality Review Committees indicate that more than half of these deaths are preventable. The budget supports data analysis on maternal deaths and efforts to identify prevention opportunities.

The United States must address emerging public health threats, both at home and abroad, to protect the health of its citizens. The budget invests $10 million to support CDC's response to Acute Flaccid Myelitis (AFM), a rare but serious condition that affects the nervous system and weakens muscles and reflexes. With this funding, CDC will work closely with national experts, health-care providers, and State and local health departments to thoroughly investigate AFM.

The budget also provides $100 million for CDC's global health security activities. Moving forward, CDC will implement a regional hub office model and primarily focus their global health security capacity-building activities on areas where they have seen the most success: lab and diagnostic capacity, surveillance systems, training of disease detectives, and establishing strong emergency operation centers. In addition, CDC will continue ongoing efforts to identify health emergencies, track dangerous diseases, and rapidly respond to outbreaks and other public health threats around the world, including continuing work on Ebola response.

The budget also strengthens the health security of our Nation by continuing CDC's support to State and local government partners in implementing programs, establishing guidelines, and conducting research to tackle public health challenges and build preparedness.

Innovations in the Food and Drug Administration

FDA plays a major role in protecting public health by assuring the safety of the Nation's food supply and regulating medical products and tobacco. The budget provides $6.1 billion for FDA, which is an additional $643 million above the FY 2019 Continuing Resolution. The budget includes resources to promote competition and foster innovation, such as modernizing generic drug review and creating a new medical data enterprise. The budget advances digital health technology to reduce the time and cost of market entry, supports FDA opioid activities at international mail facilities to increase inspections of suspicious packages, strengthens the outsourcing facility sector to ensure quality compounded drugs, and pilots a pathogen inactivation technology to ensure the blood supply continues to be safe. FDA will continue to modernize the food safety system in FY 2020.

PROMOTE EFFECTIVE AND EFFICIENT MANAGEMENT AND STEWARDSHIP

Almost one quarter of total Federal outlays are made by HHS. The Department employs more than 78,000 permanent and temporary employees and administers

more grant dollars than all other Federal agencies combined. Efficiencies in HHS management have a tremendous impact on Federal spending as a whole.

Advancing Fiscal Stewardship

HHS 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.

In an effort to operate Medicare and Medicaid efficiently and effectively, both to rein in wasteful spending and to better serve beneficiaries, HHS is implementing actions such as enhanced provider screening, prior authorization, and sophisticated predictive analytics technology, to reduce improper payments in Medicare and Medicaid without increasing burden on providers or delaying Americans' access to care or to critical medications. HHS continues to work with law enforcement partners to target fraud and abuse in health care, and the budget increases investment in health-care fraud and abuse activities. The budget includes a series of proposals to strengthen Medicare and Medicaid oversight, including increasing prior authorization, enhancing Part D plans' ability to address fraud, and strengthening the Department's ability to recoup overpayments made to States on behalf of ineligible Medicaid beneficiaries.

Implementing ReImagine HHS

HHS eagerly took up the call in the administration's Government-wide Reform Plan to more efficiently and effectively serve the American people. HHS developed a plan—"ReImagine HHS"—organized around a number of initiatives.

ReImagine HHS is identifying a variety of ways to reduce Federal spending and improve the functioning of HHS's programs through more efficient operations. For example, the Buy Smarter initiative streamlines HHS's procurement process by using new and emerging technologies.

CONCLUSION

Americans deserve health care, human services, and public health programs that work for them and make good use of taxpayer dollars. The men and women of HHS are committed, innovative, hardworking public servants who work each day to improve the lives of all Americans. President Trump's FY 2020 budget will help advance us toward that goal, accomplish the Department's vital mission, and put Americans' health first.

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

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

MEDICARE

Question. The budget proposes a policy change that would require the Centers for Medicare and Medicaid Services (CMS) to report providers who have been sanctioned for abusive prescribing of controlled substances to the Drug Enforcement Administration (DEA). I applaud the idea of coordination between agencies to root out abusive practices, especially those that harm patients. Has your Department had discussions with DEA about how it would use the CMS-reported information required by this proposal?

Answer. Today, if CMS revokes a provider's billing privileges based on improper/abusive prescribing practices, a provider's DEA Certificate of Registration will not be impacted. Following the Medicare revocation, the provider can opt out of the Medicare program, even though the provider's status has been revoked, and elect to order, refer, and/or prescribe to Medicare beneficiaries.

Under the proposal, CMS will be required to report all Medicare revocation actions or preclusion list placements to the DEA that are based totally or in part on abusive prescribing of controlled substances. In turn, the DEA would be able to use this data to consider revocation of a provider's DEA certification of registration.

CMS's and the DEA's combined efforts will prevent abusive prescribers, many of whom have histories of patient harm based on improper prescribing, from continuing to prescribe to Medicare beneficiaries, and more generally, to patients across the United States. We would be pleased to partner with the DEA on these efforts.

Question. The budget proposal to revoke or deny the enrollment needed to participate in Medicare of an individual who had a leadership role in an entity that was sanctioned highlights how an individual can "reinvent" him or herself and engage in similar nefarious activity under a new corporate entity. This is a problematic scenario that we should prevent. To help us understand the real-world implications, can you provide examples of how this has happened or can happen?

Answer. Currently, CMS cannot penalize an entity based on an affiliation that its owners, managing employees, officers, and/or directors had with a previously sanctioned Medicare entity. As a result, providers and suppliers that abuse the Medicare program evade revocation from the program by "reinventing" themselves under a new business's corporate umbrella.

For example, a provider or supplier may engage in inappropriate billing, exit Medicare prior to detection, and then change its name or business identity in order to reenroll in Medicare under this new identity. In another example, an entity may own or manage several Medicare providers and suppliers and one of the providers or suppliers may be involved in abusive behavior with the approval or at the instigation of that owner or managingentity. If the abusive provider's or supplier's enrollment is revoked, the owning/managingentity can shift its behavior to another of its enrolled entities.

Question. The budget proposal that would allow physicians to earn a 5-percent bonus for participating in an Advanced-Alternative Payment Model (A–APM) based on the actual amount of revenue they have at risk in A–APMs is an interesting alternative to the qualifying revenue thresholds in statute. The proposal would allow more physicians to receive a bonus while those who would have otherwise met the current law thresholds would receive a smaller bonus. To help us further evaluate this proposal, can you provide detail on how the number of physicians who qualify and the amount of the bonus they earn would differ under the proposal compared to current law?

Answer. The President's FY 2020 budget proposes to modify how the 5-percent incentive payment is determined in order to better reward clinicians who participate in the Advanced Alternative Payment Models (APMs) track of the Quality Payment Program (QPP). Instead of receiving a 5 percent incentive payment on all physician fee schedule (PFS) payments if they meet or exceed certain payment or patient thresholds, clinicians would receive a five percent incentive payment on PFS revenues received through the Advanced APMs in which they participate.

Under the current structure of the QPP, some clinicians who participate in Advanced APMs may not be eligible for an incentive payment simply because they do not meet arbitrary thresholds. While most Advanced AMP participants are able to meet the 25-percent threshold, CMS estimates that only 15 percent of Advanced AMP participants will meet a 75-percent payment threshold starting in 2021. Clinicians have to invest their time and financial resources to participate in an Advanced APM. Thus, if clinicians are not rewarded for that investment by becoming QPs, it will likely discourage participation in these APMs going forward.

This proposal removes these arbitrary thresholds and directly rewards clinicians along a continuum based on their level of participation in Advanced APMs. All clinicians who participate in Advanced APMs would be Qualifying APM Participants (QPs) and would be rewarded with an incentive payment. The 5-percent incentive payment would be based on the amount of the clinician's payments that are tied to an Advanced APM. Thus, the more the clinician participates in an Advanced APM, the higher the incentive payment will be.

Question. The Medicare physician payment system appropriately focuses on accountability and value, but it's important that physicians are assessed fairly based on their geographic area. I have long held that the geographic adjustment applied to the components that determine the physician fee payment amount disadvantage physicians in Iowa (and other more rural areas). While I continue to engage on how CMS makes these statutorily required adjustments, I want to highlight a situation that seems to hit Iowa physicians twice. Medicare pays physicians in Iowa less than average because of how the agency applies geographic adjustments. However, CMS strips away those geographic adjustments—essentially assuming physicians in all areas are paid the average amount—when assessing physicians on the amount of care they provide. Can you explain why this physician cost of care assessment uses an amount that is in excess of what Iowa physicians are actually paid?

Answer. As required by the statute, CMS reviews and, if necessary, adjusts the Geographic Practice Cost Indexes (GPCIs) at least every 3 years. CMS updated the

GPCIs in the CY 2017 Medicare Physician Fee Schedule final rule, and, as with other updates, this update is done with opportunity for public comment through notice and comment rulemaking. In the CY 2019 PFS proposed rule, CMS included a comment solicitation regarding the GPCIs. Any changes to the GPCIs based on the comment solicitation would be discussed in future rulemaking.

When assessing physicians on the cost of care such as through the measures in the cost performance category in the Merit-based Incentive Payment System (MIPS), we use a payment standardization process to adjust the allowed charge for a Medicare service to facilitate comparisons of resource use across geographic areas. The payments included in the MIPS cost measures (Total Cost of Care, Medicare Spending Per Beneficiary and episode-based measures) are payment-standardized to preserve differences that result from health-care delivery choices, exclude geographic differences, and exclude payment adjustments from special Medicare programs.

The allowed amounts for Medicare services can vary across geographic areas due to several factors that are not necessarily representative of differences in utilization, such as regional differences in labor costs and practice expenses, differences in the relative price of inputs in local markets where a service is provided, extra payments from Medicare in medically underserved regions, policy-driven payment adjustments such as those for teaching hospitals. In order to make service use comparisons, standardization is used to transform the actual spending amounts into a standardized amount that excludes these adjustments. Payment standardization assigns a comparable amount for an item or service to facilitate cost comparisons and limit observed differences in costs to those that reveal differences in spending that result only from care decisions and resources use. Payment standardization also removes any Medicare payment differences due to adjustments for geographic differences in wage levels or policy-driven payment adjustments, such as those for teaching hospitals.

Question. I appreciate your ongoing focus on addressing the opioid crisis and the attention to this issue is evident from the budget proposals. A provision in the SUPPORT for Patients and Communities Act (Public Law 115–271), section 6082, encouraged CMS to review Medicare payment systems to assess whether policies may incentivize use of opioids over non-opioid alternatives. CMS took a step toward increased availability of non-opioid treatments by providing coverage of an injectable alternative in the 2019 payment rules for hospital outpatient departments. I am aware that CMS has received requests for additional payment system changes that similarly would expand availability alternatives such as nerve blocks and other treatments. Is CMS considering further changes to expand non-opioid alternatives consistent with section 6082 of the SUPPORT for Patients and Communities Act?

Answer. In the Calendar Year 2019 Outpatient Prospective Payment System and Ambulatory Surgical Center rule, CMS examined our packaging policy for non-opioid pain management options as recommended by the President's Commission on Combating Drug Addiction and the Opioid Crisis and based on feedback from stakeholders. For our evaluation, we used available data to analyze the utilization patterns for specific drugs that were packaged to determine whether the packaging policy has reduced the use of the drugs. Based on the analysis, we proposed and finalized to separately pay for non-opioid drugs that function as a surgical supply in the ASC setting, which currently is only Exparel.

We also solicited comments in last year's proposed rule on other non-opioid alternative treatments besides Exparel, such as devices, that might be affected by packaging policies and whether these items warranted separate payment. We received a number of comments on this topic. We noted in the final rule that we plan to take these comments and suggestions into consideration for future rulemaking and look forward to working with stakeholders as we further consider suggested refinements to the payment systems. We also noted that we will continue to analyze this issue of access to non-opioid alternatives as we implement section 6082 of the SUPPORT Act.

CMS is also consulting with the Pain Management Best Practices Task Force as required under the SUPPORT Act. The Task Force released its final report recently identifying a number of changes related to payment for alternatives.

HUMAN SERVICES

Question. Improving access to prevention, treatment, and recovery services is a big part of HHS's strategy to address the opioid crisis. The Family First Prevention Services Act, which became law last year, helps do this by letting States use foster

care dollars to support family-based residential treatment centers—meaning more kids can stay with their parents instead of being separated and placed in foster care. HHS has not yet reported how many States are taking advantage of this new opportunity to keep families together.

Family First lets States use foster care funding to help dollars to help support family-based residential treatment centers, which will mean more kids can stay with their parents instead of being separated and placed in foster care. What is your agency doing to make sure States know about this new policy, as well as others that were part of Family First? Can you let me know how many States (and which States) are taking advantage of this new opportunity?

Answer. The First Prevention Services Act (FFPSA) provides an important opportunity for States and tribes participating in the title IV–E program to use title IV–E foster care maintenance funds. Specifically, to use funds supporting the placement of children with their parents in a licensed family-based residential treatment facility for substance abuse. This provision just became effective on October 1, 2018 (fiscal year 2019).

The Children's Bureau in the Administration for Children and Families (ACF) informed title IV–E agencies about this opportunity and other FFPSA provisions through an Information Memorandum (ACYF–CB–IM–02) issued on April 12, 2018. On July 9, 2018, the ACF Children's Bureau issued Program Instruction ACYF–CB–PI–18–07, which provided guidance to title IV–E agencies on revising their title IV–E plans in order to address provisions amended by FFPSA. In particular, their foster care, adoption assistance, and guardianship assistance programs. This issuance included instructions on the title IV–E plan amendments that States and tribes must complete to claim title IV–E foster care maintenance payments for children placed with parents in a licensed family-based residential substance abuse treatment facility.

In July 2018, the Children's Bureau hosted five calls for all title IV–E agencies, and one call specifically for interested tribes, to walk through ACYF–CB–PI–18–07 and answer questions about the new title IV–E requirements. Forty-five title IV–E agencies and six tribes participated in the calls.

On November 30, 2018, the Children's Bureau issued Program Instruction ACYF–CB–PI–18–12, which alerted title IV–E agencies of revisions made to the CB–496 title IV–E Program Quarterly Financial Report to accommodate changes in the title IV–E program, per FFPSA. The revised CB–496 form now includes a specific line for title IV–E agencies to report claims for foster care maintenance payments made for children placed with parents in licensed family-based residential substance abuse treatment facilities. It also provides an additional line to report the average monthly number of children on whose behalf such payments are being made. The updated form went into effect for claims submitted for the first quarter of Fiscal Year 2019 (October 1, 2018–December 31, 2018).

Currently, based on the first two financial quarters of fiscal year 2019, only one State (Utah) has reported claims for this type of placement.

QUESTIONS SUBMITTED BY HON. MIKE CRAPO, HON. RICHARD BURR, AND HON. ROB PORTMAN

Question. CMS recently released a proposed decision memo on coverage for CAR–T cell therapies for Medicare patients through a National Coverage Determination (NCD). Coverage with Evidence Development (CED) provides CMS with the opportunity to assess these new treatments in the older, more complex Medicare population and ensure that the government pays for care that provides value to patients.

The current patient criteria only include individuals that have relapsed or refractory cancer. However, the CAR–T pipeline continues to grow, potentially expanding the eligible patient population to more types of patients. How does CMS plan to incorporate newly FDA-approved first-line therapies and indications into the CED framework to appropriately target the coverage decision to the full range of seniors that stand to benefit from the product?

We have heard concerns that NCDs are often static and unable to adapt to new information. With the desire to balance patient safety and access in mind, will you update the coverage determination to reflect new data in the future, given the evolving nature of the CAR–T therapy?

Equal access to innovative care close to home is critical for cancer patients, especially those who are seniors and may have more difficulty traveling long distances for care. How does the CMS coverage decision ensure that all facilities that meet CMS and FDA criteria to administer CAR–T cell therapies are able to receive payment?

The National Coverage Decision of Coverage with Evidence Development is a welcome step in improving Medicare beneficiary access to CAR–T therapy. Another key component of this access is providing viable payment models for these innovative products. CMS provided some insight into agency thinking as a part of the FY 2019 Hospital Inpatient Prospective Payment System (IPPS) rule last year, but stated that, "given the relative newness of CAR–T cell therapy, the potential model, including the reasons underlying our consideration of a potential model described in greater detail in the CY 2019 OPPS/ASC proposed rule, and our request for feedback on this model approach, we believe it would be premature to adopt changes to our existing payment mechanisms. . . ." What are the outstanding policy considerations at CMS in determining the path forward on CAR–T payment? Will these considerations be a part of the FY 2020 IPPS rule?

Answer. CMS has proposed to cover FDA-approved CAR–T cell therapy, which is a new form of cancer therapy that uses a patient's own immune system to fight the disease, under "Coverage With Evidence Development." Currently, there is no national Medicare policy for covering CAR–T cell therapy, so local Medicare Administrative Contractors have discretion over whether to pay for it. The proposed National Coverage Determination would require Medicare to cover the therapy nationwide when it is offered in a CMS-approved registry or clinical study, in which patients are monitored for at least 2 years post-treatment. Evidence from the registries and studies would help CMS identify the types of patients that benefit from CAR–T cell therapy, informing a future decision by the agency regarding the types of cases in which Medicare would cover the treatment with no registry or trial requirement. CMS is currently reviewing comments on this proposed National Coverage Determination. On May 17, 2019, CMS announced a delay in finalizing the National Coverage Determination but noted that the determination is forthcoming.

After consideration of public comments on the FY 2019 Hospital Inpatient Prospective Payment System proposed rule, CMS approved a new technology add-on payment for FY 2019 for CAR–T cell therapy.

Addendum: In the FY 2020 IPPS rule, CMS proposed to continue the IPPS new technology add-on payments for CAR–T cell therapy for FY 2020. Under the proposal, if finalized, the FY 2020 new technology add-on payment for CAR–T cell therapy would increase from 50 percent of the estimated costs of the new technology to 65 percent. That is, the maximum add-on would increase from $186,500 to $242,450. We also invite public comments on other payment alternatives for CAR–T cell therapies, such as eliminating the cost-to-charge ratio in calculating the new technology add-on payment for KYMRIAH™ and YESCARTA™ by making a uniform, rather than a maximum, add-on payment. KYMRIAH™ and YESCARTA™ are the only two CAR–T cell therapies with FDA approval.

QUESTION SUBMITTED BY HON. PAT ROBERTS AND HON. DEBBIE STABENOW

Question. As you know, oral health is a critical component of overall health and wellness, and ensuring coverage of dental care has the potential to reduce costs while improving outcomes. Without dental coverage, many individuals and families are forced to forgo preventive care, which can lead to emergency room visits and expensive procedures down the road. Given the importance of expanding access to dental care, we wrote to Administrator Verma on December 18 urging CCIIO to fix a Federal health insurance marketplace issue and provide Americans with the option of purchasing dental coverage independent of medical coverage on the marketplace. This solution is consistent with existing statute and will increase access to dental care and protect consumers from the unintended termination of their dental coverage. What progress has CMS made in fixing the Marketplace issue?

Answer. Thank you for your letter regarding the independent purchase of standalone dental plans (SADPs) on the Federally Facilitated Exchanges (FFEs).

For consumers seeking to purchase coverage with advance payments of the premium tax credit (APTC), 26 U.S.C. § 36B(b)(3)(E) provides that, for purposes of calculating an eligible taxpayer's premium tax credit (PTC), if an individual enrolls in both a qualified health plan (QHP) and an SADP, the portion of the premium for

the SADP attributable to the pediatric dental essential health benefit is included as premium payable for a QHP. The vast majority of consumers who purchase coverage on the Federally Facilitated Exchanges receive financial assistance, in the form of APTC (87 percent) and cost-sharing reductions (54 percent), to offset the cost of their coverage.

To ensure that we pay APTC appropriately for consumers who choose to enroll in an SADP, we require the exchange to conduct an eligibility determination and to condition the APTC applicability to an SADP on a consumer's enrollment in an SADP that includes the pediatric dental essential health benefit. Accordingly, *HealthCare.gov* links purchases of SADP and QHP coverage by consumers receiving APTC for allocation of APTC first to medical coverage and then to SADP coverage.

We believe that the substantial investment required to alter *HealthCare.gov* to allow separate purchases of SADPs for consumers who are not eligible for APTC and who are not purchasing medical coverage would have little return for consumers and SADP issuers, given that such consumers generally can enroll in SADPs without APTC outside of the FFEs.

QUESTIONS SUBMITTED BY HON. JOHN CORNYN

BIOSIMILAR COMPETITION

Question. The committee held a hearing with industry CEOs several weeks ago. I asked a question about the role of patents in limiting competition for certain drugs, in particular biologics. I was told that patents are not blocking biosimilar competition.

I am not sure I agree with that, but for the sake of argument, can you share with the committee the specific changes that you can make administratively—or legislatively through the BPCIA—that could bring more balance to the playing field between biologics and biosimilars?

Answer. Recognizing that this is a crucial time in the emergence of biosimilars, FDA announced its Biosimilars Action Plan (BAP) last year to advance biosimilar development and approval, and facilitate access to lower-cost biological products to treat a growing number of chronic and life-threatening conditions. Under the BAP, FDA is focusing its efforts on: advancing the science and policies to make the development of biosimilars more efficient; increasing the acceptance of biosimilars; and taking action against regulatory gaming that can deter or delay competition.

Not only are we making the biosimilar development and review process more efficient and predictable, under the BAP, we are also taking new steps to communicate with patients, payers, and providers to improve the understanding of biosimilar and interchangeable products.

Of course, the FDA's efforts to improve biosimilar competition will be less impactful if rebate walls discourage payers from adding biosimilars to their formularies. By proposing to replace rebates with upfront discounts, plans will have more incentive to seek drugs with lower prices instead of those with higher rebates, which will dramatically lower the costs patients face for a number of high-cost drugs.

We are calling out abuses of the system that impede competition and are doing our part to fix them. We will act where appropriate to deter gaming of FDA requirements that unfairly delay competition among biologics. We are continuing to coordinate with the Federal Trade Commission, a vital partner in our efforts to address anti-competitive behavior in the drugs and biologics marketplace.

We continue to evaluate additional steps necessary to strike the appropriate balance between encouraging ongoing innovation in biologics while also facilitating the robust competition that can reduce costs to patients.

DRUG PRICING—MEDICARE PART D

Question. The President's budget proposes a new benefit design for Part D beneficiaries that establishes an out-of-pocket maximum for beneficiaries and shifts Medicare's liability in the catastrophic phase from 80 percent to 20 percent in 2021.

Earlier this year, *The Wall Street Journal* reported that Medicare overpaid drug plans $9.1 billion between the start of the Part D program in 2006 and 2015.

Were there considerations made to address the risk corridors? Do you believe these changes in benefit design will remedy the issue raised in that article?

Answer. The Part D benefit creates a perverse incentive structure for plans, in which drug price increases shift more drug spending into the catastrophic phase, where Medicare pays 80 percent of costs. That is why the President's budget proposes to modernize the Part D benefit structure. Under the President's budget, Part D plan sponsors' liability for drug costs incurred in the catastrophic phase of the Part D benefit would increase over 4 years from 15 percent under current law to 80 percent. Beneficiary coinsurance in the catastrophic phase would decrease from 5 to 0 percent. The President's proposal could provide a greater incentive for sponsors to manage drug costs.

In addition, in January 2019, the Center for Medicare and Medicaid Innovation announced a new model, the Part D Payment Modernization Model, to test an innovative payment model under Part D. Under the model, participating Part D plans will take on greater risk for spending in the catastrophic phase of Part D, creating new incentives for plans, patients, and providers to choose drugs with lower list prices. Our proposal to replace rebates with upfront discounts also seeks to better align incentives for Part D sponsors to encourage drugs with lower prices instead of those with higher rebates.

As the Department continues its work to advance President Trump's commitment to lower prescription drug prices, additional improvements to the Part D benefit design, such as risk corridors, may be considered.

KIDNEY INNOVATION

Question. The Center for Medicare and Medicaid Services (CMS) is the primary payer for dialysis care and plays a leading role in encouraging innovation in the delivery of dialysis care for Medicare patients with End-Stage Renal Disease (ESRD.) The standard of care for these patients had significant legged behind other disease States when it comes to innovation. The way Medicare pays for dialysis care—via a bundled payment system under which a "single payment" is made for all renal dialysis services—fails to adequately account for the prospect of innovation, thus resulting in a disincentive to improve upon the standard of care. The evidence is staggering. No real innovation has occurred in the treatment of ESRD patients since dialysis was introduced nearly 50 years ago.

I appreciate and share your commitment to improving the standard of care for dialysis patients through the adoption of incentives to promote drug innovation. CMS's proposed expansion of the Transitional Drug Add-on Payment Adjustment is a promising first step. I understand that CMS has broad statutory authority to add devices to this transitional payment adjustment.

Can you comment on the need for new technology payment incentives in the Medicare ESRD payment system and commit to engaging with me to find ways to encourage medical device innovation in dialysis care specifically?

Answer. We are committed to encouraging innovation particularly in treatment of kidney disease and ESRD. In the interest of supporting innovation, ensuring appropriate payment for all drugs and biologicals, and as a complement to the Transitional Drug Add-on Payment Adjustment (TDAPA) proposals, CMS solicited comments in the CY 2019 ESRD PPS proposed rule on whether CMS should expand the outlier policy to include composite rate drugs and supplies. With regard to composite rate supplies, an expansion of the outlier policy could support use of new innovative devices or items that would otherwise be considered in the ESRD PPS bundled payment. CMS specifically requested feedback about how such items might work under the existing ESRD PPS outlier framework or whether specific changes to the policy to accommodate such items are needed. It received a number of comments from stakeholders on this issue. CMS will take these comments into account as it consider any changes to the outlier policy and other payment adjustments such as TDAPA for future rulemaking.

We are also doing some work through the CMS Center for Medicare and Medicaid Innovation to test payment models related to kidney care. The Comprehensive ESRD Care (CEC) Model, which started in 2015 and runs through 2020, is designed to identify, test, and evaluate new ways to improve care for Medicare beneficiaries with ESRD. Through the CEC Model, CMS is partnering with health-care providers and suppliers to test the effectiveness of a new payment and service delivery model in providing beneficiaries with person-centered, high-quality care. The Innovation Center is also considering additional models related to management of chronic kidney disease and ESRD.

The Department also recently reported in the Spring Agenda the two NPRMs are under development that relate to kidney care. One through CMS focused on Organ Procurement Organization evaluation and metrics and the other through HRSA is geared toward expanding the National Living Donor Assistance Center.

HOME HEALTH

Question. The FY 2020 budget proposes to lower annual Medicare payment updates to home health agencies, among other post-acute care (PAC) providers, beginning in FY 2020 through 2024, leading up to the establishment of a unified PAC payment system in 2025.

Budgets should reflect what is in the best interest of our taxpayers, and keeping patients that need medical care in the lowest cost setting, in the comfort of their own home when possible, is where they will be best supported and most comfortable.

Should we not be encouraging increased access to lower cost settings, such as home health? I am particularly concerned that home health providers, especially rural providers in Texas, will be unable to or will have difficulty providing home health access to Medicare beneficiaries if further cuts to their services are imposed.

Answer. The budget proposes that skilled nursing facilities, home health agencies, and inpatient rehabilitation facilities will receive a lower annual Medicare payment update from FY 2020 to FY 2024 and, beginning in FY 2025, a unified post-acute care payment system would span all four post-acute care settings, with payments based on episodes of care and patient characteristics rather than the site of service. Part one of the proposal, reducing the annual payment update for post-acute care providers, is intended to more closely align payment with costs for these providers given their historically high Medicare profit margins. The proposal stipulates that any update should not go below zero in a given year, after factoring in current statutory or other reductions.

Part two of the proposal would convert the payment systems for post-acute care from four separate systems into one unified system that bases payment on patient characteristics rather than the site-of-service. The conversion to a unified post-acute care payment system would be budget neutral in its first year, maintaining estimated Medicare payments that would otherwise have been expended in FY 2025. Payment rates would be set prospectively on an annual basis, with episode grouping and pricing based on the average cost for providing post-acute care services for a diagnosis, and would be risk-adjusted. The Secretary would have authority to adjust payments based on quality of care, geographic differences in labor and other costs, and other factors as deemed appropriate.

GME

Question. Secretary Azar, as a country we are facing both supply and demand issues in regard to provider access. The patient load for the average clinician has grown considerably particularly in underserved areas and by 2030, experts predict a national physician shortage ranging between 40,800 to 104,900.

What is the administration's plan to address?

Answer. The President's Fiscal Year (FY) 2020 budget requests resources to address physician shortages in underserved areas. The FY 2020 budget provides $760 million in mandatory and discretionary resources for HRSA health workforce programs. The budget prioritizes funding for health workforce programs requiring service commitments in underserved areas, training health-care professionals to deliver integrated behavioral health services, and the National Center for Health Workforce Analysis. The FY 2020 President's budget, the budget requested funding for the National Health Service Corps (NHSC), which supports clinicians who demonstrate a commitment to serve our Nation's medically underserved populations at NHSC-approved sites located in Health Professional Shortage Areas. In addition, the President's budget includes funding for the Teaching Health Center Graduate Medical Education (THCGME) program. The THCGME program increases healthcare access in underserved communities by supporting primary care medical and dental residency programs in community-based ambulatory patient care settings. The President's budget includes $126.5 million in funding for the THCGME program in each of FY 2020 and FY 2021, for a total of $253 million over 2 years.

The FY 2020 budget also proposes to reform 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 2020 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 modernize graduate medical education funding, making it better targeted, transparent, accountable, and more sustainable.

Question. Knowing of these statistics, several Senators and I sent a letter last fall regarding the Centers of Medicare and Medicaid Services' (CMS) existing authority to extend flexibility to residency and fellowship programs when setting graduate medical education (GME) caps. The CMS Administrator responded in kind with its solution for consolidating Federal medical education programs but no real glide path for addressing the looming shortage that awaits patients to come.

Can we get your commitment to utilize this authority, which was granted back in 1997?

Answer. We share your goal of improved support for hospitals' efforts to train more residents in underserved areas. To this end, Fiscal Year 2020 President's budget includes a proposal that would consolidate Federal GME spending from Medicare, Medicaid, and the Children's Hospitals GME program into a single grant program for teaching hospitals, and direct funding toward physician specialty and geographic shortages areas. Patients and providers would be well served by these commonsense reforms and the new grant program would be operated jointly by CMS and the Health Resources and Services Administration. We will take your comments into consideration as we develop policies for future rulemaking.

QUESTIONS SUBMITTED BY HON. JOHN THUNE

Question. As we discussed in the hearing, the Indian Health Service's employment and transfer of abusive health-care providers cannot ever be allowed to happen again. You and Rear Admiral Weahkee have committed publicly to getting to the bottom of the situation with Stanley Patrick Weber. Has the Department selected the outside party and begun the independent review that has been discussed? What process changes has HHS made to its process for credentialing providers as a result of this issue?

Answer. The Indian Health Service (IHS) began the acquisition process for an external medical quality assurance review in October 2018. IHS intended to post this solicitation earlier, but the timeline was extended as a result of the 35-day lapse in appropriations that started on December 22, 2018. In February 2019, a request for proposal was published for this work. On May 10, 2019, IHS awarded a contract to Integritas Creative Solutions, LLC to conduct a medical quality assurance review to examine whether laws, policies and procedures have been followed with regard to protecting patients from sexual abuse. The final report from the contractor will (a) identify facts relating to IHS's policies and procedures regarding the reporting of allegations of sexual abuse of IHS patients by clinical staff, (b) identify past process or system failures and their causes, and (c) make recommendations for improvement and employee accountability.

The IHS has implemented a credentialing and privileging system that is being used for all new applicants and all re-applications. The system standardizes and streamlines the credentialing process across the IHS. Privileging and performance evaluations of IHS practitioners will be tracked in the new system to help address issues related to quality care and patient safety.

Question. As we've talked about in the past, with the ties between the VA and Indian Health Service's electronic health record systems, we need to ensure that IHS is making plans to move forward now that the VA will be transitioning systems. You've shared that a request for information was issued in late 2017 and that work would continue through 2018 on determining the appropriate next steps for

IHS modernization. This year's budget requests $25 million to transition EHR systems. Has the Department completed its analysis of the RFI and determined a path forward? What is the timeline?

Answer. The Department's Health Information Technology (HIT) Modernization Research Project began in September 2018 and will conclude in September 2019. This project will inform IHS with constructive options to modernize its HIT infrastructure. The project's timeline is as follows:

- Project Planning and Strategy—completed November 2018.
- Convene an Expert Advisory Panel on IHS HIT—completed January 2019.
- IHS, Tribal, and Urban Indian Organization Facility HIT Assessment—completed April 2019.
- HIT Community of Practice—completed April 2019.
- HIT Analysis and Recommendations—scheduled to be completed by June 2019.
- HIT Initiatives Roadmap and Strategy—scheduled to be completed by September 2019.

The Department's research project will inform additional planning and the development of a detailed timeline for the modernization of its electronic health record system. The 2020 budget request will help IHS complete the detailed planning work and tribal consultation necessary to make a final decision.

Question. Many members of this committee are engaged in ensuring rural communities have access to needed care. As the budget focuses on the transition to value-based care, how has the Department engaged rural providers, and what options have you explored to help them overcome some of the challenges that may exist in pursuing reforms like this?

Answer. The immediate office of the Secretary has created a senior inter-departmental Rural Health Task Force to (1) identify rural hospitals at risk of closure, encourage the development of care models that are economically viable and sustainable in rural communities, and ensure HHS policies and programs are aligned to help encourage and sustain such models of care; (2) encourage greater uptake of statutorily permitted telemedicine services (*i.e.,* under Medicare) in rural communities; (3) identify other HHS actions that could be taken to help to save or preserve access to care in rural communities, such as addressing Medicare and Medicaid payment rates that affect rural providers; and (4) identify ways to improve access to care in rural communities by encouraging States to adopt policies which allow "mid-level" practitioners practice to the maximum of their licensure.

Some of the priorities of the Task Force have already been met. For example, historic changes have been made to expand access to telehealth and covered services across the Medicare program, including virtual check-ins and stand-alone telephone consultations with clinicians at Rural Health Clinics and Federally Qualified Health Centers. Medicare Advantage plans now offer telehealth services as part of their basic benefit package.

To engage rural providers and encourage participation in alternative payment models, CMS is also expanding value-based payment arrangements that cater to the unique needs of rural communities. The new CMS Primary Cares Initiative was recently announced, which offers 2 pathways—Primary Care First and Direct Contracting—and four voluntary model options to test how payment is made for primary care. Transitioning to a value-based payment model will allow rural providers to focus on their local health needs such as maternal health, chronic diseases and substance use disorders, which we believe, will in turn, drive better health outcomes.

CMS is also working with providers to remove undue unnecessary burdens that prevent them from administering care in rural areas. As a result of added flexibilities for clinicians in small practices, 93 percent of participating providers have received a positive payment adjustment.

HHS has made rethinking, and improving, rural health a priority, and the President's budget reflects that by supporting these efforts, including the work of community health centers.

Question. Thank you for the work the administration has done to advance telehealth over the last year, particularly for including it as a priority in CMS's Rural Health Strategy. It's great to see the implementation of committee-passed provisions on stroke, substance use disorder, and home dialysis, as well as the option to reimburse for virtual check-ins in last year's fee schedule. Are there other initiatives

CMS is currently considering within its existing authority to expand telehealth? Have you identified any new areas where congressional action is needed to address statutory barriers?

Answer. CMS is working to facilitate innovation in the health-care delivery system across all its programs. Health-care innovation is serving as a catalyst to improving quality of care, enhancing access to care, increasing efficiency in the system, and lowering health-care costs. Supporting and furthering telehealth is a critical part of CMS's efforts to promote innovation. The President's budget includes a proposal to provide a Medicare Priority Care (MPC) per-beneficiary per-month (PBPM) payment for all Medicare fee-for-service (FFS) beneficiaries, which would be paid to eligible primary care providers. Providing such payments with the envisioned flexibility to provide care in the time and manner the clinician believes most appropriate, which might include telehealth, is one way the administration has proposed to make telehealth more broadly available while limiting burden and focusing on the patient-provider relationship.

CMS continues to add services to the list of Medicare telehealth services that can be furnished at authorized originating sites. In the calendar year 2019 Medicare Physician Fee Schedule final rule, CMS expanded the list of Medicare telehealth services for 2019 to include HCPCS codes G0513 and G0514 (Prolonged preventive service(s)) to the list of Medicare telehealth services. Although Medicare telehealth requirements generally must be met in order for Medicare to pay for telehealth services, section 1115A(d)(1) of the Social Security Act permits waiving those requirements as may be necessary solely for purposes of testing models under section 1115A. CMS continues to explore how best to structure waivers of telehealth requirements as necessary for purposes of testing models under section 1115A of the Social Security Act, taking into account stakeholder and Model participant feedback.

In the Medicare Advantage Value-Based Insurance Design model that Congress expanded under the Bipartisan Budget Act of 2018, plans may increase the use of telehealth by proposing access to telehealth services to meet certain requirements for network adequacy as long as an in-person option remains.

Additionally, the Emergency Triage, Treat, and Transport (ET3) Model adds a reimbursement opportunity for a provider to treat in place using telehealth.

QUESTION SUBMITTED BY HON. JOHN THUNE AND HON. SHERROD BROWN

Question. Thank you to CMS for working to implement a host of policies included in the SUPPORT for Patients and Communities Act (Pub. L. 115–271) in the 2019 Medicare Physician Fee Schedule. As you know, section 2002 of the same law provides for increased screening for substance use disorder among Medicare beneficiaries during the Welcome to Medicare exam and annual wellness visits after January 1, 2020. Is CMS on track to issue implementing regulations for section 2002 in the 2020 Physician Fee Schedule this summer?

Answer. CMS appreciates Congress's efforts to address the opioid epidemic. CMS is working diligently to implement the provisions of the SUPPORT Act.

QUESTIONS SUBMITTED BY HON. ROB PORTMAN

Question. The IMD exclusion is set to be lifted on October 1st of this year, but before this, HHS is supposed to release guidance on how States can implement these changes. Can you provide an update on the efforts to operationalize these IMD reforms, and can you provide any recommendations to the States on what steps they can be taking to prepare for these changes?

Answer. More psychiatric treatment options are needed, and that includes more inpatient and residential options that can help stabilize Americans with serious mental illness when necessary. And while different forms of treatment work for different patients, the decades-old restriction on Medicaid reimbursement for inpatient treatment at institutions for mental diseases (IMDs) has been a significant barrier to inpatient psychiatric treatment. That is why, last November, CMS sent a letter to State Medicaid Directors outlining both existing and new opportunities for States to design innovative service delivery systems for adults with serious mental illness and children with serious emotional disturbance.

The SUPPORT for Patients and Communities Act (Pub. L. 115–271) included a provision that provides State Medicaid programs with the option to cover care in certain IMDs, which may be otherwise nonreimbursable under the Federal IMD exclusion, for Medicaid beneficiaries aged 21–64 with a substance use disorder for fiscal years 2019 to 2023. CMS is developing guidance to issue to States regarding this option, and hopes to publish a letter to State Medicaid Directors this fall. CMS has also been providing technical assistance prior to issuing guidance to the few States who have contacted it.

We believe States are evaluating this provision and CMS's waiver options around IMD coverage to determine the best course of action for their State.

Question. Over the past 3 years, Congress has taken considerable efforts to fund our response to the opioid crisis. The epidemic is continuing to evolve, and we are seeing an influx of other drugs like meth creeping into Ohio. Given that CARA and Cures funding and programs have traditionally been used to target opioid abuse, are you committed to allowing these funds to be used to address the abuse of other drugs as well?

Answer. Addressing the opioid epidemic is a top priority of this administration, and we appreciate the tools Congress has provided by passing legislation such as the SUPPORT for Patients and Communities Act (Pub. L. 115–271). This law was enacted on October 24, 2018, and CMS is implementing a number of new initiatives under that law that aim to increase options for treating beneficiaries with opioid use disorder or other substance use disorders, ensure prescriber accountability and improved safety for patients across CMS programs, and illuminate Medicaid prescribing data.

CMS has issued several Informational Bulletins outlining State approaches and effective practices for addressing the opioid epidemic within Medicaid. In November 2017, CMS issued guidance to States announcing a new policy to allow States to design demonstration projects that increase access to treatment for opioid use disorder (OUD) and other substance use disorders (SUD). Through this updated policy, States will be able to pay for a fuller continuum of care to treat SUD, including critical treatment in residential treatment facilities that Medicaid is unable to pay for without a waiver.

The SUPPORT for Patients and Communities Act (Pub. L.115–271) built upon this concept and included a provision that provides State Medicaid programs with the option to cover care in certain IMDs, which may be otherwise nonreimbursable under the Federal IMD exclusion, for Medicaid beneficiaries aged 21–64 with a substance use disorder for fiscal years 2019 to 2023. CMS is developing guidance to issue to States regarding this option, and hopes to publish a letter to State Medicaid Directors this fall. CMS has also been providing technical assistance prior to issuing guidance to the few States who have contacted it. We believe States are evaluating this provision and CMS's waiver options around IMD coverage to determine the best course of action for their State. Finally, in February 2019, CMS issued guidance [1] to States on mandatory and optional items and services for non-opioid treatment and management of pain that may be provided in the State Medicaid program.

In addition, the SUPPORT for Patients and Communities Act establishes a new Medicare benefit category for opioid use disorder treatment services furnished by opioid treatment programs (OTP) under Medicare Part B, beginning on or after January 1, 2020. In the Calendar Year 2019 Medicare Physician Fee Schedule, CMS sought information regarding services furnished by OTPs, payments for these services, and additional conditions for Medicare participation for OTPs that stakeholders believe may be useful for CMS to consider for future rulemaking to implement this new Medicare benefit category.

The Substance Abuse and Mental Health Services Administration (SAMHSA) is also fully committed to the prevention of, treatment of, and recovery from all harmful substances. We recognize that the use of methamphetamines and other drugs are rising in some areas of the country and is a critical concern. Many of SAMHSA's grant programs allow—and, indeed, encourage—grantees to select priority substances based on their own data. The Substance Abuse Block Grant asks States to provide SAMHSA with their primary prevention targeted priority areas. Ohio, for example, has indicated its 2019 priority areas to be alcohol, marijuana, prescription drugs, and heroin. Other States have indicated priority areas to be metham-

[1] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib022219.pdf?linkId=63935089.*

phetamines, cocaine, inhalants, or tobacco. The Strategic Prevention Framework—Partnerships for Success grantees also target alcohol and up to two other substances identified as areas of need. And, in an effort to distribute funds to communities, as well as States, SAMHSA has initiated a new funding opportunity, which will focus on community-driven efforts to advance substance abuse prevention, allowing communities and counties to apply for funds directly. As with the programs above, grantees will be able to choose among various target substances, including methamphetamine.

The Comprehensive Addiction and Recovery Act (CARA), the 21st Century Cures Act, and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act were passed by Congress specifically to address the opioid crisis. This focus on opioids has seen successes in a short time and promises more to come. In 2017, first-time heroin use was less than half of what it was in 2016, and more Americans are getting the treatment they need. The opioid crisis is not over yet; we must continue to address this crisis in big and meaningful ways to see even more positive results.

While the primary goal of SUPPORT, CARA and Cures Acts funding is the development of strategies and programs to address the opioid crisis, SAMHSA recognizes that many individuals struggle with more than one substance and that poly-drug use is common; when individuals with opioid use disorder served with these funds have co-occurring challenges with other substances, such as methamphetamine use disorder, the comprehensive treatment services offered address both conditions.

Question. The budget notes that HHS has been collecting data from the JW modifier since January 1, 2017 and proposes to make public some of this data. Can any of that data be shared now? Does HHS believe that excessively large vial sizes, and the subsequent wasted product from the unused dose, contribute to increased costs for patients and the health-care system without delivering improved results?

Answer. For dosing based on body surface or body weight, it is impossible to develop a vial size for each and every dose. FDA aims to have the applicant develop a range of vial sizes that minimizes the volume remaining after a patient is dosed, because if a significant amount of drug is remaining a healthcare provider may be tempted to try to extract that remainder and use it or combine it with other remainders to dose a second patient. As described in FDA's guidance for industry, *Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products* (June 2015), FDA may request justification when there are questions about the appropriateness of the proposed labeled vial fill sizes in an application. In recommending a range of vial sizes, we also consider the potential that having multiple vial sizes available can raise the risk of medication errors (as the healthcare provider is selecting a vial amongst many on a shelf).

There may be a financial incentive for manufacturers to produce and providers to purchase drugs in larger packaged dosages than typically needed, because Medicare Part B pays for these discarded drugs and biologics up to the amount included in a package or vial, in addition to the amount administered to the beneficiary. Since January 1, 2017, providers and suppliers have been required to report discarded drugs and biologicals on their Part B claims with the JW modifier. This budget proposal would make public which Part B drugs have the highest reported drug wastage using data gathered from these claims. Publicly reporting this information will allow for a better understanding of which drugs would benefit from different packaging to reduce wastage and we anticipate making this information available soon.

Question. I have several questions related to unaccompanied minors crossing the border, an issue that I know we all have concerns towards. I've chaired three Permanent Subcommittee on Investigations hearings on the topic, and we've released two reports on it. From these hearings, We learned HHS was not doing background checks on the sponsors. We wrote reports, held hearings, and undertook numerous staff briefings. As a result of those efforts, HHS and DHS began requiring fingerprint background checks for parents and other sponsors, as well as other adult household members, under a Memorandum of Agreement. My questions are, first: is the Memorandum of Agreement still in place?

Answer. Yes, though implementation has been modified through HHS operational directives.

Question. Is it correct that the usage of sponsor background information to run enforcement operations led to a backlog of children in HHS care?

Answer. In December 2018, ORR found that the MOA correlated with an increase in the average length of care, without enabling ORR to identify new child welfare risks. ORR issued an operational directive that suspended fingerprinting and biometric background checks of all household members of potential sponsors based on ORR's finding.

ORR has never conducted immigration enforcement actions again UAC sponsors.

Question. Is it true that in an effort to handle this problem, HHS decided to stop doing fingerprint background checks on some of the sponsors, and all of the adult household members?

Answer. ORR implemented operational directives in December 2018 and March 2019 related to the MOA. Copies are attached.

Question. Can you clarify which sponsors do get fingerprints background checks?

Answer. Category 1 sponsors no longer undergo a fingerprint background check as part of the sponsor suitability process, *unless:* a public records check reveals possible disqualifying information; there is a documented risk to the safety of the child; the child is especially vulnerable; or the case is being referred for a home study.

Category 2 and 3 sponsors still undergo fingerprint background checks.

QUESTION SUBMITTED BY HON. PATRICK J. TOOMEY

Question. As I have said many times, Congress must at some point come to acknowledge that no government program can grow faster than the economy indefinitely without eventually causing a fiscal crisis. Our largest Federal entitlement programs seem destined to test this simple mathematical fact, as Social Security, Medicare, and Medicaid are all projected to grow faster than GDP for the foreseeable future.

I commend you for putting forth this budget that at least tries to start a conversation about reforming some of these programs. In particular, it attempts to give States flexibility to grow and contract the Medicaid program in response to exogenous impacts on eligibility but limits per beneficiary growth to a reasonable measure of inflation. I want to thank the administration for continuing to endorse this idea and embracing a discussion on how we can make this program sustainable for the long-term.

At the same time, doing something about this issue has proven difficult even in times of unified government. I hope I am wrong, but this reality, combined with the change in the party of control in the House, all but ensures these changes will remain theoretical for at least the duration of this Congress.

In the absence of broader reforms, there have been some States that have requested the ability to "partially" expand Medicaid. This would consist of extending coverage forable-bodied, working-age adults up to 100 percent of the Federal poverty line, instead of the 138 percent of FPL required today in order to receive the enhanced Federal matching rate of reimbursement created by the Patient Protection and Affordable Care Act.

My office requested an estimate from the Centers for Medicare and Medicaid Services Office of the Actuary (OACT) as to what the impact on the Federal deficit would be if all States were given the option to partially expand. In their best estimate as to how States and consumers would react to such a change, OACT estimated that some States would roll back the expansion from 138 percent FPL to 100 percent. In those States, OACT assumes 60 percent of former Medicaid beneficiaries between 100 and 138 percent FPL would enroll in individual market plans, but 40 percent would forgo coverage despite being eligible for generous subsidies in the exchanges. Even with these behavioral assumptions, OACT estimated that overall allowing "partial" Medicaid expansion would increase the Federal deficit by over $30 billion.

Furthermore, such a change in policy would increase pressure on States who have not expanded Medicaid to do so. If all of these States were to expand to 100 percent, OACT believes that would cost the Federal Government almost $600 billion over 10 years.

I think we need to continue conversations on how we can make health care more accessible for individuals that currently struggle to afford it, including the uninsured. However, I continue to believe that Obamacare's Medicaid expansion, which

perversely provides much higher Federal matching funds for the coverage of working age, able-bodied adults without dependents than the traditional Medicaid population of the aged, disabled, children, and families, is the wrong way to accomplish that goal.

Is the administration considering allowing States to partially expand Medicaid at the enhanced matching rate of reimbursement in the absence of broader reforms? If so, how would this action be consistent with your broader goals of making this program sustainable and focusing it on the most needy?

Answer. The Medicaid program is an important source of health coverage for many Americans, and we must put it on a stable long-term sustainable footing for this and future generations. That is the challenge we have as we seek to empower the States and provide the right incentives to deliver quality services while ensuring the sustainability of the program. The administration believes strongly in the important role that States play in fostering innovation in program design and financing, and HHS is currently considering how to respond to States' renewed interest interested in changing their Medicaid expansion eligibility levels. Waiver applications are considered on a State-by-State basis, and CMS will continue to work with States interested in pursuing section 1115 demonstrations that promote the objectives of Medicaid and approve them when appropriate. However, giving States the flexibility to refocus the program on the populations Medicaid was intended to serve—the elderly, people with disabilities, children, and pregnant women—will help put Medicaid on a path to fiscal stability and is a key focus in the budget.

QUESTIONS SUBMITTED BY HON. RON WYDEN

WORK REQUIREMENTS IN MEDICAID

Question. The President's FY 2020 budget proposes to terminate Medicaid coverage for all "able-bodied, working age individuals" who do not meet a work requirement. Despite the fact that work requirements clearly violate the purpose of title XIX of the Social Security Act, the Centers for Medicare and Medicaid Services (CMS) continues to approve section 1115 waivers to allow for the imposition of work requirements in State Medicaid programs. Arkansas was the first State to implement work requirements last year, leading to18,000 people being kicked off their health coverage.[2] Secretary Azar told the House Energy and Commerce Subcommittee that the Department does "not yet have data as to why they fell off the program," yet the President's budget would force this failed experiment on every State.[3]

When discussing the 18,000 people disenrolled from Arkansas Medicaid for failing to meet the paperwork requirements, Secretary Azar explained that only 1,452 of those individuals reapplied in January when they became eligible again. He said that this was "a fairly strong indication that the individuals who left the program were doing so because they got a job . . . and they have insurance elsewhere and didn't need the Medicaid program." Please provide evidence to support Secretary Azar's claim that most individuals left the program because they got jobs. Of the people that gained employment, what percentage have health insurance comparable to Medicaid coverage?

Answer. CMS continuously works with States to use data to inform its work as they pursue and implement waivers that include community engagement requirements. Currently, Arkansas publishes monthly enrollment reports that include the number of individuals who did not comply with the community engagement requirement, and subsequently, how many have been terminated due to their noncompliance for 3 consecutive months. The State has recently issued a report that, since the requirement went into effect, 4,384 Arkansas Work Participants found employment. In addition, the State reported that more individuals had their coverage terminated for other reasons than failing to meet the community engagement requirement, including an increase in household income, moving out of the State, and failing to return requested information. This type of "churn" is not uncommon in Medicaid. According to the latest report, published in February, nearly 90 percent of the

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[2] *https://www.kff.org/medicaid/issue-brief/state-data-for-medicaid-work-requirements-in-arkansas/.*

[3] House Energy and Commerce Subcommittee hearing on "Fiscal 2020 Budget Request for the Department of Health and Human Services," March 12, 2019.

116,229 beneficiaries subject to the requirement were compliant either due to work, training, or another activity for the month of February.

Question. On March 14, 2019, CMS released new monitoring metrics tools for demonstrations that include work requirements. While this guidance represents a step toward proper oversight of section 1115 demonstrations, it still fails to address the fundamental problem that the Arkansas work requirements demonstration does not appear to have an approved evaluation plan or evaluator. In follow-up to our February 19th letter to Secretary Azar, please provide an update on the status of the evaluation for each approved section 1115 demonstration that includes work requirements, including approval of the State's evaluation plan and the State's progress in hiring the evaluator.

Answer. CMS reviews all section 1115 demonstration applications to ensure they include a comprehensive monitoring and evaluation plan. To help States meet the criteria of CMS's application approval process, in March, CMS released new State tools and guidance that provide standard monitoring metrics and recommended research methods geared specifically for section 1115 demonstrations that test innovative approaches to Medicaid eligibility and coverage policies. Eligibility and coverage demonstrations specifically allow States to test new policy approaches such as requiring work or community engagement among working age adults, providing premium assistance to purchase private coverage, and engaging certain beneficiaries through incentives and disincentives for meeting certain program requirements. These programs are designed to determine whether these approaches lead to targeted outcomes like increased employment, successful transitions to private coverage, better financial independence, and improved beneficiary health and well-being.

For each approved 1115 demonstration, States must provide CMS with regular reporting on key monitoring metrics upon implementation. States are also required to conduct evaluations by partnering with an independent evaluator. States are required to submit an evaluation design to CMS for approval following approval of the final demonstration. These monitoring and evaluation tools and guidance were designed to support these activities and were developed by CMS through a rigorous process with subject matter experts, a State monitoring advisory group, and contributions from experts in the field of evaluation research.

CMS will provide support to States to use and adopt these tools through individual technical assistance and through forums like our Community Engagement Learning Collaborative. CMS will provide specific instruction on these tools and guidance through a series of technical assistance sessions for States.

CMS approved the first 1115 demonstration with community engagement requirements in January 2018. Since that time, CMS has approved demonstrations with community engagement requirements in an additional 8 States. While States are in various stages of implementing these programs, no program has yet been implemented long enough for CMS to have sufficient levels of data to analyze results. CMS will continue working with States to gather and evaluate this data, and it looks forward to using what it learns to inform future efforts.

Question. The President's budget proposal to mandate work requirements in Medicaid includes estimated savings of $130.4 billion over 10 years. The nonpartisan Kaiser Family Foundation has estimated that expanding the Arkansas experiment nationally could result in up to 4 million people losing access to health coverage, most of whom would be either working or exempt from the work requirements.[4] Please provide the estimates used to determine the savings for the President's budget proposal, including: the number of individuals who would be subject to the mandate; the number of individuals who would lose coverage for failure to meet the work requirements; the number of individuals who would lose coverage for failure to complete the paperwork even though they met the requirements for work or would have qualified for an exemption; and the basis for these estimates of disenrollment.

Answer. The President's FY 2020 budget includes a proposal that would improve consistency between work requirements in federally funded public assistance programs, including Medicaid and Temporary Assistance for Needy Families (TANF), by requiring that able-bodied, working-age individuals find employment, train for work, or volunteer (community service) in order to receive welfare benefits. This

[4] *https://www.kff.org/medicaid/issue-brief/implications-of-a-medicaid-work-requirement-national-estimates-of-potential-coverage-losses/.*

would enhance service coordination for program participants, improve the financial well-being of those receiving assistance, and ensure federally funded public assistance programs are reserved for the most vulnerable populations. CMS' Office of the Actuary estimates this proposal to save $8.3 billion in FY 2020, $55.6 billion over 5 years, and $130.4 billion over 10 years.

GREATER PAPERWORK BURDEN FOR MEDICAID BENEFICIARIES

Question. In a speech at the Federation of American Hospitals 2019 Public Policy Conference earlier this month Administrator Verma discussed the Patients over Paperwork initiative, which was launched in 2017 "to focus all of CMS on finding opportunities to modernize or eliminate rules and requirements that are outdated, duplicative or getting in the way of good patient care."[5] Yet the President's FY 2020 budget is filled with proposals that specifically increase paperwork and get in the way of good patient care.

Work requirements put mountains of paperwork between patients and their doctors and essentially serve as a backdoor scheme to kick people off Medicaid. The nonpartisan Kaiser Family Foundation examined the implications of extending work requirements nationally and found that the majority of people kicked off Medicaid would lose coverage due to the burdensome documentation requirements, not the work requirements. Please describe how work requirements fit with the goals of the Patients over Paperwork initiative, which are stated on the CMS website as: reduce unnecessary burden; increase efficiencies, and improve the beneficiary experience.

Answer. As part of the waivers CMS has granted, it has set careful guardrails that require States to protect their most vulnerable beneficiaries, and only required community engagement from beneficiaries whose circumstances allow them to participate. We are also attentive to the paperwork burdens imposed on both beneficiaries and States, although we believe the benefits of setting the right incentives can far outweigh these costs. All of these costs and benefits will be carefully evaluated for each waiver we approve.

Beyond this demonstration opportunity, this administration encourages all State Medicaid directors and stakeholders to think about how they can promote community engagement. In setting up the demonstrations, CMS is building on a robust academic literature that shows community engagement, such as employment, can have substantial benefits for well-being. Finding work is associated with significant improvements in mental and physical health—and programs set up to improve Americans' health should, where feasible, reflect that.

Question. Establishing more frequent eligibility redeterminations would put unnecessary paperwork between eligible Medicaid beneficiaries and their providers. Failing to complete the renewal paperwork, not increased income, was the primary reason people lost coverage under Indiana's Medicaid waiver in 2017.[6] The churn from dis-enrolling and re-enrolling eligible individuals not only disrupts the patient-provider relationship and continuum of care, but also increases administrative costs for States The President's FY 2020 budget proposal includes $45.6 billion in savings from allowing States to increase the frequency of Medicaid eligibility redeterminations. Please provide the estimates used to determine the savings for this proposal, including: the total number of individuals who would lose Medicaid coverage due to this change; the number of parents and children who would lose coverage; the number of individuals losing coverage who would become uninsured; the number of individuals who would likely become Medicaid eligible again within 3 months or less; and the increase in administrative costs due to more frequent redeterminations and the corresponding increase in dis-enrolling and re-enrolling beneficiaries.

Answer. Current regulations prohibit States from conducting Medicaid eligibility redeterminations more than once every 12 months for individuals eligible based on MAGI financial eligibility. This proposal would provide States with the flexibility they have asked for to allow States the option to conduct more eligibility redeterminations for MAGI populations to ensure that their Medicaid programs are focused on the individuals that need it most. It will also ensure that individuals who have incomes that exceed the Medicaid income eligibility threshold are not taking advantage of scarce Federal resources by staying on Medicaid when they are no longer

[5] *https://www.cms.gov/newsroom/press-releases/speech-remarks-administrator-seema-verma-federation-american-hospitals-2019-public-policy-conference.*

[6] *https://www.cbpp.org/research/health/locking-people-out-of-medicaid-coverage-will-increase-uninsured-harm-beneficiaries.*

eligible. The President's FY 2020 budget estimates $45.6 billion in savings over 10 years.

CHILDREN'S HEALTH INSURANCE COVERAGE

Question. For the first time in a decade, the number of uninsured children in the United States is going up. According to data from the American Community Survey an additional 276,000 children were uninsured in 2017. This change reverses 10 years of improvement in access to coverage for kids. Focusing in on most vulnerable children, last year the number of children covered by Medicaid and the Children's Health Insurance Program (CHIP) dropped by nearly 600,000 according to CMS enrollment data. Unfortunately, the data do not indicate that these children moved to private insurance coverage. Several proposals in the President's FY 2020 budget would introduce new barriers to coverage, such as more frequent redeterminations, new asset tests, and more restrictive up-front verification of immigration status.

Do you think that the American Community Survey results and the CMS enrollment data are accurate?

If these data are accurate, how concerned are you that the number of uninsured children is going up? Isn't it inconsistent with the goals of the Medicaid and CHIP programs to have the number of uninsured children increase?

Would you agree that more government red tape, like increasing the frequency of eligibility redeterminations, is likely to further depress enrollment of children in Medicaid and CHIP?

Answer. CMS is aware of the Medicaid and CHIP enrollment declines that States have reported for the past few months. There are a number of possible factors that could contribute to these enrollment declines, and CMS is looking closely at the impact those drivers may be having on enrollment. Some of the enrollment decline may be attributed to the improved economy but CMS is continuing to look at other factors to ensure that eligible people can continue to be enrolled. Regarding whether increasing the frequency of eligibility redeterminations is likely to further depress enrollment in Medicaid and CHIP, current regulations prohibit States from conducting Medicaid eligibility redeterminations more than once every 12 months for individuals eligible based on MAGI financial eligibility. The FY 2020 President's budget allow States the option to conduct more eligibility redeterminations for MAGI populations to ensure that their Medicaid programs are focused on the individuals that need it most. It will also ensure that individuals who have incomes that exceed the Medicaid income eligibility threshold are not taking advantage of our scarce Federal resources by staying on Medicaid when they are no longer eligible.

In addition, there are a number of factors that impact enrollment in Medicaid and CHIP, including: the economy, State eligibility system functionality, and State operations (*e.g.,* ability to receive and process applications and conduct timely redeterminations annually or when there is a change in circumstance that may affect eligibility). Some of these considerations, such as a strong economy, State systems and operational issues, and reducing backlog of delayed redeterminations may account for the FY 2018 decline in Medicaid and CHIP enrollment, among others. Each of the factors may impact States and their enrollment trends differently. For example, States experiencing losses in Medicaid and CHIP enrollment may also be experiencing a decrease in unemployment rates, indicating an improving economy may account for the enrollment decline. While in other States, enrollment declines may actually be influenced by State system and operational issues. More information can be found at *https://www.medicaid.gov/chip/downloads/fy-2018-childrens-enrollment-report.pdf.*

PROGRAM INTEGRITY

Question. Medicaid and CHIP beneficiaries lead complex lives. They are individuals with complex medical conditions, disabilities, and substance use disorders; individuals who are homeless or face housing instability; elderly individuals in long-term care facilities; and infants and children in low-income families. The purpose of Medicaid and CHIP is to provide health care for these individuals. It is important that we protect the fiscal integrity of these programs while not placing unnecessary barriers and government red tape between eligible beneficiaries and this essential coverage.

Evidence suggests that most Medicaid improper payments result from insufficient provider documentation, not beneficiary ineligibility.[7] Establishing new barriers to eligibility, like the President's FY 2020 budget proposal to eliminate the reasonable opportunity period for verification of citizenship and immigration status, primarily serve to prevent eligible beneficiaries from accessing the coverage to which they are entitled.

How does CMS define improper payments?

What percent of these improper payments are due to insufficient documentation?

Answer. An improper payment occurs when a payment should not have been made, Federal funds go to the wrong recipient, the recipient receives an incorrect amount of funds, or the recipient uses Federal funds in an improper manner. In addition, when an agency's review is unable to discern whether a payment was proper as a result of insufficient or lack of documentation, this payment should also be considered an error.

Since FY 2014, the Medicaid improper payment estimate has been driven by errors due to State non-compliance with provider screening, enrollment, and National Provider Identifier (NPI) requirements. The majority of improper payments have been cited on claims where a newly enrolled provider had not been appropriately screened by the State, a provider did not have the required NPI on the claim, or a provider was not enrolled.

For FY 2018, Medicaid payments for which there was insufficient or no medical documentation to support the payment as proper accounted for approximately 9 percent ($3.4 billion) of Medicaid improper payments.[8]

Question. What percent of the improper payments are attributable to true fraud where payment should still have not been made if sufficient documentation was provided?

Answer. Improper payments do not necessarily represent expenses that should not have occurred. Instances where there is insufficient or no documentation to support the payment as proper are also cited as improper payments. A majority of Medicaid improper payments were due to instances where information required for payment was missing from the claim and/or States did not follow the appropriate process for enrolling providers. However, these improper payments do not necessarily represent payments to illegitimate providers and, if the missing information had been on the claim and/or had the State complied with the enrollment requirements, then the claims may have been payable. A smaller proportion of improper payments are considered a known monetary loss to the program, which are claims where HHS determines the Medicaid payment should not have been made, or should have been made in a different amount.

Question. In the case of improper payments related to erroneous eligibility determinations under section 1903(u) of the Act since 1992, has CMS attempted to recoup any improper payments? If so, please identify the overpayment amount and the recoveries by State and year.

What are the State-by-State Medicaid eligibility error rates since the PERM program began tracking this metric in 2008?

What are the State-by-State Medicaid eligibility error rates for traditional eligibility pathways versus the newly eligible expansion pathway created by the ACA since the expansion in 2014?

What additional statutory authorities, if any, have you indicated would be beneficial for the purpose of enforcing section 1903(u)?

Answer. As you know, the Federal-State partnership is central to the success of the Medicaid program, and CMS plays a critical role in ensuring that States are compliant with Federal statute and regulations and that only eligible individuals are enrolled in Medicaid. CMS continuously works to strengthen Medicaid program integrity efforts to ensure that taxpayer dollars are spent appropriately.

As part of CMS's strategy to improve program integrity and increase oversight of States' beneficiary eligibility determinations, CMS is auditing the States previously found to be high risk by the OIG to examine how these high risk States determine

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[7] *https://ccf.georgetown.edu/2018/04/19/measuring-medicaids-mistakes-estimating-improper-payments/.*

[8] *https://www.hhs.gov/sites/default/files/fy-2018-hhs-agency-financial-report.pdf.*

eligibility for Medicaid benefits. These States are New York, Kentucky, and California. CMS also carefully reviewed the November 2018 Louisiana Legislative Auditor's report on wage verification practices and the subsequent report released in December 2018 on the State's eligibility determination practices for the expansion population as a result of the number of findings identified by the State auditor's reviews. CMS will also audit Louisiana in the coming weeks. The objectives of the audits are to determine whether beneficiary eligibility was adjudicated appropriately for the new adult group and whether services for beneficiaries in the new adult group were assessed the correct Federal Medical Assistance Percentage (FMAP).

CMS does not have statutory authority to recoup overpayments for eligibility errors that may be identified through these audits, as that would require a statutory change to section 1903(u) of the Social Security Act (the Act). The Fiscal Year (FY) 2020 President's budget includes a legislative proposal that would provide CMS with broader authority to issue disallowances and extrapolate based on future audits to recoup Federal resources from States that enrolled ineligible beneficiaries or misclassified beneficiaries. In addition, the budget proposal would eliminate the current three percent threshold for States' eligibility-related improper payments, incentivizing States to take swift action to correct eligibility-related errors.

Prior to a CMS regulation published in July 2017, any identified improper payments based on eligibility determinations were subject to recovery only under section 1903(u) of the Act, which governed the traditional MEQC program. Section 1903(u) instructs the Secretary to issue disallowances with respect to the portion of a State's erroneous payments that exceed a 3 percent error rate, though the Secretary may waive all or part of the disallowance if a State demonstrates that it cannot reach the 3 percent allowable error rate despite a "good faith effort." In 1992, States prevailed at the HHS Departmental Appeals Board (DAB) in challenging the disallowances based on the traditional MEQC program. The DAB concluded that the MEQC sampling protocol and the resulting improper payment rate calculation were not sufficiently accurate to provide reliable evidence to support a disallowance under section 1903(u). As such, although the traditional MEQC program remained in place, CMS provided States with the ability to implement MEQC pilots that were focused on prospective improvements in eligibility determinations rather than disallowances. The MEQC pilots were an alternative way for States to meet the "good faith effort" exception to section 1903(u), and a majority of States elected this alternative approach due to the pilots' flexibility to target specific problematic or high-interest areas.

Today, while CMS does not have authority to recoup overpayments identified in the new eligibility audits discussed above, CMS does have authority to issue disallowances, and, in certain circumstances, States are required to return overpayments. By virtue of CMS's July 2017 rulemaking, the PERM program has been configured to satisfy the requirements of section 1903(u) of the Act (as opposed to the traditional MEQC program that, as we note above, the DAB found failed to yield evidence sufficiently reliable to support a disallowance), thus establishing CMS's authority to issue PERM eligibility-related disallowances and clarifying the "good faith effort" exception. As a result of that rulemaking, CMS will once again measure the current improper payment rate for the eligibility component of the PERM program, beginning with the FY 2019 reporting. Under the PERM program, each State is reviewed on a rolling 3-year basis to produce an annual national improper payment rate for the Medicaid program. Current regulations will allow CMS to begin to issue potential disallowances to States based on PERM program findings in FY 2022, when all States have been reviewed once under the revised rule and allowed a chance to implement prospective improvements in eligibility determinations to demonstrate a "good faith effort."

Also as part of that July 2017 rulemaking, CMS implemented a revised MEQC program that uses State-directed reviews in the two off-cycle PERM years to address Medicaid beneficiary eligibility vulnerabilities. Under this revised program, should States find active cases for which eligibility determination errors were made, they are required to assess the financial implications of the error during the three-month period after the erroneous eligibility date and will be require to return the Federal share of any overpayments made as a result of these erroneous eligibility determinations through the quarterly CMS–64 and CMS–21 reporting processes.

National PERM eligibility improper payment rates for the time period FY 2008 through FY 2014 covered review periods for eligibility determinations made prior to the implementation of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148). With the implementation of PPACA, State eligibility determina-

tion processes and the eligibility review methodology have changed drastically. In light of changes to the way States adjudicate eligibility for applicants for Medicaid and CHIP under PP ACA, CMS did not conduct the eligibility measurement component of the PERM program for FY 2015 through FY 2018 in order to enable us to update the eligibility component measurement methodology in the July 2017 rulemaking. For reporting years FY 2015 through FY 2018, the 2014 national eligibility improper payment rate was used as a proxy rate, and all States conducted a pilot program with rapid feedback for improvement (known as the Medicaid and CHIP Eligibility Review Pilots) to maintain oversight of State eligibility determinations. Revisions made in the July 2017 rulemaking include updates to the review elements; the review process, including Modified Adjusted Gross Income (MAGI) methodologies and use of electronic data sources; and the use of a Federal contractor as the entity performing the reviews. As noted above, beginning with the FY 2019 reporting, CMS will again measure a national improper payment rate for the eligibility component of the PERM program. This information is scheduled to be reported in November of 2019.

GRAHAM-CASSIDY-HELLER-JOHNSON BUDGET PROPOSAL

Question. In the President's proposed FY 2020 budget, the administration makes clear that it once again intends to bring back the failed Graham-Cassidy-Heller-Johnson proposal, legislation that would gut the Affordable Care Act's consumer protections—legislation that the American people clearly rejected.

Please describe how the Graham-Cassidy-Heller-Johnson legislation differs from the proposal in the budget.

The Graham-Cassidy-Heller-Johnson legislation included a provision allowing insurance companies to charge older Americans more for their health care. Would the administration's legislative proposal, modeled closely after the Graham-Cassidy-Heller-Johnson bill, also include this age tax? Please describe what age rating limits would be placed on insurers. What is the projected impact on older Americans' insurance premiums?

The President's budget proposal requires States to allocate at least 10 percent of their grant to funding protections for people with pre-existing conditions. Please describe how the Department determined 10 percent to be an appropriate allocation amount.

Answer. The administration believes that States are better situated to address the health-care needs of their citizens and this proposal puts the States in the driver's seat. The administration is also committed to empowering States and consumers to reform their health insurance markets. The President's budget supports a two-part approach starting with enactment of legislation modeled closely after the Graham-Cassidy-Heller-Johnson bill that include Market Based Health Care Grants. The second part of the budget proposal includes additional reforms to make the system more efficient and to address unsustainable health-care spending trends, including proposals to align the growth rates for the Market-Based Health Care Grant Program and Medicaid per capita cap and block grant with the Consumer Price Index for All Urban Consumers (CPI–U).

Under the budget proposal, States will be required to allocate at least 10 percent of their grant funding to ensure protections for high-cost individuals, including those with pre-existing conditions. This demonstrates the importance of ensuring protections for individuals with pre-existing conditions and that all Americans have access to affordable, high value care, including those with pre-existing conditions.

1332 AND SHORT-TERM LIMITED DURATION INSURANCE

Question. Congress enacted section 1332 of the Affordable Care Act to provide States with the flexibility to improve coverage, affordability, and comprehensiveness of benefits. Consistent with these goals, States must prove that their waivers meet specific guardrails. Last year, HHS released new guidance and examples on section 1332 which weakened pre-existing condition protections and suggested some ideas for waivers that would allow a State to provide less comprehensive, less affordable coverage.

Will HHS approve a section 1332 waiver proposal if it would provide less comprehensive or less affordable coverage? Please describe the circumstances in which you will approve a section 1332 waiver if it provides less comprehensive or less affordable coverage.

Please explain whether the administration's new section 1332 examples would allow taxpayer dollars to go to short-term limited-duration insurance.

Answer. On October 24, 2018, the Department of Health and Human Services and the Department of the Treasury (the Departments) published new 1332 guidance that replaced the December 2015 guidance. The new guidance will permit States to more readily take advantage of the flexibility allowed by the statute. The guidance ensures that State residents who wish to retain coverage similar to that provided under the PPACA can continue to do so, while permitting a State waiver plan to also provide access to other options that may be better suited to consumer needs and more attractive to many individuals. The Departments believe that the new guidance will lower barriers to innovation and encourage States to implement waiver plans that will strengthen their health insurance markets by providing a variety of coverage options.

Section 1332 waivers are optional; States are free to choose to apply for a waiver or continue to have their markets subject to applicable PPACA rules. The October 2018 guidance does not create binding rights or obligations, but instead provides transparency to States and the public regarding the manner in which the Departments intend to use their discretion when they review State applications. Additionally, each section 1332 waiver application will be considered in its entirety to evaluate whether it meets the statutory guardrails, regulations, and guidance. This requirement to meet all statutory guardrails includes instances where a State waiver application proposes to make available alternative coverage options like short-term, limited-duration plans. The Departments cannot assess whether or not a proposal meets the guardrails until we receive a specific proposal from a State. The Departments wish to work with States to develop their ideas and ultimately implement these programs to benefit consumers.

A 1332 waiver cannot undermine coverage for people with pre-existing conditions. Moreover, any section 1332 waiver will need to carefully account for any impact on the individual market risk pool and guarantee that access to coverage is at least as comprehensive and affordable as would exist without the waiver.

LOWER TAX CREDITS PROPOSAL

Question. In the "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020," your Department proposed to modify the formula for indexing the tax credits that help patients and families buy insurance. This proposal could also raise the maximum out-of-pocket cost-sharing limit that people have to pay.

Please describe how the Department expects the proposed change in the premium adjustment calculation will impact premiums and out of pocket costs for consumers.

Please describe how the Department expects the proposed change in the premium adjustment calculation will impact consumer enrollment.

Answer. In the 2020 Notice of Benefit and Payment Parameters Proposed rule, we proposed a premium adjustment percentage of 1.2969721275 for the 2020 benefit year, including a proposed change to the premium measure for calculating the premium adjustment percentage. The annual premium adjustment percentage sets the rate of increase for several parameters detailed in the PPACA, including: the annual limitation on cost sharing, the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the code, and the employer shared responsibility payments under sections 4980H(a) and 4980H(b) of the code.

The proposal in the 2020 Notice of Benefit and Payment Parameters proposed rule to use private health insurance premiums (excluding Medigap and property and casualty insurance) in the premium adjustment percentage calculation would result in a faster premium growth rate measure than if we continued to use employer-sponsored insurance premiums as was used for prior benefit years. In the proposed rule, we proposed a required contribution of 8.39 percent using the proposed premium adjustment percentage in, whereas we would have proposed a required contribution of 8.18 percent if employer-sponsored insurance premiums continued to be used in the premium adjustment percentage calculation for the 2020 benefit year. Additionally, we proposed a maximum annual limitation on cost sharing of $8,200 for self-only coverage, whereas we would have proposed a maximum annual limitation on cost sharing of $8,000 for self-only coverage if employer-sponsored insurance premiums continued to be used in the premium adjustment percentage calculation for the 2020 benefit year.

The CMS Office of the Actuary estimates that the proposed change in methodology for the calculation of the premium adjustment percentage may have the following impacts between 2019 and 2023:

- Net premium increases of approximately $181 million per year, which is approximately one percent of 2018 benefit year net premiums, for the 2020 through 2023 benefit years. Net premiums are calculated for Exchange enrollees as premium charged by issuers minus APTC.
- A decrease in Federal PTC spending of $900 million in 2020 and 2021, and $1 billion in 2022 and 2023, due to an increase in the PTC applicable percentage and a decline in Exchange enrollment of approximately 100,000 individuals in benefit year 2020, based on an assumption that the Department of the Treasury and the IRS will adopt the use of the same premium measure proposed for the calculation of the premium adjustment percentage in this rule for purposes of calculating the indexing of the PTC applicable percentage and the required contribution percentage under section 36B of the code. We anticipate that enrollment may decline by 100,000 individuals in benefit year 2020, and enrollment would remain lower by 100,000 individuals in each year between 2020 and 2023 than it would if there were no proposed change in premium measure for the premium adjustment percentage for the 2020 benefit year.

HUMAN SERVICES

Question. Recent news reports suggest that the Office of Refugee Resettlement (ORR) failed to ensure unaccompanied children are properly protected against sexual abuse and exploitation. In your testimony to the Senate Finance Committee, you stated that ORR had investigated grantee facilities that had a substantiated allegation(s) of staff-on-minor sexual abuse and, in the case of at least one grantee, had shut down one or more facilities and removed the children. You also noted that this would then require those facilities, if they were to reopen and house unaccompanied children, to go through re-licensing by the State licensing authority.

How do you identify which grantee facilities should be investigated? In cases where the findings require it, describe the process for transferring detained children and closing the facility. What is the role of the State in this process?

Answer. Care providers must report sexual abuse, sexual harassment, or inappropriate sexual behavior that occurs in ORR care within four hours after learning of the allegation. Care provider facilities must follow State licensing requirements to report allegations of sexual harassment and inappropriate sexual behavior.

Care providers report allegations of sexual abuse to CPS, the State licensing agency, HHS/OIG, and the FBI. If an allegation involves an adult, the care provider must notify local law enforcement.

CPS and State licensing authorities investigate allegations of sexual abuse according to State law, and the FBI and the HHS/OIG investigate allegations according to Federal laws and procedures. CPS or the State licensing authority may, during the course of their investigations, develop a safety plan or recommend other steps to ensure the safety of an impacted child.

ORR has no formal investigative authority, but reviews every report of sexual abuse submitted by care provider facilities to ensure that care providers comply with ORR regulations and policies. ORR also reviews allegations to ensure that care providers respond appropriately to the allegations using child welfare principles.

If ORR determines that UAC are not safe with a care provider following an allegation, ORR issues a "stop placement" directive so that no unaccompanied alien children are placed at the facility. ORR then removes all children from the facility and transfers them to other facilities with available capacity. ORR and the care provider continue to cooperate with any investigations by law enforcement, CPS, or licensing authorities. ORR may also monitor the facility and issue corrective actions, as appropriate. ORR resumes placement after the issues identified in the corrective actions are satisfactorily resolved.

How many facilities has ORR shutdown since 2014 and what was the reason for each shutdown? For each case, also detail where the children were transferred to.

Answer. Since October 2014, ORR has issued a stop placement and transferred remaining UAC from one care provider due to a substantiated allegation of sexual abuse. In 2017, following reports of a staff member sexually assaulting unaccompanied alien children at Southwest Key Casa Kokopelli, ORR issued a stop place-

ment and transferred the remaining children to other local care providers. The majority of children were transferred to Southwest Key Phoenix.

Question. How many facilities were investigated by ORR but were allowed to remain operational? For each case, how is ORR ensuring that facilities make changes that ensure children are properly protected against sexual abuse and exploitation?

Answer. ORR reviews every allegation of sexual abuse to ensure that care providers take appropriate steps to protect the victim, and ensure the safety and well-being of children in their care. Care providers must use multiple protection measures to ensure the safety and security of victims, including housing changes within a facility, transfers to a different facility, and emotional support services.

In all cases of an allegation of sexual abuse, care provider facilities must:

- Report the allegation to ORR, State/local child protective services (CPS), State licensing authorities, HHS's Office of Inspector General, and the U.S. Department of Justice's FBI.
- Report allegations of sexual abuse that involve an adult to local law enforcement.
- Cooperate with any investigation of the allegation, including by CPS, licensing or law enforcement.
- Take immediate action to protect the victim and the safety of other children in the program (*i.e.,* separating the victim from the perpetrator, increasing supervision, housing changes, transfers).
- Provide follow-up services, including medical or mental health services.
- Make appropriate notifications to parents, legal guardians and sponsors, attorneys, and child advocates, if applicable.

If a sexual abuse allegation involves a staff member, the care provider facility is required by regulation to suspend the staff member from all duties that would provide the staff member with access to UAC pending investigation.

After investigation by an oversight entity substantiates the allegation, a care provider facility must take disciplinary action, up to and including termination for violating ORR's or the care provider facility's sexual abuse-related policies and procedures. Termination is the presumptive disciplinary sanction for staff who engaged in sexual abuse or sexual harassment.

In addition to routine monitoring, ORR has an Abuse Review Team (ART) that quickly reviews allegations of abuse that are particularly serious or egregious in nature. The team is composed of ORR staff with the appropriate expertise to assess these allegations, including members of ORR's Monitoring Team, the Division of Health for Unaccompanied Children, and ORR's Prevention of Sexual Abuse Coordinator.

Question. Table S–6 (on page 124) of the President's budget includes a line item stating "protect the religious liberty of child welfare providers."

Please describe what this line item is referencing. Is it associated with an HHS proposal allowing taxpayer-funded child welfare providers to choose which individuals they work with (*e.g.,* qualified volunteers, foster parents, and adoptive parents) based on the individual's religious identity? If so, please detail the proposed policy.

Answer. The Department believes faith-based providers are the bedrock of some of our most difficult placements in terms of children with disabilities and, historically, always have been. In the President's FY 2020 budget there is a line item entitled "Protect the religious liberty of child welfare providers" (page 124). This proposal is consistent with the Department's grant of an exception to the State of South Carolina. In light of the foster care crisis resulting from insufficient numbers of foster families, and the concurrent moves by some States to close foster providers on the basis of the providers' religious beliefs, the administration believes Congress should protect adoption and foster care providers from discrimination or from burdens imposed on their exercise of their faith that may eliminate them from contributing to the number of foster placements made in a State. Such an action by Congress would increase the scope of available foster and adoption care providers and help alleviate the present crisis.

Question. You and the Department of Health and Human Services (HHS) have granted South Carolina an exemption from Federal nondiscrimination laws and regulations for State-contracted child welfare agencies in the State. You have defended this decision by citing a substantial burden to faith-based providers, but you have

not addressed how foster youth being served by faith-based providers are protected under this waiver and whether their religious liberty is protected.

How will HHS ensure that foster children of a minority religion in South Carolina will not be discriminated against, harassed, prohibited from exercising their faith, or forced to exercise a faith other than their own when being placed by an agency that is devout to a singular religious ideology?

How will HHS assure that the needs of LGBTQ-identified youth in foster care in South Carolina will be addressed and protected from harassment, discrimination and forms of conversion practices when being placed by an agency that professes a deeply held belief against being LGBTQ?

Answer. In light of the request from Governor McMaster, the Department granted an exception to the religious nondiscrimination provision in 45 CFR § 75.300(c). We determined that requiring Miracle Hill Ministries to abandon its use of religious criteria as a condition of receiving title IV–E funds would substantially burden the free exercise of religion in violation of Religious Freedom Restoration Act, 42 U.S.C. § 2000bb, *et seq.* (RFRA). Our decision to grant an exception was also guided by programmatic considerations because Miracle Hill Ministries is responsible for up to 15 percent of the foster care placements in South Carolina. If it were to cease providing services, the State's foster care program would have been substantially burdened. Moreover, there are at least nine other agencies in South Carolina that may assist foster parents in the event that Miracle Hill Ministries is not able to do so as a result of its sincerely held religious beliefs.

The mission of HHS is to enhance and protect the health and well-being of all Americans. We are committed to providing top quality service regardless of race, religion, creed, ethnicity, sexual orientation, or any other socio economic identifiers. HHS does not condone any form of harassment and discrimination. Our HHS Office for Civil Rights investigates and takes appropriate action on matters that infringe on civil rights, conscience and religious freedom, privacy, and patient safety confidentiality, or violation of the law.

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

Question. During the hearing, you testified that the CDC was not conducting research on gun violence because the agency did not have the funding to do so. It is my understanding that researchers may apply for grants to study gun violence under the Injury Prevention and Control program.

Has the CDC received any grant applications for gun violence research under the Injury Prevention and Control program?

Answer. CDC has not received grant applications specifically for gun violence research, but in response to the FY 2019 Notice of Funding Opportunity (NOFO) for CE19–001, Injury Control Research Centers, some applicants did include proposals for research to develop or evaluate an intervention to prevent suicide that included one of the following topics related to guns:

- Training for health-care providers to improve their ability to identify at-risk patients and provide education to the patient and caregivers on safe firearm storage and access.
- Evaluate the impact of changing policies on health-care access and firearm laws on mortality.
- Evaluation of secondary data related to firearm laws in the interpretation of surveillance data.

Question. If yes, why were the applicants not awarded funding?

Answer. The Notice of Funding Opportunity for the Injury Control Research Centers published in FY 2018 and has not yet been awarded. CDC expects to make awards this month.

Question. What resources does the CDC need to begin research on gun violence?

Answer. The FY 2020 President's budget does not include specific funding for CDC to conduct research on gun violence. The budget includes $24 million for the National Violent Death Reporting System (NVDRS), a surveillance system which identifies violence trends at national and regional levels by linking data from law enforcement, coroners and medical examiners, vital statistics, and crime laboratories. NVDRS is a State-based surveillance system that captures information on all

types of violent deaths-including homicides and suicides. Information on firearms is collected as a mechanism of injury; the system also collects data on unintentional firearm injury deaths. The budget request focuses on public health data collection by States—activity that is core to CDC's mission.

Question. Secretary Azar stated that the HHS IG report "speculated" that there "may have been thousands not that they found them" in reference to children being separated from their parents prior to the June 26, 2018 court order in *Ms. L v. ICE.* Has ORR identified how many children were separated from parents prior to the June 26, 2018 court order? If so, what is that number? If not, why not?

Answer. ORR is presently implementing a court-approved plan to identify the separated children of *Ms. L.* class members for the time period of July 1, 2017 through June 25, 2018 (also referred to as the expanded class period). The filings by the Government explaining that plan are attached.

Question. Does ORR dispute the findings of the HHS IG report that "officials estimated that ORR received and released thousands of separated children prior to the June 26, 2018 court order" and what is the basis for disputing the report's findings?

Answer. OIG did not find that thousands of children were separated by DHS and discharged before June 26, 2018. Rather, the OIG reported that members of the HHS staff estimated that such children *could* number in the thousands. Our response to the question above addresses our estimations with respect to the number of separated children.

Question. During the hearing, I requested you follow up with my office in writing with the exact steps HHS is taking to ensure that the families that were separated prior to the June 26, 2018 are identified and reunited. The Secretary stated it would be possible for him to do so as such information is consistent with the status reports HHS provides the courts. My office is still waiting for that information.

Answer. As noted above, copies of the filings by the Government in *Ms. L,* which explain the Government's plan to identify the separated children of *Ms. L.* class members for the expanded class period, are attached. The Court has not yet addressed remedies issues in the litigation.

Question. The budget mentions the troubling upward maternal mortality trend in the United States but there are cuts to critical programs like title V, Medicaid, and other programs in HRSA that help moms and babies. Can you share the administration's strategy to reduce maternal mortality and support new moms and babies while cutting programs intended to help those groups?

Answer. The FY 2020 budget Request for the Health Resources and Services Administration includes funding specifically targeted to addressing maternal mortality by expanding access to safe, high-quality health care for women of childbearing age. Specific efforts include continued support for State Maternal Health Innovation grants and expansion of the Alliance for Innovation on Maternal Health (AIM) program's maternal safety bundles to all 50 U.S. States, the District of Columbia, U.S. territories, and tribal entities.

- As of late April 2019, AIM is now working with 26 States and has implemented maternal safety bundles in more than 1,300 birthing facilities across the country, reaching nearly two million annual births (or around half of all annual births in the United States).
- State Maternal Health Innovation Grants will support State-focused demonstrations that implement evidence-based interventions to address critical gaps in maternity care service delivery and reduce disparities in maternal morbidity and mortality.

In addition, other maternal and child health investments aim to improve the overall health and well-being of mothers and babies which is also important for reducing maternal mortality. The Healthy Start Initiative: Eliminating Disparities in Perinatal Health (Healthy Start) will continue to support efforts to address maternal mortality through hiring of nurse practitioners, certified nurse midwives, physician assistants, and other maternal-child advance practice health professionals to provide clinical services, such as well-woman care and maternity care services, within program sites nationwide. In partnership with the States, the MCH Block grant supports a wide range of activities and initiatives reaching 86 percent of all pregnant women in the U.S.

Question. The budget makes significant changes to the way the Federal Government funds graduate medical education (GME). Given we are in the midst of an

ever-growing physician shortage, are there data and projections available on how your proposal will address the shortage and ensure there are sufficient physician providers to meet America's needs today and into the future?

Answer. Funding for Graduate Medical Education (GME) comes from multiple fragmented funding streams, and HHS's GME financing system does not target training to the types of physicians needed in the United States. The President's FY 2020 budget includes a proposal that 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 2020 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 modernize graduate medical education funding, making it better targeted, transparent, accountable, and more sustainable.

Question. The budget again zeroes out funding for "Autism and Other Developmental Disorders" at HRSA. How does the administration propose to maintain the programs that funding supports and continue to invest in autism research, surveillance, and care at a time when the autism prevalence rate continues to increase with diminished investment?

Answer. The President's budget prioritizes programs that support direct health-care services and give States and communities the flexibility to meet local needs. Some of these activities could be continued by States using their Maternal and Child Health Block Grant awards.

Question. What investments can we make in Medicare and Medicaid to use claims data to flag potential price fixing collusion in the prescription drug space?

Answer. For years, American patients have suffered under a drug-pricing system that provides generous incentives for innovation, while too often failing to deliver important medications at an affordable cost. We have access to the greatest medicines in the world, but access is meaningless without affordability.

To address this issue, in May 2018, I joined with President Trump to release the American Patients First Blueprint,[9] a comprehensive plan to bring down prescription drug prices and out-of-pocket costs, using four key strategies for reform: increased competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs.

Recognizing that the status quo is indefensible, HHS has rapidly taken administrative steps where the Department has authority to turn the President's vision into action. These actions include proposals to create competition for physician-administered drugs, improve competition and negotiation between Medicare's prescription drug plans, increase price transparency for drugs advertised on television, end the payment of kickbacks that are artificially driving up prices, ensure beneficiaries are benefiting from price concessions at the pharmacy counter, and address foreign free-riding so that Americans pay prices closer to what patients in other countries pay for the same drugs.

CMS also updated its Drug Spending Dashboards with data for 2017. This administration's version of the drug dashboards, first released in May of last year, adds information on the manufacturers that are responsible for price increases and includes pricing and spending data for thousands more drugs across Medicare Parts B and D and Medicaid.

HHS will continue to use all of its administrative tools to achieve these goals, and recognizes Congress has the authority to implement more sweeping changes. The

[9] *https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.*

administration looks forward to working with Congress on bipartisan solutions that lower costs, increase transparency, and protect patient access and safety.

The FY 2020 budget legislative proposals complement the many successful administrative actions HHS has already taken to lower the cost of prescription drugs. These proposals will protect seniors and taxpayers by modernizing Medicare Part D, and improving transparency and accuracy of payments under Medicare Part B. The budget also includes proposals to ensure manufacturers pay their fair share of Medicaid rebates covering all price increases.

Question. The Democratic Republic of Congo is battling the second deadliest outbreak of Ebola in history. So far, there have been a reported 913 probable cases, with 574 fatalities, and the outbreak is not yet under control. Insecurity and community distrust of authorities—including health-care workers—have significantly hampered the response. Two treatment centers operated by Doctors Without Borders were attacked in recent weeks, prompting the organization to close them. We withdrew CDC and USAID experts in September of last year due to insecurity. While some U.S. experts have returned to Goma, security remains an obstacle to the deployment of CDC experts to Ebola epicenters to assist with training health-care workers, gathering data and lending expertise on contact tracing and building community trust.

When did the administration last conduct an on the ground assessment in eastern Congo to determine what security measures would have to be put in place to make it safe for CDC experts to return to Ebola epicenters?

Have there been any recent discussions of what security measures the administration might bring to bear to allow CDC and other USG personnel to travel to these regions?

When was the last time you spoke with Secretary of State Mike Pompeo about the Ebola response, and what additional USG efforts might be brought to bear, and specifically on the issue of provision of security?

To your knowledge, is Secretary Pompeo in active discussions with the United Nations about how the United Nations peacekeeping mission currently located in eastern Congo might be able to assist with security?

What efforts are we making to overcome community distrust, the other major barrier to an effective response?

Answer. HHS is working closely with other relevant Departments and agencies to address the Ebola outbreak. We refer you to the Department of State which can answer the other questions pertaining to security and peacekeeping.

Question. Given the risk of the Ebola outbreak spreading across borders to South Sudan, Rwanda and Uganda, is there more that we can and should do to contain this outbreak?

Answer. CDC's long-term investments in disease specific work in South Sudan, Rwanda, and Uganda have improved each country's ability to respond to this complex Ebola outbreak. To assist with screening for cases at international borders:

CPI–UCDC is assisting the DRC Ministry of Health and other partners to adapt and train on screening protocols at country-prioritized airports and ground crossings; and map population movement into and out of the outbreak zone to determine where surveillance should be enhanced across borders.

CPI–UCDC is also working with the Ministries of Health in Uganda, Rwanda, and South Sudan to assess and enhance border health capacity for surveillance and response, which includes development and implementation of border screening protocols. All four countries are conducting border screening.

As of May 4, 2019, over 55 million travelers have been screened at priority ports and crossing points in DRC since the outbreak began in August 2018. To date, there have been no confirmed cases of Ebola in the neighboring countries. CDC and its partners stand ready to provide additional assistance to South Sudan, Rwanda, and Uganda as needed.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

PUBLIC CHARGE

Question. The Department of Homeland Security has proposed to deny green cards and visas to immigrants who have used or might use public programs like Medicaid. In comments on this rule, community health centers, hospitals, insurance companies, doctors and patient advocates all stated that they believed it would lead to families to avoid using health care out of fear, and in fact, already has.

In their comments submitted on Public Charge, the Association of Community Affiliated Plans noted the following, "Well before the proposed rule was ever published, one Medicaid health plan in Texas found that leaked versions of the proposal contributed to declining enrollment in its State; it is thought that nearly 150,000 fewer individuals currently access Medicaid in Texas in part due to the leaked rule." "Another Medicaid health plan in California -along with many of its contracted providers—has already received calls from Medicaid enrollees expressing their fear of being considered a public charge and requesting information on how to disenroll from the program."

Can you speak to this proposed rule, the fear it has created in immigrant communities, and any action your agency has taken to address those fears?

Answer. HHS defers to the Department of Homeland Security regarding its proposed regulations. HHS will continue our work to ensure that Medicaid enrollees are truly eligible and are receiving services as appropriate.

OUTREACH AND ENROLLMENT

Question. Over the past 2 years, the Trump administration has made dramatic cuts to outreach and enrollment in the Affordable Care Act, cutting advertising by 90 percent and cutting the Navigator program by 80 percent. You and your staff have claimed that these programs are no longer needed.

Have you conducted any research into consumer awareness of open enrollment or the Affordable Care Act?

Have you conducted any research on people who receive in-person assistance and whether they are significantly more likely to enroll than people who try to enroll by themselves online?

Answer. Data from the 2019 Open Enrollment Period shows steady plan selections through the Federal platform *(i.e., HealthCare.gov),* with more than 8.4 million consumers selecting a plan as of the end of open enrollment, December 15, 2018. As was the case last year, CMS remained committed to its primary goal of providing a seamless enrollment experience for *HealthCare.gov* consumers, and data show that we achieved this goal. Consistent with last year, the consumer satisfaction rate at the call center remained at an all-time high—averaging 90 percent—throughout the entire Open Enrollment Period and, for the second year in a row, CMS did not need to deploy an online waiting room during the final days of Open Enrollment. As a result, *HealthCare.gov* consumers were able to shop and pick a plan with minimal interruption throughout the entire enrollment period.

When the exchanges were in their infancy, and public awareness and understanding of coverage options was low, HHS encouraged Navigators to cast a wide net and to provide intensive face-to-face assistance to consumers. Since that time, public awareness and education on options for private coverage available through the exchanges has increased. Certified application counselors, direct enrollment partners, and exchange-registered agents and brokers serve as additional resources for education on options and outreach to consumers. Enrollment data from previous years show that Navigators failed to enroll a meaningful number of people through the FFEs, comprising less than 1 percent of enrollment in both plan year 2017 and plan year 2018—not nearly enough to justify the millions of Federal dollars spent on the program. It was appropriate to scale down the Navigator program and other outreach activities to reflect the enhanced public awareness of health coverage options through the exchanges. Additionally, in the Funding Opportunity Announcements (FOA) for the FFE Navigator Program for plan year 2019 and 2020, Navigator applicants were encouraged to leverage volunteers as well as strategic partnerships with public and private organizations to target consumers who would benefit from exchange coverage and more efficiently meet their enrollment goals. These changes are based on the success of private sector-focused programs, such as those within Medicare Advantage.

Question. Last July, GAO released a report deeply critical of your agency's management of open enrollment, including the justifications for cutting outreach and Navigator funding. GAO found that the cuts, in the case of Navigators, were made with incomplete data and failed to account for the responsibilities that navigators play beyond patient enrollment in qualified health plans. GAO found that navigators grantees conducted 68 percent fewer events, laid off staff and deprioritized certain populations, such as rural individuals.

How has your agency responded to the critiques in that report and do you plan to use more accurate metrics in determining Navigator funding?

Answer. HHS appreciates the ongoing work of the GAO to study critical aspects of our health-care system, including outreach and enrollment for the Federally Facilitated Exchange, the subject of the report you mention. In that report,[10] the GAO provided a number of recommendations. We concurred with GAO's recommendation to ensure that the approach and data we use for determining Navigator award amounts accurately and appropriately reflect Navigator performance. We have provided guidance to Navigators that their grant funding will be explicitly tied to their self-identified goals and their ability to meet those goals. We also concurred with the GAO's recommendation to assess other aspects of the consumer experience to ensure we have quality information to achieve our goals. We have assessed the consumer experience through the availability of the two largest customer channels supporting exchange operations—the call center and *HealthCare.gov*—as well as customer satisfaction surveys. We believe these metrics represent a comprehensive assessment of the consumer experience. We are always looking for ways to improve the consumer experience and will consider focusing on other aspects of the consumer experience as needed. The GAO also recommended that we should establish numeric enrollment targets for *HealthCare.gov* to monitor its performance. We did not concur with this recommendation because there are numerous external factors that can affect a consumer's decision to enroll that are outside our control, such as the state of the economy, issuer rates, employment rates, and the number of people who effectuate their coverage. These are factors that are wholly unrelated to the performance of *HealthCare.gov*. The Department believes that a more informative performance metric is whether everyone who utilized *HealthCare.gov*, who qualified for coverage, and who desired to purchase coverage, was able to make a plan selection. HHS does not believe that numeric enrollment targets are relevant to assess the performance of objectives related to a successful open enrollment period for the exchange.

Question. How do you expect Navigators to fulfill their responsibilities with such cuts?

Answer. We take seriously our responsibility to safeguard taxpayer dollars and use them effectively to serve the American people. Navigator funding was reassessed as part of an effort to promote accountability and cost-effectiveness. When the exchanges were in their infancy, and public awareness and understanding of coverage options was low, HHS encouraged Navigators to cast a wide net and to provide intensive face-to-face assistance to consumers. Since that time, public awareness and education on options for private coverage available through the exchanges has increased. Certified application counselors, direct enrollment partners, and exchange-registered agents and brokers serve as additional resources for education on options and outreach to consumers. Enrollment data from previous years show that Navigators failed to enroll a meaningful number of people through the FFEs, comprising less than 1 percent of enrollment in both plan year 2017 and plan year 2018—not nearly enough to justify the millions of Federal dollars spent on the program. It was appropriate to scale down the Navigator program and other outreach activities to reflect the enhanced public awareness of health coverage options through the exchanges. Additionally, in the Funding Opportunity Announcements (FOA) for the FFE Navigator Program for plan year 2019 and 2020, Navigator applicants were encouraged to leverage volunteers as well as strategic partnerships with public and private organizations to target consumers who would benefit from exchange coverage and more efficiently meet their enrollment goals. These changes are based on the success of private sector-focused programs like those within Medicare Advantage.

As part of its adjustments in spending, CMS committed resources to cost-effective, high-impact outreach during this year's Open Enrollment Period and increased outreach efforts as the plan selection deadline approached. For instance, CMS sent over

[10] "Health Insurance Exchanges: HHS Should Enhance its Management of Open Enrollment Performance" (GAO–18–565), July 2018.

700 million reminder emails and text messages to consumers, as well as 3.2 million outreach emails to help Navigators, agents and brokers assist consumers. Data from the 2019 Open Enrollment Period for plan selections through the Federal platform shows steady plan selections, with more than 8.4 million consumers selecting a plan as of the end of open enrollment, December 15, 2018. As was the case last year, CMS remained committed to its primary goal of providing a seamless enrollment experience for *HealthCare.gov* consumers, and data show that we achieved this goal. Consistent with last year, the consumer satisfaction rate at the call center remained at an all-time high—averaging 90 percent—throughout the entire Open Enrollment Period and, for the second year in a row, CMS did not need to deploy an online waiting room during the final days of Open Enrollment.

DISPARITIES

Question. Health-care disparities continue to be a major problem in our country. People of color continue to see lower life expectancy and worse health-care outcomes due to systemic and historical barriers, in addition to simply the lack of sufficient resources going to their communities. Not only are these disparities morally wrong, but they also hurt our economy. The W.K. Kellogg Foundation and Altarum found that racial disparities cause $93 billion in excess medical care costs and $42 billion in untapped productivity, and that, if addressed, could boost the economy by $8 trillion in the next 30 years.

What actions is your agency taking to address disparities in health care?

Answer. At CMS, the Office of Minority Health (OMH) ensures that the voices and needs of the populations it represents are present as the agency is developing, implementing, and evaluating its programs and policies, and is working to ensure that all beneficiaries achieve their highest level of health.

CMS OMH leads the work on the CMS Equity Plan for Improving Quality in Medicare. The plan is intended to help Quality Improvement Organizations, Hospital Improvement Innovation Networks, and other organizations embed health equity throughout their work. The CMS Equity Plan for Medicare consists of six priority areas including:

- Expanding the collection, reporting, and analysis of standardized racial and ethnic data;
- Evaluating disparity impacts and integrating equity solutions across CMS programs;
- Developing and disseminating promising approaches to reduce health disparities;
- Increasing the ability of the health-care workforce to meet the needs of vulnerable populations;
- Improving communication and language access for individuals with limited English proficiency and persons with disabilities; and
- Increasing physical accessibility of health-care facilities.

Many of these areas are also central to the effort throughout HHS to reduce health disparities.

FAMILY SEPARATION AT THE BORDER

Question. On Friday, March 8th, Judge Dana Sabraw of the District Court for the Southern District of California ruled to increase the number of families eligible for reunification by including those which were separated between July 1, 2017 and June 25, 2018. According Jallyn Sualog, Acting Deputy Director for Children's Programs at ORR, every case within that period would have to be reviewed to identify which children were separated from a parent. In that time, a total of 43,083 children passed through ORR.

How are ORR and HHS preparing to take on this new effort?

Answer. As noted above, copies of the filings by the government in *Ms. L.*, which explain the government's plan to identify the separated children of *Ms. L.* class members for the expanded class period, are attached.

Question. It has come to light that there was a large increase in unaccompanied minors processed through ORR, well before the class action lawsuit *Ms. L. v. ICE* was filed. Further, ORR had been delivering those children to sponsors before Judge Sabraw had issued his first injunction on June 26, 2018. Without this information at that time, Judge Sabraw limited reunifications to children still in ORR care on June 26, 2018.

Why did ORR and HHS not share this information sooner?

Answer. Judge Sabraw originally limited the class definition in *Ms. L.* to certain parents of separated children in ORR care as of June 26, 2018. The numbers of separated children that ORR originally reported to the Court were based on that class definition. Judge Sabraw recently expanded the class definition to include certain parents of separated children in ORR care between July 1, 2017 and June 25, 2018. As a result, ORR is now working to identify those class members and report information about them to Judge Sabraw.

Question. What steps will ORR and HHS take to ensure greater transparency and communication with the courts and Congress?

Answer. HHS complies with all statutory authorities and court orders that govern the UAC program. HHS is committed to working with the courts and court-appointed monitors in litigation involving the UAC program.

HHS works diligently to keep Congress continuously updated and informed on the ORR/UAC program, reunification efforts, and subsequent oversight.

ORR hosted 99 individual members of Congress at ORR facilities across 10 States from June 2018 to the present. In this same time frame, ORR managed over 30 tours for members of Congress, their staff, and the Congressional Research Service.

Question. How can HHS, in conjunction with DHS, better determine which children should be considered separated and eligible for reunification?

Answer. As noted above, copies of the filings by the government in *Ms. L,* which explain the government's plan to identify the separated children of *Ms. L.* class members for the expanded class period, are attached. The *Ms. L.* Court has not yet made a ruling on remedies for the class members for the expanded class period.

Question. Our Maryland Attorney General, Brian Frosh, has written to you and asked for data on the children being held at Maryland facilities that are under the custody of the Office of Refugee Resettlement, under the Administration for Children and Families, which you oversee.

Can you provide me with the number of children separated from their parents that are placed in Maryland under ORR custody, the number of locations being used in Maryland, and the timeline for reunification of these children with their parents?

Answer. As of May 5th, there is only one newly separated child in ORR care in Maryland, and 26 children have been discharged to sponsors. (Some parents were found to be out of class for *Ms. L* based on further review.)

Length of Care	**Count**
20–29	1
40–49	4
50–59	3
60–69	5
70–79	3
80–89	1
90–99	2
100–109	1
130–139	2
140–149	1
150–159	2
180–189	1
220–229	1
Grand Total	**27**

Number of minors placed in a MD ORR funded program (n=27).

Program in MD	Admitted	Discharged	Total Number of Minors in ORR Care in MD
Bethany Christian Services Maryland	1	13	14
Board of Child Care Shelter	0	10	10
Board of Child Care TFC	0	3	3

Program in MD	Admitted	Discharged	Total Number of Minors in ORR Care in MD
Total Number of Minors in ORR Care in MD	1	26	27

Question. Are parents provided with information on the status of their children?

Answer. All minors in HHS care are assigned case managers. In the circumstance of children whose parents are in Federal custody, the case managers are in contact with the parents' ICE case managers, ICE agents, and other Federal law enforcement officials in order to verify their relationship and put the parents and children in communication.

Within 24 hours of arrival in ORR care, all minors are given the opportunity to communicate with a verified parent, guardian or relative living in or outside the United States. Every effort is made to ensure minors can communicate (via telephone or video) at least twice per week.

Safety precautions are in place to ensure that an adult wishing to communicate with a minor is a family member or potential sponsor. Attorneys representing minors have unlimited telephone access to such minors, and the minor may speak to other appropriate stakeholders, such as their consulate, case coordinator, or child advocate.

MEDICAID EXPANSION AND MENTAL HEALTH/SUD TREATMENT

Question. Under the ACA, States are permitted to enroll adults in Medicaid with incomes below 138 percent Federal Poverty Level. Currently, 36 States and DC have adopted Medicaid expansion, which has led to millions of Americans receiving affordable and quality health insurance. Included in the coverage they receive is treatment for mental health illnesses and substance use disorders.

The Trump administration supports eliminating the Medicaid expansion, which would leave millions without coverage, including those who are benefiting from substance use disorder and mental health treatments. At a time when the opioid epidemic is devastating parts of this country, we need to be working on expanding coverage for these essential services.

Can you explain how the administration plans to provide these Americans coverage for treatment of mental health and substance use disorders if the Medicaid expansion is repealed?

Answer. Successful partnership between our leadership at HHS and the leaders of every State Medicaid program is vital to delivering on the mission of HHS and the mission of the Medicaid program: improving the health and well-being of the Americans we serve. This administration is committed to granting States more freedom to design innovative local solutions. We have followed through on that promise by supporting efforts like waiving decades-old restrictions on addiction treatment services, allowing States to link working age beneficiaries to new opportunities through work and community engagement programs, and rolling back overly prescriptive Federal regulations and policies.

The Medicaid program was designed to serve our most vulnerable populations like children and people with disabilities. To strengthen the fiscal sustainability of this critical safety net for generations to come, this administration is looking at ways to facilitate State innovation and increase patient choice.

PRE-EXISTING CONDITIONS

Question. Because of the Affordable Care Act, health insurance companies cannot refuse to cover someone or charge someone more just because they have a pre-existing condition. Among the most common pre-existing conditions are high blood pressure, behavioral health disorders, high cholesterol, asthma/chronic lung disease, heart conditions, diabetes, and cancer. In 2017, HHS released a report[11] stating that as many as 133 million non-elderly Americans have a pre-existing condition.

In December, a District Court judge in Texas ruled that the ACA is unconstitutional. The Trump administration recently filed a brief with the 5th Circuit Court of Appeals stating that they support the lower court ruling, and that the provisions

[11] *https://aspe.hhs.gov/system/files/pdf/255396/Pre-ExistingConditions.pdf.*

of the ACA, including protections of those with pre-existing conditions, should be invalidated. If the 5th Circuit agrees with the administration's position and upholds the lower court decision, millions of Americans, including those with pre-existing conditions, may lose coverage.

What is the administration's plan to help those with pre-existing conditions get the care they need, including the ability to go to a doctor, receive medical tests, and purchase prescription medication?

Answer. The recent U.S. District Court's declaration regarding the Affordable Care Act is a partial final judgment that has been stayed pending appeal. Therefore, HHS will continue implementing, administering, and enforcing all aspects of the ACA, as it had before the court issued its decision. This decision does not require that HHS make any changes to any of the ACA programs it implements or administers, or its enforcement of any portion of the ACA at this time. As always, the Trump administration stands ready to work with Congress on policy solutions that will deliver more insurance choices, better healthcare, and lower costs while continuing to protect individuals with pre-existing conditions.

ORAL HEALTH TRAINING PROGRAMS

Question. In 2000, then-Surgeon General David Satcher reminded the Nation that oral health is absolutely 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'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. Additionally, without loan repayment programs to help ease dental school debt, dentists are more likely to stay in large cities where the pay is higher, rather than open up a new practice somewhere that it's really needed. The President's budget proposes to cut the entire $41 million budget of these Oral Health Training Programs for 2020.

If this program was eliminated, do you believe we would still be able to attract oral health-care providers to these underserved communities?

What is your agency doing to ensure our country's continued progress in oral health?

Answer. The President's FY 2020 budget prioritizes funding for health workforce activities that provide scholarships and loan repayment to clinicians, including oral health providers, in exchange for their service in areas of the United States where there is a shortage of health professionals. The National Health Service Corps (NHSC), which supports clinicians who demonstrate a commitment to serve our Nation's medically underserved populations at NHSC-approved sites located in Health Professional Shortage Areas, currently supports dentists and dental hygienists, who make up more than 15 percent of the NHSC's field strength.

Additionally, in FY 2017, the NHSC launched the Dental Students to Service Loan Repayment Program, which provides loan repayment up to $120,000 to dental students in their last year of school in exchange for a 3-year service obligation to practice in communities of greatest need.

Furthermore, the budget also supports the Teaching Health Center Graduate Medical Education program, which funds dental residency programs. Of the 57 teaching health center sites in AY 2017–2018, three are dental residencies.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

TOBACCO AND E-CIGARETTES

Question. Thank you for your commitment to continuing efforts to address youth smoking and e-cigarettes and for your dialogue on this issue during the hearing on March 14, 2019. I share your goal of preventing a new generation of children from

becoming addicted to nicotine through e-cigarettes and look forward to working with you to ensure this issue remains a top priority moving forward.

As you know, the National Youth Tobacco Survey indicates that 3.6 million middle school and high school kids are current e-cigarette users. As part of the President's budget, you propose to increase the Food and Drug Administration (FDA)'s budget by about $6 billion. Some of this investment is designed to increase user fees and supplement the FDA's work to increase enforcement of age-and identification-verification requirements (see pg. 27 of the FY 2020 President's HHS Budget in Brief).

However, a review of 2018 compiled statistics available from the Compliance Check Inspections Report demonstrates wide variability between the States when it comes to age verification and compliance checks. This is also true for the most recent report from 2013 on Synar Inspections. Given the surge of underage use of e-cigarettes and vaping devices such as Juul, I am concerned about the efficacy of the FDA's youth-based compliance checks.

Is there a standard Request for Proposal (RFP) for State contractors who would perform youth-based compliance checks? Please supply that RFP.

Answer. In accordance with the Federal Food, Drug, and Cosmetic Act, FDA contracts, where feasible, with the States to carry out inspections of retailers within that State. Below please find a link to the fiscal year (FY) 2018 State Tobacco Retail Compliance Check Inspection RFP: *https://www.fbo.gov/utils/view?id=3163f5f9f8240b43836d21cf797637c2.*

Note that not all contracts are awarded on the same cycle and therefore only certain States were eligible to apply for this particular RFP. FDA also issues similar RFPs for jurisdictions that contract with third-party entities and tribes and other jurisdictions are inspected by FDA inspectors.

Question. Are these contracts consistent across States? Please supply the standard contract for these contractors.

Answer. Yes, the contracts are consistent across the States with regard to the program requirements for FDA's Tobacco Retail Compliance Check Inspection program. Each year, FDA issues a Request for Proposals (RFP) for the Compliance Check Inspection contracts to which the States and territories submit proposals that detail their respective program structure, inspection plan, and cost. FDA reviews the proposal packages to determine whether the business and technical plans fulfill the requirements established in the RFP.

A representative tobacco retail compliance check inspection contract entered into between FDA and North Carolina in response to the FY 2018 RFP is enclosed (see Attachment No. 5).

Question. Are the detailed instructions for the conduct of inspections, including how youths are chosen, and what methods they use to attempt to purchase consistent across States? Please supply these instructions.

Answer. FDA's Tobacco Retail Inspection Program contracts outline the process and protocols for conducting FDA's tobacco retailer compliance check inspections, including how minors are chosen. The contractors are responsible for recruiting, hiring, and supervising inspectors and minors used in the FDA Tobacco Compliance Check Inspection Program.

Pursuant to the contract, the contractor must only use minors who are age 16 or 17 to participate in the program. The contractor must ensure that the minors are within the required age range. FDA provides training regarding the FDA Tobacco Compliance Check Inspection Program to the inspectors and minors. The contractor must ensure that all inspectors and minors participating on inspections have taken and passed the FDA Tobacco Compliance Check Inspection Program Training before beginning initial inspections.

The Contractor arranges compliance check inspections of retailers that sell or advertise tobacco products to determine whether those retailers are complying with the FD&C Act, as amended by the Tobacco Control Act, and the implementing regulations. Generally, the contractor carries out two (2) types of tobacco compliance check inspection assignments: (1) undercover buy assignments, to determine a retailer's compliance with age and photo identification requirements; and (2) advertising and labeling assignments, to cover other provisions of the Tobacco Control Act. Please note that minors are not used in FDA's advertising and labeling tobacco retail inspections. The contractor must assign compliance check inspection assign-

ments to inspectors and ensure each inspector conducts and documents each assignment according to FDA protocol, which is provided during training.

Question. Thousands of compliance checks are performed each year in each State, yet the percentage of retailers that undergo compliance checks varies from State to State. Some of this variability may be explained by differences in youth and adult tobacco use prevalence among the States, and some may be explained by each States' relative focus on youth underage sales deterrence. However, it also seems likely that variances in methodology and frequency of checks could play a role. How are these numbers chosen and what percentage of nicotine and tobacco retailers are inspected in each State?

Question. FDA's Tobacco Retail Inspection Program contracts outline the process and protocols for conducting FDA's tobacco retailer compliance check inspections. These contracts include requirements that contractors ensure inspectors conduct tobacco compliance check inspections at a variety of different locations (*e.g.,* urban, suburban, rural, and racial and ethnic minority communities) and outlet types throughout the jurisdiction. Additionally, contractors are also asked to consider geographic factors such as areas located in close proximity to middle or high schools or areas with high rates of youth tobacco use. FDA directs the contractors to conduct specific follow up compliance check inspections at retail establishments where previous violations have been observed. The number of inspections each State proposes to conduct is based on a variety of factors, including historical inspection data and State budgetary and personnel considerations.

Question. Please explain the variability in rates of compliance checks and rates of retailer compliance between States?

Answer. FDA has utilized its authorities to combat the marketing and sale of tobacco products to youth. More than a million inspections have been conducted under FDA's tobacco retail compliance check inspection program. Most retailers have been found to be in compliance with the law and even fewer are found to be continuing to violate the law upon reinspection. However, there are retailers who continue to sell tobacco products to minors. When inspectors observe potential violations during compliance check inspections of tobacco retailers, FDA may utilize several advisory and enforcement tools provided for in the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) and the Federal Food, Drug, and Cosmetic (FD&C) Act. These actions include warning letters, civil money penalties (CMP), no-tobacco-sale orders (NTSO), seizures, injunctions, and/or criminal prosecutions.

We are unable to explain the variability in rates of compliance between States; however, we continue to take steps to educate retailers to improve compliance rates nationwide. Part of our enforcement work also includes ensuring retailers know their responsibilities under the law and the consequences for violating them. Toward that end, FDA has developed extensive materials to educate industry, including retailers. CTP developed guidance documents and multiple webpages that explain FDA's tobacco requirements to retailers and provide educational resources. Specifically, CTP's Summary of Federal Rules for Tobacco Retailers, Retail Sales of Tobacco Products and its Retailer Training and Enforcement webpages provide specific information useful to retailers, such as fact sheets for retailers, in-store materials, links to compliance training webinars, and a diagram of the retail undercover purchase inspection and enforcement process.

Further, FDA does not direct inspections based on statistical analysis but rather prioritizes inspections of retailers where violations were observed, which could potentially impact a State's "compliance rate" during a period of time.

Question. What is the approximate cost per compliance check, and how is this calculated? Does the cost vary State to State? By how much?

Answer. Contractor proposals generally account for the cost of living, resources available to dedicate to the program, personnel cost, number and type of inspectors who are dedicated to the program, travel costs depending on the size of the State, geographic distribution of retailers within the State, and other circumstances unique to each State program. We have a mix of contract types; however, the majority of State contracts are cost-reimbursement type contracts.

Question. Do compliance rates vary by demographic factors such as age, gender, and race? Please supply a relative breakdown of the demography of the youths used across demographic factors.

Answer. Contractors only use 16 and 17 year-olds to conduct retail compliance check inspections. FDA does not collect information on the minors' race and gender.

The FY 2018 RFP requires contractors to use "[a] representative mix of 16 and 17 year-old Minors who look their age. The Minor group should also reflect a representative mix of male and female Minors and should reflect the racial/ethnic composition of the population where the undercover buy is conducted."

Question. Do some youth contractors have much higher buy rates than others? Please describe. Are successful buy techniques shared?

Answer. FDA does not analyze its data for trends in buys made by individual minors. Each Minor must complete the required FDA minor training prior to conducting any inspections. In addition to this training, inspectors review each inspection with the minor and advise them of any necessary adjustments prior to moving to the next inspection. FDA has held sessions for contractors to share information and best practices across States.

Further, FDA conducts routine training for all inspectors to review topics related to inspection procedures, policies, and other contractual updates. Before an inspector may begin conducting compliance check inspections, inspectors must take an initial required training. Additionally, FDA provides quarterly training to contract program coordinators and training for all inspectors twice per year. Program coordinators and inspectors must also take periodic refresher trainings. FDA monitors completion of these training requirements and will restrict inspector participation in the program in the event they are not met. Program coordinators are also responsible for providing additional training to individual inspectors, as needed.

Question. Do compliance check results vary significantly by type of retailer: convenience store, grocery, pharmacy, large discount store, tobacco or vape shop, etc.?

Answer. FDA does not categorize each inspection by type of outlet, however, inspections of brick-and mortar retail outlets and surveillance of online retailers are separate programs and are conducted in different ways. The results of our brick and mortar retail inspections are part of FDA retailer compliance check inspection program and available to the public in a searchable database online. This information includes the names and locations of the retailers inspected by FDA. Warning letters issued to other regulated tobacco entities, including online retailers are generally the result of other FDA tobacco inspection and surveillance programs and may be viewed in FDA's Electronic Reading Room.

Question. Do compliance check rates vary by type of area surveyed (such as rural, urban, suburban, racial and ethnic makeup, high or low socioeconomic status, high or low tobacco prevalence, etc.)?

Answer. The Retail Inspection RFP requires the contractor to ensure that the commissioned inspectors conduct tobacco compliance check inspections at a variety of different locations (*e.g.,* urban, suburban, rural, and racial and ethnic minority communities) and outlet types throughout the jurisdiction. Additionally, contractors are also asked to consider geographic factors such as areas located in close proximity to middle or high schools or areas with high rates of youth tobacco use. Because of the different geographical and other unique circumstances within a State, they may use different criteria to define these types of areas. Therefore, FDA cannot reliably analyze compliance check rate data based on the type of area. FDA directs the contractors to conduct specific follow up compliance check inspections at retail establishments where previous violations have been observed.

https://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.

Question. Do contractors use available information from questions above to inform and render compliance checks that are more efficient or effective?

Answer. FDA cannot reliably analyze compliance check rate data based on the type of retailer or type of area. As mentioned previously, FDA's Tobacco Retail Inspection Program contracts outline the process and protocols for conducting FDA's tobacco retailer compliance check inspections. These contracts include requirements that contractors ensure inspectors conduct tobacco compliance check inspections at a variety of different locations (*e.g.,* urban, suburban, rural, and racial and ethnic minority communities) and outlet types throughout the jurisdiction. Additionally, contractors are also asked to consider geographic factors such as areas located in close proximity to middle or high schools or areas with high rates of youth tobacco use. FDA inspects retail establishments that have previously violated the law more frequently in order to assess corrective actions and to verify compliance.

Question. If a youth does make a successful buy, that is to say there is a failure in compliance, is there a standard protocol for recheck of those particular retailers?

Answer. Yes. FDA-commissioned inspectors conduct follow up compliance check inspections at retail establishments where previous violations have been observed to verify compliance following the close-out of an advisory or enforcement action. FDA may also direct contractors to conduct certain inspections to ensure compliance with new provisions that go into effect, such as those included in the Deeming rule, and/or other enforcement priorities.

Question. Are compliance checks "realistic" in comparison to how a typical youth might attempt to buy underage? For example: may the youth lie about his or her age; may youths demonstrate to the clerk that they are already in possession of a tobacco product or vape device; may they engage the clerk in social conversation prior to the attempted purchase; may they offer the clerk extra money or other compensation?

Answer. Minors are an integral part of conducting compliance check inspections. FDA conducts undercover inspections with minors using standard protocols. The protocols include confidential enforcement strategy and FDA does not disclose the specific details. However, FDA has a number of requirements in the contract regarding the use of minors, including a requirement that the contractor ensure that all minors follow the chosen protocol consistently. FDA also requires that the contractor employ a representative mix of 16- and 17-year-old minors who look their age, reflect a representative mix of male and female minors, and reflect the racial/ethnic composition of the population where the undercover buy is conducted.

FDA protocol does not require minors to carry photo identification for the undercover buy assignments. However, the contractor may determine that minors should carry valid photo identification and present identification if requested. Such decisions are left to the discretion of the contractor.

Question. How was the FDA fine structure determined, and is there scientific evidence or compliance rate data to support that it is sufficient?

Answer. The Tobacco Control Act provides for civil money penalties for violations of FD&C Act requirements that relate to tobacco products. These violations identified in the statute include the sale or distribution of tobacco products in a manner that violates regulations addressing the sale or distribution of cigarettes, smokeless tobacco, and covered tobacco products in violation of the restrictions set forth in 21 CFR part 1140.

Maximum civil money penalty amounts are set forth in section 103(q)(2) of the Tobacco Control Act and are adjusted annually for inflation. These maximum penalty amounts take into account the requirements that are violated, the number of violations, and several other factors. If there have been repeated violations (at least 5 violations of particular requirements over a 36-month period) at the outlet and a no-tobacco-sale order would be appropriate, FDA will generally seek a no-tobacco-sale order. A no-tobacco-sale order is an order prohibiting the sale of tobacco products at a retail outlet indefinitely or for a specified period of time.

Question. If only a fraction of retailers are surveyed each year, how likely is it that a violating retailer could reach the threshold of five failures in 3 years?

Answer. Retailers who previously sold to a minor in our inspection program are prioritized for re-inspection. FDA's goal is to inspect retail establishments that have previously violated the law more frequently in order to assess corrective actions and to verify compliance. If FDA finds subsequent violations at a retail establishment after the issuance of a Warning Letter, it generally seeks CMPs in accordance with the schedule published in the Tobacco Control Act. If FDA finds a retail establishment committed five or more repeated violations in a 36-month period, it may, and generally will, seek a No-Tobacco-Sale Order (NTSO) for that retail establishment. FDA posts all retailer inspection data on its website, including the inspection results.

https://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm.

To date, FDA has issued more than 150 NTSOs. This includes six 6-month NTSOs to retailers who had already received an initial NTSO.

Question. The regulations include a two-tiered penalty structure, with more lenience granted to those retailers that have completed FDA-approved training. When and how does the FDA provide such training?

Answer. The agency does not currently approve any retailer training programs. FDA encourages retailers to implement a training program for their staff and to tailor their program to meet the needs of their employees and business, taking into consideration the size of their business and the products that they sell. FDA understands that some retailers have established various tobacco retailer training programs.

The agency has provided retailers with a number of recommendations on retailer training, including age verification, to help retailers comply with the law. These resources provide retailers with recommendations but leave the retailer the flexibility to determine which methods of compliance work best for their business. Some of the resources FDA has provided to retailers are:

- FDA Age Verification App and This is Our Watch materials: FDA has provided retailers with an FDA Age Calculator app that is available for free in both the Apple App Store and Google Play. The app is a voluntary smartphone application to help retailers comply with Federal, State, and local age restrictions for selling tobacco products. Additionally, FDA has developed a toolkit of voluntary educational resources for retailers through the "This is Our Watch" campaign.
- Tobacco Retailer Training Programs Guidance: FDA has developed a guidance document that lays out recommendations for retailers to incorporate into a retailer training program. The guidance document was updated in August 2018.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-retailer-training-programs

- Tips for Retailers webinar: FDA has also developed a webinar for retailers to use as a resource to help prevent tobacco sales to minors. The Tips for Retailers: Preventing Sales to Minors webinar is available on the FDA website.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-retailer-training-programs.

Question. In the absence of completed training mentioned in question 16 above, is the stricter penalty structure utilized?

Answer. As you know, the Tobacco Control Act established two schedules for the maximum civil money penalties that can be assessed for violations of regulations issued under section 906(d) of the FD&C Act, including violations of FDA regulations at 21 CFR part 1140—one schedule for retailers that do not have an approved training program and another schedule, with lower penalties, for retailers with an approved training program.

In determining the amount of penalty the agency will seek, CTP uses and will continue to use the lower schedule for all retailers, whether or not the retailer has implemented a training program, until regulations are developed that establish standards for retailer training programs. FDA has issued a guidance entitled "Guidance for Industry: Tobacco Retailer Training Programs," which contains examples of recommended elements that may be helpful to retailers in designing and implementing a training program.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-retailer-training-programs.

Question. After 7 years of FDA compliance checks and over $300 million in costs attributable to this system, many States still have high rates of non-compliance, including Ohio at 21 percent. Does this indicate some level of failure of the compliance system? What rate of retailer compliance failure does the FDA consider acceptable?

Answer. The vast majority of retailers are in compliance with FDA's tobacco regulations, but a small subset of retailers continue to violate the law. Please note that rates calculated using the FDA's data are not statistically significant because of repeat inspections of violators. To address the subset of retailers who continue to violate the law, FDA has taken a multi-prong approach. FDA will continue inspecting retailers and issuing warning letters and escalating enforcement actions when violations are found. Recently, FDA sent letters to thirteen national, corporate-owned chains and franchise stores with disturbingly high rates of violations for illegal sales of tobacco products to minors, asking each company to submit plans describing how they will address and mitigate illegal sales to minors.

FDA has also developed extensive materials to educate industry, including retailers. CTP developed guidance documents, multiple webpages, and compliance training webinars that explain FDA's tobacco requirements to retailers and provide educational resources. Further, FDA continues to utilize our voluntary national retailer

education program called "This is Our Watch," which includes free resources designed to support retailers' efforts to educate their staff on enforcing Federal laws and regulations. We hope retailers will protect youth in their communities by knowing the law and making use of tools that make it easier to prevent underage sales. The FDA has also developed a retailer education online platform to provide State and territorial officials with educational tools and information on retailer regulations. The program also facilitates peer-to-peer sharing, and fosters conversations around promising practices, lessons learned, and program feedback.

https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/our-watch.

Question. The clerk may safely rely on the presentation of certified identification that contains a date of birth indicating the buyer is of age. However, for those under age 21, almost two thirds have used fake IDs to purchase alcohol. How might the FDA work to mitigate this problem as more States and localities move their minimum sales age to 21?

Answer. The FDA provides retailers with Guidance Documents and webinars on our website, to assist retailers on ways to ensure that the identification being presented for the sale of tobacco or covered tobacco products is valid and accurate. Current regulations, as explained in a guidance entitled "Guidance for Industry: Tobacco Retailer Training Programs," States that retailers must verify the age of purchasers of tobacco or covered tobacco products under the age of 27 by means of photographic identification that contains the bearer's date of birth. So, while the actual age for the purchase of tobacco products may rise in different localities and States, retailers are already required to ensure that their stores are checking the identification of individuals well over the age of 21.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-retailer-training-programs.

The same Guidance for Industry provides recommendations for retailer training programs. The FDA recommends that a training program include the "age that triggers photographic identification verification and what constitutes acceptable forms of identification" and lists specific recommendations for the type of identification accepted as well as ways to determine the authenticity of a photo identification. Specifically, the FDA States that only government-issued photographic identification containing a date of birth should be accepted (such as State-issued drivers' licenses or identification cards, military identification cards, immigration cards, or passports). Retailers are informed of methods to verify the authenticity of the identification, including specific issues to look for that may signify an altered or fake identification, such as an expired ID, watermarks or State seals and signs of tampering or peeling lamination. Additionally, that Guidance for Industry also provides education on alternate means of verifying identification that retailers may want to utilize, such as electronic age verification devices or scanners. Most importantly, the FDA recommends that a training program instruct employees to decline a sale when the customer has no photographic identification, the photographic identification contains no date of birth, the photographic identification has expired, or if the identification does not appear to be authentic.

On its website, FDA provides Retailers Education Materials, including webinars discussing Retailer Training and Enforcement. The webinar "Tips for Retailers: Preventing Sales to Minors" provides training and slides that discuss age verification techniques. In this webinar, FDA provides ways to identify invalid IDs, such as spelling errors, word usage errors, or expired IDs. The webinar also provides retailers with the advantages and disadvantages of different age-verification technologies available from FDA and the marketplace and also reminds retailers to check with their States for any online trainings or resources to assist with complying with State and Federal laws.

https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/retailer-training-and-enforcement.

Question. Some complain that States "game" the system of Synar checks to ensure that risk to their SAMSA moneys is diminished. How might the State-based Synar system be strengthened to augment FDA compliance efforts?

Answer. In addition to the Tobacco Control Act, the Department of Health and Human Services works to limit youth access to tobacco through the Synar Regulation. States can choose to conduct FDA compliance check inspections at those outlets randomly selected for the Synar sample or for other tobacco enforcement efforts; however, the compliance check inspections must follow FDA's protocol and must be conducted by FDA commissioned inspectors.

Question. The current Synar failure percentage threshold is 20 percent. What effect might there be in reducing that number to 10 percent or 5 percent?

Answer. The current Synar maximum retailer violation rate (RVR) is 20 percent. However, in response to research suggesting that RVRs below 10 percent are necessary to reduce actual youth access to tobacco products, starting in 2009, SAMHSA has encouraged States to strive for an RVR below 10 percent. This did not change the regulatory requirement that States not exceed 20 percent. In the last year for which SAMHSA has final data (FY 2018), 46 States and 5 U.S. territories and Pacific Jurisdictions (PJs) reported RVRs lower than 15 percent. Moreover, 33 States and 4 U.S. territories and PJs reported RVRs below 10 percent. However, if the maximum RVR regulatory requirement were to be reduced to 10 or 15 percent, several States would likely fall out of compliance. The penalties for non-compliance would include a requirement that the State appropriate and spend new State tobacco prevention funds that can equal millions of dollars. States that have exceeded the current maximum of 20 percent have been penalized in this way.

NATIONAL INSTITUTES OF HEALTH

Question. The President's FY 2020 budget proposes 12 percent cuts across the National Institutes of Health (NIH). The NIH is the most innovative and sophisticated research institution in the world and keeps the United States on the forefront of scientific discovery. A cut of $4.5 billion would set us back behind countries who continue to ramp up their research investment to compete with our brain power.

In 2018, Ohio had nearly 2,000 active NIH grants. Thousands of my constituents are contributing to innovative medical research.

Prior to proposing this budget, did you or Dr. Collins or anyone at the Office of Management and Budget (OMB) do an analysis on how many grants this cut of $4.5 billion would impact? If so, what were the results of this analysis.

Answer. NIH analyzed the number of grants supported by the proposed NIH funding levels as part of the process of developing the President's budget. The congressional justification materials for NIH estimate that the FY 2020 funding level would support 38,565 research project grants, and a total of 45,964 research grants.

Question. Did you do any analysis to quantify the job loss that may result from these cuts? If so, what were the results of this analysis?

Answer. I am not aware of any analysis of the specific impact of the NIH funding levels on jobs. The NIH funding levels in the President's budget were developed to prioritize research in areas of public health significance.

Question. Have you done any analysis on how each State would be impacted by these cuts? If so, what were the results of this analysis for Ohio?

Answer. NIH's research plan will assure that the most valuable research is funded within this difficult budget environment. NIH estimates that the number of new and competing Research Project Grants (RPGs) awarded would decrease from about 11,675 in FY 2019 to 7,894 in FY 2020. In addition, funding for noncompeting RPGs would be reduced; the size of the reduction to specific awards would depend on the Institute involved. Similar reductions to other types of research grants would also be expected.

NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH (NIOSH)

Question. Secretary Azar, 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, Ohio. The agency is currently undergoing site acquisition activities and I understand they anticipate that both the site purchase and a design-build contract will be finalized this spring.

This project is not just about updating the NIOSH buildings—this is about improving government efficiency and creating jobs in southwest Ohio. We need your commitment that this project will remain on schedule and will remain a priority for the administration, despite the FY 2020 budget's proposed cuts to CDC.

Will you commit to working with Senator Portman and me to keep this project moving forward under your leadership at HHS?

Answer. CDC is proceeding with acquisition activities related to the property in Cincinnati, but there have been some delays, including those related to the govern-

ment shutdown, relocation of a park equipment maintenance facility, and ownership of the single residential property within the identified site assemblage that did not sell to the Uptown Consortium. CDC plans to purchase the site this summer. Immediately following the site acquisition, CDC will carry out the design and construction of the facility.

BIOSIMILARS

Question. One of the proposals in the FY 2020 budget relates to encouraging biosimilar development. I support this administration's goals in making it easier for biosimilars to enter the marketplace and lower costs, but am concerned that we aren't doing enough to ensure that we can benefit from a robust biosimilar marketplace.

What more is HHS doing to ensure a robust biosimilar marketplace?

Answer. Promoting access to biosimilars and lowering drug prices are top administration priorities.

Since enactment of the Biologics Price Competition and Innovation Act of 2009 which established an abbreviated licensure pathway for biological products shown to be "biosimilar to," or "interchangeable with," an FDA-licensed biological product, FDA has approved 19 biosimilars and held meetings with biosimilar developers for many more products. We've also made substantial progress in developing the scientific and regulatory policies needed to implement the licensure pathway.

Recognizing that this is a crucial time in the emergence of biosimilars, FDA announced our Biosimilars Action Plan (BAP) last year to facilitate access to lower-cost biological products. Under the BAP, FDA is focusing its efforts on advancing the science and policies to make the development of biosimilars more efficient; increasing the acceptance of biosimilars; and taking action against regulatory gaming that can deter or delay competition.

Not only are we making the biosimilar development and review process more efficient and predictable, under the BAP, we are also taking new steps to communicate with patients, payers, and providers to improve the understanding of biosimilar and interchangeable products.

Of course, the FDA's efforts to improve biosimilar competition will be less impactful if rebate walls discourage payers from adding biosimilars to their formularies. By proposing to replace rebates with up-front discounts, plans will have more incentive to seek drugs with lower prices instead of those with higher rebates, which will dramatically lower the costs patients face for a number of high-cost drugs.

We continue to evaluate additional steps necessary to strike the appropriate balance between encouraging ongoing innovation in biologics while also facilitating the robust competition that can reduce costs to patients.

FOOD AND DRUG ADMINISTRATION INSPECTIONS

Question. The President's FY 2020 budget proposes to eliminate funding for the FDA's office of international mail facilities. However, the HHS Budget in Brief also details FDA efforts to hire additional staff and laboratory support to inspect packages at international mail facilities as a way to help fight the opioid epidemic and crack down on the illegal sale and shipment of illicit drugs.

Please explain the President's budget proposal to eliminate $94 million in funding for the FDA Opioids—International Mail Facilities program. Why does the HHS budget propose to cut this funding?

Page 24 of the HHS Budget in Brief describes investments the President's budget would support at the FDA to support its overall approach to the opioid epidemic. One of the priorities the FDA has is to "increase enforcement activities to crack down on illegal sale of opioids" by supporting and "increase of the inspection of packages at international mail facilities." Please explain how this additional support and investment is possible given the cuts to the International Mail Facilities program detailed in the previous question. Don't these two things contradict one another?

Answer. As explained above, the FY 2020 budget includes $55 million to strengthen FDA's activities in response to the Nation's opioid crisis, which may include these activities. The FY 2018 funding for Opioid-IMF activities is displayed as a reduction, as the $94 million was provided as one-time, no-year funding, to remain available

until expended. The FY 2020 budget requests the $55 million in FDA's base budget and does not request additional no-year funding.

AREA HEALTH EDUCATION CENTERS (AHEC)

Question. Congress created the AHEC program in 1971 to encourage medical schools to increase the number of students and residents trained in underserved, community-based settings. Today, AHECs act as an effective national primary care training network built on committed partnerships of 120 medical schools and 600 nursing and allied health schools. Additionally, 261 AHEC community-based centers operate in 46 States, serving over 85 percent of the counties in the United States. The AHEC program and its partners have proven to be an effective and efficient organization to expand community-based training and ensure our health-care workforce has a strong sense of the needs of each community and skills that make them stronger practitioners.

Why does the President's FY 2020 budget propose to eliminate the AHEC program, despite its record of success in preparing a diverse, culturally competent primary care workforce? What is the justification for cutting the AHEC program?

Answer. The President's Fiscal Year FY 2020 budget request prioritizes funding for health workforce activities that provide scholarships and loan repayment to clinicians in exchange for their service in areas of the United States where there is a shortage of health professionals. While funding for the Area Health Education Centers (AHEC) Program was eliminated in the FY 2020 President's budget, the budget requested funding for the National Health Service Corps (NHSC), which supports clinicians who demonstrate a commitment to serve our Nation's medically underserved populations at NHSC-approved sites located in Health Professional Shortage Areas. In addition, the President's budget includes funding for the Teaching Health Center Graduate Medical Education (THCGME) program. The THCGME program increases healthcare access in underserved communities by supporting primary care medical and dental residency programs in community-based ambulatory patient care settings. The President's budget includes $126.5 million in funding for the THCGME program in each of FY 2020 and FY 2021, for a total of $253 million over 2 years.

CHILDREN'S HOSPITALS GRADUATE MEDICAL EDUCATION (CHGME)

Question. Last year's FY 2019 budget proposed to eliminate the CHGME program and combine it with other graduate medical education funding streams, while reducing total Federal support for graduate medical education by $50 billion over the next decade.

CHGME was created to fill a gap in the existing GME funding streams. I am concerned that the elimination of CHGME would result in fewer pediatric specialists and exacerbate the physician shortage in this country, especially those who care for our most vulnerable children. When I asked you to justify last year's decision to eliminate CHGME, you responded that "the budget proposes to better focus Federal spending on GME by consolidating spending into a new capped Federal grant program." The response failed to answer my questions, which I'm repeating in this year's QFRs.

What caused the President to reverse course on CHGME in this year's budget proposal, as compared to his FY 2018 budget proposal?

If CHGME is eliminated, how will HHS ensure that our pediatric workforce pipeline is protected and kids have access to the care we need?

Answer. While the President's FY 2020 budget does not request discretionary resources for Children's Hospitals Graduate Medical Education (CHGME), it does include funding for children's teaching hospitals. The budget proposes to consolidate Federal graduate medical education spending from Medicare, Medicaid, and the CHGME program into a single grant program for teaching hospitals to equal the sum of Medicare and Medicaid's 2017 payments for graduate medical education, plus 2017 spending on CHGME, adjusted for inflation. This amount would then grow at the CPI–U minus one percentage point each year. Pediatricians will continue to be trained under the program structure proposed in the President's budget.

The new grant program would be jointly operated by the Administrators of CMS and the Health Resources and Services Administration. 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 Secretary would have authority to modify the amounts dis-

tributed based on the proportion of residents training in priority specialties or programs and based on other criteria identified by the Secretary, including addressing health-care professional shortages and educational priorities. This grant program would be funded out of the general fund of the Treasury.

The budget prioritizes funding for health workforce activities that provide scholarships and loan repayment to clinicians in exchange for their service in areas of the United States where there is a shortage of health professionals, as well as training based in community-based ambulatory care settings. The President's budget includes funding for the Teaching Health Center Graduate Medical Education. The THCGME program increases healthcare access in underserved communities by supporting primary care medical and dental residency programs in community-based ambulatory patient care settings. Of the 57 teaching health center sites in AY 2017–2018, three are pediatric residencies. The President's budget includes $126.5 million in funding for the THCGME program in each of FY 2020 and FY 2021, for a total of $253 million over 2 years.

SOCIAL SERVICE BLOCK GRANT (SSBG)

Question. The President's FY 2020 budget proposes to eliminate the Social Service Block Grant (SSBG), a critical program that allows States to meet the needs of their communities. As the addiction epidemic continues to devastate our communities and drive more children into the foster care system, we must ensure that States have access to more support—not less. We know that many States, like Ohio, use SSBG funds to support child protective service programs.

How does the administration plan to support State child welfare agencies that rely on SSBG funding? Please provide detail on how the administration would do so if the SSBG were eliminated.

Answer. The President's 2020 budget is focused on improving participation in American society by promoting work, shifting resources to child welfare prevention, and supporting early childhood education and care. The protection and well-being of children is one of the Department's top priorities.

Federal child welfare is provided via multiple programs, the largest of which are made available under the Social Security Act (SSA).[12] In particular, title IV–B of the SSA authorizes funding for States, territories, and tribes to support a broad range of child welfare-related services to children and their families. While child welfare services are an allowable expense under the Social Services Block Grant (SSBG), the program overall lacks accountability and performance measurements, as well as duplicates other Federal funding streams. The decision to not include funding for SSBG in the 2020 budget was not made lightly. However, HHS is committed to reducing duplication of effort and better targeting Federal resources.

The budget continues SSBG's authorization under title XX of the SSA as a potential mechanism for rapid response in case of disasters and to receive transfer funding from the Temporary Assistance for Needy Families program.

HEALTHY START

Question. I appreciate the President's FY 2020 commitment to maintaining funding for the Healthy Start program, which helps support community-based strategies to reduce disparities in infant mortality and improve perinatal outcomes for women and children in high-risk areas. Ohio is home to five healthy start sites, which have helped combat our State's significant infant mortality problem.

For the most recent Healthy Start funding cycle, Congress approved $122 million for program. After settling aside $12 million for maternal mortality and $2 million for Healthy Start performance project support, $108 million remained to fund program sites across the country.

However, when the Health Resources and Services Administration (HRSA) announced the Notice of Funding Opportunity (NOFO) in fall 2018, the NOFO stated that the estimated awards would total only $95 million.

Why was there only $95 million available in grants when $108 million should have been available to fund program sites? How will HRSA spend the remaining $13 million?

[12] The Congressional Research Service provided an informative outline of Federal welfare equities in their 2017 report, *Child Welfare: An Overview of Federal Programs and Their Current Funding.*

Answer. The program received a total of $122.5 million in FY 2019 appropriated funds, all of which was allocated to the Healthy Start program. As noted, the NOFO for the Healthy Start community grants indicated that $95 million would be available to support the FY 2019 competition within the Healthy Start program. In addition to the $95 million, $12 million is being provided to the new recipients to support hiring of clinical service providers to address maternal mortality, per the appropriation report language. Funding in the amount of $4.9 million has also been allocated for 13 Healthy Start community grants from the previously funded cohort whose project periods ended March 31, 2019. Approximately $7.6 million are being used for technical assistance to Healthy Start community grantees, a quality improvement initiative, and program evaluation. The remaining funds, $3 million, will support program administration, information technology, and costs associated with operations.

Question. In addition to the strange discrepancies in funding noted above, HRSA also made a significant change to how the funds are allocated to various agencies—instead of tiers of funding (as has been done in the past), a maximum funding amount was set for each grantee. As a result, the medium and large grantees saw significant reductions in funding, while smaller grantees saw increases in funding.

What is the justification for HRSA's change to the way funds are allocated across Healthy Start program sites?

Answer. HRSA routinely adjusts how it allocates funding to grantees to ensure it has the greatest impact and meets the needs of the population being served. For the FY 2019 Healthy Start NOFO, HRSA adjusted the funding level provided per grantee to a single funding level with a common set of expectations for all grantees. The methodology for this adjustment was based on analysis of performance data collected from prior grant recipients over multiple years as well as input gathered from prior grant recipients and others during a HRSA listening session and open comment period. Some prior grant recipients noted that demand for the program exceeded their capacity to serve all interested families. Feedback also indicated a desire to increase program capacity to serve more pregnant women during the project period to promote healthy pregnancy outcomes. Revising the program to a single funding level with a common set of expectations for all grantees allows grantees to focus on serving infants and families for the first 18 months after birth and maximize the capacity of recipients to focus on service to pregnant women, infants, and families. HRSA expects to see more clients served as a result of this redesign.

Question. How does HRSA plan to support those entities that have just seen their funding reduced despite the same workload? How will HRSA help ensure the sites that received reduced funding as a result of the agency's changes do not have to shrink their programs, cut staff, or disenroll clients?

Answer. Although the FY 2019 redesign reduces funding for a small number of prior grant recipients, it also represents a reduced workload in meeting new programmatic expectations, roles, and requirements. HRSA revised the program to a single funding level with a common set of expectations and award amounts for all grant recipients in the FY 2019 competition. This approach was selected after reviewing performance data from prior grant recipients and in consideration of input gathered in HRSA listening sessions and other stakeholder feedback. The reduced funding is appropriate to the expected workload, based on this analysis. The revised approach also provides additional resources to the largest number of grant recipients, while also promoting efficiencies in overall program operations. The NOFO was published several months prior to the project start date, providing an opportunity for previously funded grant recipients to start planning for this change.

TUBERCULOSIS

Question. The President's FY 2020 budget acknowledges that "progress to reduce the number of new TB infections has slowed."

How will the changes the FY 2020 budget proposes to the TB Prevention program help ensure the CDC is able to continue to make progress toward eliminating TB in America?

Answer. To eliminate TB at home, we must reduce the burden of disease globally. Nearly 2 billion people are infected with TB worldwide, and 10.4 million people become sick with active TB disease each year. TB is the leading cause of death from an infectious disease globally and claims 1.6 million lives each year, even though there has been a cure for more than 70 years. In the United States, a total of 9,029 new TB cases were reported in 2018. To eliminate TB in the United States, we need

to reduce the burden of TB disease globally. The U.S. TB elimination effort is linked with how well other countries are doing in dedicating action and resources to finding and curing active TB cases and addressing the reservoir of latent TB infection in their populations.

Question. The FY 2020 President's budget requests $7.2 million for Global Tuberculosis activities, which will allow CDC to continue efforts to address TB globally. Reflecting a programmatic consolidation that occurred within CDC in 2017, the budget proposes to consolidate Global TB funding within the Center for Global Health to better coordinate Global TB activities across the agency and leverage resources for maximum impact. How will the CDC prioritize its global TB efforts and sustain partner countries' efforts?

Answer. To address the global threat posed by Tuberculosis (TB), CDC focuses on countries with high TB burden, including countries that have strong U.S. business and community ties, resulting in high travel volume, are directly connected to the U.S.-based TB epidemic, and that are part of the President's Emergency Plan for AIDS Relief (PEPFAR) commitment to TB as a key component of a global HIV response. CDC continues to address technical and operational challenges in high-burden TB countries that undermine progress toward achieving global TB targets by developing innovative program strategies, leveraging PEPFAR platforms, and using proven diagnostic and treatment tools to find, cure, and prevent TB.

OFFICE OF REFUGEE RESETTLEMENT

Question. The budget justification documents show an increase in asylees and unaccompanied minors last year, and we are currently seeing an increase in the number of families and unaccompanied minors who are presenting and requesting asylum at the southern border. Yet, the President's FY 2020 budget proposes a decrease in funding for refugees and entrant assistance.

Please provide specific information that led to the Department requesting reduction in this budget line.

Collaboration With the Department of Defense—Immigration

Answer. The FY 2020 budget request for Transitional and Medical Services and Refugee Support Services reflects a reduction of $91 million from the FY 2019 enacted appropriation level. HHS estimates that this level of funding will be sufficient due to lower arrivals in recent years of both refugees and other new arrivals eligible for refugee benefits. The funding for the UAC program is separate.

Question. Please provide the details of the Department's request to the Department of Defense to house unaccompanied minors on military installations.

Collaboration With Department of Homeland Security (DHS)—Immigration

Answer. ORR works with Federal partners to locate federally owned buildings and land that would be suitable to house UAC in the event that operational capacity at its State-licensed shelters exceeds 85 percent. Since 2012, ORR has partnered with the Department of Defense (DoD) to locate influx shelters at DoD facilities around the country including Lackland Air Force Base, Fort Sill, Holloman Air Force Base, and Fort Bliss. HHS and ORR are committed to ensuring that locating influx shelters at DoD facilities does not affect military operations or impact military readiness.

Each year, HHS sends a Request for Assistance (RFA) to the Defense, requesting that DoD locate facilities that could be used to locate influx facilities to shelter UAC. Earlier this year, DoD sent back a list of DoD properties that could be used as influx locations to ORR. ORR is currently in the process of doing preliminary site visits to determine if these locations are viable as influx shelter locations.

After the preliminary site visit, ORR determines if the site holds promise as a potential influx location and, if so, plans and conducts a full site assessment. Before a site assessment begins, there is full notification process, including notifications to Congress, local officials, and the media. If a site is chosen to become an influx site to house UAC, the facility is run by a grantee or contractor chosen by ORR. Additionally, another notification process is completed to inform all relevant stakeholders of ORR's plans.

ORR does not only look for influx shelter locations at DoD facilities, but is constantly working with other Federal partners to locate possible sites.

Question. How will the Department will work with DHS to ensure the reunification of any minor separated from a parent during DHS custody? Please provide a detailed plan.

Answer. HHS has completed reunifications for all those *Ms. L.* class members for the original class period who have elected reunification under the *Ms. L.* preliminary injunction. The most recent Joint Status Report in *Ms. L.*, which discusses those reunifications, is attached.

In addition, copies of the filings by the government in *Ms. L,* which explain the government's plan to identify the separated children of *Ms. L.* class members for the expanded class period, are attached. The *Ms. L.* Court has not yet made a ruling on remedies for the class members for the expanded class.

Question. Will the plan detailed in the above question require congressional funding?

Answer. HHS and CBP are working out the amount and sources of funding for this plan. While HHS has identified a significant funding shortfall for the UAC program, we do not anticipate that this plan will significantly exacerbate the funding issues for the program.

IMPLEMENTATION OF THE SUPPORT FOR PATIENTS AND COMMUNITIES ACT

Question. I appreciate the President's FY 2020 budget's commitment to combating the addiction crisis and full implementation of the SUPPORT for Patients and Communities Act.

What is CMS's timeline for implementing efforts to increase access to care at Institutions of Mental Disease (IMD) facilities, as authorized by the SUPPORT Act, for those individuals who need inpatient care?

Answer. The SUPPORT for Patients and Communities Act (Pub. L. 115–271) included a provision that provides State Medicaid programs with the option to cover care in certain IMDs, which may be otherwise nonreimbursable under the Federal IMD exclusion, for Medicaid beneficiaries aged 21–64 with a substance use disorder for fiscal years 2019 to 2023. CMS is developing guidance to issue to States regarding this option, and CMS hopes to publish a letter to State Medicaid Directors this fall. CMS has also been providing technical assistance prior to issuing guidance to the few States who have contacted it.

We believe States are evaluating this provision and CMS's waiver options around IMD coverage to determine the best course of action for their State.

Question. What is the administration doing to ensure States and communities that are seeing an uptick in the number of overdoses from drugs other that opioids (such as meth) are able to benefit from the programs Congress has passed to help address addiction?

Answer. Addressing the opioid epidemic is a top priority of this administration, and we appreciate the tools Congress has provided by passing legislation such as the SUPPORT for Patients and Communities Act (Pub. L. 115–271). HHS is also very concerned about the increasing deaths involving cocaine, methamphetamine, and other substances. It is often the case that overdose deaths involve multiple substances, and we know that fentanyl is being laced into other substances, including cocaine and methamphetamine. HHS is committed to increasing access to addiction treatment, and we are looking at ways to use the authorities Congress has provided in order to accomplish this goal.

The SUPPORT Act was enacted on October 24, 2018, and CMS is implementing a number of new initiatives under that law that aim to increase options for treating beneficiaries with opioid use disorder or other substance use disorders, ensure prescriber accountability and improved safety for patients across CMS programs, and illuminate Medicaid prescribing data.

CMS has issued several Informational Bulletins outlining State approaches and effective practices for addressing the opioid epidemic within Medicaid. In November 2017, CMS issued guidance to States announcing a new policy to allow States to design demonstration projects that increase access to treatment for opioid use disorder (OUD) and other substance use disorders (SUD). Through this updated policy, States will be able to pay for a fuller continuum of care to treat SUD, including critical treatment in residential treatment facilities that Medicaid is unable to pay for without a waiver.

The SUPPORT for Patients and Communities Act (Pub. L. 115–271) built upon this concept and included a provision that provides State Medicaid programs with the option to cover care in certain IMDs, which may be otherwise nonreimbursable under the Federal IMD exclusion, for Medicaid beneficiaries aged 21–64 with at least one substance use disorder (which means patients with substance use disorders other than opioid use disorders may participate) for fiscal years 2019 to 2023. CMS is developing guidance to issue to States regarding this option, and it hopes to publish a letter to State Medicaid Directors this fall. CMS has also been providing technical assistance prior to issuing guidance to the few States who have contacted it. We believe States are evaluating this provision and CMS's waiver options around IMD coverage to determine the best course of action for their State. Finally, in February 2019, CMS issued guidance[13] to States on mandatory and optional items and services for non-opioid treatment and management of pain that may be provided in the State Medicaid program.

The Substance Abuse and Mental Health Services Administration provides support to States through the Substance Abuse Prevention and Treatment Block Grant. This funding source allows for flexibility of States to determine what their greatest needs are. The $1.9 billion in this program serves as a safety net source of funding for substance use disorder treatment. These funds are utilized to provide services to individuals who may be affected by substances other than opioids, such as methamphetamine. In addition, SAMHSA funds the Addiction Technology Transfer Centers (ATTCs) who provide training and technical assistance on the use of evidence-based practices to treat all substance use disorders. These training programs are available to providers, communities, and States across the country.

ADOPTION

Question. The President's FY 2020 budget proposal recommends cutting adoption incentives by approximately half. In my State, and other States across the country, children in need of adoptive parents are increasing, partly due to the impacts of opioid crisis.

Please explain in detail what incentives will be eliminated under the President's proposal and what HHS will do to work to increase the number of adoptive parents throughout the country.

Answer. HHS is committed to helping all foster care children achieve permanency. When children in foster care cannot be safely reunified with their parents, it is important to help them find permanent families through adoption or legal guardianship. The Adoption and Legal Guardianship Incentive Payments program (formerly called the Adoption Incentive Payments program) supports this goal by recognizing States' improved performance in helping children and youth in foster care find permanent homes through adoption or legal guardianship. Incentive payments received by States may be used to provide a broad range of child welfare services to children and families, including post-adoption services.

The program was originally established as part of the Adoption and Safe Families Act of 1997, and has been reauthorized and revised several times. In 2014, the program was renamed to reflect that incentives will be paid to jurisdictions for improved performance in both adoptions and legal guardianship of children in foster care. Current incentive categories recognize improved performance in increasing the number of adoptions of children in foster care, the number of legal guardianships of children in foster care, the number of adoptions and legal guardianships for preadolescent children in foster care (ages 9–13), and the number of adoptions and legal guardianship for older children (ages 14 and older) in foster care.

Current year funding under the Adoption and Legal Guardianship Incentives Program is used to pay for incentives earned based on performance in prior years. When the total amount of incentive payments earned by a State in any year exceeds the amount of funds available, payments are initially pro-rated. However, it has been Administration for Children and Families' (ACF) longstanding practice to fully recognize positive performance and award all incentive payments. Therefore, ACF typically uses each annual appropriation first to payout the balance on any previous years' earnings and then, later in the year once data become available, to make an initial payment on the earnings for the most recent year.

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[13] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib022219.pdf?linkId=63935089.*

Historically, funding for the program has been provided at approximately $37.9 million annually and that is the level requested in the President's FY 2020 budget. However, Congress provided increased annual appropriations of $75 million in each of FYs 2018 and 2019. HHS is not eliminating incentives, but is requesting funds at the traditional $37.9 million.

MEDICAID WORK REQUIREMENTS

Question. As part of my questioning on March 14th, I asked you about the Department's definition of "able-bodied adult" as it relates to the work requirements the Department has approved across several different States, including my home State of Ohio. You were unable to define the term, but instead pointed me toward the approved waiver applications for me to see the variations on the term you have approved across the different States.

One of the things I asked you about was a post-partum woman—would a woman 3 months after giving birth be considered an "able-bodied adult" who would be subject to work requirements or risk losing Medicaid coverage as she tries to care for her newborn baby.

Please clarify: does your definition of "able-bodied adult" include a woman who gave birth less than 3 months ago?

What is HHS doing to ensure individuals who are kicked off of coverage for reasons outside of their control (*e.g.,* information is sent to the wrong address, the computer system doesn't work, their documentation demonstrating they should be exempt from a work requirement isn't properly filed) do not suffer from a lapse in coverage?

How are you ensuring individuals who receive coverage through Medicaid are aware of their right to re-enroll in the program if they are kicked off?

Answer. As part of the waivers we've granted, we have set careful guardrails that require States to protect their most vulnerable beneficiaries (including beneficiaries who are pregnant or post-partum), and only required community engagement for beneficiaries whose circumstances allow them to participate.

On March 15, 2019, CMS approved Ohio's 1115 demonstration project, and that approval is subject to the limitations specified in the waiver authorities and special terms and conditions included in the waiver approval. With approval of the demonstration, Ohio will require, as a condition of continued eligibility, that non-exempt beneficiaries in the new adult group at section 1902(a)(10)(A)(i)(VIII) of the Social Security Act, ages 19 through 49, engage in qualifying community engagement activities for at least 80 hours per month. As part of the guardrails to ensure that Ohio protects its most vulnerable residents, CMS provided the State with flexibility to exempt various groups that the State has determined are unlikely to be able to reasonably comply with the requirements, including beneficiaries who are pregnant or 60 days or less post-partum.

Under the demonstration, Ohio is required to notify beneficiaries of their need to participate in community engagement activities as a condition of continued coverage and eligibility. Beneficiaries will have 60 days post notification to report their compliance with the work and community engagement requirement. Beneficiaries will be allowed to report compliance with the work and community engagement requirement in person, over the phone, online, or by mail. Once the beneficiary reports one time, no further reporting is required unless the beneficiary experiences a change in circumstance. If a beneficiary does not report within the 60 days that they are completing a qualifying activity, meet the criteria for an exemption, or experience a good cause circumstance, the beneficiary will be considered non-compliant and be disenrolled from Medicaid. The beneficiary will have the option of applying to re-enroll in Medicaid. Prior non-compliance will not be a factor in any future determination of Medicaid eligibility.

CMS has also worked with Ohio to include guardrails that will protect beneficiaries. The Specific Terms and Conditions (STCs) contain a series of assurances, including that the State will: screen beneficiaries and determine eligibility for other bases of Medicaid eligibility and review for eligibility for insurance affordability programs prior to disenrollment; provide full appeal rights prior to disenrollment; ensure that there are timely and adequate beneficiary notices provided in writing which address community engagement requirement features; assess areas within the State that experience high rates of unemployment, areas with limited economic and/or educational opportunities, and areas with lack of public transportation to de-

termine whether there should be further exemptions from the community engagement requirements and/or additional mitigation strategies, so that the community engagement requirements will not be unreasonably burdensome for beneficiaries to meet; monitor the application of exemptions to ensure that there is not a disparate impact based on race and ethnicity; and maintain a system that provides reasonable modifications related to meeting the community engagement requirements to beneficiaries with disabilities, among other assurances.

QUESTIONS SUBMITTED BY HON. MICHAEL F. BENNET

Question. Last spring, the administration announced the "zero tolerance" policy that resulted in the separation of over 2,800 children at the southern border. Almost a year later since the announcement of this shameful policy, there are still children in HHS custody who were separated from their families and have not been reunified.

In January, the HHS Office of Inspector General released a report on the separated children placed in the care of the Office of Refugee Resettlement (under HHS). The report highlighted that potentially thousands of more children may have been separated from their families prior to the public announcement of the "zero tolerance" policy. A Federal judge ruled just last week to recognize the children and families that were separated since July 2017.

Is HHS working to identify the children who were separated from their families before the "zero tolerance" policy was announced? If not, why?

Answer. Yes. Copies of the filings by the government in *Ms. L,* which explain the government's plan to identify the separated children of *Ms. L.* class members for the expanded class, are attached.

Question. Will you commit to working on identifying these children and reunifying them with their families?

Answer. HHS is fully committed to implementing the court-approved plan for identifying the separated children of *Ms. L.* class members for the expanded class period. The *Ms. L.* Court has not yet made a ruling on remedies for the class members for the expanded class period. HHS has created, deployed, and trained a team of USPHS Officers to conduct individual case files review as part of a pilot project to implement the government's plan to identify substantially all separated children referred to and discharged by ORR within the expanded class period. As of June 24, 2019, the team has reviewed all of the approximately 33,000 individual case files. HHS has referred all the cases with a preliminary indication of separation to DHS for further assessment and reconciliation.

Question. What steps is your agency taking to implement the recommendations from the January OIG report in order to improve program operations based on their findings?

Answer. OIG raised concerns in its report about the inter-agency system for sharing information regarding newly separated children (that is, children whom DHS separates from a parent or legal guardian for cause and in compliance with the *Ms. L* court's orders, and refers to ORR, after June 26, 2018).

As Assistant Secretary Lynn Johnson explained in her response to the OIG report, HHS has implemented changes to the UAC Portal as well as the ORR case management process to enhance tracking and automate the aggregation of data regarding separated children. HHS still relies on DHS to provide us with data on separations. ORR is continually working with DHS to try to improve the accuracy and completeness of what DHS provides to ORR.

OIG is conducting additional evaluations of the ORR program and HHS is cooperating with the OIG across the board. We are committed to continual process improvement and welcome the engagement of the OIG in our efforts to improve the UAC program.

QUESTIONS SUBMITTED BY HON. ROBERT P. CASEY, JR.

Question. At a series of Aging Committee hearings in March, the shortcomings of the *Medicare.gov* Plan Finder tool emerged as a persistent theme. In February, the

Centers for Medicare and Medicaid Services (CMS) announced that the agency is actively engaged in a redesign of the Plan Finder.

Will the redesign process include the opportunity for public comment and dialogue with benefits counselors (including State Health Insurance Assistance Programs or SHIPs) and Medicare beneficiary advocates? If so, please describe the stakeholder comment and review process CMS will employ.

Will you commit to providing a preview of the new Medicare Coverage Tools for members of Congress and their staff? Please indicate when CMS will be prepared to provide a preview of the redesigned Medicare Coverage Tools in their entirety.

Please provide any consumer testing research that CMS is using to inform the redesign process. Please indicate how and whether CMS is leveraging this research to inform the redesign.

Please describe any outreach or training that CMS expects to provide on the revamped Medicare Coverage Tools to SHIP counselors, 1–800–MEDICARE call center employees as well as external stakeholders, including Medicare beneficiary advocates.

Answer. As part of CMS's Medicare multi-year initiative to improve Medicare service across its customer support channels, CMS is undertaking a comprehensive redesign of the Medicare Plan Finder this year. In preparation for the fall 2019 Open Enrollment Period, CMS is building on its initial investment and focusing on a fulsome redesign of the Plan Finder tool to improve usability and address feedback that we have received from users and stakeholders. The redesigned Plan Finder tool will be an important source for Medicare plan information and provide an updated platform and experience for Medicare beneficiaries, family members, caregivers, advocates, and healthcare providers with one central place to view, compare, and select Medicare Part D prescription drug and Medicare Advantage plans.

CMS has sought feedback on changes to the Plan Finder from key stakeholders, including the State Health Insurance Assistance Program (SHIP) leadership and Medicare beneficiary advocates. In addition, CMS receives continuous feedback from users through consumer testing and 1–800–MEDICARE Call Center focus groups; CMS is planning similar focus groups with SHIP counselors this summer. To ensure user and stakeholder needs are met, the redesigned Plan Finder tool will be rolled out in phases, including a phase during which CMS will provide a preview to and solicit feedback from external stakeholders, including Call Center Representatives, SHIPs, and beneficiary advocacy groups. Feedback will be incorporated into the redesigned Plan Finder tool, which will be launched for the upcoming Medicare Open Enrollment Period.

In June, CMS provided briefings to congressional staff, including staff from the Senate Special Committee on Aging, that previewed updates to the Medicare Plan Finder and presented the agency's timeline for rolling out the comprehensive redesign of the Medicare Plan Finder (Medicare Coverage Tools). The agency anticipates the beta launch for the redesigned Medicare Plan Finder to occur in July; at that time, the redesigned Medicare Plan Finder will be available in its entirety to the public well in advance of the 2019 Open Enrollment period.

Question. Far too often, people new to Medicare are uniformed or misinformed about basic Medicare enrollment rules, including knowing how and when to sign up for Medicare (Part A and Part B). The consequences of enrollment missteps can be significant, leading to lifetime late enrollment penalties, gaps in coverage and barriers to accessing needed care.

Are CMS and SSA engaged in conversations regarding updates to existing Medicare enrollment material? This includes, but is not limited to, changing or updating written or online material pertaining to Social Security statements and Medicare Part A and Part B enrollment. If so, please describe the nature of these conversations (which agency initiated and why), the updates or changes under discussion and any plans that CMS and/or SSA have to make changes based on these discussions.

Answer. The Social Security Administration (SSA) and the Centers for Medicare and Medicaid Services (CMS) have enjoyed a long-standing partnership helping millions of elderly Americans, and those with disabilities, receive the health care they need. With that spirit of cooperation in mind, SSA and CMS continue to build on that partnership and collaborate on several additional efforts to improve the customer experience of our beneficiaries when they enroll in Medicare and throughout their time in the program. CMS has reached out to SSA with new collaborative op-

portunities it would like to explore, and some that would expand existing work and collaboration. CMS has been working together with SSA on areas such as improving Medicare enrollment and strengthening the CMS–SSA partnership. Very recently, CMS and SSA worked together on the successful effort to remove Social Security Numbers from Medicare cards and transactions, which will help protect Medicare beneficiaries from identity theft.

Question. On March 4, 2019, I sent a letter with Senator Toomey to the Centers for Medicare and Medicaid (CMS) requesting information about the Special Focus Facility program, which is designed to increase oversight of nursing home facilities that persistently under perform. Will you commit to ensuring that HHS provides a complete and timely response to this letter?

Answer. CMS sent a response to this letter on May 3, 2019.

Question. Marketplace enrollees nearing Medicare eligibility face complicated and time-sensitive enrollment decisions. Without adequate and timely information, these individuals can make consequential enrollment errors about their coverage. CMS began the Medicare Periodic Data Matching Process as a way to identify and notice marketplace enrollees found to be dually enrolled in Medicare. Yet, since the inception of this process, CMS has failed to bolster their notification of marketplace enrollees nearing Medicare eligibility to prevent enrollment errors.

Please describe any outreach to marketplace enrollees nearing Medicare eligibility.

Will you commit to providing additional notification to marketplace enrollees nearing Medicare eligibility? If so, please detail CMS's intended outreach strategy including email, paper mailing, phone calls, and text messages.

Will you commit to halting plans to terminate coverage for marketplace enrollees found to be dully enrolled in Medicare absent adequate consumer protections, including sufficient notice and education?

Please detail the administration's decision making process regarding extension of Time Limited Equitable Relief for people enrolled in marketplace coverage who mistakenly delayed or declined Medicare Part B because of misinformation. Will you commit to extending this opportunity for relief beyond September 2019?

Answer. Ensuring that exchange consumers are aware of their coverage options and able to make decisions regarding the coverage that is appropriate for them is a key priority for CMS. We share your concerns regarding the consequences of dual enrollment in Medicare and exchange coverage for older Americans, including the potential risk for tax liability for advance payments of the premium tax credit (APTC) received during months of overlapping coverage or financial penalties such as the Medicare Part B late enrollment penalty (LEP) if they delay enrolling in Medicare Part B during their initial eligibility period.

CMS continues to prioritize consumer and stakeholder education regarding dual enrollment in Medicare and the exchange and transitioning between coverage through various outreach activities. For example, CMS provides webinars, newsletters, and fact sheets to stakeholders such as assisters, agents, brokers, and issuers. Additionally, CMS has developed educational materials to inform consumers, including current and future Medicare beneficiaries, of the potential consequences of dual enrollment in Medicare and exchange coverage, including penalties for not enrolling in Medicare Part B when first eligible. This information is now included in the Medicare Initial Enrollment Period (IEP) packages (mailed to all beneficiaries automatically enrolled in the Medicare program), General Enrollment Period (GEP) packages (mailed to all beneficiaries who refused or lost Medicare Part B coverage in the last year), the Medicare and You Handbook, and on the exchange application.

Medicare periodic data matching (PDM) is the process by which the exchange periodically examines available data sources to identify consumers enrolled in exchange health plans with financial help at the same time they are determined eligible for, or are enrolled in, Medicare. Based on CMS experience performing Medicare PDM, the majority of exchange consumers who become dually enrolled have become dually enrolled by aging into Medicare and many have likely forgotten to terminate their exchange coverage during their Medicare Initial Enrollment Period.

We believe that exchanges can play an important role in mitigating the risk for these beneficiaries of tax liability for overlapping months of coverage, if they received APTC, and the risk for the Medicare Part B late enrollment penalty by

proactively terminating exchange QHP coverage (if directed to do so by the enrollee) after an enrollee is found to be dually enrolled in Medicare and exchange coverage. In 2018, the Federally Facilitated Exchange added an authorization to the exchange application by which consumers could permit or deny the exchange to act on their behalf and end their exchange coverage if later found to be enrolled in other qualifying coverage such as Medicare. The text of this authorization is as follows:

> If anyone on your application enrolls in coverage through a Marketplace plan, but is later found to have other qualifying health coverage (including Medicare, Medicaid, and/or CHIP), you have the option to allow the Marketplace to end their Marketplace coverage if you select "I agree to this statement" below.
>
> If you select "I disagree to this statement," anyone in this situation will stay enrolled in Marketplace coverage and will pay full cost for their Marketplace plan since they'll no longer be eligible for advance payments of the premium tax credit or extra savings.

This authorization to permit the exchange to end QHP coverage is voluntary as consumers can opt in or opt out. Additionally, after receiving a Medicare PDM notice, consumers can return to the exchange and revoke their authorization for the exchange to terminate their QHP coverage if found to be dually enrolled; these consumers will remain enrolled in their exchange QHP coverage without APTC.

In spring 2019, CMS began the process of terminating coverage for the first cohort of enrollees who provided this authorization and were subsequently determined through PDM to be dually enrolled in Medicare and the exchange. Based on stakeholder feedback, CMS intends to conduct Medicare PDM more frequently to ensure that newly identified Medicare and exchange dual enrollees have sufficient time to sign up for Medicare Part B at the appropriate time and without penalty. Responses to the updated Medicare PDM notice content has been positive, with many dual enrollees proactively ending their QHP coverage after receipt of the initial Medicare PDM warning notice. CMS will continue to monitor the progress of future rounds of Medicare PDM and will explore ways to mitigate any gaps in coverage for the dual enrollee population.

Regarding time limited equitable relief, CMS is offering this relief for certain beneficiaries dually enrolled before September 30, 2019. These beneficiaries are allowed to enroll in Medicare Part B without incurring a LEP or, if these beneficiaries are already paying a LEP, they have an opportunity to request a reduction in the penalty. CMS is providing this relief because these individuals may not have received the information necessary at the time of their Medicare IEP or initial enrollment in the exchange to make an informed Medicare Part B enrollment decision. As a result, some people with Medicare Part A coverage may have enrolled in exchange QHP coverage believing it was an alternative to Medicare Part B coverage. These consumers may not have known they enrolled in the wrong program prior to the end of their Medicare IEP, resulting in either (1) staying in their exchange coverage or (2) enrolling in Medicare Part B during the GEP and being assessed a Part B LEP.

We will continue to monitor the transition between Medicare and the exchange to improve the overall process as necessary.

Question. The Center for Medicare and Medicaid Innovation (Innovation Center) was designed to support the development and testing of innovative health-care payment and service delivery models. The Innovation Center's objective to improve quality of care and reduce health-care costs functions most efficiently when the process is open and thoughtful. Yet, I am concerned that the process by which the Innovation Center develops models lacks transparency and that there is insufficient detail available on models the Innovation Center is currently considering. Please describe the process models go through starting from conceptualization to announcement, including the role of HHS counsel in this process. What is the current process for incorporating stakeholder comments into model development, implementation and evaluation processes?

Answer. Response: We are committed to transparency and stakeholder input in Innovation Center models. Since its inception, the Innovation Center has consulted and worked with stakeholders across the country, other Federal agencies, and other operating divisions within the Department of Health and Human Services in order to identify promising new payment and service delivery models and help design new models. For example, in 2017, in an effort to increase the transparency and effectiveness of the Innovation Center's work, CMS issued a Request for Information

(RFI) seeking feedback on a new direction to promote patient-centered care and test market-driven reforms aimed at empowering beneficiaries as consumers; providing price transparency; and increasing choices and competition to drive quality, reduce costs, and improve outcomes. To further transparency, CMS published the responses to the RFI in April 2018.[14] The responses to this RFI and other recent RFIs in addition to other public and stakeholder feedback that CMS has received, drive the development process for models that are under consideration for potential testing.

The Innovation Center uses a variety of other methods to actively seek input from a wide range of stakeholders across the country. The Innovation Center holds model-specific listening sessions and focus groups, webinars, site visits, summits, and information sharing sessions, engaging thousands of innovators from around the country at different stages of the model development process. In addition, the Innovation Center invites and seeks input on issues in health-care payment and delivery through forums that are open to the public, including RFIs mentioned above, and notice and comment rulemaking. The Innovation Center also interacts with people across the country interested in service delivery and payment innovation through its website, social media outreach, and an email listserv.

The development and design of Innovation Center models typically follows a dynamic lifecycle process that involves several steps. Over a period of months, the Innovation Center identifies ideas for new models from internal and external stakeholders and then develops ideas into model concepts. These concepts are assessed in the context of the current portfolio of models, as well as their potential to improve quality of care and reduce costs. These concepts are then developed into models with specific payment and quality components. From design to release of the model can take many months or over a year of work depending upon the complexity of the model. Each model must meet the statutory requirements to maintain or improve quality and reduce or maintain expenditures.

QUESTIONS SUBMITTED BY HON. SHELDON WHITEHOUSE

Question. The President's budget seeks to reduce health-care expenditures by repealing the Affordable Care Act and cutting $1.5 trillion in Medicaid funding over 10 years, proposals that would hurt millions of Americans. This approach actually hurts Americans twice: by drastically cutting programs on which they depend and leaving in place an inefficient health-care delivery system that wastes hundreds of billions of dollars a year. There's a better, more responsible way to lower health-care spending, and it's through reforms like Accountable Care Organizations, bundled payments, and patient-centered medical homes.

Rhode Island has two well-established Medicare Accountable Care Organizations: Coastal Medical, which over 5 years has saved Medicare $30 million, and Integra Community Care Network, which over 3 years has saved Medicare $16 million. These are big numbers in a State as small as Rhode Island.

Do you agree that ACOs and other alternative care models have the potential to reduce Federal health expenditures? If yes, how much savings would you estimate is possible from these types of delivery system reforms?

Answer. Transforming our health-care system into one that pays for value by rewarding outcomes and health instead of procedures and sickness is a key Department-wide priority. The Innovation Center is developing and testing models that complement HHS's "four Ps" of driving toward value: Patients as Consumers, Providers as Accountable Patient Navigators, Paying for Outcomes, and Prevention of Disease Before it Occurs. Getting better value from our health system and paying for value requires empowering patients to be engaged and informed consumers. In the shift toward value, empowered patients will still need physicians to help them navigate the health-care system, and HHS needs to give those physicians the right incentives to guide patients in making choices that will lead to good outcomes.

We know that the U.S. health care payment system is overly complex and often does not create sufficient incentives for higher-quality, lower-cost care. An Alternative Payment Model (APM) is a payment approach that creates added incentives to provide high-quality and cost-efficient care. APMs can apply to a specific clinical condition, a care episode, or a population. Payment for value, as measured through

[14] The New Direction RFI and the comments received are available at: *https://innovation.cms.gov/initiatives/direction/*.

outcomes, is the central premise of every model the Innovation Center tests. Following the "four Ps" we think the current portfolio of models will continue to drive the health-care system towards delivering value and have the potential to reduce Federal health-care expenditures. Additional information on estimated spending effects of models is available in the Analytical Perspectives of the FY 2020 President's budget.

Question. Why does the President's budget drastically cut Medicaid and repeal the Affordable Care Act as its first response to addressing health-care spending instead of taking the more responsible and humane approach of lowering spending through delivery system reforms?

Answer. The Medicaid program was designed to serve our most vulnerable populations, such as children and people with disabilities. To strengthen the fiscal sustainability of this critical safety net for generations to come, this administration is looking at ways to facilitate State innovation and increase patient choice. Successful partnership between our leadership at HHS and the leaders of every State Medicaid program is vital to delivering on the mission of HHS and the mission of the Medicaid program: improving the health and well-being of the Americans we serve.

This administration is committed to granting States more freedom to design innovative local solutions. We have followed through on that promise by supporting efforts, like waiving decades-old restrictions on addiction treatment services and allowing States to link working age beneficiaries to new opportunities through work and community engagement programs, under authority granted to us under section 1115 of the Social Security Act. For example, in November 2018, CMS published a State Medicaid Director letter discussing strategies under existing authorities for States to implement innovative service delivery system reforms for adults with serious mental illness, and children with serious emotional disturbance. Examples of these innovations include improving availability of behavioral health screenings and mental health and substance use disorder services in schools to identify and engage children with serious emotional disturbance sooner. The letter explained a demonstration opportunity for States to receive Federal financial support for treating Medicaid beneficiaries with these conditions during short-term acute care stays in psychiatric hospitals or in residential treatment facilities that qualify as an Institution for Mental Diseases.

Since January 2018, the Innovation Center has launched a number of bold, new models designed to provide better care at a lower cost. For example, CMS announced the Maternal Opioid Misuse (MOM) Model, which aims to improve quality of care for pregnant and postpartum Medicaid beneficiaries with opioid use disorder through State delivery system innovations. The model tests sustainable coverage and payment strategies supporting the coordination of clinical care and the integration of services essential for health, well-being, and recovery; expands access, service delivery capacity, and infrastructure based on State specific needs; and improves quality of care and reduces costs for mothers and infants. This model will run from January 1, 2020 through December 31, 2024.

Question. With health spending reaching nearly 18 percent of GDP, we still spend a larger share of our economy on health care than any other OECD nation. The second highest health spender is Switzerland at 12 percent. For all of the extra money we spend, we don't necessarily get better outcomes. [Health Spending Per Capita v. Life Expectancy Chart]

Since 2010, there's been improvement on the budget outlook for mandatory Federal spending on health care. [2010 v. 2019 CBO Baseline Chart]

I think the slowdown is evidence that structural changes in the delivery of care—many of which were ushered in by the Affordable Care Act—have taken hold, and we are seeing lower Federal spending as a result.

Do you believe there is an advantage to reducing health-care spending growth through alternative payment and delivery models?

What is the administration doing to better understand the causes of the sustained slowdown in Federal health-care spending?

Answer. In February 2019, the Office of the Actuary at the Centers for Medicare and Medicaid Services (CMS) published a report stating that national health expenditure growth is expected to average 5.5 percent annually from 2018–2027, reaching nearly $6.0 trillion by 2027.

Growth in national health spending is projected to be faster than projected growth in Gross Domestic Product (GDP) by 0.8 percentage points over the same period. As a result, the report projects the health share of GDP to rise from 17.9 percent in 2017 to 19.4 percent by 2027.

The report found that the outlook for national health spending and enrollment over the next decade is expected to be driven primarily by:

- Key economic factors, such as growth in income and employment, and demographic factors, such as the baby-boom generation continuing to age from private insurance into Medicare; and
- Increases in prices for medical goods and services (projected to grow 2.5 percent over 2018–2027 compared to 1.1 percent during the period of 2014–2017).

The report is available at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.*

These projections highlight the urgent need to ensure that our health-care programs are paying for value, as we are currently on an unsustainable trajectory. Transforming our health-care system into one that pays for value by rewarding outcomes and health instead of procedures and sickness is a key department-wide priority. The Innovation Center is developing and testing models that complement HHS's "four Ps" of driving toward value: Patients as Consumers, Providers as Accountable Patient Navigators, Paying for Outcomes, and Prevention of Disease Before it Occurs. Following the "four Ps" we think the current and future portfolio of models will continue to drive the health-care system towards delivering value.

Question. I'm pleased to see the President's budget include a number of proposals related to lowering the cost of prescription drugs, but the budget does not address the administration's recent proposed rule to require rebates from drug companies to PBMs or insurance companies to be passed along to consumers that the point of sale. This is a proposal that would certainly interact with the administration's other drug pricing efforts, and one that would, by CMS's own estimates, increase premiums in Medicare Part D. In addition to my concerns about increased premiums, I remain skeptical that this proposal will result in lower list prices for prescription drugs.

If the administration's rebate rule was finalized and you were still in your previous role as a drug company executive, would you support reducing the list prices of the company's drugs?

If so, by how much relative to the size of the rebates the company is currently providing?

Answer. Subject to the President's executive order[15] from January 28, 2017, I will not participate in any particular matter involving my former employer. You may wish to review the responses provided to Senate Finance Committee Chairman Chuck Grassley at the February 2, 2019, Senate Finance Hearing "Drug Pricing in America: A Prescription for Change, Part II." The chairman asked this question of the witnesses and all answered that they are supportive of the rule, and would consider lowering the list price of their companies' drugs.

Question. If companies are unwilling to reduce list prices by the size of the current rebates, doesn't this proposal set drug companies up to receive a substantial windfall?

Answer. The current rebate system incentivizes higher list prices. If the proposed rule is finalized, pharmaceutical companies will no longer participate in rebate schemes to compete for formulary position. Such companies would, instead, compete for lower list prices to ensure better formulary positions. Pharmaceutical Benefit Managers (PBMs) in the current system do a good job of negotiating with the manufactures for lower cost; in a system where the proposed rule referenced is finalized, PBMs will still be able to extract leverage and drive down cost.

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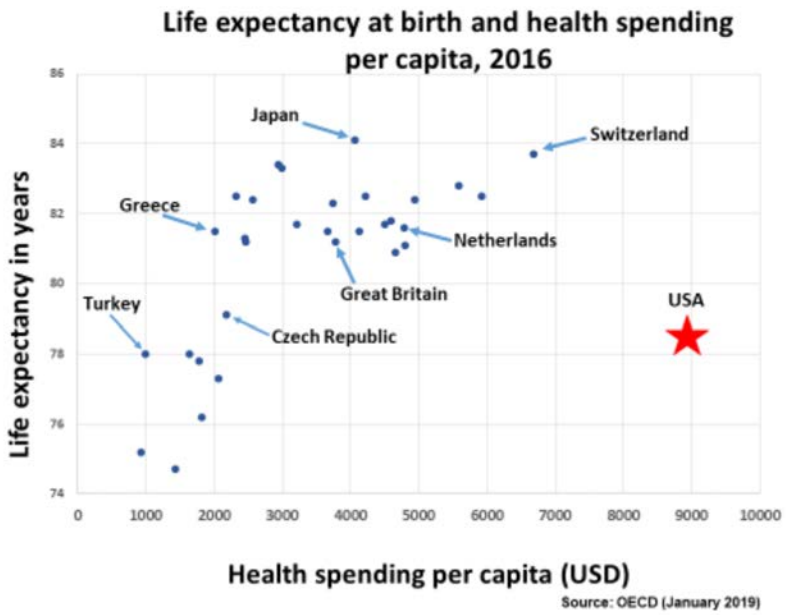
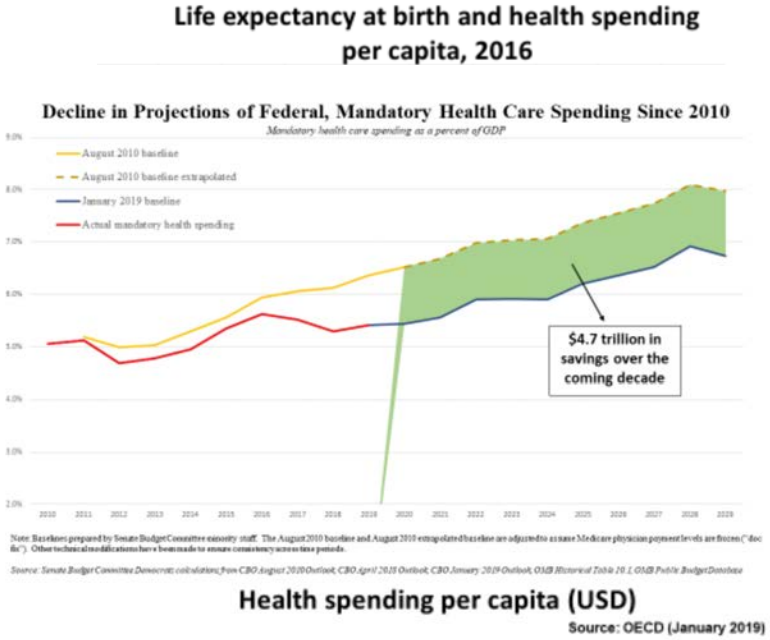
[15] *https://www.whitehouse.gov/presidential-actions/executive-order-ethics-commitments-executive-branch-appointees/.*


Life expectancy at birth and health spending per capita, 2016
Life expectancy in years
Health spending per capita (USD)
Japan
Switzerland
Greece
Netherlands
Great Britain
Turkey
Czech Republic
USA
Source: OECD (January 2019)


Life expectancy at birth and health spending per capita, 2016
Decline in Projections of Federal, Mandatory Health Care Spending Since 2010
Mandatory health care spending as a percent of GDP
August 2010 baseline
August 2010 baseline extrapolated
January 2019 baseline
Actual mandatory health spending
$4.7 trillion in savings over the coming decade
Health spending per capita (USD)
Source: OECD (January 2019)

QUESTIONS SUBMITTED BY HON. MAGGIE HASSAN

Question. This question relates to the HHS OIG's Proposed Rule entitled, "Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees."

Under the proposed rule, which entity or entities would administer and provide the point-of-sale discounts to beneficiaries? Is it the administration's intent that that Pharmacy Benefit Managers (PBMs) would administer and provide the point-of-sale discounts to the beneficiaries? If not, how will the proposed rule's point-of-sale discounts be administered?

Answer. The proposed rule referenced in your question does not specify who in the system would administer and provide the point-of-sale discounts. We solicited common on this important question in the proposed rule and have received comment letters on this topic which we will consider to help inform the rulemaking process.

Question. In June of 2018, the Medicaid and CHIP Payment and Access Commission (MACPAC) unanimously recommended under Recommendation 1.1 in their annual report to Congress that Congress remove the statutory requirement that manufacturers blend the average manufacturer price (AMP) of a brand drug and its authorized generic.[16]

This requirement created an unintended loophole. Rather than use the price of the authorized generic, drug companies can sell its authorized generic to a corporate subsidiary at an artificially lower price, and use that lower price to bring down the AMP, which in turn lowers the rebate obligation.

What information have you learned from the Health and Human Services Office of the Inspector General report regarding this issue? What is the scope of this problem, and how prevalent is this practice among drug manufacturers?

Answer. As part of our overall effort on drug prices, the President's FY 2020 budget proposes a legislative fix with which Congress could clarify authorized generic drug sales under the Medicaid Drug Rebate program. This proposal clarifies that the primary manufacturer's average price must exclude the sales of heavily discounted authorized generics to secondary manufactures.

Question. In New Hampshire, our Department of Health and Human Services has received about the same level of funding each year for the Community Mental Health Block Grant program for the last 20 years.

Why has funding for the Community Mental Health Block Grant program not been increased despite the growing need for mental health services across the country?

Answer. SAMHSA feels strongly that the needs of those with serious mental illness are critical. The Community Mental Health Block Grant (MHBG) is a major source of SAMHSA funding which supports this effort. Though the Block Grant was not proposed for increase this year, this does not indicate a lack of priority for this program. The MHBG has grown from $533 million in FY 2016 to $733 million in FY 2019. SAMHSA maintains this FY 2019 enacted level in the FY 2020 President's budget. Overall, the budget provides **$1 billion, an increase of $3 million** above FY 2019, to SAMHSA to improve access to mental health services for those with serious mental illness and children with serious emotional disturbance, and the budget also proposes $15 million for SAMHSA's Assertive Community Treatment program, which is an increase of $10 million over the FY 2019 enacted level.

QUESTIONS SUBMITTED BY HON. CATHERINE CORTEZ MASTO

Question. Since 2008, average family premiums for employer sponsored plans have increased 55 percent, twice as fast as workers' earnings (26 percent) and three times as fast as inflation (17 percent).[17] The Kaiser Family Foundation survey from

[16] MACPAC, "Improving Operations of the Medicaid Drug Rebate Program," *https://www.macpac.gov/wp-content/uploads/2018/06/Improving-Operations-of-the-Medicaid-Drug-Rebate-Program.pdf.*

[17] Kaiser Family Foundation, *https://www.kff.org/health-costs/press-release/employer-sponsored-family-coverage-premiums-rise-5-percent-in-2018/.*

2018 found that "the burden of deductibles on workers continuing to climb over time in two ways: a growing share of covered workers face a general annual deductible, and the average deductible is rising for those who face one."Do you see this rising share of health-care costs borne by employees as problematic?

We know that providers recover low reimbursements from Federal programs through higher charges to commercial plans. What kind of data do you have on the impact of your Medicaid cuts on the cost of employer-sponsored coverage? How about the impact of the hospital cuts?

Answer. We recognize that serious problems remain with the PPACA. Many Americans continue to be priced out of the market and there are 28.5 million uninsured. As a result, enrollment among unsubsidized people continues to decline. In 2019, the average monthly premium for a family of four on *HealthCare.gov* is over $1,500, which can easily exceed the family's mortgage.

The ACA did nothing to address the underlying problems behind rising health-care costs in this country. Health-care costs continue to be on a trajectory to consume nearly $1 in every $5 of the Nation's economy by 2027. At the end of the day, we have to address rising health-care costs because that is what is increasing premiums. The administration issued rules to expand short-term, limited duration insurance plans, which can be far less expensive than exchange plans and better suited to peoples' needs. The administration also issued rules to expand association health plans and health reimbursement accounts, increasing access for small businesses to offer more affordable health insurance options for their employees.

Question. If an individual with a history of cancer is priced out of health-care coverage based on their health history—for the purposes of this discussion, if their premiums exceed 9.5 percent of their income—would you still consider that individual protected from discrimination based on their pre-existing condition?

Answer. Under current law, health insurance issuers cannot refuse to cover an individual, or charge that individual a higher price, because they have a pre-existing condition (that is, a health problem that was present before the date that new health coverage starts). These rules went into effect for policy years beginning on or after January 1, 2014. Today, we know that the ACA has not delivered on its promise to people with pre-existing conditions. In particular, if you are ineligible for a premium tax credit, coverage on the individual market has likely become unaffordable for you.

Question. When CBO scored the Graham-Cassidy proposal, they determined that "millions" would lose coverage under the bill. They didn't have enough time to give us specifics; you have had 2 years to put together more specific estimates, just as CBO did for other versions of ACA repeal. Can you tell me specifically how many Americans you expect to lose coverage under this budget over the course of the 10-year budget window?

Answer. The budget supports a two-part approach to move away from Obamacare, starting with enactment of legislation modeled closely after the Graham-Cassidy-Heller-Johnson bill that includes Market-Based Health Care Grants. In Medicaid, this includes allowing States a choice between a per-capita cap or a block grant, and repealing Obamacare's Medicaid expansion, to modernize Medicaid financing and refocus the program on those it was originally intended to serve. The second part of the budget proposal includes additional reforms to address unsustainable health-care spending trends and builds upon the Graham-Cassidy-Heller-Johnson bill to make the system more efficient. This includes proposals to align the growth rates for the Market-Based Health Care Grant Program and Medicaid per capita cap and block grant with the Consumer Price Index for All Urban Consumers (CPI–U).

Question. There are a handful of policies in this budget that appear to be based on the assumption that consumers are too insulated from the true cost of their care to be informed consumers, and are thereby driving up the cost of health care (minimum contribution for premium tax credits, and increasing copayments in Medicaid). Do you think that consumers don't have enough skin in the game? What sort of clinical improvement do these policies serve? What data or evidence do you have to support that?

Answer. The President's 2020 budget proposes bold reforms to our Nation's safety net and Federal health programs, so that they actually work for the people they serve. They aim to empower States to take charge of the health-care system and create solutions that will be best suited for their citizens. These proposals also empower consumers to purchase coverage that best suits their health-care needs.

These proposals align with the administration's core values. First, they rely, to the extent possible, on competition within the private sector because that is a key way to drive down costs while improving quality. Second, these changes put patients at the center, free to make choices that work for them. Third, these reforms defer to States to innovate, rather than assuming the Federal Government knows best. Finally, these reforms aim to deliver care in an affordable, fiscally sustainable way, while maintaining a safety net for those in need.

Question. The budget proposes to give States the ability to make changes to the ten essential health benefits outline in the ACA. Which one of those do you see as "nonessential" in an insurance product?

Answer. The President's budget includes a number of proposals to improve Federal health programs so they work better for the people they serve. These reforms leverage competition within the private sector, allow patients to make choices that work for them, and give States the freedom to innovate. For 2019, average premiums have dropped for the first time since the implementation of the Federally Facilitated Exchanges in 2014, suggesting that the numerous actions taken by the administration to stabilize the market are working. These actions include implementing the market stabilization rule early in the administration, granting States flexibility to set their essential health benefit benchmark, and using waiver authority to approve reinsurance programs in seven States. For example, in the 2019 Payment Notice, CMS finalized options for States to select new EHB-benchmark plans starting with the 2020 benefit year. Based on this flexibility, Illinois made changes to its EHB-benchmark plan for plan year 2020 that aim to reduce opioid addiction and overdose by including in its EHB benchmark plan alternative therapies for chronic pain, restrictions on access to prescription opioids, and expanded coverage of mental health and substance use disorder treatment and services.

Question. Many of the proposals have no revenue or cost estimate. That includes proposals for which the fundamental purpose is to decrease costs—things like applying insurers' negotiating leverage to Part B drugs. Are those cost estimates forthcoming? Do the cost estimates from other proposals account for the interactions of these proposals? Like for example, the interaction of a Medicaid block grant with the Medicare proposals? Do they account for interactions with proposed rules like the Rebate rule?

Answer. The Office of the Actuary (OACT) reviewed proposals in the FY 2020 President's budget, but given data and time limitations related to certain proposals, cost estimates either could not be generated or were not available in time for release of the budget. Cost estimates are not anticipated to become available for the remaining proposals. OACT will update scores for the Mid-Session Review, scheduled for release in July 2019, but will not necessarily have estimates for proposals not already scored. Generally, interactions among CMS mandatory proposals that were not able to be scored are not accounted for; where possible, interactions between scored proposals are incorporated. The baseline for the President's budget assumes that proposed rules released prior to the budget, including the rule to Remove Safe Harbor Protection for Rebates, will be implemented as proposed; and the budget proposals are scored in accordance with these assumptions.

Question. The budget includes proposals to cut nearly $50 billion from graduate medical education programs. Understanding that there have been similar proposals over the years offered by administrations of both parties, $50 billion in reduced outlays dwarfs reductions in previous proposals, especially in view of the cuts to hospitals through other policies in the budget. What in this budget will bring doctors to Nevada?

Answer. Funding for Graduate Medical Education (GME) comes from multiple fragmented funding streams, and HHS's GME financing system does not target training to the types of physicians needed in the United States. The President's FY 2020 budget includes a proposal that 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 2020 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 Serv-

ices 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. How much less money will hospitals receive over the year budget window relative to the baseline?

Answer. The budget includes Medicare proposals designed to improve value-based systems of care, exercise fiscal integrity, promote competition, and address high drug prices. The package of proposals in the President's budget extends the solvency of the Medicare Hospital Insurance Trust Fund by 8 years, in part by ensuring Medicare payments are directly related to its health care financing role, financing certain payments to hospitals outside the Trust Fund and slowing their growth rate. The proposals also more closely align Medicare payment policy with private insurers.

Question. When all is said and done, how much more or less money will States receive in 2029 relative to the baseline? Nevada specifically?

Answer. Recognizing that States are better positioned to address the unique needs of their populations, the budget returns substantial control over health care from Washington, DC back to the States. States will have the option of choosing between a per-capita cap or a block grant for Medicaid, and receive additional funds via the Market-Based Health Care Grants in lieu of ACA subsidies to better serve their residents. Health-care grant funding for States will be more flexible, sustainable, and equitable than under the current Medicaid and ACA programs.

Question. When did you first become aware of the increasing numbers of separated children in ORR care? Were you aware of the zero tolerance policy or the plan to separate families before it was publicly announced in April of 2018?

Answer. HHS staff maintains that they were told by inter-agency partners that there was no family separation policy, and were not told about the zero-tolerance policy (ZTP) before DOJ announced it on April 6, 2018. I take them at their word.

ZTP was an immigration enforcement policy issued by DOJ on April 6, 2018. HHS did not issue ZTP. I became aware of the DOJ zero-tolerance enforcement policy as a result of then-Attorney General Sessions's announcement on April 6, 2018.

On May 7, 2018, A.G. Sessions announced that DHS and DOJ would implement ZTP by having DHS refer 100 percent of illegal southwest border crossings to DOJ for prosecution. Neither DOJ nor DHS consulted with me before A.G. Sessions made that announcement. I learned about the announcement through the news media.

After the April 6, 2018 announcement, I took no action because those implications were not self-evident and I was not informed of the policy's implications for the UAC program. It should be noted that I was severely ill in April. I was hospitalized in mid-April; I was then in home care and on a reduced work schedule.

On May 7, 2018, then-Attorney General Sessions announced the 100-percent referral policy. After that announcement, I was not informed of, and I did not immediately appreciate, the full implications and operational challenges that the zero-tolerance and 100-percent referral policies could have for our UAC program.

On June 20, 2018, the President issued the executive order, "Affording Congress an Opportunity to Address Family Separation." On June 26, 2018, the court in the *Ms. L.* litigation entered a class-wide preliminary injunction, ordering reunification of class member parents with their separated children in ORR care when certain criteria were met. From that point, our efforts focused primarily on complying with the court's order.

As the implications of the April 6th and May 7th policies became clearer, on June 22, 2018, I activated Robert Kadlec, M.D., Assistant Secretary for Preparedness and Response (ASPR), to ensure, *inter alia,* that (1) every child knows where his or her parent is, (2) every parent knows where his or her child is, (3) children and parents regularly communicate, and (4) reunification occurs as quickly as possible. In the UAC program, the term "reunification" has historically meant discharge to a Category 1 or Category 2 sponsor.

To comply with the June 26, 2018 order and to accomplish the goals discussed above, I asked Dr. Kadlec to lead the reunification efforts. The reunification was a resource-intensive and time-sensitive obligation. Dr. Kadlec instructed Public Health Commissioned Corps Commander Jonathan White to take charge of ASPR's Incident Management Team and to oversee the operational dynamics of ASPR's reunification mission. Several HHS senior leaders and staff, including myself, worked in a secure facility at HHS to manually review thousands of electronic case-management records on the UAC portal in order to reunite separated children with their separated parents.

Question. What is HHS doing to identify and reunify the children who were separated before the zero tolerance policy was public?

Answer. HHS is fully committed to implementing the court-approved plan for identifying the separated children of *Ms. L* class members for the expanded class period. The *Ms. L* court has not yet made a ruling on remedies for the class members for the expanded class period.

Question. Family separations continue to occur at the border. What are you doing to ensure appropriate child welfare standards are being used in making family separation determinations? Does ORR receive the information it needs from DHS to make appropriate decision on the care of a child who has been separated?

Answer. HHS has implemented changes to the UAC Portal as well as the ORR case management process to enhance tracking and automate the aggregation of data regarding separated children. HHS still relies on DHS to provide us with data on separations. ORR is continually working with DHS to try to improve the accuracy and completeness of what DHS provides to ORR.

Question. What is HHS doing to track newly separated children? Are you working with DHS to ensure there is a coordinated tracking system?

Answer. As noted above, HHS has implemented changes to the UAC Portal as well as the ORR case management process to enhance tracking and automate the aggregation of data regarding separated children. HHS still relies on DHS to provide us with data on separations. ORR is continually working with DHS to try to improve the accuracy and completeness of the information that DHS provides to ORR.

Question. Many of the children who are in ORR custody are extremely vulnerable and are at heightened risk of sexual abuse. Do your requirements and standards for ORR contractors include training on trauma and how it manifests in children?

Answer. Staff are required to complete a number of trainings pre-employment. These trainings ensure that staff understand their obligations under ORR regulations and policies. Care providers must tailor trainings to the unique needs, attributes, and sex of the unaccompanied alien children in care at the specific care provider facility. Staff must complete refresher trainings every year or with any policy change. These trainings must include:

- ORR and the care provider facility's zero tolerance policies for all forms of sexual abuse, sexual harassment, and inappropriate sexual behavior;
- The right of unaccompanied alien children and staff to be free from sexual abuse, sexual harassment, and inappropriate sexual behavior;
- Definitions and examples of prohibited and illegal sexual behavior;
- Recognition of situations where sexual abuse, sexual harassment, and inappropriate sexual behavior may occur;
- Recognition of physical, behavioral, and emotional signs of sexual abuse and methods of preventing and responding to such occurrences;
- How to avoid inappropriate relationships with unaccompanied alien children;
- How to communicate effectively and professionally with unaccompanied alien children, including unaccompanied alien children who are lesbian, gay, bisexual, transgender, questioning, or intersex;
- Procedures for reporting knowledge or suspicion of sexual abuse, sexual harassment, or inappropriate behavior as well as how to comply with relevant laws related to mandatory reporting;
- The requirement to limit reporting of sexual abuse, sexual harassment, and inappropriate sexual behavior to staff with a need-to-know in order to make decisions concerning the victim's welfare and for law enforcement, investigative, or prosecutorial purposes;
- Cultural sensitivity toward diverse understanding of acceptable and unacceptable sexual behavior and appropriate terms and concepts to use when dis-

cussing sex, sexual abuse, sexual harassment, and inappropriate sexual behavior with a culturally diverse population;
- Sensitivity regarding trauma commonly experienced by unaccompanied alien children;
- Knowledge of existing resources for unaccompanied alien children inside and outside the care provider facility, such as trauma-informed treatment, counseling, and legal advocacy for victims;
- General cultural competency and sensitivity to the culture and age of unaccompanied alien children; and
- Proper procedures for conducting professional pat-down searches, including cross-gender pat-down searches and searches of transgender and intersex unaccompanied alien children in a respectful and least intrusive manner.

In addition to training staff, care providers must individually assess children and youth for risk of being a victim or a perpetrator of sexual abuse while in ORR custody and use the results of the assessment to inform the minor's housing, education, recreation, and other service assignments. If the assessment indicates that the child experienced prior sexual victimization or perpetrated sexual abuse, the clinician must follow up with any necessary medical or mental health services.

Question. In the President's budget, funding for the Unaccompanied Alien Children (UAC) program was held level from FY 2019 at $1.3 billion. However, the budget also requests increased transfer authority as well as requesting a $2 billion contingency fund. Why doesn't your budget request the amount of money that the program is actually projected to need?

Answer. It is inherently difficult to project the amount of money that the program is actually going to need given the historical, significant variability in program needs and the legal requirement that ACF take custody of, and provide care for, every unaccompanied alien child referred by Federal law enforcement, regardless of the availability of funds. The budget proposes two mechanisms to manage this variability: (1) the provision of expanded transfer authority, which has been included in each Appropriation Act since FY 2015 and has afforded the Secretary flexibility to deal with unforeseen increases in UAC referrals to the program; and (2) a mandatory contingency fund capped at $2 billion over 3 years, which is probabilistically scored at $738 million.

ACF will continue to monitor UAC referrals and all potential program impacts, and keep Congress apprised of changes in caseload projections and any changes in the UAC population that may alter current budget estimates.

Attachment No. 1

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

MS. L, *et al.,* Case No. 3:18–cv–0428 DMS MDD

Petitioners-Plaintiffs,

vs.

U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT, et al.,

Respondents-Defendants.

DEFENDANTS' PROPOSED EXPANDED *MS. L* CLASS IDENTIFICATION PLAN SUMMARY

In accordance with the Court's March 28, 2019 Order Setting Further Status Conference, ECF No. 391, Defendants hereby submit the attached Proposed Expanded *Ms. L* Class Identification Plan Summary, and supporting declarations.

DATED: April 5, 2019

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

SCOTT G. STEWART
Deputy Assistant Attorney General

WILLIAM C. PEACHEY
Director

WILLIAM C. SILVIS
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CERTIFICATE OF SERVICE

IT IS HEREBY CERTIFIED THAT:

I, the undersigned, am a citizen of the United States and am at least eighteen years of age. My business address is Box 868, Ben Franklin Station, Washington DC 20044. I am not a party to the above-entitled action. I have caused service of the accompanying brief on all counsel of record, by electronically filing the foregoing with the Clerk of the District Court using its ECF System, which electronically provides notice.

I declare under penalty of perjury that the foregoing is true and correct.

DATED: April 5, 2019

Sarah B. Fabian

PROPOSED EXPANDED *MS. L* CLASS IDENTIFICATION PLAN SUMMARY

On March 8, 2019, the Court expanded the *Ms. L* class to include adult parents who entered the United States at or between ports of entry on or after July 1, 2017. The Court has also instructed Defendants to put forth a potential plan for identifying the class members within the class expansion period of July 1, 2017, through June 25, 2018.

Defendants' proposed plan to identify potential *Ms. L* class members within the class expansion period is explained in the attached declarations from Commander Jonathan White of the United States Public Health Service and Dr. Barry Graubard of the National Institutes for Health.

In short, Defendants would identify potential *Ms. L* class members by identifying their children out of the total population of approximately 47,000 children discharged by the Office of Refugee Resettlement (ORR) during the class expansion pe-

riod. Defendants would attempt to streamline and accelerate identification of children of potential *Ms. L* class members by using programmatic knowledge, data analysis, and statistical science to try as best as practicable to segment the population based on the probability that the child's parent is a *Ms. L* class member. If successful, segmentation would enable Defendants to prioritize children for manual reviews of ORR case management records, which would confirm whether the child was, in fact, separated from a parent who is a *Ms. L* class member for the class expansion period.

The operational leads for the work would be: Commander Jonathan White for the U.S. Department of Health and Human Services (HHS), Melissa Harper for U.S. Immigration and Customs Enforcement (ICE), and Jay Visconti for U.S. Customs and Border Protection (CBP). They would convene an inter-agency Data Analysis Team. A senior biostatistician (likely Dr. Graubard from the NIH) would serve as the lead for the Data Analysis Team.

Within approximately four weeks of plan activation, Defendants anticipate that the Data Analysis Team would conduct a regression analysis of the possible children of potential class members for the original class period reported in the most recent Joint Status Report, ECF No. 388, using the approximately 12,000 children who were in ORR care on June 26, 2018 as a "training set" to develop a prediction model. The Data Analysis Team would work to validate variables that may be predictive of a child having been separated from a parent (*e.g.,* the age of the child), and attempt to identify any additional demographic features of children separated from parents (as distinct from children who entered the United States without a parent). Through validation, the team would develop a prediction model correlating relevant variables with increased likelihood of parental class membership.

Within approximately eight weeks of plan activation, Defendants anticipate that the Data Analysis team would begin using the prediction model to rank order the children among the population of approximately 47,000 for the class expansion period according to their probability of being children of potential *Ms. L* class members. They would then begin grouping the children into segments based on statistical probability of parental class membership. Using this method, Defendants would begin targeting manual case file review on the higher-probability groups. In addition, representative samples would be taken from lower-probability groups to test them.

As children are identified as possible children of potential *Ms. L* class members, Defendants would validate their status jointly.

Within approximately 12 weeks of plan activation, Defendants would begin consolidating information about any newly-identified possible child of a potential *Ms. L* class member with information about the potential *Ms. L* class member known to Defendants. Defendants would provide final, rolling lists to Class Counsel. The rolling lists would include basic information including the names and alien numbers of the children and their class member parents, and the parents' last known contact information.

Defendants estimate that identifying all possible children of potential *Ms. L* class members referred to and discharged by ORR during the expansion period would take at least 12 months, and possibly up to 24 months. The time required to complete the work may be affected by at least three factors. The first is the efficacy of the initial prediction model and the outcomes of sampling of the lower-probability groups (which are not known at this juncture). The second is the pace of manual record review (which will depend on how many qualified contractors Defendants are able to hire and train for the Case File Review Team). The third factor is any meet-and-confer process that may occur after manual reviews for the initial, higher-probability groups are complete.

The primary benefit of Defendants' proposed plan is that, if successful, it would front-load the identification of potential *Ms. L* class members and possibly lead to a reduction in the overall time required for manual review. For this reason, it is a more rational approach than a date-ordered or randomized manual review.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

MS. L., et al., Case No. 18cv428 DMS MDD

Petitioners-Plaintiffs, Hon. Dana M. Sabraw

vs.

U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT, et al.,

Respondents-Defendents.

DECLARATION OF JONATHAN WHITE

I, Jonathan White, declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that my testimony below is true and correct:

1. I am a Commander with the United States Public Health Service Commissioned Corps, and have served at the Department of Health and Human Services ("HHS") in three successive presidential administrations. I am presently assigned to the 18 Office of the Assistant Secretary for Preparedness and Response ("ASPR"), and previously served as the Deputy Director of the Office of Refugee Resettlement ("ORR").

2. The statements in this declaration are based on my personal knowledge, information acquired by me in the course of performing my official duties, information supplied to me by federal government employees, and government records.

3. I am providing this declaration for use by the Defendants and the Court in *Ms. L. v. ICE,* No. 18–cv–428 (S.D. Cal.).

Background and Recommended Methodology

4. My understanding is that on March 8, 2019, this Court expanded the class in *Ms. L.* The class is now defined as: "All adult parents who entered the United States at or between designated ports of entry on or after July 1, 2017, who (1) have been, are, or will be detained in immigration custody by the DRS, and (2) have a minor child who has been, is or will be separated from them by DHS and has been, is or will be detained in ORR custody, ORR foster care, or DHS custody, absent a determination that the parent is unfit or presents a danger to the child." ECF No. 386. The same qualifications apply to the original and expanded classes. "[T]he class does not include migrant parents with criminal history or communicable disease, or those who are in the interior of the United States or subject to the EO." ECF No. 82.

5. The Defendants have previously identified the children of potential Ms. L. class members who were in the care of ORR on June 26, 2018. As I have previously explained, the process of identifying those children involved analysis of dozens of data sets from U.S. Customs and Border Protection (CBP) and U.S. Immigration and Customs Enforcement (ICE), manual review of approximately 12,000 individualized ORR case management records, and reconciliation with sworn testimony from the ORR grantees caring for the children. ECF No. 347–1. Ultimately, this process "was operationally feasible because the children were still in ORR custody, and ORR grantees were able to talk with them about separation and share the information with HHS." *Id.*

6. HHS cannot use the exact same methodology to identify the children of potential class members for the class expansion period of July 1, 2017 through June 25, 2018 for three reasons. First, ORR has discharged the children in its care during the class expansion period, and thus lacks access to those children through grantees. Second, my current understanding is that CBP is likely not able to produce data sets for the time period before April 19, 2018, as CBP did not track parental separation data as a separate searchable data point prior to that time. Third, the sheer number of ORR case management records, covering approximately 47,000 children referred to and discharged by ORR during the class expansion period, would overwhelm ORR's existing resources were it to attempt a manual review of a1l records in date order. See Decl. of Jallyn Sualog, ECF No. 347–2.

7. I have therefore sought to develop a methodology to try as best as practicable to streamline and accelerate the identification of potential *Ms. L.* class members in the class expansion population by first identifying their children. To that end, I have consulted with Barry Graubard, Ph.D., who is a senior biostatistician for the National Institutes of Health (NIH), National Cancer Institute, Division of Cancer Epi-

demiology and Genetics, Biostatistics Branch. NIH is an operating division of the U.S. Department of Health and Human Services (HHS).

8. Dr. Graubard has recommended pursuing a methodology that combines statistical analysis and manual review of ORR case management records. His 8 recommendation is set forth in his declaration, which is attached as Exhibit A to the Proposed Expanded *Ms. L.* Class Identification Plan. In my testimony below, I explain how Defendants, based on the information known to them today, would likely implement Dr. Graubard's recommendation. I would serve as the HHS Operational Lead for Reunification for the implementation.

Plan for Implementing Recommended Methodology

9. To implement Dr. Graubard's recommended methodology, Defendants would likely need to perform approximately 12 weeks of intensive data analysis before starting manual reviews. That is, Defendants would likely need 12 weeks to format the data, perform a regression analysis, and build a prediction model to segment and prioritize manual reviews of ORR case management records for the approximately 47,000 possible children of potential *Ms. L.* class members for the class expansion period. This approach would involve a series of steps, outlined below, that would be informed in real time by the data and would likely evolve as implementation progresses and the Defendants refine methods based on lessons learned.

Within Approximately 4 Weeks of Plan Activation

10. HHS would first prepare a data set encompassing all children referred to ORR starting July 1, 2017, and discharged from ORR care prior to June 26, 2018.[1] I understand that set to include approximately 47,000 children. *See* ECF No. 347–1.

11. Defendants would then convene a Data Analysis Team, reporting to the HHS, CBP, and ICE Operational Leads for Reunification, to conduct statistical analyses of the data set. A senior biostatistician (likely Dr. Graubard of the NIH) would serve as the Data Analysis Team lead, reporting directly to the Operational Leads for Reunification.

12. The Data Analysis Team would conduct a regression analysis of the possible children of potential class members reported in the most recent Joint Status Report, ECF No. 388, using the approximately 12,000 children who were in ORR care on June 26, 2018 9 as a "training set" to develop a prediction model. The Data Analysis Team would work to validate variables that may be predictive of a child having been separated from a parent (*e.g.,* the age of the child), and attempt to identify any additional demographic features of children separated from parents (as distinct from children who entered the United States without a parent). Through validation, the team would develop a prediction model correlating relevant variables with increased likelihood of parental separation.

13. We expect that the data will inform the development of the prediction model, which will evolve in an iterative, stepwise manner. During the process, the Data Analysis Team may request additional data from HHS, CBP, or ICE as appropriate.

Within Approximately 8 Weeks of Plan Activation

14. Once the Data Analysis Team lead determines that an initial version of the prediction model is sufficient for use, the Data Analysis Team will apply it to the approximately 47,000 children for the class expansion period, and rank order children according to their probability of being children of potential *Ms. L.* class members.

15. The Data Analysis Team would then stratify the approximately 47,000 children 24 for the class expansion period into "bands" or "segments" based on statistical probability of parental class membership. The Defendants would prioritize the highest-probability segments for manual review of ORR case management records and any other relevant information.

16. Defendants would build and launch a team of contracted administrative staff to conduct manual reviews of ORR case management records, which are maintained on the UAC Portal. This "Case File Review Team" would follow review protocols informed by the work conducted during the 2018 reunification. They would report to

[1] It is possible that some children referred to ORR care in early July 2017 would have entered the United States before July 1, 2017. Such children would not be potential children of possible *Ms. L.* class members.

the HHS Operational Lead (who would work with the ORR career staff to train them).

17. Once the manual review of the highest-probability segments begins, the Case File Review Team would begin preparing draft lists of possible children of potential *Ms. L.* class members and providing them to Defendants on a rolling, weekly basis. HHS, CBP, and ICE would review and validate these lists jointly.

18. While the Case File Review Team conducts manual review of the highest-probability segments of children, the Data Analysis Team would conduct statistical sampling of the lower-probability bands. The Case File Review Team would test the samples through blind, manual review to enable the Data Analysis Team to determine whether the sample contains any children of potential *Ms. L.* class members. The outcome of the sampling process may result in adjustments to the variables, prediction model, or segments. It may also inform the approach to manual case file review of the lower-probability bands. If, for example, the samples yield no children of potential *Ms. L.* class members, then it may become appropriate for the parties to meet and confer on further streamlining.

Within Approximately 12 Weeks of Plan Activation

19. HHS would review the discharge type and sponsor information in the UAC Portal to determine: (i) the type of discharge that resulted in the child exiting ORR care; (ii) whether a potential *Ms. L.* class member is the child' s sponsor of record; and (iii) the name, address, and relationship of the sponsor for each child of a potential *Ms. L.* class member who was discharged to an individual sponsor.

20. Defendants would consolidate the HHS and DHS information into final, rolling lists, which DOJ would provide to Class Counsel. Where available, the rolling lists would include the names and alien identification numbers for both children and their class member parents; their dates of apprehension; the dates children were referred to and discharged from ORR care, and the type of discharge; parent detention status; and last known parent contact information.

Total Time for Completion

21. Jallyn Sualog, the Deputy Director for Children's Programs for ORR, testified previously that it would likely take between 235 and 471 consecutive calendar days for 100 ORR analysts to manually review the ORR case management records for the approximately 47,000 children in ORR care during the class expansion period. If Defendants were able to hire qualified contractors, then I expect it would take at least the same number of consecutive calendar days to perform the same work on a date-ordered or randomized manual file review.

22. The goal of pursuing Dr. Graubard's recommended methodology is to identify children of potential *Ms. L.* class members in the class expansion population in a faster and more concentrated way than would occur through a date-ordered or randomized manual file review. The application of the methodology in this context is novel.

23. The time for completing the process using Dr. Graubard's recommended methodology—including manual review of ORR case management records prioritized through probabilistic segmentation—may vary for at least three reasons. First, the efficacy of the initial prediction model, and the outcomes of the sampling of the lower-probability segments, are not known at this juncture. They are likely to drive the time for completion. Second, the pace of the prioritized manual review will depend on the number of qualified contractors that Defendants are able to identify and retain for the Case File Review Team, as well as the speed with which Defendants are able to scale up the team, and the efficiencies that may or may not materialize from having a dedicated group of professionals manually reviewing case files over a period of months. Third, any meet-and-confer process that occurs after completion of the sampling phase could affect the time for completion. Many of these considerations are outside Defendants' control.

24. Given the complexity of the task and the variables and data known to Defendants at this time, a reasonable assumption is that it will take at least 12 months, and possibly up to 24 months, for Defendants to complete the process of identifying potential *Ms. L.* class members in the class expansion population through universal manual review. The primary benefit of pursuing Dr. Graubard's recommended methodology is that, if successful, it would front-load the identification of potential *Ms. L.* class members and possibly lead to a reduction in the overall time required for manual review.

Executed on April 5, 2019.

Jonathan White

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

MS. L., et al.,

Petitioners-Plaintiffs,

vs.

U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT, et al.,

Respondents-Defendants.

Case No. 18cv428 DMS MDD

Hon. Dana M. Sabraw

DECLARATION OF BARRY GRAUBARD

I, Barry I. Graubard, declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that my testimony below is true and correct:

1. I am a Senior Investigator in the Biostatistics Branch of the National Cancer Institute. *See https://dceg.cancer.gov/about/staff-directory/biographies/A-J/graubard-barry* (last visited April 5, 2019). A copy of my curriculum vitae is attached as Exhibit 1.

2. I have more than 40 years of experience conducting statistical methods research in biostatistics and survey sampling, and in collaborating with scientists on research in cancer epidemiology and other areas of epidemiology and public health. For example, I recently performed modeling to estimate the one-year probability that an individual would get oropharyngeal cancer based on various risk factors. The paper reporting this work has been submitted for publication to a peer-reviewed journal. The statistical techniques used in this study were regression modeling and cross validation.

3. I have also used other regression methods such as Cox proportional hazard regression to predict length of survival (*e.g.,* among liver transplant recipients based on patient characteristics and clinical risk factors).

4. The statements in this declaration are based on my personal knowledge, information acquired by me in the course of performing my official duties, information supplied to me by federal government employees, and government records.

5. I am making this declaration for use in *Ms. L. v. U.S. Immigration and Customs Enforcement,* No. 18cv428 (S.D. Cal.).

6. I understand that on March 8, 2019, the Court in *Ms. L.* modified the class definition. The class now includes: "All adult parents who entered the United States at or between designated ports of entry on or after July 1, 2017, who (1) have been, are, or will be detained in immigration custody by the DHS, and (2) have a minor child who has been, is or will be separated from them by DHS and has been, is or will be detained in ORR custody, ORR foster care, or DHS custody, absent a determination that the parent is unfit or presents a danger to the child." ECF No. 386. I further understand that the modified class is subject to the same qualifications as the original certified class, and that as a result, it is still the case that "the class does not include migrant parents with criminal history or communicable disease, or those who are in the interior of the United States or subject to the EO." ECF No. 82.

7. Commander Jonathan White of the United States Public Health Services has asked me to recommend a statistical methodology to try to streamline and accelerate the identification of the children of *Ms. L.* class members who were referred to and discharged by ORR during the class expansion period of July 1, 2017 through June 25, 2018, and to advise an inter-agency Data Analysis Team that would seek to implement the methodology. My understanding is that approximately 47,000 alien children were referred to and discharged by ORR during that period. An optimal statistical methodology would enable ORR to prioritize manual record reviews

for the approximately 47,000 children based on the probability that the child's parent is a *Ms. L.* class member.

8. I will refer to the approximately 47,000 children who were referred to and discharged by ORR during the class expansion period of July 1, 2017 and June 25, 2018 as the "test set."

9. I will apply two assumptions to promote an inclusive and through review. First, I will assume that any alien child who was apprehended by the U.S. Department of Homeland Security (DHS) at the southern border together with a parent, and who was referred to ORR care by DHS, was possibly separated from the parent by the federal government. Second, I will assume that any alien child who was referred to and discharged by ORR during the class expansion period is a child of a potential *Ms. L.* class member. These assumptions can be expected to include many children who were not separated from their parents, but will promote a thorough review.

10. Based on these assumptions, I recommend using an empirically-determined model to try to predict the probability for each child that a parent accompanied the child before he or she was referred to ORR care. These probabilities would be used to group children from the test set into strata based on the probability that a parent is a potential class member. A separate Case File Review Team would then review the ORR case management records for the children in the test set. The records of the children in the strata with the highest probabilities would be reviewed before strata with lower probabilities, thereby identifying more children of class members in the test set in a speedier fashion.

11. I recommend that the Data Analysis Team seek to develop a prediction model by analyzing data for the approximately 12,000 children in ORR care as of June 26, 2018 (the "training set"). I understand that at this point, the government knows which children in the training set were children of potential *Ms. L.* class members. *See* Joint Status Report, ECF No. 388. By analyzing the data associated with these children, the Data Analysis Team would seek to identify common independent variables that together would provide a framework for rank ordering other children by the likelihood that their parent is a *Ms. L.* class member. The list of potentially relevant independent variables would include:

- Child age, because tender-age and young children are more dependent on parents than older children, and may therefore be more likely to travel with parents than with other adults or children;
- The referring U.S. Customs and Border Protection ("CBP") Sector, because I understand that at least one CBP sector is alleged to have conducted a pilot program involving increased rates of referrals for prosecutions of immigration law violations;
- Sibling information, because younger children who are not in sibling groups may have a higher probability of having been separated than younger children accompanied by older siblings;
- ORR discharge type, because discharge to a family member other than a parent, or discharge type other than release to an individual sponsor, might correlate with a higher probability of a child having been separated from a parent;
- Appearance of the word "separated" or "separation" in text box data fields on the ORR Portal corresponding with either the initial assessment of the child or a Significant Incident Report; and
- Inclusion on any informal tracking list of separated children that ORR created during the class expansion period.

12. To develop a prediction model, the Data Analysis Team would analyze the training set data with statistical analysis software. If the software proposes multiple models, then the Data Analysis Team would apply a statistical method known as cross validation to identify the most appropriate model to predict parental class membership within a given subset of the training set.

13. Once the most appropriate model is identified, the Data Analysis Team would try to apply it to the available data for the test set of approximately 47,000 children referred to and discharged by ORR between July 1, 2017 and June 25, 2018. By applying the predictive model to the test set, the Data Analysis Team would identify the children in the test set who are more likely to have parents who are *Ms. L.* class members. As noted above, the use of the model in this way would enable the Data

Analysis Team to organize the test set into strata according to increasing probability of parental class membership, to prioritize manual case file review.

14. As the Data Analysis Team applies the prediction model to the test set, the process may result in refinements to the model and segments themselves. For example, if the Case File Review Team positively identifies children of potential *Ms. L.* class members within a lower-probability band of the test set, this may result in the Data Analysis Team updating the variables it considers as part of its model.

15. The feasibility of this statistical method may turn on the availability, format, and comprehensiveness of the data for the children. Assuming, however, that the data is sufficient, the statistical method that I have described is a more rational approach than a date-ordered or randomized manual record review of the test set. If successful, it would front-load the identification of potential *Ms. L* class members. It is possible that it could also reduce the overall time required for manual review.

Executed on April 5, 2019.

Barry I. Graubard

EXHIBIT 1

CURRICULUM VITAE

January 15, 2019

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Citizenship: United States

Education:

1968 High School Graduation, Groveton High School, Alexandria, VA

1968–1970 (68 Semester Hours, Major: Chemistry and Mathematics) Rensselaer Polytechnic Institute, Troy, New York

1972 B.S. (Major in Mathematics, Minor in Physics) University of Maryland, College Park, MD

1974 M.A. (Mathematics, Area: Statistics and Probability) Department of Mathematics University of Maryland, College Park, MD

1991 Ph.D. (Mathematical Statistics) Department of Mathematics, University of Maryland, College Park, MD

Other Training:

1977–1979 (12 Semester Hours) Survey Sampling and Biostatistics, George Washington University, Washington, DC

Employment:

1972–1976 Graduate teaching assistant in the Department of Mathematics, University of Maryland at College Park

1977–1980 Mathematical Statistician, National Center for Health Statistics

1980–1981 Mathematical Statistician, Alcohol Drug Abuse and Mental Health Administration

1981–1989 Mathematical Statistician, National Institute of Child Health and Human Development, Biometry Branch

1989–1996 Senior Researcher, National Cancer Institute, Biometry Branch, Clinical and Diagnostic Trials Section

1996–1997 Acting Chief Biostatistical Methodology and Cancer Control Section, National Cancer Institute, Biometry Branch

1997–1999 Senior Associate, Department of Biostatistics, Johns Hopkins University, taught a semester course "Analysis of Health Surveys"

2001–2002 Guest Lecturer, Department of Mathematics, University Maryland, taught a one semester workshop entitled "Analysis of Health Surveys"

1997–pres Senior Investigator, Title 42, National Cancer Institute, Biostatistics Branch.

Membership in Professional Societies:

1977–pres American Statistical Association

1977–pres Washington Statistical Society

1980–pres International Biometric Society Eastern North American Region (ENAR)

2010–pres American Association for the Advancement of Science

Selected Committee and Board Membership:

1988–1990 ENAR Biometrics Society Regional Advisory Board

1991–1994 Washington Statistical Society Public Health and Biostatistics Program Chair

1994–1995 American Statistical Association Biometrics Section Program Chair

1994–1997 American Statistical Association Continuing Education Advisory Committee

1994 American Statistical Association ad hoc committee to review candidates for travel awards to 50th Session of the International Statistical Institute, 1995

1997–2001 American Statistical Association, Survey Methods Research Section, Chair, Continuing Education Committee

1998–2001 ENAR Biometrics Society Regional Committee

1998–1999 NCI Surveillance Implementation Group

1999–2001 Ad hoc ENAR Biometrics Society Membership Committee

1999–pres Federal Committee on Statistical Methodology

2000 Chair of Search Committee for tenure track/tenure research mathematical statistician, Biometry and Mathematical Statistics Branch, National Institute of Child Health and Human Development, NIH

2000–pres Program Committee for Federal Committee on Statistical Methods Research Conference

2001–02 Program Committee for ENAR Biometrics Society 2002 Spring Meeting

2001 Chair of Search Committee for tenure track / tenure research mathematical statistician, Biometry and Mathematical Statistics Branch, National Institute of Child Health and Human Development, NIH

2001–04 United Nations Committee and contributor to UN Technical Report on the Analysis of Operating Characteristics of Surveys in Developing Countries.

2003–07 Editorial Board of the JNCI Cancer Spectrum

2004 Member of the National Children's Study Sampling Design Workshop, March 21–22.

2004 Institute of Medicine Workshop on Estimating the Contribution of Lifestyle-Related Factors to Preventable Death Dec. 13–14; presented "Calculating the number of deaths attributable to risk factor using national survey data."

2005–06 Co-Program Chair of Section on General Methodology, American Statistical Association, 2006 Joint Statistical Meetings

2005–10 Advisory Board for the University of Minnesota Integrated Health Interview Series Project

2005 Expert Advisory Group to advise Harvard U on statistical methods for combining data from multiple surveys for developing measures of the diffusion and use of health information technology

2006–08 ENAR Education Advisory Committee

2007–09 Chair of the American Statistical Association Committee on the Award of Outstanding Statistical Application

2007–08 Chair of the Division of Cancer Epidemiology and Genetics Committee on Scientists

2009 Chair Elect of the Biometric Section, American Statistical Association

2009 Member Expert Panel on the Redesign of the National Crime Victimization Survey

2009–10 DCEG Technical Evaluation of Protocols Committee

2009–10 Member of Selection Committee for Committee of Presidents Statistical Societies (COPSS) Snedecor Award

2010–11 Chair, Selection Committee for COPSS Snedecor Award

2009–10 Member of Selection Committee for Biometrics Section, American Statistical Association, David P Byar Award

2011 Chair Selection Committee for Biometrics Section, American Statistical Association, David P Byar Award

2009–10 DCEG Technical Evaluation of Protocols Committee

2011 Chair of Search Committee for tenure track/tenure research biostatistician/statistician, Radiation Epidemiology Branch, NCI

2011–2012 DCEG Technical Evaluation of Protocols Committee

2011–pres Member of DCEG Promotion and Tenure Review Panel

2013 Reviewer for the American Statistical Association, National Science Foundation and Bureau of Labor Statistics Fellowship Program *http://www.amstat.org/careers/pdfs/ASANSFBLSFellowshipProgram.pdf*

2013 Reviewer for proposal to the Luxembourg National Research Fund (FNR) INTER MOBILITY programme.

2014–17 Washington Statistical Society Morris Hansen Lecture Committee

2014–15 Member of the Committee of Presidents of Statistical Societies (COPSS) Elizabeth L. Scott Award Committee

2016–17 Chair, Committee of Presidents of Statistical Societies (COPSS) Elizabeth L. Scott Award Committee

2014–17 Committee of Representatives to American Association for the Advancement of Science (AAAS)

2015 Patient-Centered Outcomes Research Institute (PCORI) Obesity Observational Research Initiative Merit Review Panel

2017 Panel member of FDA Public Workshop on Abuse-Deterrent Opioids in Silver Spring, MD, July 10–11, 2017

2018–20 American Statistical Association Committee on Fellows

Editorial Boards:

1997–pres Statistical Editor, Journal of the National Cancer Institute

2008–14 Editorial Board ASA/SIAM Book Series

2008–pres Associate Editor, Annals of Applied Statistics

Selected Lectures and Presentations:

1993 Invited Presentation, The Biometric Society-ENAR Spring Meetings, Philadelphia, PA, "Statistical Validation of Intermediate Endpoints for Chronic Diseases."

1994 Invited Presentation, The Drug Information Association, Washington, DC, "Regression Analysis of Clustered Data."

1995 Invited Presentation, The Joint Statistical Meetings of the American Statistical Association, Orlando, FL, "Analysis of Population Based Case-Control Studies with Controls Selected from a Survey."

1996 Invited Presentation, Bureau of Medical Devices, Food and Drug Administration, "Analysis of Clustered Data."

1997 Invited Presentation, Department of Mathematics, University of Maryland, "Variance Estimation for Superpopulation Parameters."

1999 Invited Presentation, Department of Statistics, Texas A&M University, Variance Estimation for Superpopulation Parameters.

1994–2006 Invited Lecturer Cancer Prevention and Control Fellowship Course, NCI, "Analyzing Health Surveys: Accounting for the Sample Design."

2000 Keynote Speaker, The 2000 Statistical Science Awards Ceremony, Centers for Disease Control and Prevention, Atlanta, GA, "Statistical Issues in Analyzing Health Surveys: Applications to Cancer Studies."

2001 Invited lecturer at the University of Maryland, Department of Mathematics, College Park, to teach fall semester workshop "Analysis of Health Survey Data" (Course: STAT 798A section 0104); meets one day a week for 1.5 hours.

2002 Invited presentation Joint Statistical Meetings, "Issues in Design-based Weighted Analysis of Survey Data."

2002 Invited 1-day course "Analysis of Complex Survey Data with Applications to Health Surveys" for the Statistics Canada 2002 Methodology Symposium on Modeling Survey Data for Social and Economic Research.

2003 Invited tutorial at 2003 Spring ENAR Meeting: "Sample Survey Methods for Biostatisticians."

2003 Invited discussant at 2003 Spring ENAR Meeting "Sampling methods for selecting population controls."

2003 Invited speaker at Westat methodology seminar "Estimating of Variance Components using Survey Data."

2004 Invited Short Course at Eleventh Annual Spring Research Conference, "Analysis of Complex Surveys."

2004 Invited presentation Joint Statistical Meetings, "Development of statistical methods to analyze complex health surveys for epidemiologic studies: Some methods and applications."

2004 Invited presentation at Harvard University School of Public Health, "Analyzing Survey Data: Estimation of population attributable risk and population variance components."

2004 Invited Discussant for Distinguished Lecture by Chris Skinner for Joint Program in Survey Methodology, University of Maryland, "Other Issues in Modeling Survey Data."

2005 Invited presentation University of Maryland School of Medicine, Baltimore, "Statistical issues in analyzing health surveys: application to cancer and mortality studies."

2005 Invited Discussant for Distinguished Lecture by Alastair Scott for Joint Program in Survey Methodology, University of Maryland, "Discussion of population-based case-control studies."

2006 Invited presentation Spring ENAR Meeting, Tampa, FL. "Using national surveys to estimate the number of deaths attributable to a risk factor."

2006 Special Contributed Panel Session presentation Joint Statistical Meetings, Seattle, WA, "Finite population vs. superpopulation inference in sample surveys: How big is the difference?"

2006 Invited presentation Statistics Canada Symposium 2006, Ottawa, Canada, "Using national surveys to estimate the number of deaths attributable to a risk factor."

2006 Invited short course for the International Biometrics Conference, Montreal, Canada, "Analysis of Health Survey: Sample Survey Methods for Biostatisticians."

2007 Invited panel member of "Role of biostatisticians in policy issues" for the Spring ENAR Meeting, Atlanta, GA.

2007 Invited presentation at Mathematica, "To weight or not to weight."

2008 Invited presentation Joint Statistical Meetings, Denver, Colorado "Application of Peters-Belson to estimation of disparities."

2009 Invited presentation for Conference in Honor of Joseph Gastwirth, George Washington University, Washington, DC, "The use of the risk percentile curve in the analysis of epidemiologic data."

2009 Invited presentation for Joint Statistical Meetings, Washington, DC, "Use of Statistics at the Centers for Disease Control and Prevention and National Cancer Institute: Estimation of the numbers of all-cause and cause-specific deaths associated with body weight."

2011 Invited presentation Department of Statistics, George Washington University, "Conditional logistic regression with survey data."

2011 Invited presentation National Center for Health Statistics, "Conditional logistic regression with survey data."

2013 Invited presentation National Institute of Environmental Health Sciences, "Conditional logistic regression with survey data."

2013 Invited presentation, Scholars Summer at Census, U.S. Census Bureau, "Conditional logistic regression with survey data."

2013 Invited presentation for Fall Outreach Symposium for the International Year of Statistics at the Bureau of Labor Statistics, "Estimating sibling recurrence risk in population sample surveys."

2014 Invited presentation Statistical Society of Canada 2014 Annual Meeting, Toronto, "Estimating sibling recurrence risk in population sample surveys."

2018 Invited presentation at the 2018 Joint Statistical Meetings, "Population-Based Disease Risk Prediction Modeling Using National Survey, Clinical, and Registry Data: Application to Risk Prediction for Oropharyngeal Cancer in the U.S. Population," Vancouver, Canada.

2018 Invited Talk George Washington University, School of Public Health, "Statistical and Epidemiological Challenges in Utilizing the National Health and Nutrition Examination Survey (NHANES) Assessment of Oral Human Papillomavirus (HPV) Infection to Study Risk of HPV Infection and of Oropharyngeal Cancer in the U.S.," Washington, DC.

Recent Grants

Unpaid Collaborator
"Trends in Socioeconomic Position and Diet Relationship," CA108274 PI: Kant, Ashima, Queens College, NY July, 2004 to June, 2007.

Unpaid Collaborator
"SNP-based pseudo-semiparametric inference for the case-control studies," NIH–U01CA159424, National Institutes of Health PI: Li, Yan, University of Maryland, College Park, MD, September, 2011 to August, 2013.

Unpaid Collaborator
"Semiparametric inference for case-control studies with complex sampling," NIH–8513069, National Institutes of Health PI: Li, Yan University of Maryland, College Park, MD, September 24, 2013 to August 31, 2014.

Teaching Experience:

1972–76 Graduate Teaching Assistant—Conducted recitation classes for undergraduate courses in college algebra, calculus, linear algebra, and was a lecturer for introductory statistics course (STAT 100) for non-mathematics majors.

1980 Lecturer for a one semester undergraduate course in elementary probability and Stochastic processes for non-mathematics majors in Department of Mathematics, University of Maryland.

1997 Adjunct Professor at Johns Hopkins University Department of Biostatistics where I taught a one semester graduate course entitled "Analysis of Health Survey Data."

2001 Invited lecturer at the University of Maryland, Department of Mathematics, College Park, to teach fall semester workshop "Analysis of Health Survey Data" (Course: STAT 798A section 0104); met one day a week for about 1.5 hours.

2002 Invited 1-day course "Analysis of Complex Survey Data with Applications to Health Surveys" for the Statistics Canada 2002 Methodology Symposium on Modeling Survey Data for Social and Economic Research.

2003 Invited tutorial at 2003 Spring ENAR Meeting: "Sample Survey Methods for Biostatisticians."

2004 Invited Short Course at Eleventh Annual Spring Research Conference, "Analysis of Complex Surveys."

2006 Invited short course for the International Biometrics Conference, Montreal, Canada, "Analysis of Health Survey: Sample Survey Methods for Biostatisticians."

2015 Co-taught "Statistical Methods for Analysis of Complex Samples in Public Health" at University of Maryland, College Park, MD, course number SURV 699N for the Joint Program in Survey Methods.

Primary Mentor:

NCI Post-Doctoral Fellows:

Dr. Sowmya R Rao, 2002–2004, presently Associate Professor at the University of Massachusetts Medical School, Worchester, MA and Senior Statisticians in the Center for Health Quality, Outcomes and Economic Research (CHQOER) in the Veterans Administration Health Services Research and Development Service.

Dr. Yan Li, 2006–2008, presently Associate Professor at the Joint Program of Survey Methods, University of Maryland, College park, MD.

Dr. Sonya Heltshe 2008–2009, presently Assistant Professor and Senior Statistician at Seattle Children's Hospital, Seattle WA Center for Clinical and Translational Research.

Dr. Victoria Landsman 2009–2011, presently Scientist and Biostatistician at Institute for Work and Health and Adjunct Professor at University of Toronto, Assistant Professor.

Dr. Orestis Panagiotou 2015–2016, presently Assistant Professor of Health Services, Policy and Practice (Research) at Brown University.

Dr. Noorie Hyun 2016–2017, presently Assistant Professor, Medical College of Wisconsin, Institute for Health and Equity, Division: Biostatistics Program

Dr. Marlena Maziarz 2017–2018, presently Assistant Professor, Lund University, Sweden.

Dr. Gregory Haber 2018–present.

Co-Advisor for Ph.D. Candidates:

Blossom H Patterson, Doctoral Dissertation (1998): "Latent Class Analysis of Sample Surveys," College of Education, Department of Measurement and Statistics, University of Maryland.

Dewei She, Doctoral Dissertation (2010): "Genetic Association Studies Using Complex Survey Data," Department of Statistics, George Washington University.

Wenliang Yao, Doctoral Dissertation (2012): "Estimation of ROC Curve With Complex Survey Data," Department of Biostatistics, George Washington University.

Cong Wang, Doctoral Dissertation (2017): "Analysis of Familial Aggregation Using Recurrence Risk for Complex Survey Data," Department of Statistics, George Washington University.

April D. Kidd, Doctoral Dissertation (2017): "Mammography Utilization in African American Women," School of Nursing, Duquesne University.

Lingxiao Wang, Doctoral Dissertation (currently), Topic: Making cohort studies representative of the U.S. population using weighting methods, Dept. of Joint Program of Survey Methodology, University of Maryland.

Yan Liu, Doctoral Dissertation (currently), Topic: Generalized Score Test for Complex Sample Data, Dept. of Statistics, George Washington University.

Ph.D. Dissertation Committees:

Dr. Blossom H Patterson, Dept. of Measurement, Statistics and Evaluation, University of Maryland, College Park

Dr. Tara Vogt, Dept Epidemiology, Yale University

Dr. Steven Moore, Dept Epidemiology, Yale University

Dr. Leah M Ferrucci, Dept Epidemiology, Yale University

Dr. Jianzhu Li, Dept. JPSM, University of Maryland, College Park

Dr. Santanu Pramanik, JPSM, University of Maryland, College Park

Dr. Hiroyuki Hikawa, Dept. of Statistics, George Washington University

Dr. Wenliang Yao, Dept. of Biostatistics, George Washington University

Dr. Cong Wang, Dept. of Statistics, George Washington University. Title: Analysis of Familial Aggregation Using Recurrence Risk for Complex Survey Data, October 2017

Dr. April D. Kidd, School of Nursing, Duquesne University. Title: Mammography Utilization in African American Women, November 2017

Dr. Xia Li, Dept. Mathematics, University of Maryland, College Park. Title: Misspecified Weights in Weight-Smoothing Methods, January 2018

Research Interests:

Design and Analysis of Complex Surveys and Epidemiologic Studies

Statistical Methods for Design and Analysis of Epidemiological Studies

Analysis and Design of Cluster Randomized/Community Studies and Nonrandomized

Evaluation Studies

Classification and Discriminant Analysis

Population Genetics and Genetic Epidemiology

Reviewer for Selected Journals:

American Journal of Clinical Nutrition

American Journal of Epidemiology

American Journal of Public Health

Annals of Applied Statistics

Biometrics

Biometrika

Controlled Clinical Trials

Epidemiology

Journal of the American Statistical Association

Journal of the American Medical Association

Journal of Clinical Epidemiology

Journal of the National Cancer Institute

Statistics in Medicine

Survey Methodology

Journal of Official Statistics

Journal of the National Cancer Institute

Journal of the American Medical Association

New England Journal of Medicine

Honors and Awards:

1987 Quality Step Award, NICHD.

1990 Snedecor Award—Presented by the American Statistical Association and the Biometric Society.

1999 NCI Special Service Award of $5,000 for statistical leadership on the ASSIST Evaluation.

1999 NIH Merit Award for fundamental contributions to statistical methods for survey studies, and exemplary collaborations in the analysis and interpretation of survey data.

2000 NIH Merit Award for extraordinary efforts in developing a conceptual framework and evaluation design for the American Stop Smoking Intervention Study (ASSIST).

2000 Elected Fellow of the American Statistical Association.

2001 Division of Cancer Epidemiology and Genetics, NCI Mentor of the Year Award.

2004 NIH Merit Award for consistent and high-quality effort work on the National Health Interview Survey and the California Health Interview Survey.

2006 Charles C Shepard Science Award for Assessment and Epidemiology presented for scientific excellence by the publication of Excess deaths associated with underweight, overweight, and obesity, JAMA 2005; 293:1861–1867.

2009 NIH Merit Award for excellence in the measurement, analysis, and release of nationally representative data concerning serum biomarkers from the insulin-like growth factor axis.

2010 NCI Mentor of Merit Award for excellence in mentoring post and pre-doctoral fellows.

2013 AAAS Fellow of Statistics Section.

2015 NCI Group Merit Award: NCI Select Agents and Hazardous Biological Materials Search.

2018 NCI Mentor Award.

BIBLIOGRAPHY

Barry Ira Graubard

1. Eckardt MJ, Ryback RS, Rawlings RR, Graubard BI. Biochemical diagnosis of alcoholism: a test of the discriminating capabilities of gamma-glutamyl transpeptidase and mean corpuscular volume. *JAMA.* 1981;246:2707–10.

2. Rawlings RR, Rae DS, Graubard BI, Eckardt MJ, Ryback RS. A methodology for the construction of a multivariate diagnostic instrument: an application to alcohol abuse screening. *Comput Biomed Res.* 1982;15:228–39.

3. Eckardt MJ, Graubard BI, Ryback RS, Gottschalk LA. Pretreatment consumption as a predictor of post treatment consumption in male alcoholics. *Psychiatry Res.* 1982;982;7:337–44.

4. Rawlings RR, Graubard BI, Teper S, Eckardt MJ, Ryback RS. Two-group classification when both groups are mixtures of normals. *Biometrical J.* 1984;26:923–30.

5. Forman MR, Graubard BI, Hoffman HJ, Beren R, Harley EE, Bennett P. The Pima infant feeding study: infant feeding and gastroenteritis in the first year. *Am J Epidemiol.* 1984; 119:335–349.

6. Forman MR, Graubard BI, Hoffman HJ, Beren R, Harley EE, Bennett P. The Pima infant feeding study: breast feeding and respiratory infections during the first year of life. *Int J Epidemiol.* 1984;13:447–53.

7. Klebanoff MA, Graubard BI, Kessel SS, Berendes HW. Low birth weight across generations. *JAMA.* 1984;252:2423–27.

8. Mills JL, Graubard BI, Harley EE, Rhoads GG, Berendes HW. Maternal alcohol consumption and low birth weight: how much drinking during pregnancy is safe? *JAMA.* 1984;252:1875–79.

9. Neale EA, Sher PK, Graubard BI, Habig WH, Fitzgerald SC, Nelson PG. Differential toxicity of chronic exposure to phenytoin, phenobarbital, or carbamazepine in cerebral cortical cell cultures. *Pediatr Neurol.* 1985;1:143–50.

10. Sher PK, Neale EA, Graubard BI, Habig WH, Fitzgerald SC, Nelson PG. Differential neurochemical effects of chronic exposure of cerebral cortical cell culture to valporic acid, diazepam, or ethosuximide. *Pediatr Neurol.* 1985;1:232–37.

11. Forman MR, Fetterly K, Graubard BI, Gaines K. Socio-demographic factors associated with breast feeding in the United States: 1969 and 1980. *Am J Clin Nutr.* 1985;42:864–69.

12. Hemminki E, Graubard BI, Hoffman HJ, Mosher WD, Fetterly K. Cesarean section and subsequent fertility: Results from the 1982 National Survey of Family Growth. *Fertil Steril.* 1985;43:520–28.

13. Shiono PH, Klebanoff M A, Graubard BI, Berendes HW, Rhoads GG. Birth weight among women of different ethnic groups. *JAMA.* 1985;255:48–52.

14. Rawlings RR, Graubard BI, Teper S, Eckardt MJ, Ryback RS. Conditional quadratic discrimination in the identification of biological markers for disease screening. *Biometrical J.* 1986;28:957–64.

15. Rawlings RR, Graubard BI, Faden VB, Eckardt MJ. A study on discriminant analysis techniques applied to multivariate lognormal data. *Journal of Statistical Computation and Simulation.* 1986;26:79–100.

16. Kurinij N, Klebanoff MA, Graubard BI. Dietary supplement and food intake in women of childbearing age. *J Am Diet Assoc.* 1986;86:1536–40.

17. Hemminki E, Myrianthopoulos NC, Pomeroy J, Graubard BI. Cesarean section as a risk factor for malformations—a negative finding. *Int J Epidemiol.* 1986;15:360–3.

18. Mills JL, Graubard BI. La controversia sugli effetti del bere moderatemente durante la gravidanza. *La Tutela della Salute della Gestantee del Concepito* ACTA MEDICA. 1986:123–9.

19. Graubard BI, Korn EL. Choice of column scores for testing independence in ordered 2xK contingency tables. *Biometrics.* 1987;43:471–6.

20. Willoughby A, Moss HA, Hubbard VS, Bercus BB, Graubard BI, Vietze PM, Berendes HW. Developmental outcome in children exposed to chloride-deficient formula. *Pediatrics.* 1987;79:851–57.

21. Mills JL, Graubard BI. Is moderate drinking during pregnancy associated with increased risk of malformations? *Pediatrics.* 1987;80:309–14.

22. Mills JL, Graubard BI, Klebanoff MA. Placenta previa is not associated with an altered sex ratio at birth. *Br Med J.* 1987;294:544.

23. Korn EL, Graubard BI. Examining neighborhood confounding in a survey: an example using the National Health and Nutrition Examination Survey II. *Stat Med.* 1988;7:1087–98.

24. Eckardt MJ, Rawlings RR, Graubard BI, Faden VB, Martin PR, Gottschalk LA. Neurophychological performances and treatment outcome in male alcoholics. *Alcoholism: Clinical and Experimental Research.* 1988;12:88–93.

25. Davis M K, Savitz DA, Graubard BI. Infant feeding and childhood cancer. *Lancet.* 1988;ii: 365–8.

26. Graubard BI, Fears TR, Gail MH. Effects of cluster sampling on epidemiologic analysis in population based case-control studies. *Biometrics.* 1989;45:1053–71.

27. Forman MR, Hundt GL, Towne D, Graubard B, Sullivan B, Berendes HW, Sarov B, Naggan L. The forty-day rest period and infant feeding practices among Negev Bedouin Arab women in Israel. *Medicl Anthropology.* 1990;12:207–16.

28. Willoughby A, Graubard BI, Hocker A, Storr C, Vietze P, Thackaberry JM, Gerry MA, McCarthy M, Gist NF, Magenheim M, Berendes H, Rhoads GG. Population-based study of the developmental outcome of children exposed to chloride-deficient infant formula. *Pediatrics.* 1990;85:485–90.

29. Mills JL, Simpson JL, Rhoads GG, Graubard BI, Hoffman H, Conley MR, Lasserman M, Cunningham G. Risk of neural tube defects in relation to maternal fertility and fertility drug use. *Lancet.* 1990;336:103–4.

30. Malloy MH, Willoughby A, Graubard BI, Lynch J, McCarthy M, Mass H, Vietze P, Rhoads G, Berendes H. Exposure to a chloride-deficient formula during infancy: effect on outcome at age 9 and 10 years. *Pediatrics.* 1990;86:601–10.

31. Klebanoff MA, Shiono PH, Selby JV, Trachtenberg AI, Graubard BI. Anemia and spontaneous preterm birth. *Am J of Obst and Gyn.* 1990;164:59–63.

32. Mills JL, Klebanoff MA, Graubard BI, Carey JC, Berendes HW. Barrier contraceptive methods and preeclampsia. *JAMA.* 1991;265:70–3.

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35. Malloy MH, Graubard B, Moss H, McCarthy M, Gwyn S, Vietze P, Willoughby A, Rhoads GG, Berendes H. Hyperchloremic metabolic alkalosis after ingesting a chloride-deficient formula: outcome 9 and 10 years later. *Pediatrics.* 1991;87:811–22.

36. Korn EL, Graubard BI. Epidemiologic studies utilizing surveys: accounting for the sampling design. *Am J Public Health.* 1991;81:1166–73.

37. Korn EL, Graubard BI. A note on the large sample properties of linearization, jackknife and balanced repeated replication methods for stratified samples. *Annals of Statistics.* 1991;19:2275–79.

38. Freedman LS, Graubard BI, Schatzkin A. Statistical validation of intermediate endpoints for chronic diseases. *Stat Med.* 1992;11:167–78.

39. Forman MR, Lewando-Hundt G, Graubard BI, Chang D, Sarov B, Naggan L, Berendes HW. Factors influencing milk insufficiency and its long-term health effects: The Bedouin infant feeding study. *International Journal of Epidemiology.* 1992;21:53–8.

40. Forman MR, Yao S Graubard BI, Qiao Y, McAdams M, Mao BL, Taylor PR. The effect of dietary intake of fruits and vegetables on the odd ratio of lung cancer among Yunnan Tin miners. *International Journal of Epidemiology.* 1992;21:437–41.

41. Ziegler RG, Subar AF, Craft NE, Ursin G, Patterson BH, Graubard BI. Does beta-carotene explain why reduced cancer risk is associated with vegetable and fruit intake? *Cancer Res* (suppl). 1992;52:2060s–6s.

42. Graubard BI, Korn EL. Hypothesis testing with complex survey data: the use of classical quadratic test statistics with particular reference to regression problems. *J Am Stat Assoc.* 1993;88:629–41.

43. Mills JL, Holmes LB, Aarons JH, Simpson JL, Brown ZA, Jovanovic-Peterson LG, Conley MR, Graubard BI, Knopp RH, Metzger BE. Moderate caffeine use and the risk of spontaneous abortion and intrauterine growth retardation. *JAMA.* 1993;269:593–7.

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54. Ballard-Barbash R, Thompson FE, Graubard BI, Krebs-Smith SM. Variability in percent energy from fat throughout the day: Implications for application of total diet goals. *J Nutr Educ.* 1994;26:278–83.

55. Kant AK, Graubard BI, Schatzkin A, Ballard-Barbash R. Proportion of energy intake from fat and subsequent weight change in the NHANES I epidemiologic follow-up study. *Am J Clin Nutr.* 1995;61:11–17.

56. Korn EL, Graubard BI. Analysis of large health surveys: Accounting for the sampling design. *J R Stat Soc, Ser A.* 1995;158:263–95.

57. Kant AK, Schatzkin A, Graubard BI, Ballard-Barbash R. Frequency of eating occasions and weight change in the NHANES I Epidemiologic Follow-up Study. *Int J Cancer.* 1995;19:468–74.

58. Malloy MH, Graubard BI. Access to home apnea monitoring and its impact on rehospitalization among very-low-birth-weight infants. *Ach of Pediatr and Adolesc Med.* 1995;149(3): 326–332.

59. Forman MR, Hundt GL, Berendes, HW, Abu-Saad K, Zangwill L, Chang D, Bellmaker I, Graubard BI. Undernutrition among Bedouin Arab children: A followup of the Bedouin Infant Feeding Study. *Am J Clin Nutr.* 1995;61:495–500.

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62. Forman MR, Beecher GR, Lanza E, Reichman ME, Graubard BI, Campbell WS, Marr T, Yong LC, Judd JT, Taylor PR. Effect of alcohol consumption on plasma carotenoid concentrations in premenopausal women: a controlled diet study. *Am J Clin Nutr.* 1995;62(1): 131–135.

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68. Nebeling LC, Forman MR, Graubard BI, Snyder RA. Specific and total carotenoid intake among oral contrceptive and estrogen hormone users in the United States. *J Am Coll Nutri.* 1996;15(6):608–13.

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Attachment No. 2

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

MS. L, et al.,

Petitioners-Plaintiffs,

vs.

U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT, et al,

Respondents-Defendants.

Case No. 3:18–cv–0428 DMS MDD

DEFENDANTS' STATUS REPORT RE: EXPANDED *MS. L* CLASS IDENTIFICATION PLAN

Defendants submit this status report on their Expanded *Ms. L.* Class Identification Plan. Defendants appreciate the Court's observations about the Plan and the opportunity to respond to those observations. To that end, Defendants have attached two declarations to aid the Court by addressing: (1) Plaintiffs' April 15 filing about the Plan, ECF No. 397; (2) the Court's observations and questions about the Plan, made at the April 16 status conference; and (3) a meeting about the Plan held between the parties on April 22, which included (among other agency representatives) Commander Jonathan White (HHS's operational lead for the Plan) and Jay Visconti (CBP's operational lead for the Plan). Among other things, the attached declarations serve to highlight the following points:

- **Timeline for Completion:** Commander White believes that the Plan proposed by the government will identify the vast majority of the expanded *Ms. L* class members **within 6 months.** Commander White cannot be certain of this, however, because the Plan rests on a new process that he has not previously conducted or tested and because unknown variables could cause the process to take longer if certain variables do not proceed as Commander White anticipates. Thus, the 1–2 year timeframe noted in the government's plan serves as a cautious outside estimate that applies only if the variables developed by Commander White to speed up the process do not proceed as he expects that they should. A hard deadline is accordingly inapt in this circumstance, particularly because the Plan relies on the assessment and expertise of an operational lead—Commander White—who has been unable to pin down a deadline with certainty but who has repeatedly demonstrated to this Court strong results, good faith, and great dispatch. Defendants thus propose that, rather than setting a hard deadline, Defendants would submit a status report every 30 days informing the Court about the status of the Plan and its execution, based on

the reports of Commander White. If, upon reviewing these reports, the Court believes that a deadline or different approach is warranted, the Court can make that judgment based on the information before it at that time.

- **Review of Portal vs. Paper Files:** Review of the UAC Portal, as opposed to paper files, is the fastest and most efficient way to proceed with this review. The UAC Portal contains information that is electronically input from a variety of sources, including from DHS, as well as pdf documents from the case manager's paper files that are uploaded into the portal. The data and documents in the UAC Portal include all sources of information held by HHS that are most likely to answer the question of whether any minor was separated from a parent. Moreover, the UAC Portal is a database that can immediately be reviewed by contract reviewers working together in a centralized location under the oversight of Commander White as soon as the contract for hiring those reviewers is finalized and Commander White can train them regarding the review process. Conversely, case manager paper files are scattered among more than 100 locations and would need to be located and shipped to a centralized location, and they also are not likely to contain all of the information that would inform a reviewer about whether a child was separated from a parent.
- **April–June 2018 List:** Plaintiffs have stated that they believe that a list exists of children separated between April and June 2018 that has already been reconciled between DHS and HHS. Defendants have inquired extensively about such a list, but have not located any list that meets the description of the list provided by Plaintiffs at the parties' meeting. Moreover, if any such list existed that had been reconciled between CBP and HHS, then Jay Visconti and Commander White likely would be aware of that list. In any event, the government's Plan includes the use of separation data kept by CBP for the time period from April through June 2018. Initial lists reflecting that data have already been sent from CBP to HHS. As discussed below, HHS intends to use this information as part of its first wave of file review in the UAC Portal. Defendants hope that this information and these efforts put to rest any concern about an April–June 2018 list.
- **Defendants Will Review Files During the Initial 12-Week Plan Period:** As the Court is aware, Commander White estimates that it will take approximately 12 weeks to develop its statistical prediction model and apply it to the approximately 47,000 relevant records. Defendants assure the Court that they will review files in the UAC Portal during that 12-week period—that review will not be delayed by any "ramp up" period. In particular, during that 12-week period, Defendants will undertake UAC portal case-file review with prioritized groups of files—such as those identified by the CBP data from the April to June 2018 time period and unofficial ORR lists that were kept during the relevant time period. The government anticipates that this initial case file review effort will be underway within 10 days.
- **Defendants Will Review DHS Files, Not Just HHS Files:** Plaintiffs have said that the Plan should include review of DHS files. Defendants agree—and indeed, review of DHS files has always been part of the government's Plan. On a regular basis, CBP will receive information from HHS about children whose file revealed some indicia of separation. CBP will then search its electronic systems of record to determine whether there is a record of the child being encountered with a parent, whether there is a record of the child being separated from that parent, and the reason for such a separation. CBP will send relevant information about the parent and the reason for the separation to both HHS and ICE for further review and an ultimate determination of class membership. Once this coordinated review has been completed and a determination of class membership has been made, the government intends to provide the lists of potential expanded class members to Plaintiffs on a rolling basis.

Commander White and Jay Visconti will both be present at today's hearing. Defendants intend to provide information about the government's Plan, expand on the matters described above, and respond to any questions the Court may have.

DATED: April 25, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

IT IS HEREBY CERTIFIED THAT:

I, the undersigned, am a citizen of the United States and am at least eighteen years of age. My business address is Box 868, Ben Franklin Station, Washington DC 20044. I am not a party to the above-entitled action. I have caused service of the accompanying brief on all counsel of record, by electronically filing the foregoing with the Clerk of the District Court using its ECF System, which electronically provides notice.

I declare under penalty of perjury that the foregoing is true and correct.

DATED: April 25, 2019

Sarah B. Fabian

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

MS. L., et al.,

Petitioners-Plaintiffs,

vs.

U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT, et al.,

Respondents-Defendants

Case No. 18cv428 DMS MDD

Hon. Dana M. Sabraw

SUPPLEMENTAL DECLARATION OF JONATHAN WHITE

I, Jonathan White, declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, 13 that my testimony below is true and correct:

1. The statements in this declaration are based on my personal knowledge, information acquired by me in the course of performing my official duties, information supplied to me by federal government employees, and government records.

2. This declaration supplements the declaration that I executed on April 5, 2019, which is attached here as Exhibit 1. The purposes of this declaration are to summarize the case management information that ORR keeps on the UAC Portal, provide additional details about the Government's Proposed Plan to identify members of the

expanded class (which would rely on the UAC Portal), and share my concerns about Plaintiffs' proposed plan.

Individualized Case Management and the UAC Portal

3. ORR administers the Unaccompanied Alien Children (UAC) program through a network of approximately 115 care providers located in 17 states. The care providers are ORR grantees. They help ORR conduct individualized case management of UAC.

4. ORR uses an information system called "the UAC Portal" to administer the 27 UAC program across the ORR care provider network. The main purpose of the UAC Portal 28 is to enable individualized case management of UACs, not population-level analysis of all the most relevant information that HHS possesses for each child.

5. The case management process begins when ORR receives a referral of the 4 unaccompanied child from DHS through the UAC Portal. Upon receiving the referral, the ORR Intakes Team uses the UAC Portal to designate a bed for the child at a facility in the ORR care provider network. Once the child arrives at the facility, the care provider staff documents in the UAC Portal all aspects of the UAC's care while in ORR custody. This includes comprehensive assessments of the child's history and family systems, as well as any child needs assessments, youth care services, health care and behavioral health care, significant incident reporting, child protection, and discharge planning for the UAC.

6. The information about the UAC that DHS provides to ORR at the time of 12 referral is captured in the Portal. This would include any information derived from the I–213 or other law enforcement apprehension records which DHS shares with ORR. Any 14 such information conveyed by DHS is included in the Referral section of the Portal and, in 15 that way, becomes part of the child's case management record.

7. The case management record for an individual child on the UAC Portal also includes information entered directly by care provider staff-including case managers (professionals who coordinate discharge planning and family connection services for children), youth care workers (state-certified individuals who provide individual line-of-sight supervision and care to children), clinicians (licensed behavioral health professionals who provide mental health care to children), health care personnel such as doctors and nurses who conduct children's initial medical evaluation and subsequent medical care, teachers who provide classroom educational services to the child, and any other professionals who interact with the child.

8. Additionally, the case management record for an individual child on the UAC. Portal includes uploaded documents in portable document format (PDF) for relevant information which was originally on paper (and was not entered directly into the UAC 28 Portal). This includes paper records of health care services delivered, legal documents related to the child, as well as documents provided by the family relevant for sponsor vetting and discharge, such as birth certificates, printouts related to background checks, employment verification. Significant paper documents related to the child are uploaded into the UAC Portal so as to be available to ORR Federal staff as well as care provider staff.

9. Separate from the case management record for the child, which is entirely contained in the UAC Portal, individual care providers may maintain paper files on each child. In my experience, the paper files kept by care providers are usually duplicative of the uploaded PDFs and other contents of the UAC Portal. In those instances where the paper files contain information beyond what appears on the UAC Portal, such additional information is typically immaterial to the case management process. That is, the additional information is not material to the child's welfare while in ORR care, or the process of identifying and vetting family members to serve as sponsors for the child.

10. In addition, the paper files do not contain critical information that is maintained on the UAC Portal, such as the referral information from DHS.

The Government's Proposal to Identify Potential Expanded Class Members

11. On April 5, 2019, the Government submitted a Proposed Expanded *Ms. L.* Class Identification Plan that is designed to identify substantially all class members **within 6 months.** The Government recognized that the identification process might take longer to complete, possibly up to 1 to 2 years, if the Government were to instead conduct a randomized or date-ordered manual review of all HHS and DHS

records for all of the approximately 47,000 children from the class expansion period. *See* ECF No. 394.

12. The Government seeks to streamline and accelerate the record review—and condense the time period for identifying substantially all class members from 1 to 2 years down to 6 months—by applying a statistical prediction model to the records in the UAC Portal, as developed from an analysis of variables associated with the children of original class members. *See* ECF No. 394. The purpose of the model would be to prioritize the record review based on the likelihood of parental class membership, and front-load the identification of potential class members.

13. To accomplish the Plan, the Government would hire and train a team of data scientists and scalable teams of record reviewers on a contract basis. Ordinarily, Federal procurements for services of this type would require approximately three to four months for the Federal acquisition process and an additional thirty days for recruitment of staff. Here, the Government seeks to complete the procurement within six weeks. The contract personnel for record review would arrive with cleared background checks, and would work full-time reviewing and reconciling case management records and other information for the population of children discharged from ORR care during the expansion period.

14. The Government estimates it would take approximately 12 weeks to develop its statistical prediction model and apply it to the approximately 47,000 relevant records. During that time, the Government would conduct concurrent record review for prioritized populations such as the list produced by Customs and Border Protection (CBP) of children separated after April 19, 2018, as well as the informal tracking list of children identified as separated by ORR beginning in 2017. My preliminary assessment is that those two lists combined are likely to yield between 500 and 1,000 children for record review, after the lists are compared against the children who were in ORR care as of June 26, 2018.

15. My professional opinion is that the statistical analysis is essential to the rapid and accurate identification of possible children of potential class members for the expanded class period. Nevertheless, the process of record review can be initiated with prioritized populations prior to the completion of the statistical analysis process.

16. I anticipate that record review of the two prioritized populations would begin on a limited basis within 10 days. While finalizing the procurement of contract personnel, the Government would deploy specialized Federal personnel from the U.S. Public Health Service Commissioned Corps to conduct record review. The Federal personnel would be trained by ORR subject matter experts and overseen directly by me.

17. The initial focus of the record review would be on factual indicia of separation. If the record review team were to find an indicator of separation, then it would reconcile 28 that indicator with the other information in the child's case management record. If the record review team were to conclude that the child was likely separated, it would obtain any additional, available information about the child's parent from DHS. Such information would be used to determine potential class membership. The Government would provide lists of potential class members to Plaintiffs on a rolling basis.

18. The Government used a similar process to identify possible children of potential class members in 2018. The key difference is that the Government does not have custody of the children for the expansion class period and cannot speak with them directly. The information that the Government obtained from children in ORR care in 2018 was critical to identifying separations on an expedited basis. Without that information, the reconciliation of indicia of separation becomes all the more critical.

Concerns With Plaintiffs' Proposal

19. On April 15, 2019, Plaintiffs objected to the Government's proposal, and claimed that U.S. Immigration and Customs Enforcement ("ICE") already had a list of children separated from their parents and released from ORR custody between April and June 2018. (ECF No. 397). I have no knowledge of such a list. Since April 15, CBP has produced to me a list of children who were potentially separated between April and June 2018. We are in the process of comparing that list against the children who were in ORR care as of June 26, 2018, to determine which children should undergo record review.

20. Plaintiffs also made recommendations on how to identify class members for the expansion period. Some of those recommendations—such as reviewing records during the first 90 days of the work—are part of the Government's plan. Other recommendations would decrease the accuracy or speed of the process, or possibly harm ORR's current operations and ability to care for the UACs presently in custody.

21. For example, Plaintiffs recommended that case managers review ORR care providers' paper files to identify class members during the expansion period. This would require a redeployment of case managers from 115 facilities to search for, retrieve, and review the paper files at a time when ORR is operating at approximately 97% of its bed capacity, and facing an influx of UACs across the Southern Border. ORR needs all case managers fully engaged in day-to-day case management to achieve a discharge rate that keeps pace with the rate of UAC referrals. If discharges were to fall below referrals due to a redeployment of case managers to paper file reviews, ORR might exhaust its bed capacity. The result would be backups of UACs at CBP border stations, which are short-term holding facilities not suitable for children for stays of longer than 72 hours.

22. My professional opinion is that pulling even a few case managers away from their normal duties to conduct or support a paper file review would slow the discharge rate for all UACs, and create a risk of a backup at CBP Border Stations. As the person who led the UAC Program's emergency operations in past influx events in 2012, 2014, 2016, and 2017, I am deeply opposed to any proposal to take case managers away from their urgent mission of safe and timely discharge of children currently in care.

23. Plaintiffs' approach is also problematic because the UAC Portal is a better tool for quickly identifying possible children of potential class members.The UAC Portal contains the information from the paper files that the case managers themselves deemed material to the case management process. Plus, it contains highly relevant information that does not appear in the paper files, such as the referral information from DHS. The UAC Portal is the natural starting point for any review because it already aggregates the most relevant information available to the Government. Plaintiffs' proposal to review all paper records at all care providers' facilities across the country would result in a duplicative, wasteful, and slower process than review of the UAC Portal online. The far better approach is to review the UAC Portal, and expand the analysis to paper records on a case-by-case basis when there is a specific, identified reason to do so.

24. Plaintiffs request that the Government review DHS I–213s and Event ID numbers. As indicated in my previous declaration, *see* ECF No. 394–2, at ¶ 20, the Government plans to review available DHS records that bear on class membership. I envision that the record review team will identify children who were likely separated. The names and Alien Numbers of the children will be conveyed on a rolling basis to CBP and ICE, which will conduct reviews within their own information systems on those Alien Numbers, including the DHS I–213s and information corresponding to the Event ID. This DHS analytic process would inform the development of the lists of potential class members which will be provided to the Plaintiffs on a rolling basis.

25. Plaintiff's proposed three-month timeframe for the Government to complete the identification of potential class members is unrealistic. Plaintiff's proposal assumes the Government could simply replicate its extraordinary mobilization of resources from last summer. But, at that time, the children were in ORR custody, and the Government was able to reconcile its records quickly by asking the children whether they were separated from their parents. Plus, a similar mobilization would jeopardize current ORR operations given the influx of UACs across the Southern Border.

Conclusion

26. It is my belief based upon my experience that it is possible to accelerate the accurate identification of potential class members. The timeframe of 1 to 2 years is accurate as an outer bound, and the plan proposed by the Government is intended to compress that timeframe to 6 months. Because this effort would be unprecedented, I cannot guarantee a specific timeframe, but it is my firm belief that the Government's plan is the fastest means available to identify potential class members for the expansion period. I am fully committed to working in good faith with the Court and Plaintiffs to implement the plan.

Executed on April 24, 2019.

Jonathan White

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

Ms. L., et al.,
Plaintiffs,

v. No. 3:18–cv–00428–DMS–MDD

U.S. Immigration and Customs Enforcement, et al.,
Defendants.

DECLARATION OF JAY VISCONTI

I, Jay Visconti, pursuant to 28 U.S.C. § 1746, and based upon my personal knowledge and information made known to me from official records and reasonably relied upon in the course of my employment, hereby declare as follows, relating to the above-captioned matter:

1. I am an Assistant Chief with the United States Border Patrol (USBP) currently serving in the capacity as a Senior Advisor to the Chief Operating Officer and Senior Official Performing the Functions and Duties of the Commissioner, U.S. Customs and Border Protection (CBP), Department of Homeland Security. I have been in this role since July 2016. In this role, I am responsible for directly supporting and advising the Chief Operating Officer and Senior Official Performing the Functions and Duties of the Commissioner, as well as the Deputy Commissioner, on issues such as USBP's strategic, operational and tactical plans, and policies and procedures governing threats, such as: terrorist organizations, criminal organizations, illegal immigration/human smuggling, narcotics and contraband smuggling, transnational gangs, threats to legitimate trade and travel, and imported consumer products jeopardizing public safety. An additional role that I perform is as the Director of the CBP Statistical Tracking and Analysis Team (STAT), which provides high-level analysis and reporting into CBP's immigration and seizure data. Because of my work with the CBP STAT, and my previous position as the Assistant Chief over the USBP's Statistics and Data Integrity (SDI) Branch, I was involved in the previous *Ms. L* reunification efforts, and was again called upon to be the CBP Operational Lead for the government's plan to account for the members of the expanded *Ms. L* class.

2. Prior to serving in this position, I was the Assistant Chief over the USBP SDI Branch, where I provided day to day statistics and analysis to USBP senior leadership and worked to ensure data quality within the USBP data. I have been a U.S. Border Patrol agent since January 2, 1996. The U.S. Border Patrol (USBP) is the operational component of CBP with the responsibility of, among other things, apprehending individuals who enter between the ports of entry. USBP maintains information about individuals in its custody in a system of records known as e3. E3, which is a suite of applications containing multiple modules, contains information that USBP collects and maintains to prevent the illegal entry of people, terrorists, terrorist weapons, and contraband from entering the United States between ports of entry. This information includes, among other things, biographic, biometric, and other enforcement and detention data associated with encounters of individuals between the ports of entry. I am familiar with the development, capabilities and updates to the e3 system. Prior to serving as the Assistant Chief over the USBP SDI Branch, I was the program manager for the requirements gathering, design and development of the e3 suite of applications (Processing, Prosecutions, Biometrics, Assaults, and Detention modules).

3. The Office of Field Operations (OFO) is the operational component of CBP which has responsibility for, among other things, inspecting individuals who present themselves at ports of entry seeking admission. OFO uses a system which is in many way similar to e3, known as SIGMA. I have general familiarity with SIGMA and its capabilities.

4. I am familiar with the *Ms. L* litigation, and have personally participated in CBP efforts related to this litigation. In July 2018, I served as CBP's main point of contact in the interagency effort to identify and reunify the children of *Ms. L* class members. During this role, I worked closely with the Department of Health and Human Services (HHS) and U.S. Immigration and Customs Enforcement (ICE). I worked with the HHS ASPR Data team to reconcile unaccompanied alien children file records identified by HHS as possible separations with the relevant data in CBP's electronic systems of records.

5. I am also familiar with CBP's efforts to record and track family separations in CBP's electronic systems of records, and work closely with relevant individuals in both USBP and OFO on such efforts. I also communicate regularly with my colleagues at ICE Enforcement and Removal Operations (ERO).

6. I am CBP's Operational Lead for the government's plan to identify members of the expanded *Ms. L* class, as identified in the filing submitted to the Court on April 5, 2019. In this role, I am working closely with a team of data experts to review relevant CBP files and provide relevant information to the Data Analysis Team for further review. I provide more detail about this process below.

7. I make this declaration in order to explain the efforts that CBP has already undertaken as part of the government's plan to identify the members of the expanded class, and to explain CBP's role in the process.

Identifying Children Separated between April 19 and June 26, 2018

8. Following the expansion of the *Ms. L* class on March 8, 2019, I became CBP's Operational Lead for the government's plan to identify members of the expanded class.

9. CBP's USBP began tracking separations in our electronic systems of record starting on April 19, 2018. I understand that OFO took steps to identify separations prior to June 29, 2018, when the system was updated. Thus, I determined that CBP would provide Commander White and his team with the data reflecting all separations documented by CBP between April 19 and June 26, 2018. This information is not a final list of class members, but it is important data that can be used in the process of identifying the children of potential expanded *Ms. L* class members. CBP maintained this information in USBP and OFO's electronic system of records.

10. In the past week, using the separations data from this time period, USBP and OFO have pulled the relevant cases out of their electronic systems of records, as well as information that was manually tracked, and compiled that data into lists contained in spreadsheets. These lists included all separations of children from their parents or legal guardians recorded from April 19, 2018 through June 26, 2018, regardless of the reasons for the separation. I provided Commander White with the OFO list on April 17, 2019 and with the USBP list on April 19, 2019. The OFO list reflected data retrieved through June 28, 2018, but no separations were recorded after June 26, 2018.

11. It is my understanding that Commander White and his team will use this and other data to prioritize HHS case files for review to identify possible children of potential class members. Once Commander White and his team have finished their review of their own case files and identified these possible children of potential class members, both CBP and ICE will review its own data to make a determination regarding the circumstances of any separation and to assess class membership. The Data Analysis Team expects that this review will be an iterative, collaborative process.

CBP's General Role in the Government's Identification Plan

12. In general, as described in the government's April 5th filing, the government's plan is intended to be a collaborative, interagency review process, with each agency reviewing their own respective data and exchanging relevant data on a rolling basis. The government's ultimate goal is to identify members of the *Ms. L* class with as much accuracy as possible.

13. Specifically, I expect that CBP will regularly receive information from HHS about children whose file revealed some indicia of separation. CBP will then search its electronic systems of record to determine whether there is a record of the child being encountered with a parent, whether there is a record of the child being separated from that parent, and the reason for such a separation.

CBP will generally conduct this review by searching for the child's Alien File number (A-number), and then reviewing all relevant records relating to that particular child's encounter.

14. For instance, CBP may search a child's A-number and find that the child was encountered as part of a group of individuals. It would then be possible for CBP to look through other members of this group to determine whether the child's parent was also part of that group, or whether the child entered the country unaccompanied. CBP will also review the child's documentation in its systems of records, as well as the documentation of any accompanying parent, to attempt to determine the reason for any separation. CBP will then send relevant information about the parent, and the reason for the separation, to both HHS and ICE for further review and an ultimate determination of class membership.

15. Without having information from HHS about which children to search for, however, it would not be practical to simply review every file in a particular event. Some events may reflect the apprehension of hundreds of individuals at one time, all of whom would have the same event number. Thus, without knowing whether there is some indicia that a child in that group was separated from a parent, such a search would not, in my opinion, be likely to lead to information about potential family separations.

16. This is particularly true given the number of individuals that CBP encounters at the southwest border. In FY 2018, for instance, CBP apprehended or deemed inadmissible more than 520,000 individuals at the southwest border. In FY 2019 to date (through the end of March), CBP has apprehended or deemed inadmissible over 422,000 individuals. The records for all of these encountered are contained in two different systems of records, e3 for USBP and SIGMA for OFO, and there are multiple records related to each individual. Thus, without some method of targeting CBP's review, such as HHS' determination that there is indicia of separation, manual review of these records would require extensive time, resources, and effort, which would dramatically increase the time it would take for the government to complete its complete accounting of the expanded *Ms. L* class.

17. I declare that the foregoing is true and correct to the best of my knowledge, information, and belief.

Executed this 25th day of April, 2019.

Jay, Visconti
Senior Advisor
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Attachment No. 3

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

MS. L, *et al.,*

Petitioners-Plaintiffs,

vs.

U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT, et al.,

Respondents-Defendants.

Case No. 3:18–cv–0428 DMS MDD

STATUS REPORT REGARDING EXPANDED *MS. L* CLASS IDENTIFICATION PLAN

In accordance with the Court's April 25, 2019 Order Following Status Conference, ECF No. 405, Defendants hereby submit this Status Report Regarding Expanded *Ms. L.* Class Identification Plan, which consists of the attached declaration from Commander Jonathan White. Commander White will be available during the May 17, 2019 telephonic status conference to answer any questions the Court may have.

DATED: May 16, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

IT IS HEREBY CERTIFIED THAT:

I, the undersigned, am a citizen of the United States and am at least eighteen years of age. My business address is Box 868, Ben Franklin Station, Washington DC 20044. I am not a party to the above-entitled action. I have caused service of the accompanying brief on all counsel of record, by electronically filing the foregoing with the Clerk of the District Court using its ECF System, which electronically provides notice.

I declare under penalty of perjury that the foregoing is true and correct.

DATED: May 16, 2019

Sarah B. Fabian

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

Ms. L., et al.

Petitioners-Plaintiffs,

vs.

Case No. l8cv428 DMS MDD

Hon. Dana M. Sabraw

U.S. IMMIGRATION AND CUSTOMS
ENFORCEMENT, et al.,

Respondents-Defendants.

DECLARATION OF JONATHAN WHITE

I, Jonathan White, declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that my testimony below is true and correct:

1. The statements in this declaration are based on my personal knowledge, information acquired by me in the course of performing my official duties, information supplied to me by federal government employees, and government records.
2. The purpose of this declaration is to update the Court on the Government's implementation of its Plan for identifying possible children of potential members of the expanded class of parents in this case.
3. On April 25, 2019, the Court approved the Government's Proposed Plan that is designed to identify substantially all class members within 6 months.
4. Since April 25, 2019, the Department of Health and Human Services ("HHS"), U.S. Customs and Border Protection ("CBP"), and U.S. Immigration and Customs Enforcement ("ICE") Operational Leads have consulted and developed a work-flow process to optimize interagency validation and consolidation of information.
5. In addition, a team of U.S. Public Health Service Commissioned Corps ("USPHS") Officers has been created, deployed and trained to conduct case file review asbpart of a pilot project. As of May 13, the USPHS case file review pilot team had conducted preliminary UAC Portal case file review of 4,108 cases. These cases are for the prioritized populations such as the list produced by CBP of children separated after April 19, 2018; the informal tracking list of children identified as separated by ORR beginning in 2017; and children referred to ORR during the class expansion period who were 12 years of age or younger on the date of referral.
6. On May 6 and 13, HHS transmitted data sets on minors with some preliminary indication of separation to CBP and ICE for further assessment, reconciliation with CBP and ICE information, and determination of potential parental class membership. The data sets are currently under review at CBP and, as CBP review is completed, will move to ICE.
7. HHS is expediting the procurement to hire and train a team of data scientists and scalable teams of record reviewers. HHS is in the process of engaging a Federally Funded Research and Development Center to provide this skilled labor and support. The procurement is proceeding rapidly toward finalization. Ordinarily, Federal procurements for services of this type would require a minimum of four months, but this process is being expedited.
8. Once DHS has completed its reconciliation process and potential class membership is determined, the Government will provide lists of potential class members to Plaintiffs on a rolling basis.

Executed on May 16, 2019.

Jonathan White

Attachment No. 4

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

MS. L, et al.,

Petitioners-Plaintiffs,

vs.

U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT, et al.,

Respondents-Defendants.

Case No. 18cv428 DMS MDD

JOINT STATUS REPORT

The Court ordered the parties to file a joint status report ("JSR") by 3:00pm on May 7, 2019, in anticipation of the status conference scheduled at 1:00pm on May 8, 2019. The parties submit this joint status report in accordance with the Court's instruction.

I. DEFENDANTS' POSITIONS

A. Update on Reunifications for the Original Class Period

As of May 6, 2019, Defendants have discharged 2,766 of 2,814 possible children of potential class members for the original class period. That is, Defendants have discharged 2,766 of the 2,814 possible children of potential class members who were in the care of the Office of Refugee Resettlement (ORR) as of June 26, 2018. *See* Table 1: Reunification Update. This is an increase of seven discharges reported in Table 1 since the JSR filed on April 12, 2019. *See* ECF No. 396. Four of the seven children were reunified with the separated parent; the remaining three were discharged under other appropriate circumstances, such as discharges to other appropriate sponsors.

Currently, there is one child of a class member from the original class period who remains in ORR care and is proceeding towards reunification or other appropriate discharge. This child has a parent who departed from the United States, but the Steering Committee has advised that resolution of parental preference will be delayed. Defendants are supporting the efforts of the Steering Committee to obtain a statement of intent from the parent. Once Defendants receive notice from the Steering Committee, Defendants will either reunify the child or move him into the TVPRA sponsorship process, consistent with the intent of the parent.

The current reunification status for the 2,814 children ages 0 through 17 for the original class period, who have been the focus of Defendants' reporting to date, is further summarized in Table 1. The data in Table 1 reflects approximate numbers on these children maintained by ORR at least as of May 6, 2019. These numbers are dynamic and continue to change as more reunifications, determinations on class membership, or discharges occur.

Table 1: Reunification Update

Description	Phase 1 (Under 5)	Phase 2 (5 and above)	Total
Total number of possible children of potential class members	107	2,707	2,814
Discharged Children			
Total children discharged from ORR care:	106	2,660	2,766
• Children discharged by being reunified with separated parent	82	2,084	2,166
• Children discharged under other appropriate circumstances (these include discharges to other sponsors [such as situations where the child's separated parent is not eligible for reunification] or children that turned 18)	24	576	600
Children in ORR Care, Parent in Class			
Children in care where the parent is not eligible for reunification *or* is not available for discharge at this time:	0	1	1
• Parent presently outside the U.S.	0	1	1
◦ Steering Committee has advised that resolution will be delayed	0	1	1
• Parent presently inside the U.S.	0	0	0
◦ Parent in other federal, state, or local custody	0	0	0
◦ Parent red flag case review ongoing—safety and well being	0	0	0
Children in ORR Care, Parent out of Class			
Children in care where further review shows they were not separated from parents by DHS	1	8	9
Children in care where a final determination has been made they cannot be reunified because the parent is unfit or presents a danger to the child	0	15	15
Children in care with parent presently departed from the U.S. whose intent not to reunify has been confirmed by the ACLU	0	21	21
Children in care with parent in the U.S. who has indicated an intent not to reunify	0	1	1
Children in care for whom the Steering Committee could not obtain parental preference	0	1	1

B. Update on Removed Class Members for the Original Class Period

The current reunification status of removed class members for the original class period is set forth in Table 2 below. The data presented in this Table 2 reflects approximate numbers maintained by ORR as of at least May 6, 2019. These numbers are dynamic and continue to change as the reunification process moves forward.

Table 2: Reunification of Removed Class Members

REUNIFICATION PROCESS	REPORTING METRIC	NO.	REPORTING PARTY
STARTING POPULATION	Children in ORR care with parents presently departed from the U.S.	23	Defs.
PROCESS 1: Identify and Resolve Safety/Parentage Concerns	Children with no "red flags" for safety or parentage	23	Defs.
PROCESS 2: Establish Contact with Parents in Country of Origin	Children with parent contact information identified	23	Defs.
	Children with no contact issues identified by plaintiff or defendant	23	Defs. & Pls.
	Children with parent contact information provided to ACLU by Government	23	Defs.
PROCESS 3: Determine Parental Intention for Minor	Children for whom ACLU has communicated parental intent for minor:	21	Pls.
	• Children whose parents waived reunification	21	Pls.
	• Children whose parents chose reunification in country of origin	0	Pls.
	• Children proceeding outside the reunification plan	0	Pls.
	Children for whom ACLU has not yet communicated parental intent for minor:	1	Pls.
	• Children with voluntary departure orders awaiting execution	0	Defs.
	• Children with parental intent to waive reunification documented by ORR	0	Defs.
	• Children whose parents ACLU has been in contact with for 28 or more days without intent determined	0	Pls.
	Children whose parents steering committee could not obtain parental preference	1	PIs
PROCESS 4: Resolve Immigration Status of Minors to Allow Reunification	Total children cleared Processes 1–3 with confirmed intent for reunification in country of origin	0	Pls.
	• Children in ORR care with orders of voluntary departure	0	Defs.

Table 2: Reunification of Removed Class Members—Continued

REUNIFICATION PROCESS	REPORTING METRIC	NO.	REPORTING PARTY
	• Children in ORR care w/o orders of voluntary departure	0	Defs.
	○ Children in ORR care whose immigration cases were dismissed	0	Defs.

C. Update Regarding Government's Implementation of Settlement Agreement

SETTLEMENT PROCESS	DESCRIPTION	NUMBER
Election Forms[1]	Total number of executed election forms received by the Government	**353 (225 Parents/128 Children)**[2]
	• Number who elect to receive settlement procedures	**195 (124 Parents/71 Children)**
	• Number who waive settlement procedures	**158 (101 Parents/57 Children)**[3]
Interviews	Total number of class members who received interviews	**139**[4]
	• Parents who received interviews	**73**
	• Children who received interviews	**66**
Decisions	Total number of CFI/RFI decisions issued for parents by USCIS	**66**[5]
	• Number of parents determined to establish CF or RF upon review by USCIS	**66**[6]
	• Number of parents whose CF or RF finding remains negative upon review by USCIS	**0**
	Total number of CFI decisions issued for children by USCIS	**73**[7]
	• Number of children determined to establish CF by USCIS	**73**[8]
	• Number of children determined not to establish CF by USCIS	0

SETTLEMENT PROCESS	DESCRIPTION	NUMBER
Removals	Number of class members who have been returned to their country of origin as a result of waiving the settlement procedures	**100 Parents** [9]

[1] The number of election forms reported here is the number received by the Government as of April 30, 2019.

[2] The number of children's election forms is lower than the number of parent election forms because in many instances a parent electing settlement procedures submitted an election form on his or her own behalf or opposing counsel e-mailed requesting settlement implementation for the entire family, but no separate form was submitted on behalf of the child.

[3] The number of children's waivers is lower because some parents have submitted waivers only for themselves and some parents who have waived reunification also waived settlement procedures and have therefore not provided a form for the child.

[4] Some individuals could not be interviewed because of rare languages; these individuals were placed in Section 240 proceedings.

[5] This number is the aggregate of the number of parents whose negative CFI/RFI determinations were reconsidered, number of parents whose negative CFI/RFI determination was unchanged, and individuals who were referred to 240 proceedings without interview because of a rare language. This number excludes 12 cases where a parent already had an NTA from ICE or was already ordered removed by an IJ (which are included in the interview totals).

[6] This number includes parents who received positive CF/RF determinations upon reconsideration, parents who received a Notice to Appear based on their child's positive CF determination, and parents who were placed in Section 240 proceedings due to a rare language.

[7] This number is the aggregate of the number of children who received a positive CF determination, the number of children who received a negative CF determination, and children who were referred to 240 proceedings without interview because of a rare language.

[8] This number includes children who received a positive CF determination, children who received a Notice to Appear as a dependent on their parent's positive CF determination, and children who were placed in Section 240 proceedings due to a rare language.

[9] This number is as of April 27, 2019.

D. Parents Who ICE Records Reflect Have Absconded After Being Released

Absconders	Number of Parents who absconded from enrollment in ATD (Alternatives To Detention)	**153** [10]

[10] Data from time period of May 4, 2018 to April 30, 2019.

E. March 8, 2019 Order Regarding Class Definition

On April 25, 2019, the Court approved Defendants' Plan for identifying members of the expanded class, and ordered the parties to provide a status report regarding implementation of this plan on May 16, 2019, ECF No. 405. In accordance with that order Defendants will separately update the Court regarding Plan implementation in the May 16 status report.

F. Pending Motion Regarding Released Settlement Class Members

The parties met and conferred regarding this issue on March 27, 2019. On April 3, 2019, Plaintiffs sent a list of questions regarding the information provided by Defendants. Defendants responded to these inquiries on April 12, 2019. Plaintiffs sent some follow up inquiries regarding the information provided by Defendants on May 3, 2019, and the parties spoke again on May 6, 2019 regarding these inquiries. Defendants are following up on a couple of issues discussed on that call, but otherwise understand that Plaintiffs are satisfied with the information that Defendants have provided and have no further requests at this time.

G. Children Awaiting Placement

On April 3, 2019, Plaintiffs sent an email requesting information regarding the status of 17 children who remain in ORR custody, and whose parents were removed and waived reunification. Defendants provided information in response to this inquiry in the last JSR, and also concurrently provided additional information to Plaintiffs. Defendants have received no further inquiries on this topic and believe the matter to be resolved.

H. Settlement Agreement Related to Removed Parents

In the April 12, 2019 JSR, Plaintiffs stated that they "expect[ed] that [this] issue will need to be addressed in the next JSR and status conference." Despite this state-

ment, Plaintiffs have not raised the issue with Defendants in advance of this filing. If Plaintiffs make any assertions about this issue in this JSR, at tomorrow's status conference Defendants will be prepared to propose how the Court should proceed.

I. Government Processes, Procedures, and Tracking, for Separations Since June 26, 2018

1. Data Requested by Plaintiffs

Defendants will provide Plaintiffs updated reports containing information regarding parents and children separated since the Court's June 26, 2018 preliminary-injunction order on the Friday following the filing of each JSR.

2. Processes and Procedures

Defendants have provided a summary outline memorializing the processes, procedures, tracking, and communication between the agencies that have been adopted by the agencies since June 26, 2018. The outline also included an overview of the options for separated parents and children to obtain information about reunification options. Defendants also have reached out to representatives for the Bureau of Prisons and the U.S. Marshals Service to ensure that those entities are included in discussions regarding these processes and procedures.

On March 4, 2019, Plaintiffs and lawyers for the children's legal service providers sent comments and questions in response to the government's proposals. Defendants have reviewed those comments and questions, and the parties met and conferred on April 15, 2019, regarding those inquiries. Defendants have received no follow-up comments or inquiries from Plaintiffs since that meet and confer.

II. *MS. L.* PLAINTIFFS' POSITION

1. Centralized Database and Procedures and Standards to Govern Further Separations

The parties continue to meet and confer on how to address the continuing separations.

2. Deported Parents and Settlement

The parties continue to confer on this issue. Plaintiffs expect, however, that the issue will need to be addressed in the next JSR.

3. Information Regarding Parents Separated from Children After June 26

Plaintiffs have requested rolling disclosures of separations, as the last government disclosure, on April 12, included only separations between June 26, 2018 and March 16, 2019. The parties continue to meet and confer on this issue, and on the level of detail that the government discloses for the basis of a separation.

4. Additional Information Requests

Plaintiffs have made requests for additional information about class members, including as to parents who have been treated as if they were class members while in ICE detention (*e.g.,* the government identifies them as having "waived reunification") but who have yet to appear on class lists. The parties continue to meet and confer on these issues.

5. Steering Committee Progress

The Steering Committee has successfully contacted and confirmed the preferences of nearly all removed parents with respect to reunifications. On April 12, the government reported that, as of April 11, 30 children with removed parents remained in ORR custody. The Committee has advised the government that no preference will be forthcoming for one of those parents due to complex and individualized family circumstances, leaving 29 children with removed parents in the operative group. The Committee has delivered preferences for the parents of 28 of those children. The parent of the remaining child is seeking to return to the United States under the Settlement Agreement, and the Steering Committee has advised the government that the delivery of a parental reunification election in this case will therefore be delayed.

The status of efforts based on the operative group of 29 children in ORR custody with removed parents appears in the table immediately below.[11]

[11] As discussed at the October 25 Status Conference, Plaintiffs are reporting a set of detailed numbers based on the government's most recent list of children in ORR custody with removed parents. The numbers presented in this Joint Status Report are based on the numbers provided

Removed parents identified by the government to the Steering Committee as of 4/12/2019	29
Parent's final preference has been communicated to the government	28 [12]
• Parent has elected reunification in Country of Origin	0
• Parent has elected to waive reunification in Country of Origin	28
Total number of cases where the parent seeks to return to the U.S.	1

[12] The Steering Committee determined that for one child it was appropriate to report the preference of a non-removed parent because the Steering Committee was unable to reach the removed parent.

F. Children Whose Parents Have Submitted Preferences and Are Still Detained

On February 12, the Steering Committee provided to the government information regarding 22 children who had been in ORR custody for at least five months following the submission of a final reunification election. The government provided detailed information regarding these children most recently on April 12, which the Steering Committee appreciates. According to the government's April 12 data, 13 children in ORR custody as of that date remained separated from their parents for more than six months following the submission of a final reunification election, with seven children having been in ORR custody for more than eight months following the submission of a final reunification election. The Steering Committee will continue to meet and confer with the Government regarding the remaining children.

III. *MMM-Dora* Plaintiffs' Report Regarding Settlement Implementation

The parties continue to work together to implement the settlement agreement approved on November 15, 2018. Counsel for Plaintiffs are providing the government with signed waiver forms as they are received from class members. The parties are meeting and conferring on settlement implementation issues as they arise (including a productive meeting earlier this week), and are working together to resolve various issues regarding implementation, interviews for class members, statistical reporting, and various individualized issues as they arise. The parties will alert the Court of any issues that require the Court's guidance.

As reported in the prior JSR, and per the Court's February 22, 2019 Order (ECF No. 362), the Government provided *Dora* and *M.M.M.* counsel with a list of class members with removal orders, which includes individuals with either expedited removal orders or final removal orders. The parties are continuing to meet and confer about the data and the best way to identify class members who may be in need of settlement relief. The Government has recently provided Plaintiff's counsel with additional address information to facilitate outreach to class members.

by the government in the April 12 Joint Status Report, excluding the one child for which no preference will be forthcoming.

DATED: May 7, 2019

Respectfully submitted,

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Attachment No. 5

AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) ▶ RATING

PAGE 1 OF PAGES 4

2. CONTRACT (Proc. Inst. Ident.) NO.
HHSF223201810043C

3. EFFECTIVE DATE
See Block 20C

4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
1200555

5. ISSUED BY CODE DSAAG

DHHS/FDA/OAGS/DSAAG
ATTN: Madeline Bryant
5630 Fishers Lane
RM 2016 HFA-500
Rockville MD 20857

6. ADMINISTERED BY (If other than Item 5) CODE

7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, Country, State and ZIP Code)

HEALTH & HUMAN SERVICES, NORTH CAROLINA DEPARTMENT OF 1390054
HEALTH & HUMAN SERVICES, NORTH CARO
3001 MAIL SERVICE CTR
RALEIGH NC 276992000

CODE 1390054 FACILITY CODE

8. DELIVERY
☐ FOB ORIGIN ☒ OTHER (See below)

9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ▶ ITEM

11. SHIP TO/MARK FOR CODE W075

WHITE OAK CAMPUS, BUILDING 75
The US Food and Drug Administration
10903 New Hampshire Avenue
Building 75
Silver Spring MD 20993

12. PAYMENT WILL BE MADE BY CODE FDA

FDA Payment Svcs
US Food and Drug Administration
10903 New Hampshire Avenue
Bldg 32, Rm 2162, Mail Hub 2145
Silver Spring MD 20993-0002

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:
☐ 10 U.S.C. 2304 (c) ( ) ☒ 41 U.S.C. 253 (c) (5)

14. ACCOUNTING AND APPROPRIATION DATA
2018.6CB9AVN.252Z.B70013C090STC60

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				

15G. TOTAL AMOUNT OF CONTRACT ▶ $1,162,878.00

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
X	A	SOLICITATION/CONTRACT FORM	1-4	X	I	CONTRACT CLAUSES	49-60
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	5-8			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	8-23	X	J	LIST OF ATTACHMENTS	60
X	D	PACKAGING AND MARKING	23			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
X	E	INSPECTION AND ACCEPTANCE	24-25		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	25-29				
X	G	CONTRACT ADMINISTRATION DATA	29-36		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
X	H	SPECIAL CONTRACT REQUIREMENTS	36-48		M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18. ☐ SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER (Type or print)
Katherine Nichols

20A. NAME OF CONTRACTING OFFICER
ERIKA A. EAM

19B. NAME OF CONTRACTOR
BY Katherine Nichols
(Signature of person authorized to sign)

19C. DATE SIGNED
6/13/18

20B. UNITED STATES OF AMERICA
BY Erika A. Eam -S
(Signature of the Contracting Officer)

Digitally signed by Erika A. Eam -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Erika A. Eam -S, 0.9.2342.19200300.100.1.1=2002517094
Date: 2018.06.13 16:12:13 -04'00'

20C. DATE SIGNED
6/13/18

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STANDARD FORM 26 (Rev. 8/2011)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
HHSF223201810043C

PAGE 2 OF 4

NAME OF OFFEROR OR CONTRACTOR
HEALTH & HUMAN SERVICES, NORTH CAROLINA DEPARTMENT OF 1390054

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: [REDACTED] DUNS Number: [REDACTED] THREE WAY INVOICING				
	COR- Benny Guevara				
	North Carolina Compliance and Enforcement Tobacco etail In pections Appr. Yr.: 2018 CAN: [REDACTED] Object Class: 252Z Ce 70013C090STC 0 terTa FOB: Destination Period of Performance: 06/15/2018 to 06/14/2019				
	North Carolina Compliance and Enforcement Tobacco Retail Inspections Contract - Base Year Obligated Amount: $1,162,878.00				1,162,878.00
2	North Carolina Compliance and Enforcement Tobacco Retail Inspections Contract - Option Year 1 (Option Line Item)				
3	North Carolina Compliance and Enforcement Tobacco Retail Inspections Contract - Option Year 2 (Option Line Item)				
4	North Carolina Compliance and Enforcement Tobacco Retail Inspections Contract - Option Year 3 (Option Line Item)				
5	North Carolina Compliance and Enforcement Tobacco Retail Inspections Contract - Option Year 4 (Option Line Item)				

FDA Three-Way Match Invoicing Procedures

A. The contractor shall submit all invoices to:

U.S. FOOD AND DRUG ADMINISTRATION

Attn: Vendor Payments
Division of Payment Services
10903 New Hampshire Ave
WO32 - Second Floor
MAIL HUB 2145
Silver Spring, MD 20993-0002
301-827-3742
FDAVendorPaymentsTeam@fda.hhs.gov

*** Acceptable methods of delivery include: E-mai (pre er ed) and Stan ard Mail.

Continued ...

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED	PAGE	OF
	HHSF223201810043C	3	4

NAME OF OFFEROR OR CONTRACTOR

HEALTH & HUMAN SERVICES, NORTH CAROLINA DEPARTMENT OF 1390054

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	B. Invoices submitted under this contract must comply with the requirements set forth in FAR Clauses 52.232-25 (Prompt Payment) and 52.232-33 (Payment by Electronic Funds Transfer - System for Award Management) and/or other applicable FAR clauses specified herein. To constitute a proper invoice, the invoice must be submitted on company letterhead and include each of the following: (i) Name and address of the contractor; (ii) Invoice date and invoice number; (iii) Contract/Order number (including a reference to any base award for Indefinite-Delivery/Indefinite-Quantity Contracts or Blanket Purchase Agreements); (iv) Description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed, including: (a) period of performance for which costs are claimed; (b) itemized travel costs, including origin and destination; (c) any other supporting information necessary to clarify questionable expenditures; (d) the contractor shall include the award item number for each description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed; (v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on government bill of lading; (vi) Terms of any discount for prompt payment offered (Prompt Payment terms other than NET 30); (vii) Name and address of contractor official to whom payment is to be sent (must be the same as that in the contract or in a proper notice of assignment); (viii) Name, title, and phone number of person to notify in event of defective invoice; (ix) Taxpayer Identification Number (TIN); (x) banking routing transit number of the financial institution receiving payment for Electronic funds transfer (EFT) ; (xi) Name and telephone number of the FDA Approving Official (i.e., Contracting Officer (CO) or Contract Specialist (CS), as referenced in the award document); (xii) Name and telephone number of the FDA Contracting Officer Representative (COR) or other program center/office point of contact, as referenced in the award document; (xiii) Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes: (a) list of all invoices submitted to date under the subject award, including the following: Continued ...				

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED HHSF223201810043C	PAGE 4 OF 4

NAME OF OFFEROR OR CONTRACTOR

HEALTH & HUMAN SERVICES, NORTH CAROLINA DEPARTMENT OF 1390054

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	(1) invoice number, amount, & date submitted (2) corresponding payment amount & date received (b) total amount of all payments received to date under the subject contract or order (c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance; (xiv) Any other information or documentation required by the contract/order award. C. An electronic invoice is acceptable if submitted in adobe acrobat (PDF) format. All items listed in (i) through (xii) of this clause must be included in the electronic invoice. Electronic invoices must be on company letterhead and must contain no ink changes and be legible for printing. [amend/delete, as necessary] D. Questions regarding invoice payments should be directed to the Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue. The total amount of award: $5,731,876.00. The obligation for this award is shown in box 15G.				

AUTHORIZED FOR LOCAL REPRO

OPTIONAL FORM 336 (4-86)
Sponsored by GSA
FAR (48 CFR) 53.110

PREPARED STATEMENT OF HON. CHUCK GRASSLEY,
A U.S. SENATOR FROM IOWA

Good morning. This hearing will come to order.

I want to welcome our witness, the Secretary of the Department of Health and Human Services, Mr. Alex Azar.

I appreciate Secretary Azar coming before the committee to talk about the health and human services proposals in President Trump's budget for fiscal year 2020.

Congress decides how much the government spends and how to allocate those resources. But the President gets to have a say, and it's our duty to consider those recommendations.

We're here today to discuss the Trump administration's recommendations for HHS programs.

These programs impact the day-to-day lives of many people in Iowa and throughout the country. Medicare and Medicaid cover health care for over 130 million people. Human services programs administered by HHS help millions of families in need while promoting upward mobility. The programs this committee oversees spend over $1 trillion and take hundreds of millions of dollars to administer.

The President's budget proposal aims to tackle a number of pressing challenges. It looks to get a better handle on the opioid epidemic and improve child welfare outcomes. This committee has been active on these issues and has a role in overseeing HHS's implementation of laws that Congress has passed in these areas.

The budget also strives to lower the high cost of prescription drugs. I share that goal and look forward to working with my colleagues on this committee to find ways to make medications more affordable in Medicare and Medicaid while protecting taxpayers who fund these programs.

President Trump and Secretary Azar deserve tremendous credit for highlighting the need to reduce drug costs for patients. Their sustained efforts have helped to make big drug pricing policy changes possible.

The budget serves as a reminder that Congress needs to act to make sure Medicare and Medicaid are around for future generations. Putting these programs on a sustainable financial path while ensuring patients can get the care they need is hard work.

As I've said many times, regardless of the issue, the legislative heavy lifting needs to be done in a bipartisan manner to achieve a lasting solution.

This hearing provides an opportunity to talk about issues important to our constituents and country. So whether you agree or disagree with specific policy proposals in the budget, it's important that we engage with Secretary Azar on the issues.

I appreciate that Secretary Azar is here to perform the time-honored tradition of testifying on the budget, which enables us to execute our duty to consider the President's proposals. I look forward to a robust discussion.

With that, I recognize Ranking Member Wyden for his opening statement.

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

It's budget week on Capitol Hill. There's a lot to discuss this morning, so I'll get right to it.

The Trump administration seems to have an inexhaustible supply of destructive health-care ideas that would harm vulnerable Americans.

Let's start with the Arkansas paperwork requirements. With the Trump administration's blessing, Arkansas went ahead inflicting a right-wing experiment onto people enrolled in Medicaid. They say it's all about work requirements, not about reducing coverage. They're wrong. Eighteen thousand people in Arkansas have lost their health care. They're people who want to work, and they're people who are working.

Secretary Azar was asked on Tuesday why so many people in Arkansas have lost coverage. He answered that the administration was basically clueless. The Trump budget takes this experiment national. In fact, it makes it mandatory—in every State.

Bottom line, this doesn't make people healthier. It's not about promoting work. This is a back-door scheme to kick people off their Medicaid coverage by putting mountains of paperwork between patients and their doctors.

Next issue, another hare-brained right-wing experiment. A cadre of Republican Governors and Attorneys General recently sued HHS in an attempt to get the entire Affordable Care Act ruled unconstitutional. Their legal argument wouldn't get a passing grade in Con. Law 101. But instead of defending the law of the land against this lawsuit, as is the longstanding bipartisan practice, the Trump Justice Department decided it would jump on board.

And in fact, the Justice Department focused its attack on key protections for pre-existing conditions. It wants them ruled unconstitutional. The legal brief involved is so absurd, three career officials refused to put their names on it. One even resigned. After a political appointee agreed that he would be the public face of this attack, he was rewarded with a nomination to the Sixth Circuit Court of Appeals.

On the topic of hurting those with pre-existing conditions, let's turn to junk insurance. The fight against junk insurance goes back decades. I was part of the effort to crack down on Medigap supplemental plans targeting seniors. More recently there was a similar effort in the private insurance market. The Trump administration said, "Enough cracking down, let's bring junk insurance back." Once again, scam artists are free to sell bargain-basement plans on the individual market that don't cover the health care people actually need.

Next, the Trump administration wants to fillet Medicaid by block-granting and capping the program. That's an idea so destructive it couldn't pass when the Congress was under unified Republican control. Not only would it put essential care on the chopping block for millions, including children and people with disabilities, it's a surefire way to create a nationwide crisis of nursing home closures. Despite those dangers, the administration is now reportedly exploring how to block-grant Medicaid through administrative fiat.

The administration cut open-season for health insurance in half. It also slashed funding for the advertising and in-person assistance that helps people sign up for coverage under the ACA. The budget would take away middle-class tax credits for health care. The list of health-care sabotage goes on. Bottom line, it's stunning how creative the Trump administration has been at making health care worse in America.

Now let's turn to the pharmaceutical checklist. Donald Trump made the skyrocketing costs of prescription drugs a core issue on the campaign trail. He's talked a lot about it in office, even criticized a few companies on Twitter. He famously said in early 2017 that drug makers are "getting away with murder."

Two years later, he gets a failing grade on doing anything about it. The President once said he wanted to let Medicare negotiate to bring down drug prices, but that's nowhere to be found in his budget. There's nothing in the budget that would force drug manufacturers to lower their prices. So far, there's been no concrete action to back up the President's promises.

I'll close with two final issues. First, on the separation of migrant children from their parents: last year, Secretary Azar came before this committee and told us that HHS had everything under control, the kids were accounted for, and reunification would proceed smoothly. He said the Department and parents, I quote, "With just basic keystrokes, within seconds, could find any child in our care."

Based on available evidence, it now appears that was dead wrong. Reports suggest the government cannot account for the whereabouts of potentially thousands of children who were in its care. HHS documents that were recently released also show that there were thousands of allegations of sexual abuse inflicted on children in government custody. So while Secretaries Azar, Nielsen, and other Trump officials tried to send reassuring messages, behind the scenes these kids were subjected to chaos and abuse. This is an ongoing, horrifying scandal at the border, and now there's evidence the Trump administration is working to intimidate and silence the journalists trying to expose it.

Finally, I need to address an issue dealing with foster care. In January, the Trump administration gave South Carolina a green light for religious discrimination in its foster care program. That announcement came with the assurance that it was only one State, it was a very particular set of circumstances, and there wouldn't be any discrimination. Then the President got up at the National Prayer Breakfast and suggested that this policy could become national.

In my view, this road heads directly toward taxpayer-funded discrimination on religious grounds. The first victims of that discrimination will be people who want to step up and provide safe and loving homes for foster kids. People who are Jewish, who are Catholic, who are Muslim, who choose to practice no religion, LGBTQ Americans, potentially others. The next victims will be vulnerable youngsters, since this policy would limit the number of foster homes available to them. There are also alarming questions about what this would mean for Jewish kids and Catholic kids who wind up in settings that are hostile to their faiths. What would it mean for LGBTQ kids, or children who are struggling with their sexual orientation?

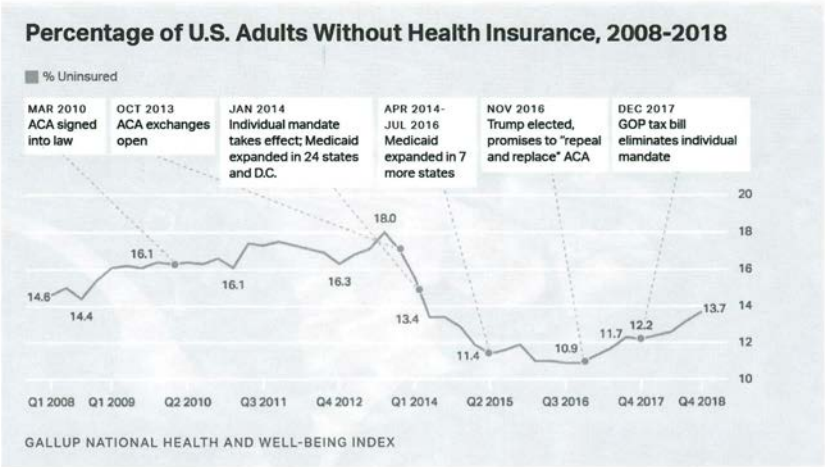
I'm extremely troubled by what the administration is doing in this area. So I'm going to have more questions about that, as well as the other issues I've discussed today, and more.

Gallup
January 23, 2019

U.S. Uninsured Rate Rises to Four-Year High
By *Dan Witters*

- The U.S. uninsured rate has risen steadily since 2016
- Women, younger adults, the lower-income have the greatest increases
- All regions except for the East reported increases

WASHINGTON, DC—The U.S. adult uninsured rate stood at 13.7% in the fourth quarter of 2018, according to Americans' reports of their own health insurance coverage, its highest level since the first quarter of 2014. While still below the 18% high point recorded before implementation of the Affordable Care Act's individual health insurance mandate in 2014, today's level is the highest in more than four years, and well above the low point of 10.9% reached in 2016. The 2.8-percentage-point increase since that low represents a net increase of about seven million adults without health insurance.



Nationwide, the uninsured rate climbed from 10.9% in the third and fourth quarters of 2016 to 12.2% by the final quarter of 2017; it has risen steadily each quarter since that time. Since Gallup's measurement began in 2008, the national uninsured rate reached its highest point in the third quarter of 2013 at 18.0%, and thus, the current rate of 13.7%—although it continues a rising trend—remains well below the peak level.

These data, collected as part of the Gallup National Health and Well-Being Index, are based on Americans' answers to the question, "Do you have health insurance coverage?" Sample sizes of randomly selected adults in 2018 were around 28,000 per quarter.

The ACA marketplace exchanges opened on October 1, 2013, and most new insurance plans purchased during the last quarter of that year began their coverage on Jan. 1, 2014. Medicaid expansion among 24 states (and the District of Columbia) also began at the beginning of 2014, with 12 more states expanding Medicaid since that time. Expanded Medicaid coverage as a part of the ACA broadens the number of low-income Americans who qualify for it to those earning up to 138% of the federal poverty level. The onset of these two major mechanisms of the ACA at the be-

ginning of 2014 makes the uninsured rate in the third quarter of 2013 the natural benchmark for comparison to measure the effects of that policy.

Uninsured Rates Increase Most Among Women, Young Adults, the Lower-Income

The uninsured rate rose for most subgroups in the fourth quarter of 2018 compared with the same quarter in 2016, when the uninsured rate was lowest. Women, those living in households with annual incomes of less than $48,000 per year, and young adults under the age of 35 reported the greatest increases. Those younger than 35 reported an uninsured rate of over 21%, a 4.8-point increase from two years earlier. And the rate among women—while still below that of men—is among the fastest rising, increasing from 8.9% in late 2016 to 12.8% at the end of 2018.

At 7.1%, the East region, which has in recent years maintained the lowest uninsured rate in the nation, is the only one of the four regions nationally whose rate is effectively unchanged since the end of 2016. Respondents from the West, Midwest and South regions all reported uninsured rates for the fourth quarter of 2018 that represent increases of over 3.0 points. The South, which has always had the highest uninsured rate in the U.S. but has seen some of the greatest declines at the state level, has had a 3.8-point increase to 19.6%.

Percentage of Uninsured U.S. Adults, by Subgroup

% Uninsured

	Q4 2016 %	Q4 2018 %	Change pct. pts.
Age			
18–34	16.8	21.6	+4.8
35–64	11.0	13.7	+2.7
65+	2.3	3.7	+1.4
18–64	13.1	16.3	+3.2
Gender			
Men	12.9	14.5	+1.6
Women	8.9	12.8	+3.9
Annual household income			
Under $24,000	22.6	25.4	+2.8
$24,000–<$48,000	16.1	19.1	+3.0
$48,000–<$90,000	7.8	9.1	+1.3
$90,000–<$120,000	3.2	5.9	+2.7
$120,000 or more	2.4	3.6	+1.2
Region			
East	7.5	7.1	−0.4
West	9.6	13.2	+3.6
Midwest	7.7	10.9	+3.2
South	15.8	19.6	+3.8

Gallup National Health and Well-Being Index

Implications

A number of factors have likely played a role in the steady increase in the uninsured rate over the past two years. One may be an increase in the rates of insurance premiums in many states for some of the more popular ACA insurance plans in 2018 (although most states saw premiums stabilize for 2019). For enrollees with incomes that do not qualify for government subsidies, the resulting hike in rates could have had the effect of driving them out of the marketplace. Insurers have also increasingly withdrawn from the ACA exchanges altogether, resulting in fewer choices and less competition in many states.

Other factors could be a result of policy decisions. The open enrollment periods since 2018 have been characterized by a significant reduction in public marketing and shortened enrollment periods of under seven weeks, about half of previous periods. Funding for ACA "navigators" who assist consumers in ACA enrollment has also been reduced in 2018 to $10 million, compared with $63 million in 2016. Overall, after open enrollment in the ACA federal insurance marketplace (*i.e.,*

healthcare.gov) peaked in 2016 at 9.6 million consumers, it declined by approximately 12.5%, to 8.4 million in 2019, based on recently released figures.

Other potential factors include political forces that may have increased uncertainty surrounding the ACA marketplace. Early in his presidency, for example, President Donald Trump announced, "I want people to know Obamacare is dead; it's a dead healthcare plan." Congressional Republicans made numerous high-profile attempts in 2017 to repeal and replace the plan. Although none fully succeeded legislatively, the elimination of the ACA's individual mandate penalty as part of the December 2017 Republican tax reform law may have reduced participation in the insurance marketplace in the most recent open enrollment period.

Trump's decision in October 2017 to end cost-sharing reduction could also potentially have affected the uninsured rate. The cost-sharing payments were made to insurers in the marketplace exchanges to offset some of their costs for offering lower-cost plans to lower-income Americans. The Trump administration had previously renewed the payments on a month-by-month basis but later concluded that such payments were unlawful. In April 2018, a federal court granted a request for a class-action lawsuit by health insurers to sue the federal government for failing to make the payments. Such lawsuits continue to be litigated.

MIRACLE HILL MINISTRIES FOSTER CARE PROGRAM
117 Drummond Lane
Pickens, SC 29671
www.miraclehill.org

Miracle Hill Ministries, Inc. has been approved to license individual foster homes. The foster homes can be licensed to care for a specific age or gender child. Among the requirements for becoming foster parents, one would have to be fingerprinted and pass SLED and DSS background checks for criminal activity and child abuse. Also, any prospective home would need to pass a health and fire inspection to assure a healthy and safe environment for the child. Fourteen hours of training are also required of each foster parent and is provided by Miracle Hill staff. When the licensing process is complete, Miracle Hill foster parents are qualified to receive foster children through our agency. These children have been referred by local DSS offices.

A foster parent for Miracle Hill must: (1) be a born-again believer in the Lord Jesus Christ as expressed by a personal testimony and Christian conduct; (2) be in agreement without reservation with the doctrinal statement of Miracle Hill Ministries; (3) be an active participant in, and in good standing with, a Protestant church; (4) have a genuine concern for the spiritual welfare of children entrusted to their care; (5) have a lifestyle that is free of sexual sin (to include pornographic materials, homosexuality, and extramarital relationships); (6) abstain from activities or addictions that have a detrimental effect on clients* including: undiscerning choices related to literature and entertainment; excessive or imprudent use of alcohol; use of illegal drugs; abuse of prescription medications; and the use of tobacco in the presence of foster children and inside the foster home or foster parent's vehicle.

In accordance with Title VI of the Civil Rights Act of 1964, the Multiethnic Placement Act of 1994 and Section 1808 of the Small Business Job Protection Act of 1996, 42 U.S.C. 622(b)(9), 671(a)(18), 674(d) and 1996b, Miracle Hill is prohibited from discriminating on the basis of race, color and/or national origin when making foster care decisions.

If you are interested in becoming a foster parent and feel that you meet the requirements, please complete the information in the "Getting Started" section of the website. The Miracle Hill foster home staff will review the information. If you have met the requirements, a licensing worker will contact you to make an appointment to meet your family and aid you in the licensing process.

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*According to the teachings of Romans 14:13–23, we are to keep from becoming a stumbling block to others. It is important to exercise biblical discretion by restricting your freedom and demonstrating sound judgment based on biblical principles that displays evidence of spiritual growth and maturity. This is especially important considering ⅔ of children in foster care come from homes with a substance abusing adult and individuals that have been in foster care are 50% more likely to abuse substances in their lifetime. (Titus 2:11–12)

How can I learn more? If you would like to know more about Miracle Hill Ministries, Inc., have a tour of our facilities, or set up an appointment regarding your needs, please call us at 864–878–9987, or write to us at:

Miracle Hill Ministries, Foster Home Program
117 Drummond Lane
Pickens, SC 29671

You can also visit our web site at *www.miraclehill.org.*

ADMINISTRATION FOR CHILDREN AND FAMILIES
Office of the Assistant Secretary
330 C Street, SW, Suite 4034
Washington, DC 20201
www.acf.hhs.gov

January 23, 2019

Governor Henry McMaster
State House
1100 Gervais Street
Columbia, SC 29201

Re: Request for Deviation or Exception from HHS Regulations 45 CFR § 75.300(c)

Dear Governor McMaster:

This correspondence responds to your letter of February 27, 2018, to the Acting Assistant Secretary for Children and Families, written "on behalf of South Carolina and faith-based organizations" operating under South Carolina's Title IV–E Foster Care Program ("the SC Foster Care Program"). As clarified through follow-up telephone calls, your letter requested that the SC Foster Care Program be granted an exception from U.S. Department of Health and Human Services' ("HHS" or the "Department") regulations at 45 CFR § 75.300(c), prohibiting subgrantees from selecting among prospective foster parents on the basis of religion, to the extent that such prohibition conflicts with a subgrantee's religious exercise. We understand that one such faith-based subgrantee, Miracle Hill Ministries ("Miracle Hill"), exclusively recruits foster parents of a particular religion and accounts for up to 15% of your total foster care placements. We also understand that you believe that there are other participating faith-based organizations with similar religious exercise concerns and that other entities in the SC Foster Care Program do not have the same conflicts with § 75.300(c) and would work with prospective foster parents of different faiths or no faith.

Section 75.300(c) says:

> (c) It is a public policy requirement of HHS that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services based on non-merit factors such as age, disability, sex, race, color, national origin, religion, gender identity, or sexual orientation. Recipients must comply with this public policy requirement in the administration of programs supported by HHS awards.

These requirements are broader than the nondiscrimination requirements specified in the Foster Care Program Statute, 42 U.S.C. § 671(a)(18), which says:

> (a) Requisite features of State plan. In order for a State to be eligible for payments under this part, it shall have a plan approved by the Secretary which—(18) not later than January 1, 1997, provides that neither the State nor any other entity in the State that receives funds from the Federal Government and is involved in adoption or foster care placements may—(A) deny to any person the opportunity to become an adoptive or a foster parent, on the basis of the race, color, or national origin of the person, or of the child, involved; or (B) delay or deny the placement of a child for adoption or into foster care, on the basis of the race, color, or national origin of the adoptive or foster parent, or the child, involved.

The statutory requirements of § 671(a)(18) are incorporated into the grant for the SC Foster Care Program through 45 CFR § 75.300(a), which requires "that Federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements." Other federal civil rights statutes may likewise apply to the SC Foster Care Program directly, as a recipient of

federal financial assistance, or through 45 CFR § 5.300(a). Your letter did not request an exception from § 75.300(a).

In support of your exception request, you state that South Carolina has more than 4,000 children in foster care, that South Carolina needs more child placing agencies, and that faith-based organizations "are essential" to recruiting more families for child placement. You specifically cite Miracle Hill, a faith-based organization that recruits 15% of the foster care families in the SC Foster Care Program, and you state that, without the participation of such faith-based organizations, South Carolina would have difficulty continuing to place all children in need of foster care. You make the case that, if the SC Foster Care Program is not provided an exception from § 75.300(c) in this regard, certain faith-based organizations operating under your grant would have to abandon their religious beliefs or forego licensure and funding. You contend this would cause hardship to faith-based organizations and to the SC Foster Care Program. Your letter seeking the exception argued that certain requirements in § 75.300(c) and (d) exceed any nondiscrimination requirements or authority imposed by statute, and that § 75.300(c) and (d) limit the free exercise of religion of faith-based organizations in violation of the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb, *et seq.* ("RFRA"). In follow-up telephone conversations with your chief legal counsel, the request for an exception was narrowed to the religious nondiscrimination provision in § 75.300(c).

On December 18, 2018, Miracle Hill wrote to HHS stating that, in prohibiting Miracle Hill's use of religious criteria in selecting prospective foster parents under the SC Foster Care Program, HHS's regulations substantially burden Miracle Hill's free exercise of religion (including under RFRA), and are also *ultra vires* because they exceed the scope of the relevant statutes. Miracle Hill notes that the South Carolina Department of Social Services, pursuant to the requirements imposed on it through its grants from HHS, declined to renew Miracle Hill's license to provide foster services and "instead granted [Miracle Hill] a provisional license that would be revoked if [Miracle Hill] continued [its] ministry consistent with [its] religious beliefs." It is HHS's understanding that this provisional license will be revoked in January 2019 unless Miracle Hill agrees to partner with foster parents in accordance with § 75.300(c), which Miracle Hill cannot do, because Miracle Hill "believe[s] those who hold certain positions of spiritual influence and leadership—including foster parents—should share [Miracle Hill's] religious mission and beliefs."

The HHS Office for Civil Rights ("OCR") is the HHS component with delegated authority to ensure compliance with RFRA by the Department, its programs, and the recipients of HHS federal financial assistance. OCR has reviewed Miracle Hill's letter as part of an ongoing investigation and has determined that subjecting Miracle Hill to the religious nondiscrimination requirement in § 75.300(c) (by requiring South Carolina to require Miracle Hill to comply with § 75.300(c) as a condition of receiving funding) would be inconsistent with RFRA.

OCR specifically found that Miracle Hill's sincere religious exercise would be substantially burdened by application of the religious nondiscrimination requirement of § 75.300(c), and that subjecting Miracle Hill to that requirement, by denying South Carolina's exception request, is not the least restrictive means of advancing a compelling government interest on the part of HHS. Relevant to this determination is the fact that the religious nondiscrimination provision in § 75.300(c) exceeds the scope of the nondiscrimination provisions found in the federal statutes applicable to the SC Foster Care Program, and provides no exceptions for religious organizations as are found in other statutes prohibiting religious discrimination. *See, e.g.,* 42 U.S.C. § 2000e–1(a) (Title VII); 42 U.S.C. § 3607(a) (Fair Housing Act). In addition, the interest of allowing potential foster parents into the SC Foster Care Program appears capable of being served by other providers in the program, since at least nine other foster care providers in Miracle Hill's area appear available to assist potential foster parents in the event Miracle Hill is unable to partner with certain potential foster parents because of Miracle Hill's religious beliefs. Of additional relevance is the fact that the OMB Uniform Administrative Requirements, located at 2 CFR § 200.300, do not contain provisions analogous to the broad religious nondiscrimination provision in 45 CFR § 75.300(c). As the Supreme Court recognized in *Holt v. Hobbs,* 135 S. Ct. 853, 866 (2015); consideration of analogous programs operated by other governmental entities is relevant in determining whether the government has a compelling interest "of the highest order" in requiring such a burden on religious exercise. Finally, 45 CFR Part 75 provides a mechanism for granting an exception from requirements of that part, including § 75.300(c): namely, as applicable here, case-by-case exceptions available under 45 CFR § 75.102(b). The Supreme Court has emphasized that, where exceptions are available, the government

has a difficult burden to meet before refusing an exception under RFRA. *See, e.g., Gonzales v. O Centro Espirita Beneficenfe Uniao do Vegetal,* 546 U.S. 418, 434 (2006). Accordingly, OCR concluded that Miracle Hill (and any other similarly situated religious organization in the SC Foster Care Program) is entitled under RFRA to an exception from the religious nondiscrimination requirements of 45 CFR § 75.300.

Section 75.102(b) of 45 CFR states that "[e]xceptions on a case-by case basis for individual non-Federal entities may be authorized by the HHS awarding agency or cognizant agency for indirect costs, except where otherwise required by law or where OMB or other approval is expressly required by this part." This provision permits the HHS awarding agency (or the "cognizant agency for indirect costs") to grant exceptions on a case-by-case basis.

After reviewing all of the information you have provided, we have determined that requiring your subgrantee Miracle Hill to comply with the religious non-discrimination provision of 45 CFR § 75.300(c) would cause a burden to religious beliefs that is unacceptable under RFRA. While this determination is sufficient to require the granting of your request for an exception from such provision of the regulation, we also note that the application of the regulatory requirement would also cause a significant programmatic burden for the SC Foster Care Program by impeding the placement of children into foster care.

For these reasons, under 45 CFR § 75.102(b), HHS is hereby conditionally granting the requested exception from the religious non-discrimination requirement of 45 CFR § 75.300(c). The exception applies with respect to Miracle Hill or any other subgrantee in the SC Foster Care Program that uses similar religious criteria in selecting among prospective foster care parents. The exception applies on the condition that Miracle Hill, or any other subgrantee making use of this exception, be required to refer potential foster parents that do not adhere to the subgrantee's religious beliefs to other subgrantees in the SC Foster Care Program, or to refer them to the SC Foster Care Program staff themselves, if the SC Foster Care Program staff is equipped to refer those persons to other willing subgrantees. This condition is added on the understanding that Miracle Hill, and any other subgrantee making use of this exception, does not object on religious grounds to making such referrals and, therefore, the condition does not implicate additional RFRA concerns.

Please note that this exception does not relieve the SC Foster Care Program of its obligation to comply with any other requirements of 45 CFR Part 75.300(c), of other paragraphs of 45 CFR Part 75.300, of 42 U.S.C. § 671(a)(18), or of any provisions of civil rights statutes, including Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, and section 504 of the Rehabilitation Act of 1973 that may apply.[1]

If you require any additional information, please contact me at 202.205.7747.

Sincerely,

Steven Wagner
Principal Deputy Assistant Secretary
Administration for Children and Families

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[1] 42 U.S.C. § 2000d *et seq.,* 20 U.S.C. § 1681 *et seq.,* 42 U.S.C. § 6101 *et seq.,* and 29 U.S.C. § 794, respectively.

COMMUNICATIONS

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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 2020 Budget Request.

The federal budget process is broken. The solution must include incentives to keep the process moving. Automatic appropriations would occur at *Joint Budget Resolution* marks, and if no resolution is passed, revised *Budget Control Act* spending caps would end this difficulty and spur action by both parties. Because BCA levels are too low, the marks in the Act could be increased by the legislation amending the process itself. These marks should be realistic rather than punitive. Part of any reform must include new caps be set through 2025, when parts of the TCJA expire as well.

We have added a Carbon Value-Added Tax to the first bullet of our comprehensive four part approach to tax reform. An 25% Asset Value-Added Tax will be added to the second bullet so that capital gains taxes can be repealed, making automatic filing possible based on submissions to the IRS from federal NBRT income and tax credit data provided by state revenue agencies (see bullet four). Aside from these changes, our proposals are identical to what we have stated previously, and can be found in Attachment One.

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: Center for Fiscal Equity Detailed Proposals

Most of our proposals are about tax and entitlement policy and the process of estimating discretionary spending, rather than specific recommendations for departmental budgets. As a reminder and to education new members, here is our four-part approach to tax reform:

- A Value-Added Tax (VAT) to fund domestic military spending and domestic discretionary spending with a rate between 10% and 13%, which makes sure very American pays something. A Carbon VAT is included.
- Personal income surtaxes on joint and widowed filers with net annual incomes of $100,000 and single filers earning $50,000 per year to fund net interest payments, debt retirement and overseas and strategic military spending and other international spending, with graduated rates between 5% and 25%. Capital Gains Taxes will be replaced by a 25% VAT on Asset Sales, making automatic filing possible.
- Employee contributions to Old-Age and Survivors Insurance (OASI) with a lower income cap, which allows for lower payment levels to wealthier retirees without making bend points more progressive.
- A VAT-like Net Business Receipts Tax (NBRT), which is essentially a subtraction VAT with additional tax expenditures for family support, health care and the private delivery of governmental services, to fund entitlement spending and replace income tax filing for most people (including people who file without paying), the corporate income tax, business tax filing through individual income taxes and the employer contribution to OASI, all payroll taxes for hospital insurance, disability insurance, unemployment insurance and survivors under age

60. Collection would be accomplished by the states, who would forward data to the IRS.

Discretionary activities of the Department of Health and Human Services would be funded by the VAT. While some of our VAT proposals call for regional breakdowns of taxing and spending, they do not for this department. While some activities, such as the Centers for Disease Control, exist outside the Washington, DC metro area, even these are site specific rather than spread out on a nation-wide basis to serve the public at large. While some government activities benefit from national and regional distribution, health research will not.

The one reform that might eventually be considered in this area is to more explicitly link government funded research with ownership of the results, so that the Department might fund some of their operations with license agreements for some of the resulting research, enabling an expanded research agenda without demanding a higher budget allocation.

Of course, regionalization is possible if the Uniformed Public Health Service is put into the role of seeing more patients, particularly elderly patients and lower income patients who are less than well served by cost containment strategies limiting doctor fees. Medicaid is notoriously bad because so few doctors accept these patients due to the lower compensation levels, although we are encouraged the health care reform is attempting to reduce that trend. Medicare will head down that road shortly if something is not done about the Doc Fix. It may become inevitable that we expand the UPHS in order to treat patients who may no longer be able to find any other medical care. If that were to happen, such care could be organized regionally and funded with regionally based taxes, such as a VAT.

The other possible area of cost savings has to do with care, now provided for free, on the NIH campus. While patients without insurance should be able to continue to receive free care, patients with insurance likely could be required to make some type of payment for care and hospitalization, thus allowing an expansion of care, greater assistance to patients who still face financial hardship in association with their illnesses and a restoration of some care that has been discontinued due to budget cuts to NIH. This budget contains even more cuts. These should not be allowed. Rather, previous cuts must be restored.

The bulk of our comments have to do with health and retirement security.

One of the most oft-cited reforms for dealing with the long-term deficit in Social Security is increasing the income cap to cover more income while increasing bend points in the calculation of benefits, the taxability of Social Security benefits or even means testing all benefits, in order to actually increase revenue rather than simply making the program more generous to higher income earners. Lowering the income cap on employee contributions, while eliminating it from employer contributions and crediting the employer contribution equally removes the need for any kind of bend points at all, while the increased floor for filing the income surtax effectively removes this income from taxation. Means testing all payments is not advisable given the movement of retirement income to defined contribution programs, which may collapse with the stock market—making some basic benefit essential to everyone.

Moving the majority of Old-Age and Survivors Tax collection to a consumption tax, such as the NBRT, effectively expands the tax base to collect both wage and nonwage income while removing the cap from that income. This allows for a lower tax rate than would otherwise be possible while also increasing the basic benefit so that Medicare Part B and Part D premiums may also be increased without decreasing the income to beneficiaries. Increasing these premiums essentially solves their long term financial problems while allowing repeal of the Doc Fix.

If personal accounts are added to the system, a higher rate could be collected, however recent economic history shows that such investments are better made in insured employer voting stock rather than in unaccountable index funds, which give the Wall Street Quants too much power over the economy while further insulating ownership from management. Too much separation gives CEOs a free hand to divert income from shareholders to their own compensation through cronyism in compensation committees, as well as giving them an incentive to cut labor costs more than the economy can sustain for consumption in order to realize even greater bonuses.

Employee-ownership ends the incentive to enact job-killing tax cuts on dividends and capital gains, which leads to an unsustainable demand for credit and money

supply growth and eventually to economic collapse similar to the one most recently experienced.

Congress just adopted a Chained CPI, but no additional fund has been proposed for poor seniors or the disabled, which means there will be suffering. This should not be allowed without some readjustment of base benefit levels, possibly by increasing the employer contribution and grandfathering in all retirees. This is easily done using our proposed NBRT, which replaces the Employer Contribution to OASI and all of DI and should be credited equally to all workers rather than being a function of income.

The NBRT base is similar to a Value-Added Tax (VAT), but not identical. Unlike a VAT, an NBRT would not be visible on receipts and should not be zero rated at the border—nor should it be applied to imports. While both collect from consumers, the unit of analysis for the NBRT should be the business rather than the transaction. As such, its application should be universal—covering both public companies who currently file business income taxes and private companies who currently file their business expenses on individual returns.

A key provision of our proposal is consolidation of existing child and household benefits, including the Mortgage Interest and Property Tax Deductions, into a single refundable Child Tax Credit of at least $500 per month, per child, payable with wages and credited against the NBRT rather than individual taxes. Ending benefits for families through the welfare system could easily boost the credit to $1,000 per month for every family, although the difference would also be made up by lowering gross and net incomes in transition, even for the childless.

Assistance at this level, especially if matched by state governments may very well trigger another baby boom, especially since adding children will add the additional income now added by buying a bigger house. Such a baby boom is the only real long-term solution to the demographic problems facing Social Security, Medicare and Medicaid, which are more demographic than fiscal. Fixing that problem in the right way adds value to tax reform. Adopting this should be scored as a pro-life vote, voting no should be a down check to any pro-life voting record.

The NBRT should fund services to families, including education at all levels, mental health care, disability benefits, Temporary Aid to Needy Families, Supplemental Nutrition Assistance, Medicare and Medicaid. Such a shift would radically reduce the budget needs of HHS, while improving services to vulnerable populations, although some of these benefits could be transferred to the Child Tax Credit.

The NBRT could also be used to shift governmental spending from public agencies to private providers without any involvement by the government—especially if the several states adopted an identical tax structure. Either employers as donors or workers as recipients could designate that revenues that would otherwise be collected for public schools would instead fund the public or private school of their choice. Private mental health providers could be preferred on the same basis over public mental health institutions. This is a feature that is impossible with the FairTax or a VAT alone.

To extract cost savings under the NERT, allow companies to offer services privately to both employees and retirees in exchange for a substantial tax benefit, provided that services are at least as generous as the current programs. Employers who fund catastrophic care would get an even higher benefit, with the proviso that any care so provided be superior to the care available through Medicaid. Making employers responsible for most costs and for all cost savings allows them to use some market power to get lower rates, but not so much that the free market is destroyed. Increasing Part E and Part D premiums also makes it more likely that an employer-based system will be supported by retirees.

Enacting the NBRT is probably the most promising way to decrease 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. While not all employers would participate, those who do would dramatically alter the market. In addition, a kind of beneficiary exchange could be established so that participating employers might trade credits for the funding of former employees who retired elsewhere, so that no one must pay unduly for the medical costs of workers who spent the majority of their careers in the service of other employers. Conceivably, NBRT offsets could exceed revenue. In this case, employers would receive a VAT credit.

The Administration believes that the Affordable Care 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.

We suggest to the Secretary that he have an option ready when this occurs. Enactment of a tax like the NBRT will likely be necessary in the unlikely event the ACA collapses. It could also be used to offset non-wage income tax cuts proposed by the House, rather than cutting coverage for older, poorer and sicker Americans. Single-payer is inevitable unless the President is simply blowing smoke about the ACA failing.

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Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairman Grassley, Ranking Member Wyden, and the Members of the United States Committee on Finance for the opportunity to submit a statement on "The President's Fiscal Year 2020 Budget."

NACDS and the chain pharmacy industry are committed to partnering with Congress, HHS, patients, and other healthcare providers to improve access to quality, affordable healthcare services. NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 157,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit *nacds.org*.

As this Committee examines the President's Fiscal Year 2020 Budget, we offer the following for your consideration, with a specific focus on the FY 2020 Department of Health and Human Services (HHS) Budget Request.

Lowering Costs Through Pharmacy DIR Reform

The FY 2020 HHS Budget Request notes steps the Department took in the past year aimed at lowering the cost of prescription drugs, including ensuring beneficiaries are benefiting from price concessions at the pharmacy counter. We urge HHS to continue these actions in FY 2020 by finalizing provisions in the November 2018 Centers for Medicare and Medicaid Services (CMS) proposed rule "Modernizing Part D and Medicare Advantage to Lower Prices and Reduce Out-of-Pocket Expenses" that would increase competition in the Medicare Part D program and lower beneficiary out-of-pocket costs by reforming pharmacy direct and indirect remuneration (DIR) fees. CMS has proposed to reform pharmacy DIR by requiring that pharmacy price concessions are passed on to patients.[1] Specifically, these reforms include:

- **Redefining the "'negotiated price" to include all pharmacy price concessions.** Including all pharmacy price concessions in the negotiated price would reduce its amount and result in lower beneficiary cost sharing;
- **Developing a broad definition of "price concession" to include all forms of discounts, direct or indirect subsidies, or rebates that serve to reduce costs incurred by Part D sponsors.** Again, this would help ensure the lowest negotiated price and thus, lower beneficiary cost-sharing; and
- **Developing standardized pharmacy performance metrics for 2020 as the first step toward the development of Medicare Part D pharmacy**

[1] 83 Fed. Reg. 62152, 62190–92 (Nov. 30, 2018).

quality incentive program. HHS needs to develop a pharmacy quality incentive program to align incentives between plans, pharmacies and beneficiaries. Pharmacy incentive payments would support higher quality and health outcomes. Examples are medication optimization and improved medication adherence, which would improve patient outcomes and reduce downstream healthcare costs.

The use of pharmacy DIR fees grew an astonishing 45,000 percent between 2010 and 2017.[2] Because of this, Medicare beneficiaries are paying more out-of-pocket, the federal government is not fully understanding what it is paying for prescription drugs, and retail pharmacies are conducting business in an environment where they are unsure whether a payment will be clawed back at some later date as "DIR."

As CMS has thoroughly documented, pharmacy DIR fees increase beneficiary drug costs and increase taxpayer costs for catastrophic coverage and low-income cost-sharing subsidies.[3] CMS also recognizes that pharmacy DIR fees harm pharmacies by reducing transparency and predictability of reimbursement.[4] More broadly, pharmacy DIR fees undermine drug price transparency, which is necessary for efficient market competition that would reduce prescription drug costs.[5] CMS has recognized the harms caused by pharmacy DIR fees for years.[6]

Pharmacy DIR fees obfuscate true drug prices, thus undermining the transparency needed to allow all stakeholders, notably patients and providers, to make informed decisions about how to best meet healthcare needs. As CMS also points out, "consumers cannot efficiently minimize both their costs and costs to the taxpayers by seeking and finding the lowest-cost drug or a plan that offers them the lowest-cost drug and pharmacy combinations."[7]

Beneficiaries are likely unaware that the increasing use of pharmacy DIR fees has led to inflated drug costs, and thus higher cost-sharing. The impact of higher cost-sharing for beneficiaries also negatively impacts medication adherence, leading to increased total cost of care and poorer health outcomes.

Better Medication Adherence and Medication Optimization Reduce Healthcare Costs

Finalizing pharmacy DIR reform needs to be coupled with the development of standardized pharmacy quality metrics and a pharmacy quality incentive program. Without a standard set of metrics, beneficiaries, pharmacies, and plans are unable to make comparisons of pharmacy quality. As a result, there is not an effective means for consumers to compare plans and pharmacies within the Part D program, undercutting market competition.

Pharmacy DIR fee reform and the development of a standardized pharmacy quality incentive program will save taxpayers billions of dollars by aligning incentives for the entire Medicare program, which will encourage a more systematic investment in pharmacy quality programs designed to facilitate care coordination, reduce medical errors, advance population health, and empower and motivate beneficiaries to achieve better health outcomes through medication optimization services and improved medication adherence.

Medication optimization services encompass patient-centered activities that improve health outcomes by addressing medication appropriateness, effectiveness, safety, adherence, and access. Medication optimization services delivered by community pharmacies are central to the care of beneficiaries. Nearly all Americans (91.7 percent) live within 5 miles of a community retail pharmacy and in 2017 nearly 73 percent of prescriptions dispensed in theU.S. were filled at retail pharmacies. Face-to-face interactions with beneficiaries at the point-of-dispensing allow the pharmacist to

[2] *Id.* at 62147.
[3] *Id.* at 62190–92.
[4] *Id.* at 62191.
[5] *Id.* at 62176.
[6] *See, e.g.,* 82 Fed. Reg. 56336, 56420–21 (Nov. 28, 2017) (explaining how pharmacy DIR fees increase beneficiary costs and decrease drug price transparency necessary for competition among plans); CMS, Medicare Part D—Direct and Indirect Remuneration (DIR) (Jan. 19, 2017) (noting the negative impact of pharmacy DIR fees on beneficiary drug costs, taxpayer subsidies and plan cost-avoidance); CMS, "Fact Sheet—Medicare Part D—Direct and Indirect Remuneration (DIR)" (Jan. 19, 2017), available at *https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir.*
[7] *Id.* at 62176.

counsel and educate the patient and are critical to achieving national-scale improvements in health outcomes and lowered costs.[8]

The better use of medicines will also reduce medication non-adherence—that is, patients not taking their medications as prescribed by their healthcare provider. Medication non adherence contributes to $100–$290 billion in unnecessary healthcare expenditures every year as a result of increased hospitalizations and other avoidable, expensive medical services.[9, 10, 11] Numerous studies have shown that reducing patient drug costs increases medication adherence, which, in turn, reduces overall healthcare costs. For example, a recent study found that medication nonadherence for diabetes, heart failure, hyperlipidemia, and hypertension resulted in billions of dollars in Medicare fee-for-service expenditures, millions of hospital days, and thousands of emergency department visits that could have been avoided.[12] Specifically, the study estimated that avoidable costs from medication nonadherence of four chronic conditions is $28.9 billion, representing 8 percent of the total expenditures. A 2017 white paper found that the direct medical costs and consequences related to not taking medication as prescribed is estimated to be 7 to 13 percent of national health spending annually—approximately $250 billion to $460 billion in 2017, translated to a potential cost to taxpayers of $6 trillion over 10 years.[13] And a 2016 cost-benefit analysis concluded that between one and two thirds of medication-related hospitalizations are caused by poor adherence. Improving adherence could result in annual per-person savings ranging from $1,000 to $7,000, depending on the disease state.[14] Multiple, credible sources have drawn the same conclusion: medication non-adherence is a costly, preventable problem that dramatically affects total cost of care.

Value of Pharmacy

NACDS urges Congress and HHS to explore opportunities to utilize pharmacists to their fullest extent in improving access to high-quality, affordable healthcare and improving overall health outcomes. For generations, Americans have relied on their local, community pharmacists to meet their healthcare needs—trusted, highly accessible healthcare providers deeply committed to providing accurate prescriptions and helping patients take medications as prescribed.

Pharmacist Provider Status

The full value of pharmacy is broader in scope, however. Pharmacies and pharmacists are being recognized for their abilities to provide high-quality healthcare services at an overall lower cost.

Millions of Medicare beneficiaries lack adequate access to primary healthcare services, and this is only expected to increase as the number of enrollees grows. According to the American Association of Medical Colleges (AAMC), by 2030, we will face

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[8] Patients who participated in brief face-to-face counseling sessions with a community pharmacist at the beginning of statin therapy demonstrated greater medication adherence and persistency than a comparison group who did not receive face-to-face counseling. The intervention group had statistically greater Medication Possession Ratio (MPR) than the control group every month measured. Taitel, M., Jiang, J., Rudkin, K., Ewing, S., and Duncan, I.; "The impact of pharmacist face-to-face counseling to improve medication adherence among patients initiating statin therapy;" *Patient Prefer Adherence;* 2012;6:323–9; *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3340117/*. Likewise, a systematic review was conducted using 51 studies determining the optimal modes of delivery for interventions to improve adherence to cardiovascular medications. Among person-dependent interventions (nonautomated phone calls, in-person interventions), phone calls showed low success rates (38%). In-person pharmacist interventions were effective when held in a pharmacy (83% successful) but were less effective in clinics (38%). Cutrona, S.L., and Chaudhry, N.K., et al.; "Modes of Delivery for Interventions to Improve Cardiovascular Medication Adherence;" *AJMC;* December 2010; *https://www.ajmc.com/journals/issue/2010/2010-12-vol16-n12/ajmc_10dec_cutrona929to942?p=1.*

[9] Rosenbaum, L. and Shrank, W.H.; "Taking Our Medicine—Improving Adherence in the Accountability Era;" *New England Journal of Medicine;* Aug. 22, 2013.

[10] Network for Excellence in Health Innovation; "Bend the Curve: A Health Care Leader's Guide to High Value Health Care;" 2011.

[11] The NCPIE Coalition; "Enhancing Prescription Medicine Adherence: A National Action Plan;" 2007.

[12] Lloyd, Jennifer T., Maresh, Sha, Powers, Christopher, Shrank, W.H., and Alley, Dawn E.; "How Much Does Medication Nonadherence Cost the Medicare Fee-for-Service Program?"; *Medical Care,* January 2019.

[13] "A Treatable Problem: Addressing Medication Nonadherence by Reforming Government Barriers to Care Coordination;" Prescriptions for a Healthy America; October 2017.

[14] Patterson, J.A., et al.; "Cost-Benefit of Appointment-based Medication Synchronization in Community Pharmacies;" *American Journal of Managed Care*; 2016.

a shortage of more than 120,000 doctors.[15] Pharmacists are uniquely positioned to help address this anticipated shortage by playing a greater role in the delivery of healthcare services in collaboration with other healthcare team providers.

NACDS' member chain community pharmacies are accessible, patient-centered healthcare destinations. One study of a high-risk Medicaid population found that patients visited their pharmacies 35 times per year, compared to seeing their primary care doctors 4 times per year, and specialists 9 times per year.[16] Voters agree:

- 83% of voters say that pharmacies are easy to access.[17]
- 80% of voters have visited a pharmacy in the past twelve months.[18]

Community pharmacists are among the advanced healthcare professionals with doctorate level education and years of clinical training. Pharmacists' education and training equips them to provide many services in addition to dispensing and educating patients on their medications. Such services include health tests and screenings, management of chronic conditions and related medications, point of care testing (*e.g.,* flu, strep) and immunization screening and administration. Pharmacists have been recognized by numerous states through their scope of practice laws to provide these and other services to patient populations. However, while physicians and certain other providers are already reimbursed under Medicare Part B for providing similar services, pharmacists are not.

Community pharmacists reduce the costs of health care by improving patient care and collaboration among providers, optimizing medication use for improved patient outcomes, contributing to medication error prevention, and preventing hospital readmissions cost avoidance, which cost Medicare $26 billion annually.[19]

Pharmacists can also be better utilized to respond to immediate public health needs. For example, in the battle against the opioid crisis pharmacists can help identify and treat those with opioid addiction or who may be prone to addiction. This includes providing services such opioid antagonist counseling or opioid risk factor intervention services.

We urge members of the Committee to support soon-to-be introduced legislation that will recognize pharmacists as Medicare providers, allowing them to offer a greater role in the delivery of healthcare services and work in collaboration with other providers in addressing opioid abuse and misuse.

Addressing the Opioid Epidemic

In addition to recognizing pharmacists as key providers in the battle against the opioid epidemic, NACDS supports additional policy solutions to reduce the incidence of opioid addiction and abuse, including:

- Requiring that all prescriptions be issued electronically with limited exceptions;
- Legislate a 7-day supply limit for the prescribers of initial opioid prescriptions issued for acute pain;
- Collaboration with stakeholders on a nationwide prescription drug monitoring program (PDMP) database; and
- Providing manufacturer-funded mail-back envelopes for unused opioid drugs, available to patients at pharmacies upon request.

NACDS seeks to partner with lawmakers to advance these key policy initiatives. NACDS seeks the support of members of the 116th Congress to enact legislation establishing a 7-day supply limit for initial opioid prescriptions written for acute pain.

Per the Centers for Disease Control and Prevention (CDC), a greater amount of opioid exposure increases the risk of long-term use and addiction. Notably, the average day supply per opioid prescription has increased in recent years, from 13.3 to 18.1 days per prescription between 2006 and 2016. Considering this trend and the risk of exposure to higher amounts of opioids, lawmakers must adopt policies to promote careful prescribing practices for prescription opioids.

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[15] HIS Markit, LTD; "The Complexities of Physician Supply and Demand: Projections from 2016 to 2030;" Prepared for Association of American Medical Colleges, March 2018.

[16] Moose, J. and Branham, A.; "Pharmacists as Influencers of Patient Adherence;" *Pharmacy Times,* August 21, 2014.

[17] Poll conducted by Morning Consult from January 4–6, 2019, among a national sample of 1995 registered voters.

[18] *Id.*

[19] Agency for Healthcare Research and Quality. Statistical Brief #172, April 2014. Available from: *http://www.hcup-us.ahrq.gov/reports/statbriefs/sb172-Conditions-Readmissions-Payer.pdf* (accessed Dec. 9, 2014).

Enactment of 7-day supply limits for acute opioid prescriptions is supported by the CDC prescribing guidelines, as it helps reduce the incidence of misuse, abuse, and overdose of these drugs. So far, over 30 states have adopted laws or other policies limiting the maximum day supply that can be authorized on an initial opioid prescription for acute pain.

NACDS encourages members of the Committee to support legislation that is standardized nationwide to promote consistent patient care and implementation that limits initial opioid prescriptions for acute pain to no more than a 7-day supply. If pain continues, the prescriber may issue any appropriate new prescription.

When addressing our nation's opioid epidemic, voters are most likely to understand that pharmacists are part of the solution, rather than the problem. This is a distinction that pharmacists share with law enforcement. For example:

- 65% of voters support allowing pharmacists to work with Medicare patients to help prevent, detect or treat potential opioid abuse (17% oppose; 28% don't know/no opinion).[20]
- 61% of voters support requiring that all prescriptions be issued and handled electronically to reduce fraud and abuse (19% oppose; 20% don't know/no opinion).[21]
- 58% of voters support limiting the initial fill of certain opioid prescriptions to a seven-day supply to reduce the incidence of addition and abuse (24% oppose; 28% don't know/no opinion).[22]

Pharmacies and pharmacists are integral to our nation's healthcare system. They are among the most accessible healthcare providers and provide high-quality healthcare services that are not only lower cost, but also prevent more costly downstream healthcare services.

Specific Medicare Part D Concerns

Beyond our concerns that HHS address DIR reform, we also ask the Committee to raise the following issues with HHS:

Broader Use of Prior Authorization and Step Therapy, New Formulation and Drug Price Increases Exceptions

In the November 2018 Part D Rule, CMS proposed providing Part D plans with a number of utilization management tools designed to drive the utilization of lower cost drugs.[23] Specifically, CMS is proposing to allow plans: (1) to use prior authorization for protected class drugs or to determine use for protected class indications or both, (2) to exclude from their formularies a protected class single-source drug or biological product for which the manufacturer introduces a new formulation with the same active ingredient or moiety that does not provide a unique route of administration, and (3) to exclude from their formularies any single-source drug or biological product that is a protected class drug whose price increases, relative to the price in a baseline month and year, beyond the rate of inflation.

NACDS supports efforts to curb the rising costs of prescription drugs but cautions that any action that HHS takes must be balanced with ensuring access to needed prescriptions drugs for Medicare beneficiaries. Plans should only be allowed flexibility to make changes to the treatment of protected class drugs and manage drugs through exception processes to the extent that doing so does not reduce drug coverage. Limiting access to prescription drugs can have unintended consequences, including decreased medication adherence, which further leads to poorer health and increased costs down the road.

In order to ensure beneficiary access and adherence is not jeopardized, NACDS recommends that any policies making changes in utilization management of protected classes be based on clinical parameters focused on the best treatment for the patient. Specifically, we recommend the following parameters be considered in allowing plans more flexibility with respect to utilization management tools:

- Only apply to new starts *and* only if guided by drug-selection assay criteria (*e.g.,* genotypic assay),
- Not apply to products that show improved adherence, convenience, or tolerability profile, and

[20] Poll conducted by Morning Consult from January 4–6, 2019, among a national sample of 1995 registered voters.
[21] *Id.*
[22] *Id.*
[23] 83 Fed. Reg. 62152 (Nov. 30, 2018).

- Apply only to non-protected class indications.

We believe implementing such protections will help ensure beneficiaries will continue to have access to the treatments they need to best address their healthcare needs.

Ensuring access to needed medications is particularly crucial for the most vulnerable beneficiaries, such as those being treated with antiretrovirals (ARVs) and antineoplastics. The treatment of those with HIV and cancer involves unique challenges not present with other patients and therapies within the Part D program. For example, patients with HIV are now living longer than ever before due to advances in clinically superior treatment options, however, challenges such as evolving HIV population demographics and increases in costs for HIV treatment contribute to suboptimal adherence to drug regimens and risk of ARV resistance.

Similarly, the use of individualized and targeted therapy, tumor-agnostic therapy, CAR T-cell, gene and other therapies for cancer patients have greatly improved the specificity of treatment as well as long-term outcomes and survival. This has only increased the importance of immediate access to a wide array of therapies, as any delay can have catastrophic effects. Traditional utilization management tools are of limited usefulness due to the individualized and targeted nature of modern cancer treatments that do not have other clinically interchangeable options.

The unique challenges that patients living with HIV/AIDS and cancer face must be balanced with traditional utilization management tools and approached in a manner that ensures access to a broad array of treatment options. These challenges require that effective treatment options be available among the six protected drug classes. We ask that the Committee members communicate to HHS that the agency must ensure that any changes to drug management or drug formularies do not come at the cost of patient access and medication adherence, and especially so for vulnerable patient populations.

Prohibition Against Gag Clauses in Pharmacy Contracts

NACDS applauds Congress for passing the "Know the Lowest Price Act of 2018" (Pub. L. 115–262) that prohibits plans from restricting their network pharmacies from informing their plan enrollees of the availability of prescription drugs at a cash price that is below what that the enrollee would be charged (either the cost sharing amount or the negotiated price when it is less than the enrollee's cost sharing amount) for the same drug under the enrollee's plan. We are encouraged that CMS states that the measure will become effective with the plan year starting January 1, 2020. The prohibition of gag clauses in contracts among plans, Medicare Advantage plans, PBMs, and pharmacies will enhance patient access to medications, enable pharmacists to have improved relationships with patients, and keep healthcare costs for patients to a minimum. We look forward to working with you to implement this important requirement.

Part D Explanation of Benefits

CMS also proposed to require that plans include the cumulative percentage change in the negotiated price since the first day of the current benefit year for each prescription drug claim in the explanation of benefits (EOB). NACDS agrees that providing beneficiaries with necessary information to make informed choices about their health care, including making determinations about whether a prescription is covered under their plan is a valuable goal and could help reduce costs and lead to better health. However, the usefulness of the information is time sensitive and providing this information after a prescription has been filled, such as through the EOB or through an end-of-the-year annual statement, may allow a beneficiary to make a more informed choice going forward, but misses the opportunity to make an immediate change, as could be done if the information were provided at the point of prescribing.

To this end, we ask members of the Committee to communicate to HHS that the agency should adopt provisions that allow the prescriber to make a coverage determination and access cost information at the point of prescribing. Providing information at the point of prescribing will allow the beneficiary to work with his or her prescriber to find alternative or lower cost solutions and avoid unnecessary delay and potential lapses in therapy.

Electronic Prescribing and the Part D Prescription Drug Plan

NACDS strongly supports patient-centered policies and legislation that lower patient costs, including the efforts of HHS and CMS in integrating a patient-specific real-time benefit tool (RTBT) into the Part D benefit to drive lower prescription

drug spending and minimize beneficiary out-of-pocket costs. Beneficiaries often arrive at the pharmacy counter with little or no insight as to what a medication will cost them, which can lead to overuse of unnecessarily expensive medications and the underuse of essential medications. We strongly agree with CMS that "reducing medication cost also yields benefits in patients' medication adherence" and that "increasing patient cost-share for a medication [is] associated with a significant decrease in medication adherence."[24] The integration of a RTBT into the Part D benefit will give providers and beneficiaries the information needed to make better informed choices on their healthcare treatment.

While appreciating CMS' efforts to improve access to clinically appropriate and cost information, NACDS cautions policies utilizing RTBTs must be designed to provide information in a manner that allows the prescriber to make a determination about whether a prescribed drug is covered by the beneficiary's insurance plan without fear of "steering" a beneficiary to certain pharmacies or to mail order. This could be accomplished by requiring the beneficiary to select his or her pharmacy of choice prior to the prescriber utilizing the RTBT to access the enrollee cost-sharing information. Moreover, we believe that the RTBT must provide sufficient information to the prescriber and pharmacy to facilitate clinical decision making that will inform prescribers and pharmacists to assist in determining optimal patient medication regimens.

RTBTs must also be able to take into consideration pharmacy-level cost-containment programs, such as $4.00 generic programs, or patient assistance programs. Moreover, absent system safeguards, RTBTs can inadvertently drive physician prescribing of expensive, therapeutically alternatives that are subject to high rebate arrangements between PBMs and manufacturers. Such results would needlessly drive up the overall spending of the Part D program. Policies utilizing RTBTs must:

1. Preserve patient's right to pharmacy selection at the outset;
2. Ensure accurate and complete patient's out-of-pocket costs at formulary and pharmacy levels;
3. Avoid unintended economic costs to taxpayers and beneficiaries associated with steering patients to therapeutic alternatives that are subject to "spread pricing" due to excessive list prices and rebates;
4. Not allow commercial messaging within RTBT transmissions; and
5. Ensure information integrity, fairness and accuracy among others.

Again, we ask members of the Committee to communicate to HHS the need for RTBTs to be implemented in a way that serves its goals of providing timely information that would lower prescription drug costs.

Conclusion

NACDS thanks the Committee for your consideration of our comments. We urge members of the Committee to ask HHS to use their authority to include pharmacy DIR fee reform, the development of standardized pharmacy quality metrics, and the development of a pharmacy quality incentive program in the Final Part D Rule for FY 2020. Additionally, we encourage the Committee to support policy solutions that recognize the value pharmacy provides in helping combat the opioid epidemic and helping reduce patient costs while improving overall health.

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[24] *Id.* at 62165.