Energy & Commerce Subcommittee on Health QFRs
Hearing on
"The Fiscal Year 2020 HHS Budget"
Hearing Date: March 12, 2019

Drug Pricing

The Honorable Frank Pallone, Jr. (D-NJ)

Prescription Drug Rebate Rule

On January 31st, the Department of Health and Human Services (HHS) and the HHS Office of Inspector General (HHS OIG) issued a proposed rule to exclude from safe harbor regulations certain prescription drug discounts currently protected from liability under Federal anti-kickback statute. If finalized, this rule would ban the use of certain rebates in the Medicare Part D and Medicaid managed care programs and dramatically alter the payment structure for prescription drugs in these programs.

The Centers for Medicare & Medicaid Services (CMS) Office of the Actuary (OACT) estimated that Federal spending would increase by $196 billion over 10 years as a result of this rule, and that premiums would increase by $50 billion for Part D enrollees. This is a significant price tag for a proposed rule, especially when the goal of the rule is to lower costs for consumers.

1. In addition to the Office of the Actuary's analysis, the proposed rule also included two additional independent analyses that were commissioned by HHS. Why did HHS include these additional analyses in the proposed rule?

   Response: The proposed rule addressing the removal of safe harbor protections for rebates involving prescription pharmaceuticals included the perspectives of the CMS Office of the Actuary and two external actuarial firms, Milliman and Wakely, who were chosen by ASPE based on their commercial experience assisting plan sponsors with their plan bids.

2. Why were Milliman and Wakely Consulting Group selected to perform these independent analyses? Did HHS provide Milliman and Wakely Consulting Group with any directions or assumptions to factor into their analyses?

   Response: Milliman and Wakely are independent actuarial firms experienced with helping Part D plans and other insurers file their annual plan bids. As such, they were engaged to help the department anticipate strategic behavioral responses to future rulemaking and, ultimately, have a more informed regulatory impact analysis. Specifically:

   - HHS/ASPE studied actuarial models related to Part D rebates as part of its work evaluating a proposed rule published by CMS in November 2017.

   - The CMS Office of the Actuary conducted the analyses contained in that

proposed rule.

- During a literature review conducted by ASPE in 2017, Milliman was identified as a consulting actuary with experience providing actuarial estimates for both manufacturers and PBMs. As such, they were chosen because of their insights into the strategic behavior used on either side of the negotiating table.

- Wakely was similarly engaged because they were already under contract with ASPE for a different project, and had expertise related to commercial health plans outside of the Part D program.

- As a result, the Department's rulemaking was informed by actuarial estimates assuming a variety of industry responses, included manufacturers keeping a portion of their rebate and Part D plans negotiating larger price concessions from manufacturers.

3. Going forward, does HHS plan to include additional commissioned analyses in all proposed rules, or just in the rules in which HHS disagrees with its own actuary?

   Response: HHS believes it is important for taxpayers to understand the potential real-world impact of economically significant rules and will commission future outside analyses where appropriate.

4. Which actuarial analysis should be considered the official estimate for the purposes of considering this rule?

   Response: All three estimates are included in the proposed rule for public consideration.

5. The Office of the Actuary determined that the majority of beneficiaries in Medicare Part D would see an increase in their total out of pocket costs, as well as their premiums. Does HHS have concerns regarding the beneficiary impact of this rule?

   Response: If there is a change in the safe harbor rules effective in 2020, CMS will conduct a demonstration that would test an efficient transition for beneficiaries and plans to such a change in the Part D program. The demonstration would consist of a modification to the Part D risk corridors for plans. For Calendar Year 2020, under the demonstration, the government would bear or retain 95 percent of the deviation between the target amount, as defined in section 1860D-15(e)(3)(B) of the Social Security Act (the Act) and the actual incurred costs, as defined in section 1860D-15(e)(1) of the Act, beyond the first 0.5 percent. Participation in the two-year demonstration would be voluntary and plans choosing to participate would do so for both years. Further guidance regarding the application process for the demonstration will be provided at a later date.

6. In the rule, HHS acknowledges that it is difficult to predict how manufacturers and insurers might respond to this rule. Does HHS agree that there is significant uncertainty around the implications for this policy?

Response: HHS wants to be certain that the rule is beneficial for American patients and taxpayers. That is why we commissioned additional studies and issued further guidance to Part D plans to help industry and the public understand the changes proposed and to ensure as smooth a transition as possible.

7. Is there anything in the proposed rule that would directly require drug manufacturers to reduce the list prices for their drugs?

8. Is it fair to say this proposal relies on the assumption that pharmaceutical companies will voluntarily reduce their prices?

9. I understand that the Administration believes that beneficiaries may see deeper discounts at the pharmacy counter, but is there anything in this rule that would affirmatively require this?

10. Does HHS disagree with the Office of the Actuary's analysis that manufacturers may use this rule as an opportunity to recoup lost revenue?

Response to 7-10: The current rebate system rewards list price increases, which benefit everybody but patients and taxpayers. If the proposed rule were to be finalized, plan sponsors would have an incentive to select lower-cost drugs over high-cost drugs with higher rebates and manufacturers would have an incentive to lower list prices or provide additional price concessions. Nothing in the proposed rule reduces the ability of PBM or plan sponsors to negotiate, nor relies on voluntary discounts by drug companies. Rather, the competitive nature of the Part D market would reward plan sponsors able to negotiate lower drug prices, reduce gross drug costs, and continue to offer affordable premiums.

Medicare Part D Protected Classes

On November 26th, CMS issued a proposed rule that would make changes to Medicare Part D's six protected classes. These six protected classes ensure that Medicare beneficiaries with serious conditions, such as HIV/AIDS, mental health conditions, cancer, and epilepsy have access to the medications they need. By ensuring that all Part D plans cover all or substantially all drugs within the six classes of drugs, beneficiaries with these conditions can know that their drugs will be covered when they need them the most.

Beneficiaries with these conditions are especially vulnerable to significant health consequences if there are interruptions in their drug therapies and often their medications are not easily substituted with other medications.

1. Does HHS believe the Administration has sufficiently considered the impacts this proposal could have on patients with conditions within the six protected classes?

2. Does HHS have concerns that changes to the protected classes could increase costs elsewhere if patients have lapses in their drug therapies, such as through increased hospital costs or emergency room visits?

3. Does HHS believe the savings from this rule outweigh the impact it could have on beneficiaries?

Response to 1-3: Under the current protected class policy, Part D sponsors are permitted to utilize step therapy (ST) and prior authorization (PA) on new starts (that is, enrollees initiating the therapy), with respect to five out of the six protected classes (i.e., anticonvulsants, antidepressants, antineoplastics, antipsychotics, and immunosuppressants for the treatment of transplant rejection but not antiretrovirals). Further, CMS conducts reviews of ST and PA criteria as part of the annual formulary review and approval process, and will only approve PA and ST criteria that are clinically supported. As such, under the current policy, a Part D sponsor is not permitted to interrupt a patient's course of treatment to require the patient to meet step therapy requirements.

In CMS' Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses Proposed Rule, issued in November 2018, CMS proposed broadening the use of prior authorization and step therapy. CMS' goal was to provide additional flexibility so that Part D sponsors could better manage the benefit from a clinical as well as a cost savings perspective. CMS believes that the existing beneficiary protections, including our extensive clinical formulary review and approval process, would adequately protect enrollees from the inappropriate application of PA and ST requirements. Moreover, CMS would effectively limit most ST criteria to new starts as best practice, except when a change in therapy is clinically supported by the recognized compendia or widely accepted treatment guidelines. When step therapy is applied, CMS would expect to approve PA or ST requirements with initial treatment that is comparably supported by recognized compendia or widely accepted treatment guidelines.

In the Final Rule issued on May 16, 2019, CMS concluded, based on comments received during the rulemaking process, that the risks associated with inappropriately interrupting therapy for stabilized patients receiving protected class drugs for protected class indications by potentially subjecting them to PA or ST requirements outweighs the potential clinical benefits that some enrollees could gain from switching therapies that might be more appropriate and the potential cost savings that would accompany the additional formulary management flexibility. Therefore, in the Final Rule, CMS finalized a codification of existing policy that allows Part D sponsors to apply PA and ST requirements for protected class Part D drugs, except for antiretroviral medications, only for new starts, to determine if a drug's intended use is for a protected class indication, ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval. PA and ST will continue to be prohibited for antiretroviral medications.

Exclusivity Forfeiture

1. In the FY2020 budget request, HHS proposes triggering an initial generic drug applicant's

180-day exclusivity when a subsequent application is tentatively approved, subject to specific conditions. Some have noted that federal law already forces a forfeiture of exclusivity when an initial generic drug applicant fails to market a drug. Why are forfeiture events already specified in law not sufficient to ensure first filers have the incentive to bring their drug to market in a reasonable time frame? Are further changes needed to FDA's current forfeiture authority to ensure timely entry of generics?

Response: Further statutory changes are needed because, currently, some generic drug applicants who file first limit competition by intentionally delaying seeking final approval in order to not trigger their 180-day exclusivity, thereby blocking subsequent generic competitors. The proposal, if enacted, would ensure that first-to-file generic applicants awarded a 180-day exclusivity period would not be able to unreasonably and indefinitely block subsequent generics from entering the market beyond the exclusivity period.

National Institutes of Health

1. In the FY2020 budget request, HHS proposes cutting funding at the National Institutes of Health (NIH) by more than $4.5 billion. Americans rely on the NIH for groundbreaking research in healthcare therapies, treatments, and cures. Although the HHS budget suggests that the requested funding level would preserve "research in the highest priority areas," the Administration has proposed cutting nearly every account at NIH by millions of dollars, including a $897 million cut from that National Cancer Institute, a $769 million at the National Institute of Allergy and Infectious Diseases, and a $486 million cut at the National Heart, Lung, and Blood Institute. Invariably, some high-priority research will not be funded. Can HHS provide context and detail on what specific programs and research initiatives the Administration is proposing to cut across the NIH?

   Response: 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. In general, NIH seeks to avoid reductions of a magnitude that would end programs or close labs, so that existing research activities can continue on a smaller scale or slower timeline.

Healthy People 2030

1. The Healthy People 2030 objectives for immunization and infectious disease are a cornerstone to federal, state, and local efforts to monitor our progress as a nation in protecting against vaccine-preventable conditions across the lifespan. I understand the draft Healthy People 2030 objectives includes very few immunization objectives (eight total). At a time when we are seeing increased outbreaks of diseases that were virtually eliminated in this country, can HHS explain the rationale behind the reduction in immunization objectives in the draft Healthy People 2030 framework and what the process looks like moving forward?

   Response: Ensuring that the United States' population is protected from infectious

diseases is an important national public health priority. While the number of immunization objectives proposed to be included in Healthy People 2030 has been reduced, the overarching strategic goal remains to increase vaccination across the lifespan for all Advisory Committee on Immunization Practices (ACIP) recommended vaccines. HHS and its agencies will continue to focus on monitoring, assessing, and responding to, any threats from infectious diseases.

As part of the process to develop Healthy People 2030, HHS issued a charge to the members of the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 (the Committee) to assist "in reducing the number of objectives while ensuring that the selection criteria identify the most critical public health issues that are high-impact priorities supported by current, national data sets." With guidance from this Committee, input from Healthy People's Federal Interagency Workgroup (a group of more than 30 Federal departments, agencies, and offices, who provide ongoing guidance to the initiative), and with leadership and support from the HHS Office of Disease Prevention and Health Promotion and the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics, criteria were developed to select objectives for Healthy People 2030. These criteria include: having current and regularly available, nationally representative data; addressing health concerns of national importance; having evidence-based approaches for improvement; and having an impact on reducing health disparities and achieving health equity. Federal subject matter experts were asked to prioritize the objectives that were the most crucial to the field and to improving the health and well-being of the Nation.

Experts from CDC spearheaded the efforts to prioritize the immunization and infectious disease objectives for Healthy People 2030. Using the criteria provided, they strategically chose the proposed priority areas to provide proxy measures for vaccination coverage across the lifespan. The broad national goal that HHS and its agencies are working towards in this area remains to increase and support vaccination coverage across the lifespan, and progress toward this goal will be monitored carefully.

While this set of objectives is being proposed for the launch of Healthy People 2030, there will be opportunities throughout the decade to review these objectives. If necessary, new or revised objectives can be proposed to help ensure that the health of the public across the lifespan is protected from infectious diseases by immunizations.

Nursing Workforce

1. For more than 50 years, nursing workforce development programs have helped us ensure that we have adequately trained nursing professionals. Nurses provide high quality care across the country and are vital for ensuring the long-term health of all Americans. I was dismayed when I saw that once again the Trump Administration has proposed cutting HRSA's nursing workforce programs, this time by 67 percent. Despite the success of these programs and the fact that demands are only increasing for nurses, the Trump budget proposes eliminating all but one Title VIII nursing workforce program. Can HHS explain how the Trump Administration believes cutting the Title VIII nursing programs will help ensure that we have the nursing workforce needed to meet the increasing health

needs of the U.S. population? Please detail the steps the Administration is taking to ensure that nursing workforce needs are met now and in the future.

Response: The Fiscal Year (FY) 2020 President's Budget includes funding for the Nurse Corps Scholarship and Loan Repayment Programs, both of which seek to ensure that we have the nursing workforce needed to meet the increasing health needs of the U.S. population. The Nurse Corps Scholarship Program provides scholarships to nursing students in exchange for a minimum two-year full-time service commitment (or part-time equivalent), at an eligible health care facility with a critical shortage of nurses. The Nurse Corps Loan Repayment Program provides loan repayment assistance to professional registered nurses (RNs), including advanced practice nurses (APRNs), in return for a minimum two-year full-time service commitment to work at eligible health care facilities with a critical shortage of nurses or serve as nurse faculty in eligible schools of nursing.

Title VII Workforce Programs

1. Title VII workforce development programs help ensure that we have a robust and diverse workforce of healthcare professionals who provide quality care. The programs promote ethnic and cultural diversity in the healthcare workforce and help ensure that the needs of all Americans, including those in rural and underserved areas, are met. As we continue to see an aging population and greater needs across many already underserved communities, the Trump budget once again slashes these critical workforce programs, including eliminating the Primary Care Training and Enhancement program, Health Professions Training for Diversity, Area Health Education Centers, and Geriatric Programs. Can HHS explain how the Trump Administration believes eliminating these workforce programs will help ensure that we have a diverse and sufficient workforce to care for the aging population and those in rural and underserved areas?

   Response: The FY 2020 President's 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. While funding for the cited programs has been eliminated in the FY 2020 President's Budget, the budget continues to request 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.

   Moreover, the Budget requests $83.1 million for the Nurse Corps Scholarship and Loan Repayment Programs. The Nurse Corps Scholarship Program provides scholarships to nursing students in exchange for a minimum two-year full-time service commitment (or part-time equivalent), at an eligible health care facility with a critical shortage of nurses. The Nurse Corps Loan Repayment Program provides loan repayment assistance to professional registered nurses (RNs), including advanced practice registered nurses (APRNs), in return for a minimum two-year full-time service commitment to work at eligible health care facilities with a critical shortage of nurses or serve as nurse faculty in eligible schools of nursing.

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 two years.

Tobacco

In July 2017, the FDA announced a new Comprehensive Plan for Tobacco and Nicotine Regulation. It is critical that the agency follows through on these efforts to improve public health and reduce the hundreds of thousands of premature deaths per year linked to the use of tobacco products.

1. Commissioner Gottlieb outlined a broad tobacco prevention plan during his time at FDA that, if implemented, would have a significant impact on tobacco use in the United States. Following Commissioner Gottlieb's recent departure from FDA, will HHS commit to continuing to move his agenda forward to prohibit the sale of flavored cigars and menthol cigarettes as well as reduce nicotine levels in cigarettes to non-addictive levels?

   By what dates does HHS intend to have notices of proposed rulemaking and final rules issued for each of these regulations? Specifically, what is the Department's timeline for promulgating regulations pertaining to the ANPRM released on March 16, 2018, "Tobacco Product Standard for Nicotine Level of Combusted Cigarettes" and the ANPRM released on March 21, 2018, "Regulation of Flavors in Tobacco Products"?

   Response: HHS is fully supportive of FDA's Comprehensive Plan for Tobacco and Nicotine Regulation, including the Youth Tobacco Prevention Plan. Protecting our nation's youth from the dangers of tobacco products is a priority for the Department. Specifically, the epidemic use of e-cigarettes among children is one of our biggest public health challenges. This disturbing and accelerating trajectory of use in youth, and the resulting path to addiction, must end. While we are unable to provide specific timelines for issuing any regulations, HHS continues to take these issues very seriously and we will keep you updated on our work related to the comprehensive plan.

2. The most recent National Youth Tobacco Survey data from FDA and CDC reflects a worsening public health crisis. What additional steps is HHS taking to curb youth usage and access to tobacco products?

   Response: The 2018 National Youth Tobacco Survey (NYTS) data highlights a troubling epidemic of e-cigarette use among youth. Protecting our nation's youth from the dangers of tobacco products is among HHS's most important responsibilities, and FDA will continue to take aggressive steps to make sure tobacco products are not being marketed or sold to kids. These efforts are a cornerstone of FDA's comprehensive plan for the regulation of nicotine and tobacco, and are also the focus of the multi-pronged Youth Tobacco Prevention Plan. FDA's Youth Tobacco Prevention Plan demonstrates the

Agency's commitment to using its authorities to protect our children. These authorities include enforcement, product standards, premarket review, sales and promotion restrictions, and public education.

One of the ways FDA is addressing the sharp increase in youth use of e-cigarettes is to revisit the compliance policy for premarket review of these products.

Additionally, FDA continues to take aggressive enforcement action to address youth access to these products. These include the largest coordinated enforcement effort in Agency history that resulted in more than 1,300 warning letters and civil money penalty complaints (fines) to retailers who illegally sold JUUL and other e-cigarette products to minors during a nationwide, undercover blitz of brick-and-mortar and online stores last summer and actions to address products that were misleadingly labeled and/or advertised, including e-liquids resembling kid-friendly food products such as candy and cookies. FDA has also taken action against e-cigarette and e-liquid products that are adulterated under section 902(6)(A) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 387b(6)(A)) for not having a required FDA marketing authorization order in effect and/or being misbranded under section 903(a)(6) of the FD&C Act (21 U.S.C. § 387c(a)(6)) because a required notice or other information respecting the products was not provided. FDA has issued warning letters to companies, and sent letters to more than 60 companies seeking information about whether more than 90 tobacco products, including e-cigarette and e-liquid products, may be currently on the market without requisite premarket authorization and outside of the Agency's compliance policy.

HHS continues to educate both youth and parents about the public health concern of youth e-cigarette use. For example, FDA expanded its public education efforts to prevent youth use of e-cigarettes. Last year, FDA launched "The Real Cost" Youth E-Cigarette Prevention Campaign to educate teens about the dangers of nicotine on the developing brain and other health consequences associated with e-cigarette use. This new effort targets nearly 10.7 million youth, aged 12-17, who have used e-cigarettes or are open to trying them. The campaign features advertising on digital and social media sites popular with teens, as well as posters with e-cigarette prevention messages in more than 37,000 high schools nationwide. Additional materials have been provided to over 700,000 teachers and school administrators across the country. The Centers for Disease Control and Prevention (CDC) has also published fact sheets on the risks of e-cigarettes for youth and young adults.

Currently, the Tobacco Control Act does not provide a means for FDA calculation of user fees for Electronic Nicotine Delivery Systems (ENDS) products and certain other deemed products. These products represent an increasing share of the tobacco marketplace as well as FDA's tobacco regulatory activities. The FY 2020 Budget requests an additional $100 million in tobacco fees and requests authority to include manufacturers and importers of all deemed products among the tobacco product classes for which FDA assesses tobacco user fees. To ensure that resources keep up with new tobacco products, the proposal would also index future collections to inflation.

3. Flavored cigars are widely popular among youth; nearly two-thirds of those 12 to 17 years of age who have ever smoked cigars report using a flavored cigar as their first product. Some flavored cigars are grandfathered onto the market and are not subject to product review. In May 2016, FDA announced that it intended to issue a proposed rule that would eliminate characterizing flavors in grandfathered cigars. Commissioner Gottlieb reiterated FDA's intention to ban flavored cigars in November 2018. When can we expect to see the agency finally issue this proposed rule to prevent more youth from becoming addicted to these flavored tobacco products?

   Response: As you know, FDA announced the Agency's intention to advance an NPRM that would ban characterizing flavors in cigars. A product standard can only be done through the rulemaking process, and we remain committed to issuing an NPRM. At this time, we are unable to provide a timeline, however, we will continue to keep you informed of our progress.

4. The Draft Guidance that FDA released last month restricts the sale of some flavored e-cigarettes to age-restricted locations but allows mint and menthol e-cigarettes to avoid even these modest age restrictions. Mint and menthol e-cigarettes are widely popular among youth; more than half of high school students who currently use e-cigarettes use menthol or mint products according to the 2018 National Youth Tobacco Survey. Why did the FDA choose to allow mint and menthol e-cigarettes to stay on the market when these products are so popular with young people?

   Response: FDA is revisiting its compliance policy as it applies to flavored ENDS products other than tobacco, mint, and menthol flavored ENDS products. The change in policy reflects a careful balancing of public health considerations.

   Data indicate that mint- and menthol-flavored electronic nicotine delivery systems (ENDS) products are preferred more by adults than minors, and that some adult smokers may be using mint- and menthol-flavored ENDS products with the goal of ceasing combusted tobacco use, seeking potential health benefits at the individual level, and may be at risk of migrating back to cigarettes. Recent evidence also indicates that mint- and menthol-flavored ENDS products are preferred more by adults over other flavors, but that other flavors are preferred by minors over mint and menthol flavors. Wave 4 of the PATH Study found that, in a combined response option, mint- and menthol-flavored e-cigarettes ranked fourth among youth (age 12 to 17 years), third among young adults (age 18-24 years) and second among adults (age 25 years and older).

   FDA will continue to monitor the rates and use patterns among youth and adults for menthol, mint, and other flavored ENDS products, and the Agency will reconsider its policies with respect to these products, if appropriate. In addition, the Agency continues to take a comprehensive approach to prevent youth from using all tobacco products, including ENDS products. This approach includes aggressive compliance and enforcement actions and a new public education campaign focused on preventing youth use of ENDS products.

5. Use of e-cigarettes and other Electronic Nicotine Delivery Systems (ENDS) skyrocketed from 2017 to 2018. How does the Department plan to build on efforts such as FDA's The Real Cost Campaign to educate minors on the harms of e-cigarettes?

   Response: To address the rising rates of youth e-cigarette use, the FDA's Center for Tobacco Products has invested significant resources in a media prevention campaign. In September 2018, the FDA launched a campaign to prevent youth vaping by expanding its successful youth tobacco prevention brand, "The Real Cost," to reach the more than 10 million youth ages 12-17 who have used e-cigarettes or are open to trying them. The campaign urges these teens to "know the real cost of vaping," with advertising designed to snap youth out of their "cost-free" mentality by educating them about the potential risks of using e-cigarettes.

   "The Real Cost" Youth E-cigarette Prevention Campaign reaches teens where they spend most of their time: in school and online. In addition to a suite of digital content on "The Real Cost" campaign website and social media channels, ads run on digital platforms where age is verified, including Hulu, Facebook, Spotify, and YouTube. As teens are increasingly faced with peer pressure to use e-cigarettes when they are in the school environment, the campaign places e-cigarette prevention materials in high schools across the nation, both in school bathrooms and on educational digital platforms accessed by students during the school day. The campaign also sent educational materials to every high school in the United States—over 37,000 schools—through the Scholastics network and with Students Against Destructive Decisions (SADD).

   In the coming months, FDA plans to expand its education efforts by:
   - Launching new "The Real Cost" youth e-cigarette prevention advertising;
   - Extending paid media to include broadcast television channels such as Teen Nick, MTV, Adult Swim, and Hulu; and
   - Developing a toolkit for stakeholders to educate at-risk youth audiences.

   As of May 2019, FDA's e-cigarette prevention messages were seen by teens nearly 500 million times and have higher than average online engagement rates. FDA is evaluating this comprehensive effort with a longitudinal, nationally representative study that measures teen tobacco-related knowledge, attitudes, beliefs, and behaviors.

6. Commissioner Gottlieb previously stated that if the 2019 National Tobacco Youth survey reveals an additional increase in youth e-cigarette use, market withdrawal of pod and cartridge-based e-cigarettes may be necessary. Does HHS agree?

   Response: HHS has made clear that absent a reversal in the trends of youth e-cigarette use, we envision a world where the FDA will continue to narrow the off-ramp for adults seeking a less harmful alternative to combustible cigarettes, in order to close the on-ramp that has resulted in the widespread and increasingly frequent use of e-cigarettes by teens. It is premature to make any decisions or prejudge the results of the 2019 National Youth Tobacco Survey (NYTS). Once we have the benefit of the updated data, we will review our efforts to reduce youth use of e-cigarettes. We are taking a comprehensive approach

to addressing the youth use of e-cigarettes and will take further action, as appropriate.

7. Last fall, the FDA sent warning letters to 21 companies that it suspected of introducing new tobacco products to the market without the required review from the agency. Has the FDA received any response from these companies or taken any action to remove these products from the market? How does FDA currently monitor the market for the illegal introduction of new products? With the delay in product review for newly deemed tobacco products, how does FDA determine whether a deemed product entered the market after August 8, 2016?

   Response: As part of its comprehensive enforcement effort to address the illegal sale of tobacco products, FDA investigates and pursues companies that it believes are selling or distributing deemed new tobacco products, including ENDS products, that first entered the market after August 8, 2016, and have not been authorized for marketing by FDA. The marketing and distribution of these products without FDA review and authorization is outside the Agency's compliance policy (the compliance policy only applies to deemed new tobacco products that were on the market as of August 8, 2016), and the products are adulterated and misbranded under the Federal Food, Drug, and Cosmetic Act. However, after an investigation, FDA may find that a deemed new tobacco product was on the market as of August 8, 2016. For example, in some instances, FDA has found that companies who had marketed their products as of August 8, 2016, have changed their products' labels, including the product name, after August 8, 2016. Pursuant to an August 2016 court decision, FDA explained in the December 2016 guidance for industry, https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM436468.pdf that a change to an existing tobacco product's label, standing alone, does not result in a separate new tobacco product. Alternatively, the FDA may find evidence of a reported violation or other potential violations that require additional surveillance, monitoring, or inspections. FDA's investigation is essential to determining whether a particular product was on the market as of August 8, 2016, the critical date for the Agency's compliance policy.

   As of April 2019, FDA has sent letters to more than 60 companies seeking information on over 90 brands of tobacco products to determine if those products are being illegally marketed outside the FDA's compliance policy. These letters indicate that regulated industry may be promoting a tobacco product in a manner that potentially violates the Federal Food, Drug, and Cosmetic Act and its implementing regulations, and are not intended to communicate that FDA is considering enforcement action. After completing investigations, FDA may take advisory or enforcement actions in instances when it has determined that products are unlawfully marketed and sold outside the FDA compliance policy. FDA will continue to investigate potential violations of the FD&C Act and regulations, and will take action when appropriate.

   FDA's activities, including inspecting physical retail establishments, monitoring and reviewing tobacco sales and advertising in publications and online, including other sales and promotional activities, inspecting manufacturing establishments, investigating qualified adult-only facilities that distribute free samples of smokeless tobacco, and

reviewing complaints, as well as other FDA observations, may lead to an advisory or enforcement action, if appropriate.

Within the last year, FDA has taken action in multiple instances when the Agency has determined that products are unlawfully marketed and sold outside the FDA compliance policy. FDA has issued warning letters to a number of ENDS product manufacturers, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm626249.htm, as a result of inspection findings that revealed they were, among other things, selling new e-liquids that were not on the market as of August 8, 2016 without the required premarket authorization, and illegally selling e-liquids with labeling and/or advertising that cause the product to imitate kid-friendly food products.

Oversight of Medicaid

HHS has not always provided the necessary oversight of state Medicaid managed care to ensure that vulnerable people have the care they need and are entitled to. For example, the Dallas Morning News reported last year that managed care plans in Texas systematically denied access to needed services for extremely frail people with disabilities.

One such example is the case of D'ashon Morris, a foster care child with special healthcare needs who needed a breathing tube. Unfortunately, because of the reductions in D'ashon's in-home nursing care, when D'ashon dislodged his breathing tube, he choked and went without oxygen for 40 minutes.

Another tragic example is Heather Powell, who is completely paralyzed from the neck down, and had to fight Superior HealthPlan, the managed care plan she was enrolled in, for a special mattress that her doctors prescribed to relieve pain and prevent sores that can kill immobilized people.

In spite of these and other shocking examples, HHS recently proposed to further weaken beneficiary access standards and quality measurement, and did nothing to strengthen beneficiary protections.

1. Does HHS believe that it is acceptable for managed care plans to deny necessary services to individuals with disabilities to the extent that it causes irreversible, sometimes life-threatening, harm?

2. Can HHS point to the budget proposals intended to prevent tragedies such as this from ever happening again?

3. Does HHS believe that weakening access standards and quality standards, as the Department has proposed, is likely to improve care for vulnerable children who rely on Medicaid managed care plans to keep them alive?

   Response to 1-3: Please be assured that HHS remains steadfast in its commitment to providing access to high quality healthcare to all beneficiaries, including those enrolled in Medicaid managed care plans. The Medicaid program was designed to

serve our most vulnerable populations including children and persons with disabilities. Indeed, the President's FY 2020 Budget includes a number of proposals to improve federal health programs so they work better for the people they serve and to ensure that Medicaid can adequately serve the most vulnerable populations.

ACA Navigator Program

On August 31, 2017, the Trump Administration reduced funding for the Navigator program from $63 million to $36.8 million, a 40 percent cut from the previous year. The Administration further reduced funding for 2019 to $10 million. A report by the Government Accountability Office (GAO) found that the Administration's decision to cut Navigator funding was based on "incomplete and problematic data." The report also found that CMS described the enrollment goals in an "unclear manner" and "failed to provide Navigators guidance on the performance measure." The GAO report concluded that the decision to distribute funding based on inaccurate data likely meant that certain Navigators did not receive the appropriate level of funding.

1. What actions will HHS take to address the issues identified in the GAO report?

2. Going forward, what metrics will HHS use to evaluate Navigators' performance and what process will be used to review applications?

   Response to 1-2: 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. In the report,[1] the GAO provided a number of recommendations. CMS 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. CMS has provided guidance to Navigators that their grant funding will be explicitly tied to their self-identified goals and their ability to meet those goals. CMS also concurred with the GAO's recommendation to assess other aspects of the consumer experience to ensure we has quality information to achieve our goals. CMS has 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. CMS believes these metrics represent a comprehensive assessment of the consumer experience. CMS is 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 CMS establish numeric enrollment targets for HealthCare.gov to monitor its performance. CMS 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

[1] "*Health Insurance Exchanges: HHS Should Enhance Its Management of Open Enrollment Performance"* (GAO-18-565), July 2018.

not believe that numeric enrollment targets are relevant to assess the performance of objectives related to a successful open enrollment period for the Exchange.

The Administration's decision to reduce funding has compromised Navigators' ability to perform the full range of duties specified in statute. Navigator entities reported conducting 68 percent fewer outreach events during the 2018 Open Enrollment period as compared to the 2017 period. Eight Navigator organizations have withdrawn from the program, and 81 of the 98 organizations have experienced a loss of funding.

3. How does HHS expect Navigator entities to fulfill the wide breath of responsibilities legally required of Navigators at the $10 million funding level?

4. What steps will HHS take to ensure that Americans wishing to enroll in Marketplace coverage are well informed about opportunities to enroll?

Response to 3-4: 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 our primary goal of providing a seamless enrollment experience for HealthCare.gov consumers, and data show that CMS 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 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 Federally Facilitated Exchanges (FFE)s, 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. By contrast, agents and brokers assisted with 42 percent of FFE enrollment for plan year 2018, which cost the FFE only $2.40 per enrollee to provide training and technical assistance. 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 Announcement (FOA) for the FFE Navigator Program for plan year 2019, 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.

Navigators differ from agents and brokers in that they are required to provide unbiased information to consumers. The Committee has heard stories from consumers who have been misled about the nature of their coverage by agents and brokers who had their own financial interest in mind rather than the consumer's interest. Commissioner Jessica Altman of the Pennsylvania Insurance Department testified in front of the Committee at a legislative hearing that her Department has suspended the licenses of at least eight insurance brokers and agents who misled consumers about the nature of the coverage they were selling.

5. What steps will HHS take to ensure that consumers are protected from bad actors, such as unscrupulous agents and brokers, moving forward in the Marketplaces?

Response: CMS Marketplace Program Integrity is an increasing concern in the Health Insurance Exchanges – both in the Federally-facilitated Exchanges and the State-based Exchanges. CMS has conducted a fraud risk assessment of the Health Insurance Exchange consistent with best practices developed by the Government Accountability Office. In FY 2017, CMS's Exchange integrity team performed investigations to identify areas of fraud and abuse in the Exchanges to include pilots to test the value of consumer complaints and identify leads that could result in administrative action, test the value of monitoring the license status of insurance agents once they register with CMS, and identify areas that appear to have a higher risk of fraud and abuse. CMS will continue these activities, including implementing an Exchange Program Integrity Contractor (EPIC) to facilitate analysis and investigations.

Office of Civil Rights

In October 2018, the New York Times reported on a leaked memo from the Department of Health and Human Services that called on other Departments—including the Departments of Justice, Labor, and Education—to adopt a uniform definition of sex. The proposed definition would narrowly define sex as a "biological, immutable condition determined by genitalia at birth". Such a definition would effectively erase protections for transgender people under federal civil rights laws.

1. Was HHS consulted about this reported memo or is the Department aware of its contents?

2. What is HHS trying to achieve with this definition of sex?

3. Does HHS agree with this proposed definition of sex—which would limit the application of federal civil rights laws only to people who fully conform with gender stereotypes?

4. Will HHS commit to not pursuing this change?

Response to 1-4: HHS does not comment on alleged leaked documents. HHS believes every person should be treated with dignity and respect and given every protection afforded by the Constitution and the laws passed by Congress. On May 24, 2019, HHS

issued a proposed rule to revise regulations implementing and enforcing Section 1557 of the Affordable Care Act (ACA) (published in the Federal Register on June 14, 2019 at 84 Fed. Reg. 27846). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities. The proposed rule would maintain vigorous civil rights enforcement of existing laws and regulations prohibiting discrimination on the basis of race, color, national origin, disability, age, and sex, while, consistent with the position the Department of Justice has taken in briefs filed with the Supreme Court on behalf of the United States on a similarly worded civil rights statute, revising certain provisions of the current Section 1557 regulation that a federal court has said are likely unlawful.

HHS is in the process of revising a 2016 ACA rule related to nondiscrimination in health programs, specifically the Department has stated its intent to revise the rule's sex discrimination protections, including its protections related to transgender status. This reversal of Administration position comes even though the overwhelming majority of federal courts have found that sex discrimination laws—including the ACA—protect transgender people.

5. In an absence of any meaningful change in case law, what prompted HHS to reverse its position that transgender people are included in the ACA's nondiscrimination protections?

6. What outside groups did HHS consult in arriving at this position?

7. When does HHS anticipate releasing a revised version of the rule?

8. What is HHS doing to uphold the right of transgender people to access health care free from discrimination?

9. How many complaints of discrimination on the basis of gender identity has HHS received since January 2017? What is HHS doing with these complaints?

Response to 5-9: HHS believes every person should be treated with dignity and respect and given every protection afforded by the Constitution and the laws passed by Congress. On May 24, 2019, HHS issued a proposed rule to revise regulations implementing and enforcing Section 1557 of the Affordable Care Act (ACA) (published in the Federal Register on June 14, 2019 at 84 Fed. Reg. 27846). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities. The proposed rule would maintain vigorous civil rights enforcement of existing laws and regulations prohibiting discrimination on the basis of race, color, national origin, disability, age, and sex, while, consistent with the position the Department of Justice has taken in briefs filed with the Supreme Court on behalf of the United States on a similarly worded civil rights statute, revising certain provisions of the current Section 1557 regulation that a federal court has said are likely unlawful.

Although Congress prohibited discrimination on the basis of sex in 1972 (Title IX), and

Section 1557 applied that law to healthcare and the Exchanges established under the ACA, HHS's 2016 Section 1557 regulation redefined discrimination "on the basis of sex" to include gender identity and termination of pregnancy, and defined gender identity as one's internal sense of being "male, female, neither, or a combination of male and female." As a result, several states and healthcare entities filed federal lawsuits against HHS. On December 31, 2016, the U.S. District Court for the Northern District of Texas issued an opinion in Franciscan Alliance, Inc. et al. v. Burwell, preliminarily enjoining HHS's attempt to prohibit discrimination on the basis of gender identity and termination of pregnancy as sex discrimination in the Section 1557 regulation. This federal court concluded the provisions are likely contrary to applicable civil rights law, the Religious Freedom Restoration Act, and the Administrative Procedure Act. The preliminary injunction applies on a nationwide basis. A separate federal court in North Dakota agreed with the reasoning of the Franciscan Alliance decision, and stayed the rule's effect on the plaintiffs before it. Consequently, HHS does not have legal authority to implement the provisions on gender identity and termination of pregnancy in light of the court's injunction which remains in full force and effect today.

The Honorable Eliot Engel (D-NY)

1. Secretary Azar, last year over 40 bipartisan members of Congress, including the original authors of the legislation, wrote to HHS and CMS stating that CMS was not following Congressional intent in the implementation of the new home infusion transitional benefit. However, CMS still chose to implement a short-sighted, misguided policy that will actually push more patients back into a costlier nursing home setting.

   As you know, home infusion therapy allows patients with heart disease, pulmonary hypertension, immune deficiencies, certain cancers, and other conditions to access intravenous, infused drugs in the safety and comfort of their own homes.

   The Agency's decision to reimburse services only on a day when a professional is present in the patient's home, ignoring the fact that lifesaving and life-improving treatment is occurring, is inexplicable. It is not what we intended when we passed the law, it is not how private payers reimburse for these services, and it is incompatible with efforts in increase access to cost-effective home-based care.

   - Can you commit to me that officials at CMS will fix this issue and insure patients will have access to home infusion therapy? If not, I think this Committee is going to have to consider legislation to instruct CMS to do this all over again.

   Response: Section 50401 of the Bipartisan Budget Act of 2018 establishes a temporary transitional home infusion therapy services payment for eligible home infusion suppliers for two years (CYs 2019 and 2020) for the provision of home infusion therapy services pending full implementation of the home infusion therapy benefit in 2021 required by section 5012 of the 21st Century

Cures Act. This home infusion therapy services payment is a single payment that covers the cost of the professional services, including nursing services, training and education (not otherwise paid under the durable medical benefit), and monitoring and remote monitoring services furnished in accordance with the plan prescribing the type, amount, and duration of infusion therapy services that are to be furnished. This home infusion therapy services payment is required to be made on an infusion drug administration calendar day.

In the Calendar Year 2019 final rule, CMS defined infusion drug administration calendar day as the day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration. CMS recognizes the concerns from stakeholders and members of Congress on its interpretation of "infusion drug administration calendar day", including with respect to professional services that may be provided outside of the home and, as applicable, payment amounts for such services. CMS stated in the final rule that it is our intention to ensure access to home infusion therapy services in accordance with the Bipartisan Budget Act of 2018. Therefore, CMS plans to monitor the effects of finalizing this definition on access to care in a patient's chosen setting and, if warranted and within the limits of its statutory authority, engage in additional rulemaking or guidance regarding this definition.

2. Mr. Secretary, home infusion wouldn't be possible without the professional expertise and services of a pharmacist, who is responsible for a range of activities, including sterile drug compounding, care planning and implementation, care coordination, and other services that are typically furnished by a pharmacist. Congress enacted the 21st Century Cures Act and the Bipartisan Budget to assure that beneficiaries have access to home infusion therapy. The law called on CMS to reimburse for each day that a patient receives a drug infusion. For many patients, that's every day.

   Unfortunately, CMS interpreted the law in a way that home infusion providers only get reimbursed on a day when a nurse is present in the patient's house, which might only be once a week for those patients receiving daily infusions, despite the costs that are incurred every day a patient is treated. So home infusion providers went from getting paid every day under the law, to only once a week.

   To compound this situation, in a recently issued "Frequently Asked Question" document for home infusion therapy providers, CMS determined that home infusion providers cannot bill for home infusion therapy services for patients that are under a home health episode of care. So for homebound patients, home infusion providers who originally thought they were going paid every day, and then thought they were going to get paid only one day a week, are now learning that, for about one-third of their patients, they won't get paid at all.

   - Mr. Secretary, do you think we can reasonably expect health care providers to keep delivering care when they don't get paid? I don't think the current policy is what Congress intended, and needs to be fixed by you immediately.

Response: The Bipartisan Budget Act and the 21st Century Cures Act requires the payment for home infusion therapy services to be a single payment that covers the cost of the professional services, including nursing services, training and education (not otherwise paid under the durable medical benefit), and monitoring and remote monitoring services furnished in accordance with the plan prescribing the type, amount, and duration of infusion therapy services that are to be furnished.

CMS plans to monitor the effects of the home infusion therapy services payment on access to care in a patient's chosen setting and, if warranted and within the limits of its statutory authority, engage in additional rulemaking or guidance on the implementation of this new benefit.

3. Mr. Secretary, do you think we can reasonably expect health care providers to keep delivering care when they don't get paid? I don't think the current policy is what Congress intended, and needs to be fixed by you immediately.

Response: The Bipartisan Budget Act and the 21st Century Cures Act requires the payment for home infusion therapy services to be a single payment that covers the cost of the professional services, including nursing services, training and education (not otherwise paid under the durable medical benefit), and monitoring and remote monitoring services furnished in accordance with the plan prescribing the type, amount, and duration of infusion therapy services that are to be furnished.

CMS plans to monitor the effects of the home infusion therapy services payment on access to care in a patient's chosen setting and, if warranted and within the limits of its statutory authority, engage in additional rulemaking or guidance on the implementation of this new benefit.

The Honorable G. K. Butterfield (D-NC)

Medicaid is a critical source of financial support for hospitals and other health care providers that serve communities and middle-class families across the country. The Government Accountability Office found that states that expanded Medicaid had fewer rural hospitals close than states that chose not to expand. In my state of North Carolina, which has not yet expanded Medicaid, five rural hospitals have closed since 2010. Currently, Washington County Hospital in Plymouth North Carolina and in North Carolina's First Congressional District is in danger of closing. Capping Medicaid through a block grant will make that problem worse, not better. In fact, hospitals have previously said that capping Medicaid "would have serious negative consequences for communities across America."

1. Has the Administration considered the effects of the Medicaid cuts in this budget on rural hospitals?

2. Can you promise that block granting Medicaid will not result in hospital closures that put entire communities, not just Medicaid beneficiaries, at risk?

   Response to 1-2: The Trump Administration has placed an unprecedented priority on improving the health of Americans living in rural areas. CMS furthered this commitment by introducing the first ever Rural Health Strategy as part of its Rethinking Rural Health Initiative to focus on ways CMS can strengthen the rural healthcare system and avoid unintended consequences of CMS policy and program implementation. The Rural Health Strategy focuses on applying a rural lens to the vision and work of CMS, improving access to care through provider engagement and support, advancing telehealth, empowering patients in rural areas about making decisions on their healthcare and leveraging partnerships to improve rural health. CMS's goal is to develop programs and policies that ensure rural Americans have access to high quality care, support rural providers and not disadvantage them, address the unique economics of providing healthcare in rural America, and reduce unnecessary burdens in a stretched system to advance the Administration's commitment to improving health outcomes for Americans living in rural areas.

   States play a critical role in fostering innovation in program design and financing, and CMS is committed to giving them the flexibility they need to meet the needs of their residents, including their residents in rural areas. The FY 2020 President's Budget proposal to allow states to choose block grant or per capita cap proposals would restore significant flexibility to the states, enable them to manage their programs more efficiently and hold them accountable for producing positive outcomes within a defined budget.

3. The budget proposes to take away Medicaid from jobless and underemployed Americans. Does the budget prevent laid-off workers, people who are going to school, and those taking care of family members from qualifying for Medicaid?

4. Arkansas is currently the only state that takes away coverage from individuals that do not meet a work requirement. In the first seven months of that effort, one in five people who were previously eligible for coverage lost it. Should work requirements be implemented nationally, how many individuals does the Administration estimate will lose coverage?

   Response to 3-4: Millions of adults became eligible for Medicaid through the Medicaid expansion provisions in the Patient Protection and Affordable Care Act (PPACA). While medical coverage is important, public assistance programs trap many individuals in dependency. In addition to ensuring access to health care for Americans, the Trump Administration also prioritizes personal responsibility and helping individuals obtain economic self-sufficiency. That's why 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 certain individuals find employment, train for work, or volunteer (community service) in order to receive welfare benefits. This would enhance service coordination for program participants, improve the health and financial well-being of those receiving assistance, and conserve funding for public assistance

programs to help ensure that they are available for the most vulnerable populations. This proposal is estimated to save $8.3 billion in FY 2020, $55.6 billion over 5 years, and $130.4 billion over 10 years.

In January 2018, the Administration announced its intention to break the cycle of poverty and dependence through approval of Section 1115 community engagement demonstrations. Since then, CMS approved community engagement demonstrations in nine states. The demonstrations promote community engagement activities (e.g., volunteering, caregiving, educational activities, job training or employment) for certain adults to promote improved health and well-being. States may also choose to consider caregivers as an exempted population, in alignment with TANF work-related requirements.

CMS remains committed to supporting states in their efforts to develop new and innovative solutions to improve their Medicaid programs and to provide individuals on Medicaid with better health, the ability to experience the dignity of a job and personal responsibility, and move individuals forward on the path to independence and greater well-being.

5. Secretary Azar, while your budget provides $4.5 billion for combatting the opioid epidemic, it decimates the ACA and slashes Medicaid by $1.5 trillion. Those numbers pale in comparison. How many millions of Americans utilize Medicaid and the ACA to receive opioid treatment?

6. Can the Administration guarantee that slashing the ACA and Medicaid will not exacerbate the nation's opioid crisis?

7. Secretary Azar, by eliminating the ACA's Medicaid expansion, 12 million low-income adults will lose coverage, including many with substance use disorders. Can you guarantee those 12 million individuals will still have access to substance use treatment if they no longer are eligible for Medicaid?

Response to 5-7: Combatting the opioid epidemic is a top priority of this Administration, and promoting access to prevention, treatment, and recovery services for substance use disorder is a critical part of HHS's strategy. HHS continues to pursue a five-point strategy to combat the opioid epidemic by (1) improving access to prevention, treatment, and recovery support services;(2) collecting opioid epidemic data; (3) updating guidance for pain management; (4) targeting of overdose-reversing drugs; and (5) increasing support for research on pain and addiction.

This Administration has made historic investments to address opioid misuse, abuse, and overdose, and the President's FY 2020 Budget provides $4.9 billion in discretionary funding to combat the opioid overdose epidemic. In addition, Medicare and Medicaid policies and funding will play a critical role in combating the opioid crisis. The President's FY 2020 Budget proposes to make it easier for states to provide full Medicaid benefits for one-year postpartum for pregnant women diagnosed with a substance use

disorder. The Budget also proposes to set minimum standards for Medicaid Drug Utilization Review programs, allowing for better oversight of opioid dispensing in Medicaid. Additionally, it proposes a collaboration between CMS and the Drug Enforcement Administration to stop providers from inappropriate opioid prescribing.

The President signed the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, which includes Medicaid provisions to address the opioids crisis. This bold, bipartisan legislation addresses the opioid crisis by expanding access to substance abuse treatment, cracking down on shipments of illicit drugs, and providing more grant funding for prevention, treatment, and recovery. For instance, the SUPPORT for Patients and Communities Act includes a $55 million Medicaid demonstration project over 4.5 years. CMS will oversee efforts to increase substance use provider capacity, by providing an enhanced Medicaid match rate for select states. CMS may select at least 10 states to receive planning grants to assess their behavioral treatment and provider needs to improve provider networks treating substance use disorders. CMS may choose up to five (provided they meet specified criteria) of the 10 states to award planning grants to receive the enhanced federal match rate and implement the activities under this demonstration:

- Supporting ongoing analysis of state behavioral health treatment needs;
- Supporting recruitment training and providing technical assistance for providers offering substance use disorder treatment or recovery services;
- Improving reimbursement for and expanding the amount or treatment capacity of participating providers through the provision of education, training and technical assistance authorized to dispense Food and Drug Administration-approved drugs; and
- Improving reimbursement for and expanding the amount or treatment capacity of providers through the provision of education, training and technical assistance to address the treatment needs for certain populations enrolled under the State plan or waiver.

In addition, on November 1, 2017, CMS offered states the to pursue demonstration projects under section 1115 of the Social Security Act for states to receive the authority to pay for short-term residential-treatment services in an institution for mental disease for individuals diagnosed with substance use disorders (SUDs), including opioid use disorder. Since January 2019, CMS has approved SUD waivers for 22 states to expand access to inpatient options for patients with a SUD diagnosis. We believe that these waivers will strengthen the treatment s options available to individuals with substance use disorders and we encourage additional states to consider this option as well.

The Honorable Debbie Dingell (D-MI)

1. Secretary Azar, as you may know, the EPA recently released its PFAS Action Plan. Did HHS play any role in advising, assisting, or contributing to the proposed action plan? And does HHS have anything in the works currently to propose its own action plan to address PFAS in consumer products, like food substance containers, dental floss, and cosmetics?

Response: As part of an intergovernmental review process, HHS agencies reviewed the PFAS Action Plan during development. In addition, HHS agencies participated in EPA-lead meetings to discuss PFAS including regional summits and consultations.

More specifically, FDA recently established a working group to consider whether further action is needed to address potential health risks arising from the presence of PFAS in food and food contact substances. The work group will also address issues associated with the potential contamination of FDA-regulated foods from an environmental source. At present, FDA is not aware of any food use of PFAS aside from their limited use in food contact materials. In 2010, FDA identified safety concerns with long-chain PFAS used as "grease-proof" coatings on fast-food wrappers, to-go boxes, and pizza boxes. These PFAS are no longer authorized or are no longer in use.[2] FDA is currently evaluating new scientific literature to determine whether short-chain PFAS present food safety concerns when used in food packaging.

For FDA-regulated products more generally, FDA is committed to taking appropriate actions under its authority to protect public health, consistent with available scientific and safety data. With regard to cosmetics, the information available to FDA is limited because FDA does not have pre-market review authority for cosmetics, and manufacturers are not required to tell FDA what ingredients are used in their cosmetic products. Regarding dental floss, FDA has assessed all currently available information regarding dental floss and PFAS and has determined that, at this time, it does not have sufficient evidence to warrant further action beyond this assessment. FDA will continue to monitor and assess the evidence as new information becomes available, as it does with medical devices generally.

2. Secretary Azar, at what level (in parts per trillion) is PFOA and PFOS considered harmful to human health in adults, according to HHS experts? At what level is PFOA and PFOS considered harmful to human health in children, according to HHS experts?

Response: The science around the relationship between PFAS and human health effects is constantly evolving as more information becomes available. HHS is constantly evaluating new research and identifying gaps. The Agency for Toxic Substances and Disease Registry (ATSDR) has developed draft Minimal Risk Levels (MRLs) for four PFAS, including PFOA and PFOS. MRLs are screening levels that ATSDR uses to identify environmental exposures that might harm people's health. ATSDR sets each MRL well below a value that is likely to cause a health effect. If an exposure is below the MRL, it is not expected to result in adverse health effects. It is important to note that MRLs are a screening tool that help identify exposures that could be potentially hazardous to human health. Exposure above the MRLs does not mean that health problems will occur. Instead, it may act as a signal to health assessors to look more closely at a particular site where exposures may be identified.

[2] https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm528911.htm

3. Secretary Azar, the CDC and ATSDR are looking to conduct PFAS exposure assessments, community engagement activities, and a number of studies—specifically the Pease Study and the Multi-Site Health Study. Will either of these studies or activities look at or will be conducted in Michigan? My state of Michigan has been hit hard by PFAS contamination.

   Response: CDC and ATSDR are committed to addressing PFAS in communities across the US. Currently, the agency is providing support through health assessments and consultations in over 30 communities. We are aware of the PFAS concerns in Michigan, and have been working in multiple sites in Michigan. In consultation with the Michigan Department of Health and Human Services (MDHHS) and the Kent County Health Department, ATSDR has been providing assistance in the development of study protocols, data management, communications, and overall project coordination. In addition, as a result of the state-wide testing of municipal water systems for PFAS, in July 2018, the City of Parchment (Kalamazoo County) found that their drinking water system had contamination with PFAS. CDC/ATSDR provided assistance to the Kalamazoo County Health Department regarding clinician guidance and communication with healthcare workers. ATSDR's Region V office continues to provide technical assistance and support the MDHHS and the Michigan PFAS Action Response Team regarding PFAS issues.

   In the National Defense Authorization Act, Congress asked CDC/ATSDR to conduct a health study looking at the relationship between PFAS exposure and health outcomes. The goal of the multi-site health study is to learn more about the relationship between PFAS exposure and health outcomes among differing populations. CDC/ATSDR recently announced a competitive funding opportunity, and all states, universities and communities are eligible to apply. The information about the relationship between PFAS exposure and health outcomes can be applied to communities across the nation, including those that are not selected as a site.

4. Secretary Azar, Michigan recently had a Medicaid work requirement approved by this Administration. One study estimated that between 61,000 and 183,000 people in Michigan will lose their health insurance because of this policy. Did your Department consider the potential impact on children's health insurance coverage when approving this policy?

5. Secretary Azar, do you think your Department could have done anything differently to prevent so many children from losing health insurance in the past two years, and is that reflected in this budget?

6. Secretary Azar, it's clear to me, based on this large increase in the number of uninsured children after years of steady progress, that this Administration's policies are not serving children's interests. How large would the increase in uninsured children have to be in order for you to be convinced to change course and revise your policies?

   Response to 4-6: CMS approved Michigan's request to extend its section 1115

demonstration project, the "Healthy Michigan Plan (HMP)" on December 21, 2018. This five year extension with amendment allows Michigan, no sooner than January 1, 2020, to require all demonstration beneficiaries, ages 19 through 62, with certain exemptions, to participate in and report 80 hours per month of community engagement activities, such as employment, education, job skills training, or community service, as a condition of continued Medicaid eligibility.

HMP covers beneficiaries in the new adult group (defined at section 1902(a)(10)(A)(i)(VIII) of the Social Security Act) from age 19 to 64 with incomes up to 133 percent of the federal poverty level (FPL). Children are not included in community engagement requirements under the demonstration.

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. CMS knows some of the enrollment decline can be attributed to the improved economy and state functionality and operational issues in conducting the eligibility renewal process. We are 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.

The Honorable Tony Cárdenas (D-CA)

1. According to the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which coordinates Federal efforts to enhance public health preparedness, there are several medical countermeasures in the Strategic National Stockpile (SNS) that will need to be restocked in the near term. However, the President's budget does not take into account the need to replenish the existing inventory in the SNS. What are the implications for not adequately funding the SNS? What new procurements will ensure we are prepared to meet public health threats could be delayed or cancelled due to lack of funds?

   Response: At the FY 2020 President's Budget level of $620 million, the Strategic National Stockpile (SNS) will replace the highest priority expiring countermeasures identified through an HHS requirements setting process. This includes $61.4 million for two products transitioning to the SNS from Project BioShield funded contracts (a thermal burn bandage and smallpox antiviral drug).

The Honorable Joe Kennedy (D-MA)

Work Requirements

When you testified before the Energy and Commerce Committee on March 12th, you stated, in response to my inquiry into the reason over 18,000 beneficiaries lost Medicaid coverage in Arkansas, "We do not yet have data as to why they fell off the program." Additionally, you said, "We just don't know at this point." However, two days later, when testifying before the Senate Committee on Finance, you stated, "Only 1,452 of those 18,000 people even reapplied for Medicaid…That seems a fairly strong indication that the individuals who left the program were doing so because they got a job…"

1. What information did you receive between March 12th and March 14th that caused you to change your understanding of why Medicaid beneficiaries fell off the program in Arkansas because of the work requirements? Provide a full explanation why your answer changed from when I questioned you at the Energy and Commerce Committee hearing to the point when you provided different information at the Senate Committee on Finance hearing two days later.

2. What evaluations has the Department of Health and Human Services or the Centers on Medicare and Medicaid Services conducted into the reason more than 18,000 Arkansas residents lost coverage due to the work requirements? Provide all studies, evaluations, and data regarding the impact of work requirements in Arkansas and all other states for which you have this information. Provide a list of all the states for which you do not have this data.

3. According to Georgetown University's Center for Children and Families, less than one percent of those subject to the new rules in Arkansas are newly reporting work hours. Of that one percent, how many Arkansas residents have secured health insurance coverage through their new employers? Of the total number of Arkansas residents who lost Medicaid coverage because of the work requirements, how many now have health insurance?

   Response to 1-3: Currently, the State 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 disenrolled from Medicaid due to their noncompliance for three 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. Pursuant to the last report, which was published in February, nearly 90 percent of the 116,229 beneficiaries subject to the requirement were compliant either due to work, training, or another activity.

Addendum with updated information: On March 5, 2018, CMS approved Arkansas's request for an amendment to this demonstration which allowed the state, no sooner than June 1, 2018, to require all Arkansas Works beneficiaries ages 19 through 49, with exemptions for certain groups, to participate in and timely document and report 80 hours per month of community engagement activities, such as employment, education, job skills training, or community service, as a condition of continued Medicaid eligibility.

On March 27, 2019, the U.S. District Court for the District of Columbia vacated the amendment approved on March 5, 2018. While we have appealed this court decision, the Centers for Medicare & Medicaid issued a letter to the state indicating that the state is required to administer their section 1115 demonstration waiver under the special terms and conditions that were approved as of December 8, 2016.[3]

HHS and CMS believe that it is critical to conduct regular and robust monitoring and rigorous evaluation in order to understand the impacts of Medicaid 1115 demonstrations.

As a condition of approval, CMS requires that, from the onset of the implementation of any community engagement demonstration, states collect, analyze and report meaningful data on a quarterly basis in a way that will assist CMS and states to understand the short-term effects (through monitoring) and longer-term impacts and outcomes (through an independent, research-driven evaluation) of community engagement policies. These monitoring reports do not include the full range of information that will be collected and provided under the state's evaluation plan, which will permit CMS to track the impact of the demonstration on Medicaid enrollees' employment or health status. CMS is working with all participating states to ensure that each has a CMS-approved evaluation design that meets our expectations. Through both monitoring and evaluation, states and CMS will learn whether these Medicaid demonstrations support states' hypotheses and achieve expected outcomes.

CMS has devoted substantial effort to establishing expectations for state evaluation designs that reflect the high standards of evaluation research. For instance, CMS has developed tools for use by states and independent evaluators to guide the development of evaluation designs and to prepare evaluation reports for Medicaid section 1115 demonstrations.[4] CMS has developed resources and best practices in causal inference, selecting comparison groups, and creating evaluations specific to managed long-term services and supports, among other specific demonstration projects.[5]

Last year, the State of Ohio published as assessment of the State's Medicaid program. It found Medicaid enrollment facilitates and enables employment. Almost nine out of ten respondents who are employed and who participated in the survey said having Medicaid make it easier to

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[3] https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ar/Health-Care-Independence-Program-Private-Option/ar-works-court-decision-ltr-20190504.pdf

[4] https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html

[5] https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/index.html

continue working. It is no surprise that having health insurance means people can fill prescriptions and go to the doctor in order to get and stay healthy. And being healthy is an important part of being able to get up and go to work every day. However, it's important to note this logic only works in one direction. Health insurance yields healthier people and healthier people are thus more able work. Ensuring access to coverage and benefits is the first step, not the last step, in making Americans healthier and empowering them to find work and to stay in the workforce.

1. Can you provide any and all studies that say taking away someone's health care, or threatening to do so, such as with work requirements, improves health outcomes for current Medicaid beneficiaries? Similarly, can you provide any and all studies that say taking away someone's health care, or threatening to do so, such as with work requirements, improved health outcomes for previous beneficiaries who lost coverage as result of Arkansas' work requirements?

2. Of the 18,000 Arkansas Medicaid beneficiaries who lost coverage because of work requirements, how many of them are healthier now? What studies has the Department of Health and Human Services or the Centers on Medicare and Medicaid Services conducted into the health status of those individuals who lost coverage and what are the results of those evaluations?

3. The Centers of Medicare and Medicaid Services recently approved work requirements for the State of Ohio. How many individuals will lose health insurance as a result of those work requirements? Provide all evaluations your department conducted, prior to approving the Ohio work requirements, indicating the number of Ohioans who will lose coverage.

   Response to 1-3: CMS believes that programs that incentivize community engagement have the potential to further Medicaid objectives by promoting better mental, physical, and emotional health, by helping individuals and families rise out of poverty and attain independence, and by promoting the fiscal sustainability of state Medicaid programs. While high-quality health care is important for an individual's health, there are many other determinants of health. CMS recognizes that a broad range of social and economic factors can have a major impact on an individual's health and wellness, and a growing body of evidence suggests that targeting certain health determinants, including community engagement, can improve health outcomes for the individual. Community engagement programs can also help individuals and families rise out of poverty and preserve the fiscal sustainability of the safety net for those individuals who need it most.

   We understand your concerns regarding the potential impact that community engagement requirements may have on Medicaid beneficiaries. However, CMS carefully reviews each state's request for a section 1115 demonstration on an individual basis and only approves state requests for demonstration projects if, in the Secretary of Health & Human Services's judgment, the demonstration project is likely to help promote the objectives of the Medicaid program.

We agree that it is critical to conduct regular and robust monitoring and rigorous evaluation in order to understand the impacts of Medicaid 1115 demonstrations. As a condition of approval, CMS requires that from the onset of the implementation of any community engagement demonstration, states collect, analyze and report meaningful data on a quarterly basis in a way that will assist CMS and states to understand the short-term effects (through monitoring) and longer-term impacts and outcomes (through an independent, research-driven evaluation) of community engagement policies. These monitoring reports do not include the full range of information that will be collected and provided under the State's evaluation plan, which will permit CMS to track the impact of the demonstration on Medicaid enrollees' employment or health status. CMS is working with all participating states to ensure that each has a CMS-approved evaluation design that meets its expectations. Through both monitoring and evaluation, states and CMS will learn whether these Medicaid demonstrations support states' hypotheses and achieve expected outcomes.

CMS has also devoted substantial effort to establishing expectations for state evaluation designs that reflect the high standards of evaluation research. For instance, CMS has developed tools for use by states and independent evaluators to guide the development of evaluation designs and to prepare evaluation reports for Medicaid section 1115 demonstrations.[6] CMS has developed resources and best practices in causal inference, selecting comparison groups, and creating evaluations specific to managed long-term services and supports, among other specific demonstration projects.[7] CMS has also developed evaluation guidance specific to more recent demonstration project approvals in state Medicaid director letters, including demonstrations designed to expand access to substance use disorder treatment.

As you indicated, CMS recently approved Ohio's section 1115 demonstration project on March 15, 2019. 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 l9 through 49, engage in qualifying community engagement activities for at least 80 hours per month. Included in the waiver approval are certain guardrails to ensure that Ohio protects its most vulnerable residents, including beneficiaries who are pregnant or 60 days or less post-partum.

In assessing the coverage impact of proposed demonstration features, the state noted in its application that, of the 710,000 beneficiaries expected to be enrolled in the new adult group, approximately 36,000 would not be considered exempt or currently working and would need to complete qualifying activities to comply with the community engagement requirement. Of the beneficiaries considered not to be exempt, the State estimates that 10 percent of beneficiaries will elect not to comply

[6] https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html
[7] https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/index.html

and would thus lose their Medicaid coverage.[8] Actual coverage impact will greatly depend on the choices made by each individual beneficiary, and it is therefore challenging to estimate the impacts of this new program before it even begins. It is important to CMS that, for all community engagement requirements, compliance is achievable for every beneficiary subject to the new requirements, such that every beneficiary enrolled in Medicaid can stay enrolled in Medicaid unless and until they move into other forms of coverage or become ineligible for reasons such as income. In light of the safeguards discussed above, CMS has determined that compliance with Ohio's community engagement requirement should be achievable for every beneficiary. Furthermore, CMS is undertaking vigorous evaluation and monitoring of a variety of metrics, including enrollment metrics.

Mental Health

Medicaid is the largest payer of mental health services in the United States. Its role in providing access to mental health care is critical to the health and wellbeing of millions of Americans; yet, this budget proposes to cut Medicaid by $1.5 trillion over ten years, endangering every single beneficiary with mental illness. Instead of supporting and fixing the mental health system, this budget would worsen the system on every metric, whether through beneficiaries' loss of coverage, weakened network adequacy, inadequate reimbursement levels, or unnecessarily burdensome paperwork requirements for states and beneficiaries.

1. Given this Administration's proposed funding cuts, and the inevitable, wide-spread loss of coverage that would occur, how does the Administration predict Americans will be able to afford and access timely mental health care? When millions of Americans lose Medicaid coverage, what is the anticipated impact on the opioid crisis?

   Response: The Administration has made historic investments to address opioid misuse, abuse, and overdose. Successful partnerships between 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, including ways to improve access to timely mental health care, and we have followed through on that promise. For example, 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. In addition, 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

[8] https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/oh/oh-work-requirement-community-engagement-ca.pdf

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.

The President's FY 2020 Budget provides $4.9 billion to combat the opioid overdose epidemic. The Substance Abuse and Mental Health Services Administration (SAMHSA) will continue all current opioid activities at the same funding level as FY 2019, including the 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. The Budget also provides new funding for grants to accredited medical schools and teaching hospitals to develop substance abuse treatment curricula. In FY 2020, the Health Resources and Services Administration (HRSA) will continue to make investments to address substance abuse, including opioids abuse, 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 making it easier for states to provide full Medicaid benefits for one-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 programs. Additionally, it proposes a collaboration between the Centers for Medicare & Medicaid Services and the Drug Enforcement Administration to stop providers from inappropriate opioid prescribing.

The President's 2020 budget proposal includes a proposal to make it easier for states to provide full Medicaid benefits, for one year postpartum, to women who have substance use disorders and have given birth. I certainly agree in the value of ensuring long-term, continuous care for individuals who have given birth. There is no substitute for good health when parents bring home a new baby and work hard at raising a family, and this is especially important when it comes to mental health.

2. How does the Administration expect twelve months of continuous coverage to post-partum women will benefit them and their families? Additionally, does the proposal extend a guarantee of coverage for the newborn children and the older children of a postpartum parent?

3. There is well-documented evidence showing the value of mental health care to individuals who have given birth; yet this budget would extend twelve months of care only to women with a substance use disorder. What is the rationale for limiting the benefit to women with substance use disorders only versus expanding the benefit to all postpartum individuals with mental illness? What is the rationale for limiting the benefit to women with substance use disorder versus expanding the benefit to all individuals who have given birth regardless of their mental health status at delivery?

Response to 2-3: HHS is home to a range of agencies whose work touches the health care of pregnant women, mothers, and infants, as protecting maternal and infant health is one of our health care system's most important responsibilities. As the single largest payer for maternity care, Medicaid plays an important role in perinatal and maternal health, and has a significant opportunity to improve maternal and infant health outcomes, including during the postpartum period.

The President's FY 2020 Budget includes a number of proposals aimed at improving maternal mortality and morbidity rates in the U.S., including making it easier for states to extend Medicaid coverage to pregnant women with substance use disorders for a full year postpartum. The postpartum period is often stressful, particularly for infants with neonatal abstinence syndrome (NAS) and their mothers. These infants have numerous needs and are twice as likely as infants without such conditions to be readmitted to the hospital within 30 days of discharge. After these infants leave the hospital, the needs of the infant and the mother require care from multiple providers and programs, including obstetric and addiction treatment for the mother in addition to pediatric care for the infant, as well as the potential involvement of child welfare services. Navigating all of these services requires significant care coordination and case management, access to which frequently ends when mothers with a substance use disorder (SUD) lose their Medicaid coverage. Ending coverage for treatment after 60 days may put the mothers of these infants at increased risk for relapse because relapse is more common during the postpartum period than during the pregnancy and because women with SUDs have a heightened risk of relapse after delivery due to postpartum depression and the stress of parenting, among other factors.

Improving access to treatment and care coordination during the postpartum period should improve the health and wellness of mothers, increase the ability of these mothers to care for their infants born with NAS, and reduce the risk of neglect resulting from the mothers' SUDs. The postpartum period is a time when women with SUDs may be particularly motivated to engage in treatment, and therefore extending coverage is critically important during that window of opportunity. Improved access to treatment among new mothers with SUDs should help reduce the impacts of the opioid crisis on child welfare systems.

In addition, this proposal is intended to improve the ability of women with SUDs, including opioid use disorder (OUD), to care for their infants. The first year of life is a difficult transition time. The Substance Abuse and Mental Health Services Administration's (SAMHSA's) recent clinical guideline on treating pregnant and parenting women with OUD recommends that discontinuation of pharmacotherapy be delayed until, at the very least, after the infant is consistently sleeping through the night, has completed breastfeeding, and mother and baby have multiple indicators of life stability. These milestones are unlikely to be reached earlier than the end of the first year postpartum. Under this proposal, states would also have to ensure the benefits provided to these women include coverage for SUD and mental health

treatment as well as case management and care coordination, since these services may not be included in the state plan Medicaid benefits in all states.

The President's FY 2020 Budget also proposes to use CMS's Center for Medicare and Medicaid Innovation (CMMI) to develop and test innovative health care payment and service delivery models to improve maternal and child health. CMMI is currently working on two recently released opportunities, the Integrated Care for Kids (InCK) and Maternal Opioid Misuse (MOM) payment and service delivery models. These models were designed to expand access to health care services for vulnerable Medicaid and CHIP beneficiaries, in particular those affected by the nation's opioid crisis, and to improve quality of care and reduce expenditures for beneficiaries.

In addition to these current projects, CMS launched previously several initiatives and pilot programs to improve the well-being of women and children. In 2012, CMS, the Health Resources and Services Administration, and the Administration for Children and Families launched the Strong Start for Mothers and Newborns (Strong Start) initiative to reduce preterm births and improve outcomes for pregnant women and newborns. The Strong Start initiative was comprised of two strategies. The first was a public-private partnership and awareness campaign to reduce the rate of early elective deliveries. The second was a four-year initiative testing the effectiveness of three enhanced prenatal care models – Birth Centers, Group Prenatal Care, and Maternity Care Homes – among pregnant Medicaid and CHIP beneficiaries at high risk for preterm births. Strong Start funded 27 awardees and 211 provider sites across 32 states, the District of Columbia, and Puerto Rico. Birth Centers were the most successful of the models, and CMS determined that women who received prenatal care in Strong Start Birth Centers had better outcomes and lower costs compared to similar Medicaid beneficiaries not enrolled in the initiative.

Further, in 2014, CMS launched a three-year Pilot Mobile Health Program to engage pregnant and postpartum women enrolled in Medicaid. The program delivers evidence-based health education messages and links these women to needed community-based resources, using a free text messaging service, Text4baby, as the core intervention. The pilot was implemented with Medicaid agencies in California, Louisiana, Ohio, and Oklahoma. These Medicaid agencies work to integrate Text4baby into their processes to complement their states' current maternal and infant health activities. In the first year, progress included a substantial growth in partnerships to support outreach.

Lastly, section 1115 demonstration projects offer states additional freedom to test and evaluate innovative solutions to improve the quality, accessibility, and health outcomes of pregnant and postpartum women and infants in the Medicaid program.

The Honorable Raul Ruiz (D-CA)

1. Mr. Secretary, 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 shortage ranging

between 40,800 to 104,900 physicians. What is the Administration's plan to address this growing shortage?

2. Mr. Secretary, many of our country's medical residents traveled to Washington, D.C. recently to meet with their representatives. They spoke about a variety of policy matters, and especially highlighted problems related to the dearth of residency programs. Given that medical school enrollment is on the rise, but residency positions have not increased at the same pace, what steps is the Department taking to ensure future students don't end up without a residency program to continue their education?

Response to 1-2: 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, 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 two years.

The FY2020 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.

3. Mr. Secretary, last year, Dr. Bucshon and I, along with several other members of this Committee, sent a letter to your Department regarding the Centers for Medicare and Medicaid Services' existing authority to extend flexibility to residency programs when setting Medicare graduate medical education caps. Will you commit to utilizing this authority, granted in 1997, to give new residency programs in medically underserved areas longer to build out their programs before they are capped by Medicare?

   Response: HHS shares your goal of improved support for hospitals' efforts to train more residents in underserved areas. New teaching hospitals have a 5-year cap-building period, which CMS adopted primarily to allow sufficient time for these hospitals to meet accreditation requirements and gain experience in training residents. However, new and existing rural teaching hospitals, unlike urban teaching hospitals, are not limited to a single cap-building period. Rural teaching hospitals receive a 5-year cap-building period each time they participate in training residents in a new residency training program and as such, can receive multiple permanent adjustments to their caps.

   In addition, the President's FY 2020 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. 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. Patients and providers would be well served by these commonsense reforms and the new grant program would be operated jointly by the Administrators of CMS and the Health Resources and Services Administration.

The Honorable Lisa Blunt Rochester (D-DE)

1. I understand that CMS is currently reconsidering the 2012 National Coverage Decision (NCD) for Transcatheter Aortic Valve Replacement (TAVR), which treats aortic stenosis, a condition affecting more than two million people in the United States. Data shows proposed volume requirements put in place with the existing NCD for this service restricts access for patients to this safer, more preferred technology without necessarily improving quality. Do you agree that CMS should not increase volume requirements for hospitals and instead, focus on quality metrics and prioritize access to TAVR for all patients?

   Response: On March 26, CMS proposed to update its national coverage policy for Transcatheter Aortic Valve Replacement (TAVR), a procedure for a condition known as "aortic stenosis" in which the heart valve that propels blood from the heart to the rest of the body becomes narrowed. The current national coverage determination, effective May 1, 2012, established CMS coverage for TAVR under Coverage with Evidence Development (CED). Since the finalization of the 2012 national coverage determination, TAVR programs have been established in over 500 hospitals across the country.

   Under the coverage proposal, CMS would continue to cover TAVR under CED when

furnished according to an FDA-approved indication. However, CMS is updating the coverage criteria for hospitals and physicians to begin or maintain a TAVR program. The proposed decision provides more flexibility in how providers can meet the requirements for performing TAVR, while continuing to ensure good health outcomes for patients receiving the procedure.

In developing the proposed decision, CMS met with numerous stakeholders including medical professional societies which continue to recommend requirements for providers to perform a certain volume of heart procedures. The proposed decision includes requirements for providers to perform a certain volume of procedures, given the link between heart procedure volume and patient outcomes in the medical literature and the risks from receiving care in low-volume settings. However, the proposed decision provides more flexibility in how providers can meet these requirements to reflect the latest evidence on volume and outcomes. The proposal is generally consistent with the 2018 Consensus Statement from the American College of Cardiology, the American Association for Thoracic Surgery, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons.

In the proposed decision, CMS is also seeking to gather more information about metrics other than volume that could be used to assess quality and safety. CMS is specifically proposing a question regarding the relationship between other metrics and patient health outcomes, which could inform a future change to replace the volume criteria with a different metric.

The proposed decision was made in response to a formal request and is consistent with recommendations from a meeting of the MEDCAC (Medicare Evidence Development & Coverage Advisory Committee) on July 25, 2018. The MEDCAC provides CMS with an external review of medical literature, technology assessments, public testimony, and other data and information on the benefits, harms, and appropriateness of therapies under review.

CMS issued a final decision on June 21, 2019. The decision memo is available at: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=293&bc=AAAAAAAAACAA&

The Honorable Michael C. Burgess, M.D.

1. Home visiting for pregnant and post-partum mothers, specifically visits conducted by a trained nurse, have been shown to have a demonstrated impact on not only the health of the baby, but also the mother. A 20-year follow-up study of the Nurse-Family Partnership shows that the Partnership is effective at reducing all-cause mortality among mothers and preventable-cause mortality in their first-born children living in highly disadvantaged settings. Can you explain what HHS is doing to invest in and promote smart, evidence-based solutions like Nurse-Family Partnership that improve maternal health outcomes and reduce maternal mortality?

   Response: HHS has a number of agencies and program areas whose missions involve

caring for pregnant women, mothers, and infants. Of particular note is the work done by the Centers for Medicare and Medicaid Services (CMS) and the Health Resources & Services Administration (HRSA).

CMS measures maternal morbidity and mortality through Child and Adult Core Sets, which assess the quality of care women receive at each step in their lifecycle. The collected data is used to improve transparency and accountability in maternal and infant health through the Medicaid Scorecard. It also directs the work of CMS's Maternal and Infant Health Initiative.

The President's FY 2020 Budget proposes using CMS's Center for Medicare and Medicaid Innovation (CMMI) to develop and test innovative health care payment and service delivery models to improve maternal and child health. CMMI is currently working on two recently released opportunities, the Integrated Care for Kids (InCK) and Maternal Opioid Misuse (MOM) payment and service delivery models. These models were designed to improve quality of care, reduce expenditures for beneficiaries, and expand access to health care services for vulnerable Medicaid and Children's Health Insurance Program (CHIP) beneficiaries, especially those affected by the nation's opioid crisis. MOM will run from January 1, 2020 through December 31, 2024. The InCK model is anticipated to begin on January 1, 2020 and run through December 31, 2026.

In 2012, CMS, HRSA, and the Administration for Children and Families launched the Strong Start for Mothers and Newborns (Strong Start) initiative to reduce preterm births and improve outcomes for pregnant women and newborns. Strong Start was comprised of two strategies. The first was a public-private partnership and awareness campaign to reduce the rate of early elective deliveries. The second was a four-year initiative testing the effectiveness of three enhanced prenatal care models – Birth Centers, Group Prenatal Care, and Maternity Care Homes – among pregnant Medicaid and CHIP beneficiaries at high risk for preterm births.

Strong Start has funded 27 awardees and 211 provider sites across 32 states, the District of Columbia, and Puerto Rico. Birth Centers were the most successful of the models and CMS determined that women who received prenatal care in Strong Start Birth Centers had better outcomes and lower costs compared to similar Medicaid beneficiaries not enrolled in the initiative.

HRSA leads the Department in addressing maternal mortality and morbidity through health promotion, risk prevention, and the training of health care professions. More specifically, HRSA supports the Alliance for Innovation on Maternal Health and Safety Initiative which is working with 26 states and more than 1,300 hospitals to implement maternal safety bundles to improve the quality and safety of maternity care. The goal is to prevent 100,000 maternal deaths and severe morbidity by 2018.

Maternal, Infant, and Early Childhood Home Visiting Program, which is funded at $400 million for each Fiscal Year through FY 2022, helps states, territories, and tribal entities fund, develop, and implement evidence-based, voluntary home visiting programs for at-

risk pregnant women and parents with young children up to kindergarten. This builds upon decades of scientific research showing that home visits by a nurse, social worker, early childhood educator, or other trained professional during pregnancy and early childhood improve the lives of pregnant women, mothers, young children and their families.

The FY 2020 Budget provides HRSA $661 million for the Maternal and Child Health Block Grant, which address states' highest maternal child health priorities and serves an estimated 56 million people, including 86 percent of pregnant women, 99 percent of infants, and 55 percent of children nationwide. More information about how HRSA addresses maternal morbidity and mortality can be found at https://www.hrsa.gov/maternal-mortality/index.html.

2. Secretary Azar, I have introduced a bill, H.R. 1510, that would allow states to use the available funds for reinsurance, but also for services such as maternity coverage and newborn care, promoting participation in the markets, and reducing out-of-pocket costs for patients. What are the benefits of coupling reinsurance with other efforts to reduce costs and improve quality of care for patients?

   Response: Reinsurance programs have lowered premiums for consumers, improved market stability, and increased consumer choice. Using flexibility available under section 1332 of the PPACA to provide for State Empowerment and Relief waivers, CMS has worked with States to implement a variety of models to operate their state-based reinsurance programs. To date, seven such state-based programs are currently operating.

3. You noted that the budget "supports a five-part strategy to improve access to prevention, treatment and recovery services, including the full range of medication-assisted treatments." Section 3204 of H.R. 6 was written to assist health care providers who want to prescribe next-generation, injectable or implantable buprenorphine to treat their patients for opioid overuse disorder (OUD). Unfortunately, the Administration has not yet clarified the key provisions of section 3204, including the following:

   a. Dispensing of these next-generation buprenorphine products is now allowable through specialty pharmacies, not only through "buy and bill" with specialty distributors;

   b. Injectable and implantable buprenorphine may now be dispensed to non-waivered health care professionals for injection but only pursuant to a prescription from a DATA-waivered prescriber;

   c. There will be requirements that accompany this distribution method, such as record-keeping safeguards, an inability to stockpile, a 14-day limit on administration, and compliance with state law.

      Response to a-c: HHS is committed to expanding access to evidence-based treatments for opioid use disorder (OUD) including access to medication assisted

treatment (MAT). We agree that it is important to provide patients with OUD with the full range of MAT services in order to best meet an individual patient's treatment needs. HHS continues to work with its federal partners to educate providers and supply them with the information they need to effectively treat OUD. As directed by Section 3204 of the SUPPORT Act, HHS is committed to supporting DEA's efforts to implement key components of this provision.

4. Experts agree that health care providers treating opioid overuse disorder should be empowered to inform their patients about all the potential treatment options to best meet the individual patient's needs. While the language of Section 3204 amends law under the authority of the DEA, nonetheless, the purpose of this language is entirely consistent with the goals you enunciated for improving access to treatment services, including the full-range of MAT services. Will HHS work with DEA on a priority basis to provide health care providers with the information they need about how this provision will be implemented?

   Response: HHS is committed to expanding access to evidence-based treatments for opioid use disorder (OUD) including access to medication assisted treatment (MAT). We agree that it is important to provide patients with OUD with the full range of MAT services in order to best meet an individual patient's treatment needs. HHS continues to work with its federal partners to educate providers and supply them with the information they need to effectively treat OUD. As directed by Section 3204 of the SUPPORT Act, HHS is committed to supporting DEA's efforts to implement key components of this provision.

5. Due to challenges in securing research funding, recent graduates are discouraged from pursuing careers in research. Congress emphasized the importance of support for early career researchers in passing the 21st Century Cures legislation. Can you describe the current efforts at the National Institutes of health (NIH) on this issue, including the Next Generation of Researchers Initiative and how they would be impacted by the administration's proposed budget for the National Institutes of Health (NIH) in FY2020?

   Response: NIH leadership, scientists in the research community, Congress, and the public have grown increasingly concerned about the long-term stability of the biomedical research enterprise. Over time, the number of applications seeking NIH support has increased faster than available funding, which may contribute to early-stage career scientists turning away from careers in research. But they are our future, and we cannot afford to lose them.

   In August 2017, NIH launched the Next Generation Researchers Initiative (NGRI). This initiative – which also responds to provisions in the 21st Century Cures Act – addresses challenges faced by early-stage investigators trying to embark upon and sustain independent research careers. As a key part of the initiative, NIH is prioritizing meritorious applications from early stage investigators seeking their first award, and also for investigators currently supported by NIH who are at risk of losing all research support. Moreover, in their award decisions, NIH Institutes and Centers will consider

factors such as emerging areas of scientific inquiry, the distribution of the scientific portfolio, and the projected needs of the scientific workforce, including enhanced workforce diversity.

The FY 2020 Budget includes a dedicated $100 million in the Office of the Director for NGRI to supplement efforts undertaken by the Institutes and Centers with their own appropriations.

6. The opioid epidemic is driving increased rates of multiple infectious diseases, including HIV, hepatitis B and C, and infections of the heart, skin, soft tissue, bones, and joints among people who inject drugs. For instance, according to the Centers for Disease Control and Prevention (CDC) the number of reported cases of hepatitis C more than tripled from 2010 to 2016 nationwide, with most new infections due to increased injection drug use associated with the opioid epidemic. While there are less available data on many other infections due to insufficient reporting and surveillance, regional and state analyses indicate a significant increase in hospital infections due to endocarditis (an infection of the heart valve) linked to injection drug use. The administration's plan addresses the opioid crisis, in part, by proposing $58 million in new funding for the CDC to explicitly address the infectious diseases impacts and is supported by many infectious disease organizations. How will this additional funding be utilized to ensure that the federal response to the opioid epidemic includes greater emphasis on public health interventions, research, and workforce support to prevent, track, and treat opioid-related infectious diseases?

   Response: CDC is committed to protecting the public's health and preventing infectious diseases associated with the opioid epidemic, particularly viral hepatitis, and HIV, bacterial and fungal infections (which can cause heart, skin, soft tissue, bones, and joint infections) and related co-morbidities. CDC works to help prevent and treat infections and reduce overdose deaths through community-based programs that provide comprehensive preventive services and ensure people are linked to care.

   The proposed FY 2020 President's Budget level of $58 million for Infectious Disease and the Opioid Epidemic activities would build upon the $5 million received in FY 2019 for Infectious Disease and the Opioid Epidemic. CDC will work to reduce new infections and prevent morbidity and mortality from infectious diseases related to the opioid crisis.

   In FY 2020, CDC would target resources to state and local jurisdictions to address identified infectious disease vulnerabilities. CDC's support for state and local jurisdictions would provide increased capacity to test for viral hepatitis and HIV in high-impact settings, link people to treatment for infectious diseases, and, where needed, refer people for substance use disorder treatment, and ensure quality implementation of programs. CDC will also strengthen surveillance and laboratory capacity, providing critical information to guide patient-centered response, including information on co-morbidities. CDC will also work to ensure that evidence-based and comprehensive preventive services are provided for people who use drugs. With these investments, CDC will help reduce new infections, prevent morbidity and mortality of infectious diseases,

and help reduce overdose and overdose deaths.

7. The standard base monthly Part D premium is $33.19 in 2019, an increase of only 3% from 2006 whereas the standard Part B premium has increased 53% in that same time. Can you explain how Part D's design has led to this constraint on premiums? How do we insure in tackling the cost of prescription drugs we maintain the program's ability to control premiums?

   Response: Rebates and other price concessions are growing faster than Part D gross drug costs. Plan sponsors may subtract expected rebate amounts from their bids. Because premiums are based on bid amounts, rebate growth has held down premiums – even during period of double-digit increases in Part D gross drug costs. However, rebates are not subtracted from point-of-sale prices paid by Medicare beneficiaries. As a result, beneficiaries pay more out of their own pocket than they would if rebates were paid at the point of sale. These higher pre-rebate prices can also cause faster progress into the catastrophic phase of the benefit, where the Federal Government pays a greater share of drug costs. As a result, the Medicare Trustees have annually documented an increase in drug prices, rebates, and Federal reinsurance spending, while Part D premiums and Federal direct subsidy spending have remained relatively flat.

   The Administration has proposed to address these perverse incentives with a proposed rule removing safe harbor protection for manufacturer rebates, and an FY 2020 budget proposal encouraging Part D plans to better manage beneficiary costs by restructuring catastrophic coverage and requiring Part D plans to bear more of the risk.

   In addition, under the American Patients First Blueprint, the Administration has been working to strengthen the negotiating power of Part D plans so that they can offer the best value to beneficiaries. With improved negotiation between plans and drug companies, premiums could be held constant and savings could be even greater.

8. The budget asks for reform to the calculation of True out of Pocket calculations to exclude manufacturer discounts. Can you explain why this proposal is important and how the current means of calculating TROOP is not reflecting of what beneficiaries pay out of pocket and shifts costs onto the taxpayer?

   Response: Under the current benefit structure, Part D plans are incentivized to encourage beneficiaries to use costly brand drugs in order to accelerate their progression through the coverage gap into the catastrophic phase, where Medicare covers 80 percent of costs. Required discounts paid by brand drug and biosimilar manufacturers in the coverage gap are included in the calculation of a beneficiary's "true out-of-pocket costs (TrOOP)," which are a combination of a beneficiary's actual out–of-pocket costs and these discounts. In contrast, generic drugs are not subject to a manufacturer discount that counts toward TrOOP. Once a beneficiary's out-of-pocket spending reaches the annually updated TrOOP threshold, a beneficiary moves out of the coverage gap and into the catastrophic phase of the benefit. The manufacturer discounts mean that patients using

generic drugs are required to spend more out of their own pockets before reaching this threshold, compared with patients using brand drugs. The Budget proposal restructures the coverage gap discount program to exclude manufacturer discounts from the calculation of true out-of-pocket costs in order to correct this misaligned incentive that encourages plans to promote costly brand drugs.

9. States, most notably Louisiana, have proposed contracting with drug manufacturers of expensive medications to set up a guaranteed payment subscription model. This has the potential to guarantee returns for manufacturers but allow the state to spread out payments making them more likely to try to target as much of the drug at needy populations instead of looking at ways to control costs by restricting access. Can you tell the Committee your thoughts on this proposal and what the Administration can do to explore this option with states?

   Response: Increasing access to quality, affordable medication is a priority for this Administration. HHS worked with the State to provide technical assistance in developing a model that ensured access for the state's Medicaid population and 340B drug discount program.

10. The budget has several proposals regarding site neutral payments. Can you detail what these proposals are and why they are necessary to protect the trust fund but also save beneficiaries money in their coinsurance?

    Response: The Administration is focused on ensuring Federal health programs produce quality outcomes and results at the lowest possible cost for the American people. The President's FY 2020 Budget supports an expansion of value-based payments in Medicare. That expansion, along with implementation of a package of other reforms, would improve quality, promote competition, reduce the federal burden on providers and patients, and focus payments on value instead of volume or site of service.

    The President's FY 2020 Budget includes a proposal to redesign outpatient hospital and ambulatory surgical center payment systems to make risk-adjusted payments. Under current law, Medicare bases payments for services furnished at outpatient hospital and ambulatory surgical centers on the setting of care rather than patient acuity. The proposal would risk-adjust payments to these facilities based on the severity of patients' diagnoses. These adjustments would be made in a budget neutral manner. This proposal would promote site neutrality in payments for similar services and similar patient characteristics at these facilities.

    The President's FY 2020 Budget includes a proposal to pay on-campus hospital outpatient departments at the physician office rate for certain services. Medicare generally pays on-campus hospital outpatient departments substantially more than physician offices for the same services. Effective CY 2020, this proposal would make site neutral payments between on-campus hospital outpatient departments and physician offices for certain services such as clinic visits, eliminating the disparity between what Medicare pays in these settings for the same services. This would result in an estimated

$131.4 billion in savings over 10 years.

The President's FY 2020 Budget includes a proposal to address excessive payment for post-acute care providers by establishing a unified payment system based on patients' clinical needs rather than site of care. Medicare payment for post-acute care service can differ substantially for similar beneficiaries depending on the setting, due to variation in supply and lack of evidence-based criteria regarding patient eligibility, the most appropriate setting, and level of care required. Under this proposal, skilled nursing facilities, home health agencies, and inpatient rehabilitation facilities would 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. Payment rates would be budget neutral in FY 2025, risk adjusted, and 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, similar to the Diagnosis-Related Group methodology under the Inpatient Prospective Payment System. This proposal would reduce costs, increase fairness, and give the Secretary the authority to adjust payments based on quality of care, geographic differences in labor and other costs, and other factors as deemed appropriate. This would result in an estimated $101.2 billion in savings over 10 years.

The President's FY 2020 Budget includes a proposal to pay site neutral rates to all hospital-owned physician offices located off-campus. Medicare pays most off-campus hospital outpatient departments higher rates than the Physician Fee Schedule for the same services. These facility types include emergency departments, cancer hospitals, and grandfathered off-campus hospital outpatient departments billing under the Outpatient Prospective Payment System or under construction before November 2, 2015. This proposal would require all off-campus hospital outpatient departments to be paid under the Physician Fee Schedule, effective CY 2020. This change would promote site neutrality by aligning payments to hospital outpatient departments with payments to physician offices, regardless of hospital ownership or facility type. This would result in an estimated $28.7 billion in savings over 10 years.

The President's FY 2020 Budget includes a proposal to authorize long-term care hospital site neutral exceptions criteria. Medicare pays a higher prospective payment rate to Long Term Care Hospitals (LTCHs) when admissions follow an acute care hospital stay with three or more days in an intensive care unit, or the LTCH provides at least 96-hours of mechanical ventilation services. Absent meeting these criteria, LTCHs receive a lower Medicare payment rate comparable to acute care hospitals under the Inpatient Prospective Payment System. Effective FY 2020, this proposal would raise the intensive care unit stay threshold from three days to eight days to more accurately identify the chronically ill patients who typically receive the specialized care LTCHs provide. This change would promote site neutrality by basing payment on clinical characteristics and the needs of patients, rather than on location of care. This would result in an estimated savings of $10 billion over 10 years.

11. Can you detail the impending solvency of the Medicare Trust Fund and what will happen to beneficiaries if Medicare is not reformed?

    Response: On April 22, the Medicare Board of Trustees released their annual report for Medicare's two separate trust funds – the Hospital Insurance (HI) Trust Fund, which funds Medicare Part A, and the Supplementary Medical Insurance (SMI) Trust Fund, which funds Medicare Part B and D.

    The Trustees project that total Medicare costs (including both HI and SMI expenditures) will grow from approximately 3.7 percent of GDP in 2018 to 5.9 percent of GDP by 2038, and then increase gradually thereafter to about 6.5 percent of GDP by 2093. The faster rate of growth in Medicare spending as compared to growth in GDP is attributable to faster Medicare population growth and increases in the volume and intensity of healthcare services.

    The report found that the HI Trust Fund will be able to pay full benefits until 2026, the same as last year's report. The SMI Trust Fund, which covers Medicare Part B and D, had $104 billion in assets at the end of 2018. Part B helps pay for physician, outpatient hospital, home health, and other services for the aged and disabled who voluntarily enroll. It is expected to be adequately financed in all years because premium income and general revenue income are reset annually to cover expected costs and ensure a reserve for Part B costs. However, the aging population and rising health care costs are causing SMI projected costs to grow steadily from 2.1 percent of GDP in 2018 to approximately 3.7 percent of GDP in 2038. Part D provides subsidized access to drug insurance coverage on a voluntary basis for all beneficiaries, as well as premium and cost-sharing subsidies for low-income enrollees. Findings revealed that Part D drug spending projections are lower than in last year's report because of slower price growth and a continuing trend of higher manufacturer rebates.

    The President's Fiscal Year 2020 Budget, if enacted, would continue to strengthen the fiscal integrity of the Medicare program and extend the solvency of HI Trust Fund by about 8 years. Under President Trump's leadership, CMS has already introduced a number of initiatives to strengthen and protect Medicare and proposed and finalized a number of rules that advance CMS's priority of creating a patient-driven healthcare system through competition. In particular, CMS is strengthening Medicare through increasing choice in Medicare Advantage and adding supplemental benefits to the program; offering more care options for people with diabetes; providing new telehealth services; and lowering prescription drug costs for seniors. CMS is also continuing work to advance policies to increase price transparency and help beneficiaries compare costs across different providers.

12. Mr. Secretary, under the Obama Administration, premiums in the individual market increased every year. But President Trump has enacted several deregulatory reforms, and premiums decreased. Is this true?

13. Democrats like to say the President is sabotaging Obamacare. But under his leadership and as a result of the deregulatory actions he's taken, premiums have dropped for the first time since 2014. Not to mention, the number of counties with only one insurer has dropped from 56% last year to 39% this year. Is lowering health care costs and increasing plan options, "sabotage," in your view?

    Response to 12-13: This Administration took action to address the skyrocketing price of health insurance, and we are starting to see the results in the form of lower premiums, more stable markets, and increased choice. Our 2019 Open Enrollment Report confirms another successful open enrollment period coinciding with a stabilization of premiums after years of substantial increases. Specifically, the report showed plan selections in Exchange plans in the 50 states and D.C. remained steady at 11.4 million, representing a minimal decline of around 300,000 plan selections from the same time last year. Also, as outlined in the report, average total premiums for plans selected through HealthCare.gov dropped by 1 percent from the prior year, the first decline since the Exchanges began operations in 2014.

    Recognizing individual health insurance premiums are no longer affordable for many Americans, the Trump Administration is committed to expanding more affordable coverage options to this group of people left behind by the PPACA, which spurred recent actions to try to expand access to association health plans and short-term health plans, as well as to extend the "grandmothered" plan non-enforcement policy for another year.

14. House Republicans believe in the importance of ensuring protections for individuals with pre-existing conditions. This is a commitment you and President Trump share, correct?

    Response: This Administration is committed to protecting individuals with pre-existing conditions. For example, 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.

15. The budget proposes reducing the grade period for exchange premiums from 90 days to 30 days. Dr. Burgess has a bill that would make this proposal law. Do you believe this is smart policy?

16. Are individuals gaming the system by taking advantage of the 90 day grace period?

    Response to 15-16: The President's FY 2020 Budget includes a proposal to reduce the premium payment grace period for individuals enrolled in Health Benefit Exchange plans and receiving Advanced Payments of the Premium Tax Credit (APTC) from 90 days to 30 days. This proposal closes a loophole that allows for a subsidized enrollee in an Exchange plan to discontinue their premium payments for up to 90 days, deciding to "catch up" only if he or she has sudden medical needs during the 90-day grace period.

Current law dictates that individuals receiving APTC to subsidize their enrollment in Exchange plans are entitled to a 90-day grace period to give additional time to pay monthly health insurance premiums before coverage is terminated for non-payment of premium. The Patient Protection and Affordable Care Act (PPACA) established a uniform timeframe for subsidized enrollees to "true up" any past due payments prior to their health insurance policy being terminated. During the 90-day grace period, issuers must pay claims for the first month and are allowed to set aside claims for the second and third months of coverage until past due premiums are settled. Before the enactment of the PPACA, grace periods were determined by states and varied among them, with the majority of states providing for a 30-day grace period. These state laws continue to apply for consumers not receiving subsidies through an Exchange.

This proposal places more responsibility on individuals that fall behind on premiums, thereby reducing the amount of time payments remain outstanding. It would result in an estimated $78 million in savings to Treasury over 10 years, and may also reduce health insurance premiums on the Exchanges by reducing some of the uncertainty associated with "gaming" that issuers may load into their premiums.

17. Mr. Secretary, ad you may know, eight Democratic members of this subcommittee helped write their party's single-payer, government run Medicare for All bill. Would Medicare for All speed up the insolvency of the Medicare Trust Fund?

Response: Proposals for "Medicare for All" would put the program's funding further into jeopardy. We need to focus on a conversation about the drivers of health care costs in America, where health care spending is on course to eclipse one-fifth of national GDP by 2026. The answer to the skyrocketing cost curve is not greater government intervention leading to the evisceration of the private insurance marketplace, but just the opposite: increase choices, unleash private competition and innovation, and lighten regulations on plans, doctors and providers.

18. To date, 14 states have submitted waivers under section 1332. Eight of these states have active waivers. Mr. Secretary, would you agree that instead of a one-size-fits-all approach under narrow bounds established by the previous Obama administration interpretation of the statute, we should allow states to continue to review and reform their markets based off Trump administration guidance, so they can continue their appropriate role as laboratories of innovation?

Response: Last November, CMS issued guidance[9] related to section 1332 of the PPACA. This guidance intends to expand state flexibility, empowering states to address problems with their insurance markets and increase coverage options for their residents, while at the same time encouraging states to adopt innovative strategies to reduce future overall health care spending. The overarching goal of 1332 waivers is to empower states to develop innovative health coverage options that best fit the states' individual needs. This aligns with the Administration's goal to give all Americans the opportunity to gain quality and affordable health coverage regardless of income, geography, age, sex, or

[9] https://www.federalregister.gov/documents/2018/10/24/2018-23182/state-relief-and-empowerment-waivers

health status. Through section 1332 waivers, CMS aims to assist states with developing health insurance markets that offer more choice, competition, and affordability to Americans.

19. According to CMS, for plan year 2019, the Trump administration "…sent over 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." Mr. Secretary, do you think this is a more efficient and effective way to reach younger consumers than spending tens of millions of dollars on Navigators?

    Response: When 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 Federally Facilitated Exchanges (FFE)s, 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 Announcement for the FFE Navigator Program for plan year 2019, 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.

20. Regulation of combination products has a direct impact on the cost of things insulin, epi-pens, and naloxone auto-injectors. Can you provide an update on the progress that has been made in modernizing regulation of combination products at FDA?

    Response: Combination products present significant opportunities for improvement in patient care. Because combination products often combine a drug or biologic with a device, these products can sometimes be more complex to develop and it can be less clear to innovators on how to best engage the regulatory process to advance these innovations. For example, potential differences in the premarket review pathways across medical product centers can impact the regulatory processes and timelines for development.

    Just this past February, FDA announced a framework designed to enhance clarity, predictability, efficiency and consistency of premarket review for combination products. This framework will help ensure that the FDA coordinates effectively around the premarket review of these products. Among other steps, FDA clarified what pathways to approval are available, depending on whether a combination product is drug-led, biologic-led, or device-led. FDA will also be publishing additional guidance on specific

premarket considerations for combination products to ensure efficient product development. FDA is focused on implementing an efficient framework to ensure the timely and effective review of combination products to create the most robust pathway to advance these kinds of innovations.

The Honorable John Shimkus

1. 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' 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?

   Response: We are committed to supporting Medicare beneficiaries with access to innovative technologies that are necessary and improve beneficiary health outcomes, including in the treatment of kidney disease and ESRD. In the interest of supporting innovation, ensuring appropriate payment for all drugs and biologics, 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 we 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. CMS received a number of comments from stakeholders on this issue. We will take these comments into account as we consider any changes to the outlier policy and other payment adjustments such as TDAPA for future rulemaking.

   CMS is also doing some work through CMMI 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 Honorable Brett Guthrie

1. H.R. 6, the SUPPORT for Patients and Communities Act included language from the Eliminating Opioid-Related Infectious Diseases Act, which expands surveillance and education about infections associated with injection drug use. How does this program complement the Administration's broader plan to end the HIV Epidemic in America?

   Response: CDC is committed to protecting the public's health and preventing infectious

diseases that are associated with the opioid epidemic, particularly viral hepatitis and HIV, by increasing testing in high-impact settings, helping to refer people for substance use disorder treatment, and ensuring high quality implementation of public health programs. The intersection of opioids and infectious diseases puts our progress in HIV prevention at risk. One of the greatest successes in HIV prevention has been the 80 percent decrease in incidence of injection drug use-associated HIV infections over the past two decades. But, since 2011, our progress has stalled and is impacted by injection drug use-associated HIV.

The Administration's initiative to end the HIV epidemic in the U.S. complements and enhances other CDC programs addressing the infectious disease consequences of the opioid crisis through three strategies of the HIV initiative: diagnose, protect and respond.

- **<u>Diagnose</u> all individuals with HIV as early as possible after infection.**
    - Systems to make HIV testing more accessible in non-traditional settings will support efforts to increase knowledge of status and linkage to care for people who use drugs and their partners (i.e., make testing routine in syringe services programs (SSPS), medication-assisted therapy (MAT), STD services, and jails/prisons).
- **<u>Protect</u> the target populations using proven prevention approaches.**
    - Comprehensive SSPs are proven prevention interventions. CDC will support comprehensive SSPs as they provide a suite of care, treatment, and prevention services for people who inject drugs and can serve as an entry point to HIV care and treatment, recovery services, and overdose prevention.
- **<u>Respond</u> rapidly to detect, characterize, contain, and control growing HIV clusters.**
    - Large increases in drug use across the country have resulted in multiple HIV clusters and outbreaks. Currently nationwide, there is limited capacity to detect and respond to growing clusters and outbreaks. Expanding and accelerating the deployment of effective cluster detection and responses systems is critical to quickly identify and respond to every concerning cluster of new HIV infections – and stop the spread of HIV.

<u>The Honorable Gus M. Bilirakis</u>

1. In December 2018 comments to CMS, a group of eight leading clinical respiratory groups and organizations representing patients with severe health challenges expressed concern that putting ventilators under the DMEPOS bidding program would "undoubtable create grave clinical risks" and "result in patient deaths and increased hospital and nursing home costs." These groups included the American Lung Association, the ALS Association, The COPD Foundation, and the National Association for the Direction of Respiratory Care. Do you know what kind of analysis CMS has done to assure that these kind of drastic outcomes won't come to pass for medically vulnerable populations who depend on non-invasive ventilators?

Response: CMS is required by law to phase items into the DMEPOS competitive bidding

program. Items that are to be phased in are those items with high Medicare spending or rapidly increasing Medicare spending. In November 2018, CMS sought comments on phasing in new items, including non-invasive ventilators, for the next round of the DMEPOS competitive bidding program.

Under the DMEPOS competitive bidding program, CMS will be conducting real-time claims analysis to monitor health status of Medicare beneficiaries in competitive bidding areas, including emergency room visits and admissions to skilled nursing facilities. This monitoring is to ensure that there are no negative changes in beneficiary health outcomes or access to DMEPOS items.

2. I would like to first commend the work you and the FDA have and continue to do to address e-cigarettes and other tobacco products that cause public policy health officials youth usage and access concerns. I am aware FDA sought and received public comments from industry and other interested parties for a Cigar ANPRM last year which have been indefinitely shelved for long term consideration. Can you provide an update on the current status of this ANPRM?

   Response: As you know, last year, FDA issued an ANPRM to provide an opportunity for the public to provide new information for the Agency to consider in the regulation of "premium" cigars. FDA sought comments and scientific data related to how to define a "premium" cigar and the patterns of use and resulting public health impacts from these products. FDA received over 32,000 comments in response to the ANPRM on the regulation of "premium" cigars and it continues to review these comments.

   In the meantime, all cigars remain subject to regulation based on FDA's previous determination that there was no appropriate public health justification to exempt "premium" cigars.

3. Congress passed legislation to allow Physical Therapists to use locum tenens in rural and underserved areas. Since the passage of the law can you provide us information on the implementation of the program?

   a. How many patients were seen by a locum tenens physical therapist since it became law? Please provide the answer for each year, as well as each quarter.
   b. Was the provision used more in exclusively rural, rural medically underserved areas, or urban medically underserved areas?
   c. What was the average number of consecutive visits where a locum tenens was utilized?
   d. What was the longest duration where a locum tenens physical therapist provided care?
   e. What was the shortest number of visits where care was provided by a locum tenens physical therapist?
   f. What was the average age of the Medicare beneficiary who was seen by a locum tenens physical therapist?

Response to 3a-f: Approximately 60 million people live in rural areas, including millions of Medicare and Medicaid beneficiaries. HHS recognizes the many obstacles that rural Americans face, including living in communities with disproportionally higher poverty rates, having more chronic conditions, being uninsured or underinsured, as well as experiencing a fragmented healthcare delivery system with an overworked and shrinking health workforce, and lacking access to specialty services. That's why CMS developed the Rural Health Strategy (issued in May 2018) to focus on areas where the agency can better serve individuals in rural areas and avoid unintended consequences of policy and program implementation for these communities. The strategy applies a rural lens to new and ongoing activities of the Agency and informs the pathway by which CMS can achieve its rural health vision through intra-agency collaboration, stakeholder engagement, and the elevation of programs and policies that will advance the state of rural health care in America.

HHS appreciates the tools given by Congress in the 21st Century Cures Act to help improve the quality of health care services in rural and underserved areas. Under section 16006 of the 21st Century Cures Act, a Medicare-enrolled physical therapist may use a substitute physical therapist to furnish outpatient physical therapy services in a Health Professional Shortage Area, a Medically Underserved Area, or a rural area under a locum tenens or reciprocal billing arrangement on or after June 13, 2017.

A patient's regular physical therapist may submit the claim, and receive the Part B payment, for covered visit services of a substitute physician or physical therapist, if:

- The regular physical therapist is unavailable to provide the services;
- The Medicare beneficiary has arranged or seeks to receive the services from the regular physical therapist;
- The regular physical therapist pays the substitute for his/her services on a per diem or similar fee-for-time basis;
- The substitute physical therapist does not provide the services to Medicare patients over a continuous period of longer than 60 days subject to the following exception: A physical therapist called to active duty in the Armed Forces may bill for services furnished under a fee-for-time compensation arrangement for longer than the 60-day limit; and
- The physical therapist indicates that the services were provided by a substitute physical therapist under a fee-for-time compensation arrangement meeting the requirements of this section by entering HCPCS code modifier Q6 (service furnished under a fee-for-time compensation arrangement by a substitute physical therapist furnishing outpatient physical therapy services in a health professional shortage area, a medically underserved area, or a rural area) after the procedure code.

While CMS has not analyzed the specific data you referenced, it is always looking for ways to improve its programs, and CMS is committed to making sure

beneficiaries in rural and underserved areas have access to the care they need, including physical therapy services. We welcome the opportunity to work with your office on this and other issues.

4. Over the course of the last several years, there have been significant advancements in the development of gene therapies. In response to those developments, FDA and NIH proposed an update of the federal oversight framework for gene therapies last summer and the FDA released draft guidance to aid the development of gene therapies for rare diseases, retinal disorders, and hemophilia in 2018. In addition, FDA indicated recently that it plans to take a number of steps related to gene therapies in the coming year, including developing a guidance document related to the development of gene therapies for particular neurodegenerative diseases. Given the potential promise of these new therapies, particularly for patients with life threatening or disabling conditions, such as Parkinson's disease or sickle cell disease, and the government's updated regulatory framework and newly introduced guidance documents, does HHS plan to take additional steps to educate patients, health care providers, and other key stakeholders about the evolution of the field of gene therapies and its potential for addressing significant unmet health needs?

   Response: Cell-based and directly administered gene therapies hold tremendous promise for addressing some of the most intractable diseases. But with their novelty comes new uncertainties and some unique potential risks. Our efforts are aimed at helping innovators proactively address these potential risks, while we outline a modern and efficient pathway for the continued development of these innovations. FDA intends to work with stakeholders working in the field, including patient advocacy organizations and other groups, to help provide additional education about the nature of gene therapy, its potential risks, and the potential benefits. Some of the steps that the FDA has taken include the following:

   In early 2019, FDA's Center for Biologics Evaluation and Research (CBER) published its 2019 guidance agenda.[10] This list includes the guidance documents CBER intends to publish during calendar year 2019. Since the beginning of 2019, CBER has issued the following guidances identified on the agenda that are related to cell and gene therapies:

   - Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Guidance for Industry (Issued February 2019)
   - Evaluation of Devices used with Regenerative Medicine Advanced Therapies; Guidance for Industry (Issued February 2019)
   - Standards Development and their Use in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research; Guidance for Industry and Food and Drug Administration Staff (Issued March 2019)

   In addition, as noted on the 2019 guidance agenda, CBER intends to finalize the six draft guidance documents related to gene therapies during calendar year 2019.

[10] The 2019 CBER Guidance Agenda is available at https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/ucm431409.pdf.

- Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus during Product Manufacture and Patient Follow-up; Guidance for Industry
- Long Term Follow-Up After Administration of Human Gene Therapy Products; Guidance for Industry
- Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications; Guidance for Industry
- Human Gene Therapy for Hemophilia; Guidance for Industry
- Human Gene Therapy for Retinal Disorders; Guidance for Industry
- Human Gene Therapy for Rare Diseases; Guidance for Industry

However, CBER is not bound by the list of topics on the guidance agenda, required to issue every guidance on the list, or precluded from developing guidance documents on topics not on the list. CBER intends to be responsive to the needs of stakeholders as it considers what guidance documents are most urgently needed to facilitate the development of products to benefit patients. CBER will update the guidance agenda if it intends to develop guidance on new topics, including for diseases such as neurodegenerative diseases.

Recognizing the promise that such products hold, as part of the 21st Century Cures Act, Congress established the Regenerative Medicine Advanced Therapy Designation (RMAT) designation program, which is intended to help facilitate the development and review of certain regenerative medicine therapies. The benefits of RMAT designation include earlier and more frequent interactions with FDA, similar to those available to Breakthrough Therapy-designated products, potential eligibility for priority review and accelerated approval, and flexibility regarding fulfillment of postmarketing requirements if accelerated approval is granted. CBER has robustly implemented these provisions since the enactment of the 21st Century Cures Act and has interpreted the RMAT designation program to apply to gene therapies, including genetically modified cells, that lead to a sustained effect on cells or tissues.

Building on the benefits that such early discussions with product developers can have in facilitating advancement of product development, CBER established a new meeting program - INitial Targeted Engagement for Regulatory Advice on CBER producTs (or INTERACT). The INTERACT meeting program was created for potential sponsors to engage with CBER staff and obtain initial, nonbinding advice on a specific topic or issue that is critical to early product development. These discussions can help answer important questions, remove roadblocks, and ultimately help create a clearer route to getting safe and effective products to patients.

FDA remains committed to facilitating access to promising investigational medicines for patients with serious or immediately life-threatening diseases or conditions outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

5. CMS has proposed changes to Part D to shift rebates to the point-of-sale in 2020. From conversations I've had with the Part D plans, there is concern that they will have to submit bids before the OIG finalizes its rule and CMS issues guidance on the new rebate system. How will CMS get the plans to be able to successfully bid and understand the payment requirements in time for January 2020?

   Response: On February 6, 2019, the Department of Health and Human Services, Office of Inspector General (OIG), published a proposed rule that would expressly exclude from safe harbor protection under the Anti-Kickback Statute rebates on prescription drugs paid by manufacturers to Part D plan sponsors, Medicaid managed care organizations, and pharmacy benefit managers under contract with them. The rule also proposed the creation of two new safe harbors.

   In guidance released through a memorandum to Part D Plan Sponsors on April 5, 2019, CMS specified for CY 2020 the following practice and procedure with respect to the submission of bids: plan sponsors will submit bids for CY 2020 in a form and manner that is consistent with the Anti-Kickback Statute law and regulations in effect as of the bid submission deadline, including, for the purposes of bid development, the treatment of manufacturer rebates pursuant to CMS' existing rules and guidance related to Direct and Indirect Remuneration.

   In addition, in the memorandum, CMS stated that if there is a change in the safe harbor rules effective in 2020, CMS will conduct a demonstration that would test an efficient transition for beneficiaries and plans to such a change in the Part D program. The demonstration would consist of a modification to the Part D risk corridors for plans for which a bid is submitted. Under the demonstration, the government would bear or retain 95 percent of the deviation between a target amount and actual incurred costs beyond the first 0.5 percent. Participation in the two-year demonstration would be voluntary and plans choosing to participate would do so for both years. If the OIG rule is finalized and CMS conducts the demonstration, further guidance regarding the application process will be provided.

6. Approximately 3 million Medicare beneficiaries take the drug Coumadin and rely on regular blood tests to monitor their levels of clotting factor to reduce their risk of stroke or hemorrhage. For many of these patients, home testing has been a patient-friendly option to minimize lab or physician office visits. Patients who self-test have been demonstrated to achieve improved therapeutic management, resulting in fewer hospitalizations, reduced occurrence of stroke, and reduced drug related complications. Despite the importance of regular testing for Coumadin patients, CMS has reduced reimbursement for self-testing by 35% since 2017. The reimbursement reductions occurred because the pricing for testing in the home is being calculated as if it was done in a physician's office which does not account for indirect costs such as those associated with home visits, additional capital equipment to allow for each patient to have a testing device in the home, and continued patient follow-up calls. Do you think that we should be looking for ways to promote home based care options when appropriate, rather than pushing patients into less convenient

clinical settings, especially if that change causes compliance to suffer, resulting in increased medical costs?

Response: In the calendar year (CY) 2018 Medicare Physician Fee Schedule (PFS) final rule, CMS changed the prothrombin time (PT/NR) test home monitoring codes and finalized payment rates for these services based on updated resource assumptions. In response to public comments on our proposed policy, CMS increased the number of included test strips, lancets, and alcohol swab-pads by two each. CMS used paid invoices to update the price of the supply "INR test strip."

With regard to indirect practice expense for particular services paid under the PFS, CMS generally does not conduct a separate indirect practice expense survey for individual specialties or services. Instead, it uses survey data on specialty level indirect practice expense incurred per hour. In this way, CMS has data for all specialties.

In the CY 2019 PFS final rule, CMS repriced many of the items in the direct practice expense category. CMS initiated a market research contract to conduct an in-depth and robust market research study to update the PFS direct practice expense inputs for supply and equipment pricing for approximately 1,300 supplies and 750 equipment items for CY 2019. Among the items it reported on was the INR test strip used in these codes, which had a CY 2018 price of $5.66, and which was updated to a price of $4.71, based on invoice submissions, to be phased in over four years. The current CY 2019 price for the supply is $5.42.

The complete list of updated supply and equipment pricing is available in the final rule and on CMS' website. CMS welcomes the submission of updated pricing information regarding these particular supply items through the submission of valid invoices from commenters and other stakeholders to consider in future rulemaking.

The Honorable Markwayne Mullin

1. As you know, 42 CFR Part 2 creates barriers for providers to treat patients with substance use disorder. My bill, the Overdose Prevention and Safety Act passed the House with wide bipartisan support in the last Congress by a vote of 357-57. Do you believe that modernizing Part 2 is imperative to allow physicians to give the highest quality treatment to patients with substance use disorder?

    a. Through the rulemaking process, what can HHS do to further modernize Part 2?
    b. Is this something that HHS is considering?

    Response to a-b: It is critical that we protect the rights of individuals with substance use disorders while also providing these individuals the safest and most effective treatment possible when they experience medical illnesses. This requires that healthcare providers be able to share information and for care to be provided in a coordinated and integrated manner. The FY2020 Budget proposes changes that would further align Part 2 and its governing statute with HIPAA. Additionally, in

both the 2017 final rule and 2018 supplemental final rule, SAMHSA signaled its intent to continue to monitor implementation of 42 CFR Part 2 and explore potential future rulemaking, in an ongoing effort to better address the complexities of health information technology, patient privacy, and interoperability. HHS has submitted to the Office of Management and Budget, for interagency review under Executive Order 12866, two draft proposed rules that would amend Part 2.

2. As you know, the Indian Health Service is in disarray. Numerous reports and watchdogs over the years that highlighted the failings of the agency. Most recently a Wall Street Journal investigation highlighted the mishandling of a pediatrician who sexually assaulted his patients for over 25 years. IHS needs more than an investigation, it needs a complete overhaul and change in leadership.

    a. How does your agency plan on reforming IHS?

    Response: The Trump Administration established a new leadership team at the Indian Health Service (IHS), led by RADM Michael Weahkee, who is vigorously pursuing and is committed to ensuring a culture of quality, leadership, and accountability across the agency. The IHS mission of providing quality health care requires a safe environment for patients. Patient security and protection is a crucial responsibility, especially when children are involved. We are committed to continuously improving our IHS health care delivery system to uphold this important responsibility.

    In February 2019, I requested the HHS Office of Inspector General to review the effectiveness of IHS actions concerning Dr. Weber. In addition, IHS recently selected an independent contractor to conduct a medical quality assurance review to examine whether laws, policies, and procedures have been followed. The review will also recommend additional improvements IHS can implement to better protect patients.

    Recently, IHS has realized significant improvements to quality care for American Indians and Alaska Natives. These improvements include establishing an Office of Quality; implementing credentialing and privileging software agency-wide for all applicants; and, awarding a new contract for an adverse events reporting and tracking system that replaces an older legacy system.

    Also, after consultation with tribes and tribal organizations, IHS developed and is implementing an IHS Strategic Plan for Fiscal Years 2019-2023. The new Strategic Plan includes ongoing efforts to provide health care for American Indians and Alaska Natives throughout the United States. The plan details how IHS will achieve its mission through three strategic goals, each of which are supported by objectives and strategies.

    IHS's new Office of Quality was formally established in January 2019, with a new Deputy Director for Quality Healthcare. The Office of Quality will oversee, direct,

and evaluate, agency-wide activities to ensure quality health care, and will include four divisions: Enterprise Risk Management (ERM), Quality Assurance, Innovation and Improvement, and Patient Safety and Clinical Risk Management. The Office of Quality supports IHS hospitals and health centers by providing resources and tools for quality assurance and improvement, to attain and maintain compliance with Centers for Medicare & Medicaid Services regulations and accreditation standards. The Office of Quality will collaborate with the IHS Office of Information Technology to ensure that the agency has effective systems in place to promote patient care, encourage data collection and reporting, provide secure credentialing and privileging, and prepare for the reporting and evaluation of adverse events. The Office of Quality will also focus on building a quality improvement capability and encouraging innovations that promote safe, effective, and efficient care delivery.

In 2017, IHS implemented a national provider credentialing and privileging system. This system standardizes and streamlines the credentialing process across the IHS. Privileging and performance evaluations of IHS practitioners is a key element tracked in the new system that helps address quality and patient safety. The IHS credentialing and privileging policy is being updated to support the new system.

b. The Inspector General has already looked into IHS and have issued numerous recommendations, the majority of which remain outstanding. Where are IHS and HHS on implementing OIG's recommendation?

Response: The OIG review described above was initiated on March 22, 2019. This OIG review is in progress, and no recommendations have been made at this time. It is titled "*Sufficiency and Implementation of IHS Patient Abuse Policies.*" OIG anticipates completing its investigation with recommendations for IHS by the end of calendar year 2019 or early 2020.

The OIG is continuously monitoring IHS in its audit, investigation, and evaluation work. IHS is actively working through the implementation of all open recommendations, and submitting timely progress reports to OIG. Current open recommendations on a variety of audit and evaluation reports include:

- OIG reports issued in 2018 – 9 open recommendations (purchase and travel cards, audit resolution).
- OIG reports issued in 2017 – 15 open recommendations (IT controls).
- OIG reports issued in 2016 – 5 open recommendations (quality of care).

3. The President's budget includes a $1.6 billion request for the VA's electronic health record modernization. The budget also begins a multiyear effort to modernize the Indian Health Service's electronic health record system. How does HHS plan on assisting IHS on modernizing their electronic health records (EHR)?

Response: The HHS Health Information Technology (HIT) Modernization Research

Project began in September 2018 and will conclude in September 2019. The results from this project will serve to inform IHS about the options best suited 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 in draft by July 2019 and completed by September 2019.

Once the project is completed, IHS will be better positioned to plan and develop a detailed timeline for the modernization of its electronic health record system. The FY 2020 Budget proposes $25 million for IHS to begin transition to a new and modernized Electronic Health Record system. This funding will lay the groundwork to improve the quality of care, reduce the cost of care, promote interoperability, simplify IT service management, increase the security of patient data, enhance cybersecurity, and update infrastructure across rural locations to enable a successful Electronic Health Record transformation.

The IHS manages advisory committees composed of members of tribes, tribal organizations, and representatives of the federal government to ensure participation in addressing issues such as the Resource and Patient Management System and the HIT modernization effort, including the Direct Service Tribal Advisory Committee and the Tribal Self-Governance Advisory Council. In addition, IHS established the Information System Advisory Council (ISAC) to guide the development of a co-owned and co-managed Indian health information infrastructure and information systems.

With help from IHS' tribal partners, the ISAC examines the larger impact of IHS' HIT platforms. The ISAC has a chartered responsibility to make technology recommendations and priorities to the IHS Director. IHS concurrently engages in tribal consultation and urban confer to gather input and assist our decision making process. This process has included several listening sessions combined with a broad array of stakeholder and community engagements. Feedback from the ISAC, listening sessions, and engagement with HHS and other federal programs will ultimately converge to provide the IHS with good information to help determine a best path forward.

The Honorable Richard Hudson

1. Mr. Secretary, I want to ask you about cybersecurity at the Department. As estimated in the Budget-in-Brief, the annual estimated cost of cyber attacks for the health industry is $6.2 billion. HHS has a critical role as the Sector Specific Agency for the health sector to help prepare the sector for attacks, and to respond when one occurs, like the 2017

WannaCry ransomware attack. This, of course, is a separate and distinct role from HHS' internal enterprise cybersecurity work to keep the networks and data secure. The Healthcare Sector Coordinating Council, which provides for collaboration between the health sector and the government has, in the last year, significantly increased its resources and support to the sector. As part of its Sector Specific agency responsibilities, how is HHS working to help and support the Sector Coordinating Council in this work?

Response: The Department of Health and Human Services (HHS) is the Sector Specific Agency (SSA) for the Healthcare and Public Health Sector and co-SSA, with the Department of Agriculture, for the Food and Agriculture Sector. HHS's Office of the Assistant Secretary for Preparedness and Response (ASPR) leads healthcare and public health cybersecurity efforts within the sector. ASPR also serves as a co-lead on the Healthcare and Public Health (HPH) Joint Councils Cybersecurity Working Group (JCWG), to address issues and develop solutions to improve cybersecurity among a wide variety of HPH Sector stakeholders. In 2018, HPH JCWG membership increased from 58 individual members to 330 and there is currently seven federal departments on board.

HHS established the Health Sector Cybersecurity and Coordination Center (HC3) to support the defense of the Healthcare and Public Health Sector's information technology infrastructure by strengthening coordination and information sharing within the sector and by cultivating cybersecurity resilience, regardless of organizations' technical capacity.

HHS is strengthening the Health Sector Government Coordination Council (GCC) for the Healthcare and Public Health Sector, that includes Federal, State, Local, Tribal, and Territorial (FSLTT) agencies, to reinforce and expand the FSLTT engagement with the Sector.

Recent HHS accomplishments include:

- Maintaining 12 active Task Groups within the HPH JCWG examining critical cyber security issues faced by the Sector.
- Published "Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients (HICP)." The four-volume publication seeks to raise awareness for executives, health care practitioners, providers, and health delivery organizations, such as hospitals on cybersecurity issues and practices. Specifically, it explores the five most relevant and current threats to the industry and recommends 10 cybersecurity practices to help mitigate these threats.
- Hosted a weekly webinar series based on the HICP to focus on the five cybersecurity threats and corresponding mitigation practices.
- In coordination with FDA, published the "Medical Technology and Health IT Joint Security Plan." This plan provides guidance on better cybersecurity practices for health information technology professionals in developing a security plan.
- Supported four Joint Cybersecurity exercises simulating complex attacks against the Critical Health Sector infrastructure.

The Honorable Earl L. "Buddy" Carter

1. As a pharmacist, I am keenly aware of how important it is for a patient to have access to the medicine they need. While I understand the desire to lower drug prices, I have some concerns about the administration's proposal regarding the six protected classes within Medicare. For example, I am worried about epilepsy patients not having the same access to innovative anticonvulsants for the treatment of epilepsy. Even though there are more than 20 antiepileptic drugs (AED's) available, patients with this kind of chronic disease can still have a difficult time maintaining control of the symptoms without the full range of medicinal options available. Studies show that as many as 40% of patients with epilepsy are still unable to completely control their seizures. What's more, patients with epilepsy forced to step through several therapies prior to the one prescribed by their physician may have reduced effectiveness of that final drug than if they had simply started with the doctor-prescribed treatment in the first place. The risk of a patient not having access to the drug that works for them, particularly for a disease like this, can literally be a matter of life and death. How have you balanced the implications of interrupting an otherwise stable patient in considering the protected classes proposal?

   Response: Under the current protected class policy, Part D sponsors are permitted to utilize step therapy (ST) and prior authorization (PA) on new starts (that is, enrollees initiating the therapy), with respect to five out of the six protected classes (i.e., anticonvulsants, antidepressants, antineoplastics, antipsychotics, and immunosuppressants for the treatment of transplant rejection, but not antiretrovirals). Further, CMS conducts reviews of ST and PA criteria as part of the annual formulary review and approval process, and will only approve PA and ST criteria that are clinically supported. As such, under the current policy, a Part D sponsor is not permitted to interrupt a patient's course of treatment to require the patient to meet step therapy requirements.

   In CMS' *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses Proposed Rule,* issued in November 2018, CMS proposed broadening the use of prior authorization and step therapy. Our goal is to provide additional flexibility so that Part D sponsors could better manage the benefit from a clinical as well as a cost savings perspective. We believe that the existing beneficiary protections, including our extensive clinical formulary review and approval process, would adequately protect enrollees from the inappropriate application of PA and ST requirements. Moreover, we would have effectively limited most ST criteria to new starts as best practice, except when a change in therapy is clinically supported by the recognized compendia or widely accepted treatment guidelines. When step therapy is applied, we would have expected to approve PA or ST requirements with initial treatment that is comparably supported by recognized compendia or widely accepted treatment guidelines.

   In the Final Rule issued on May 16, 2019, CMS concluded, based on comments received during the rulemaking process, that the risks associated with inappropriately interrupting therapy for stabilized patients receiving protected class drugs for protected class indications by potentially subjecting them to PA or ST requirements outweighed the

potential clinical benefits that some enrollees could gain from switching therapies that might be more appropriate and the potential cost savings that would accompany the additional formulary management flexibility. Therefore, in the Final Rule, CMS finalized a codification of existing policy that allows Part D sponsors to apply PA and ST requirements for protected class Part D drugs, except for antiretroviral medications, only for new starts, to determine if a drug's intended use is for a protected class indication, ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval. PA and ST will continue to be prohibited for antiretroviral medications.