Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
"The Fiscal Year 2022 HHS Budget"
May 12, 2021

The Honorable Xavier Becerra, Secretary, U.S. Department of Health and Human Services

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

Question 1:
As we discussed during the hearing, the lack of consistent support for public health infrastructure is a serious problem for this pandemic response and future preparedness efforts. What are the policies supported by HHS for ensuring stable, long-term public health infrastructure?

Response: HHS and CDC are working to ensure that public health decisions are based on the highest-quality scientific information. Looking to the future, I want to work within the Administration and with you to address long-standing vulnerabilities in our core public health infrastructure, including in the areas of data, workforce, laboratory, domestic preparedness, and global health security. We must work together over the months and years ahead to reinforce and support the foundations, partnerships, modernizations, and innovations that we have initiated during this pandemic – ensuring robust public health systems continue to be grounded in science.

Question 2:
Worsening rates of substance use disorder (OUD) and overdose have become a crisis in our country only worsened by the pandemic. Many of these overdose deaths could have been prevented as evidence-based treatments are available. For example, the life-saving overdose prevention medication Buprenorphine has been shown to cut the risk of overdose from opioids in half. This medication has been FDA-approved for OUD since 2002, is available in a generic form, and is the only medication for opioid use disorder that can be initiated via telehealth.

However, before healthcare providers can prescribe Buprenorphine for OUD, they are required by law to apply for a special registration with the federal government. Furthermore, if they treat over 30 patients with OUD, they must complete additional training and comply with a requirement for counseling referrals. These requirements have resulted in less than 20 percent of patients with OUD receiving treatment and over 20 million people living in a community where there no providers are available to prescribe Buprenorphine.

Many stakeholders have advocated for either streamlining requirements in this space, or removing entirely the x-waiver required currently. What further actions does HHS intend to take to expand access to treatment for those with OUD, and what is your position on removing federal barriers to prescribing Buprenorphine?

Note: Responses are provided as of the date of the hearing, May 12, 2021.

Response: Fighting the opioid epidemic is a priority for HHS. I am committed to utilizing all possible tools to combat the opioid use epidemic. The FY 2022 budget takes action to address the epidemic of opioids and other substance use disorder, investing $11.2 billion, including $10.7 billion in discretionary funding, across HHS, $3.9 billion more than in FY 2021. The impact of this epidemic is felt in our communities, and the budget will direct funding to states and Tribes to increase community-level response. The budget will also increase access to medications for opioid use disorder and expand the behavioral health provider workforce, particularly in underserved areas.

Question 3:
HHS under the Biden administration made changes to the registration requirements for prescribers seeking to become licensed to provide Buprenorphine to their patients with OUD in April 2021. What impact has this change had on the number of providers now able to provide buperenorphine to patients with OUD and how many are prescribing buperernophrine at patient capacity?

Response: In an effort to get evidenced-based treatment to more Americans with opioid use disorder (OUD), last April SAMHSA and HHS announced buprenorphine practice guidelines that remove certain training and certification requirements which some practitioners have cited as a barrier to treating more people. The Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder (Practice Guidelines) provides an exemption from certain statutory certification requirements for eligible physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives, who are state licensed and registered by the Drug Enforcement Administration to prescribe controlled substances. Specifically, the exemption allows these practitioners to treat up to 30 patients with OUD using buprenorphine without having to make certain training-related certifications. This exemption also allows practitioners to treat patients with buprenorphine without certifying as to their capacity to provide counseling and ancillary services.

The Honorable Anna G. Eshoo (D-CA)

Question 4:
Two weeks before this hearing, Drs. Francis Collins and John Brooks of the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) testified before this Subcommittee about the great toll Long-COVID is taking on this nation. However, when I asked them who was leading the coordinated, whole-of-government response to the Long-COVID crisis, they told me that there was no such leader or coordinator at HHS. Do you support appointing a leader to coordinate a federal health strategy to address Long-COVID?

Response: Early in the COVID-19 response, HHS recognized the need to understand the long-term post COVID conditions. Over the past year, HHS has funded a number of projects specific to or including patients with long-term post COVID conditions. In June 2021, NIH will launch the Researching COVID to Enhance Recovery (RECOVER) Initiative, which aims to rapidly improve understanding of why, after SARS-CoV-2 infection, some individuals experience persistent, or develop new or returning, symptoms. The initiative will be co-led by the National

Heart, Lung and Blood Institute (NHLBI), National Institute of Neurological Disorders and Stroke (NINDS), and the National Institute of Allergy and Infectious Disease (NIAID). RECOVER also hopes to answer whether SARS-CoV-2 infection triggers changes in the body that increase the risk of other conditions, such as chronic heart, lung, or brain disorders. At the heart of RECOVER is a meta-cohort of diverse research participants that will include patients from Long COVID clinics, NIH's COVID studies and trials, and other long-standing cohort studies. In addition, RECOVER research studies will include autopsy cohort studies, electronic health record (EHR), and other real-world data-based studies. RECOVER will also include exploratory clinical trials aimed at treating and preventing Post-Acute Sequelae of SARS-CoV-2 infection (PASC).

The Biden Administration and HHS, through the Office of the Assistant Secretary for Health, will continue to advance our nation's understanding of Long COVID and its associated conditions, promote high-quality care for patients and help individuals access supportive services—especially for those from communities disproportionately affected by the pandemic.

Question 5:

How are you allocating the $6 billion provided to HHS for therapeutics in the American Rescue Plan? What is HHS's strategy for supporting development of effective COVID-19 therapeutics and what roles will BARDA and NIH play respectively? As of May 6, 2021, BARDA had closed Area of Interest 9.2 COVID-19 Therapeutics in its Broad Agency Announcement. Why, during a public health emergency, has BARDA suspended critical areas of COVID-19 therapeutic development?

Response: Early in the pandemic, NIH recognized the importance of safe, easy to administer, and scalable treatments for people who become ill from COVID-19, from mild to severe disease. Accordingly, NIH has made significant investments in the development of new treatments, as well as research on repurposing existing therapeutics for use in the treatment of COVID-19. NIH, in collaboration with BARDA and other public and private sector partners, launched the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership to coordinate research strategies for prioritizing and speeding development of the most promising treatments. The ACTIV public-private partnership has evaluated hundreds of available therapeutic agents with potential application for COVID-19, prioritized the most promising candidates, designed and harmonized adaptive master protocols for ACTIV clinical trials, and selected numerous NIH-supported networks to launch these clinical trials to test prioritized therapeutic candidates.

Funds from the American Rescue Plan may be used to support NIH ACTIV Phase 2 and 3 clinical trials of novel and repurposed therapeutics to identify efficacy against COVID-19. These studies include the National Institute of Allergy and Infectious Diseases-supported ACTIV-2 and ACTIV-3 trials, which are evaluating therapeutics to treat COVID-19 in outpatient and inpatient settings, respectively, and the ACTIV-5/Big Effect Trial (BET), an adaptive Phase 2 clinical trial which is designed to streamline the identification of experimental COVID-19 therapeutics that demonstrate the most promise for use in hospitalized patients. American Rescue Plan funds are also being used, through BARDA, to fund the ACTIV-1 and ACTIV-6 trials managed by the National Center for Advancing Translational Sciences. ACTIV-1 will test

promising immune modulator compounds, a class of drugs that help minimize the deleterious effects of an overactive immune response to SARS-CoV-2 infection. ACTIV-6 will study repurposed drugs – those already approved by FDA for other conditions – and test their safety and effectiveness in treating mild to moderate COVID-19. These funds also could be used to support future pandemic preparedness efforts focused on developing novel therapeutics targeted for use in outpatients.

As of May 2021, approximately $2.3 billion from the American Rescue Plan (ARP) has supported investments in therapeutics at HHS. Since January 2021, the federal government has invested in development of multiple therapeutic candidates. We commit to keeping Congress informed of these activities. In addition, information is posted in real-time as products come online and are approved for use. (https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/default.aspx). Development of these candidates have benefited from funding of NIH's ACTIV trials.

Question 6:
How much money remains in the Provider Relief Fund? When do you plan to disburse that money? Is there a priority order for who receives it next?

Response: HHS is working on approaches to distribute Provider Relief Fund (PRF) funding as quickly and equitably as possible while maintaining effective safeguards for taxpayer dollars. HHS is considering feedback from Congress and stakeholders, as well as operational lessons learned from prior PRF payments, as part of this process. The PRF also continues to provide claims reimbursement to healthcare providers for COVID-19 testing, treatment, and vaccine administration services for the uninsured, and COVID-19 vaccine administration for the underinsured. Additional information on future distributions will be published on HHS' Provider Relief Fund webpage, at www.hhs.gov/providerrelief, as soon as it becomes available.

Question 7:
As a result of the pandemic, FDA delayed critical inspections of both domestic and foreign drug manufacturing facilities. According to a recent FDA report, "Resiliency Roadmap for FDA Inspectional Oversight," 68 applications for approval have been delayed due to this lack of inspections and FDA's ability to conduct routine surveillance inspections, especially foreign inspections, is expected to remain limited in FY21. How can HHS aid Congress in ensuring we are never in this position again?

Response: The Coronavirus Disease 2019 (COVID-19) pandemic constitutes one of the world's largest public health emergencies in a century. It has both challenged traditional oversight activities and afforded the FDA an opportunity to consider regulatory approaches that increase efficiency and ensure product quality while fulfilling FDA's public health mission.

The pandemic required FDA to pause most foreign and domestic facility inspections due to global travel restrictions and to protect the health and safety of its workforce and the employees of the industries they oversee. However, FDA has continued to conduct inspections considered critical to its mission throughout the pandemic. The *Resiliency Roadmap* notes that only seven of

the 68 applications delayed solely due to a pending inspection were related to a product considered to be mission critical.

FDA is committed to returning to a more consistent state of operations as expeditiously as possible by focusing first on the most critical work and prioritizing other responsibilities, including product approvals, based on risk criteria. The Agency will make optimum use of its existing authorities to conduct inspections, where possible, and use other oversight tools to maximize its public health impact.

FDA will soon begin a multi-year modernization effort to further transform its data enterprise platforms and cross-program interoperability infrastructure to better support innovation related to our regulatory oversight role, including remote approaches. This modernization effort will include a review of approaches to regulatory oversight using next-generation assessment technologies and improvements and available authorities for any potential legislative proposals. HHS looks forward to continuing to work with the Congress on these new approaches and tools.

Question 8:

The National Cancer Institute has predicted almost 10,000 excess deaths over the next decade from breast and colorectal cancer alone because of pandemic-related delays in diagnosing and treating these two cancers, which can often be detected early through screening. The U.S. Preventive Services Task Force (USPSTF) plays an important role in getting new cancer screening tests reviewed and to patients, but they are under-staffed and under-funded, limiting the speed of their recommendations. What is your plan to accelerate the USPSTF process and ensure that patients can get access to blood tests and other innovative cancer screening technology as soon as FDA approves these products?

Response: Consistent with its mandate and using the funds that are provided, AHRQ will continue to provide administrative, research and technical support to the USPSTF to expeditiously produce recommendations on clinical preventive services as it balances the need to respond quickly to new evidence with the commitment to rigorous evidence-based methods and comprehensive stakeholder and public input. Over the years, AHRQ has worked with the USPSTF on developing and implementing strategies to make its processes more transparent and efficient in an effort to respond to important health needs.

Question 9:

In May 2019, the Pain Management Best Practices Inter-Agency Task Force released a report that lists several recommendations to combat the opioids crisis while still addressing the needs of those who suffer from acute and chronic pain. In it, the report states "Non-opioids should be used as first-line therapy whenever clinically appropriate in the inpatient and outpatient settings." What steps has HHS/CMS taken to incentivize the use of non-opioid alternatives and how can CMS align reimbursement policies to best incentivize the use of non-opioids?

Response: CMS worked with the HHS Pain Management Best Practices Inter-Agency Task Force (PMTF), a federal advisory committee established by section 101 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) (P.L. 114-198), to review available data and develop criteria for revisions to payment for opioid alternatives that are effective for pain relief

or in reducing opioid use. In May 2019, the PMTF published a final report that includes numerous recommendations for agencies across the Administration.

Section 6032 of the SUPPORT for Patients and Communities Act includes a requirement for the HHS to develop an "Action Plan on recommendations for changes under Medicare and Medicaid to prevent opioid addictions and enhance access to medication-assisted treatment" in collaboration with the PMTF. On June 26, 2019, CMS convened virtually with the PMTF to discuss its recommendations with specific relevance to CMS payment and coverage policies for chronic and acute pain, service delivery models, access to therapies and medical devices, and other issues outlined in Section 6032 of the SUPPORT for Patients and Communities Act. This Action Plan will accompany a Report to Congress also required by Section 6032 of SUPPORT for Patients and Communities Act. We expect to release this Action Plan and Report soon.

In addition, Section 6082 of the SUPPORT for Patient and Communities Act requires the Secretary to review payments under the Medicare Outpatient Prospective Payment System (OPPS) for opioids and evidence-based alternative for pain management, to ensure there are no financial incentives to use opioids instead of evidence-based non-opioid alternatives. Since implementation of this provision in the CY 2018 OPPS rule, CMS annually reviews its outpatient hospital and ambulatory surgery center payment policies to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives.

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

Question 10:
As co-chair of the Rare Disease Caucus, I have been informed that the COVID-19 pandemic has resulted in a major disruption in the research on, and clinical trials for, those suffering from rare diseases. According to a recent article in the Lancet, NIH estimated that approximately 80% of non-COVID-19 related clinical trials were stopped or interrupted in 2020, resulting in long lasting effects on medical science. This is especially true when considering that rare disease clinical trials often comprise vulnerable populations who are most at risk from exposure to COVID-19.

As you are aware, minority patients with rare diseases already face greater barriers and obstacles to care and are often underrepresented in clinical trials. FDA guidance has acknowledged that due to the impact of COVID-19, companies conducting clinical trials may be forced to consider virtual patient visits or other telemonitoring. This can be especially challenging for minority populations, or for trials requiring in person visits.

We have started to make progress in this area, but our work is far from finished. While we cannot get this lost year of research and progress back, we can and should continue to support those companies who are working hard to find treatments and cures for these rare diseases and encourage the continuation of this vital research.

For the millions of Americans with rare diseases, for whom the promise of clinical investigations and pharmaceutical innovation holds the possibility of a better, longer life, will you commit to working with the FDA, NIH, and members of Congress to identify ways to incentivize those

companies who have struggled with the negative impacts of COVID-19 on rare disease innovation? We owe these rare disease and underrepresented minority populations a commitment to supporting the valuable information gained by the process of conducting clinical trials.

Response: The Department of Health and Human Services is committed to advancing equity across the health care system, including access to clinical trials and treatments for patients from minority populations with rare diseases. Specifically, NIH is committed to working with the FDA and members of Congress to identify ways to reduce the impact of the COVID-19 pandemic, particularly with respect to rare disease research and therapeutic development and innovation.

Research on specific rare diseases is supported by NIH Institutes and Centers (ICs) based on where a particular rare disease falls within their mission, with the National Center for Advancing Translational Sciences (NCATS) being the home of the Office of Rare Diseases Research (ORDR). NCATS is focused on finding ways to speed the development of treatments for multiple diseases simultaneously, in collaboration across NIH ICs, with the goal of ultimately helping more patients more quickly.

There are over 7,000 rare diseases, affecting approximately 30 million Americans. Based on a recent NCATS pilot study,[1] rare diseases result in an estimated $400 billion per year in total direct medical costs, similar to annual direct medical costs for cancer, heart failure, and Alzheimer's disease. For the millions of people living with a rare disease, the novel coronavirus disease COVID-19 presented extra challenges, from potential reduced access to needed medical care to possible heightened anxiety and stress. In 2020, the NIH-supported Rare Diseases Clinical Research Network (RDCRN)[2], in addition to continuing its existing research, launched a survey to find out how the COVID-19 pandemic impacted individuals with rare diseases, their families and caregivers. Preliminary results[3] indicated the pandemic negatively affected rare disease patients in several ways including, access to regular health care, treatment for the rare disease, and special diets.

To enable research to continue to the fullest extent possible during the pandemic, the NIH has also directly worked with grant awardees, including small businesses, to offer flexibilities to help mitigate the effects of the COVID-19 pandemic for all research. This included both no cost and funded extensions to allow researchers to continue their work. In addition, administrative supplements for unanticipated costs due to the impact of COVID-19 were awarded, often to allow extended enrollment of patients in clinical trials or for travel costs for clinical research participants.

In addition to these flexibilities, NCATS continued during the pandemic to foster as much research and research-related activities that address rare diseases.

[1] https://ncats.nih.gov/news/releases/2021/nih-study-suggests-people-with-rare-diseases-face-significantly-higher-health-care-costs
[2] https://ncats.nih.gov/rdcrn
[3] https://www.rarediseasesnetwork.org/news/2021-02-10-COVID19-survey-preliminary-results

We also have a long-standing commitment to supporting innovation in clinical development programs to help bring safe and effective drugs to patients more efficiently. Although the COVID-19 pandemic accelerated the use of innovative trial designs, FDA's policy development in this area long preceded the current public health emergency. FDA recognizes that there are emerging shifts in how diseases, specifically rare diseases, are diagnosed, prevented, and treated, and in the development of therapeutics. FDA is working on multiple fronts to provide guidance on innovative approaches to drug development, such as complex, innovative trial designs, master protocols, decentralized trials, trials utilizing real world data and evidence (RWD/RWE), modelling, and simulation. Our engagements with stakeholders have supported innovative trial designs as part of the COVID-19 pandemic response. These designs improve clinical trial efficiency and may optimize product development for other diseases, including rare diseases.

FDA continues to promote innovation in clinical trial design and conduct, and to encourage the utilization of advanced technologies. The Agency is already working in many ways to facilitate pharmaceutical development and improve the overall clinical trial enterprise. FDA is also leveraging the importance of strong national and global partnerships in collectively advancing scientific knowledge to ultimately benefit patients. The Agency is invested in helping advance innovations, such as decentralized clinical trials and the use of digital health tools that have the potential of making clinical trials more efficient and may allow for wider inclusivity of diverse populations. Further, recognizing the value of innovative designs, FDA is committed to continuing the Complex Innovative Designs Meeting Program, which provides applicants accepted into the program with additional meetings with FDA to discuss proposed innovative designs.

Question 11:

I, along with many members of the Committee remain concerned with the lack of targeted therapies for rare cancer patients. Rare cancers account for 380 of 400 distinct forms of cancer and almost 1/3 of all diagnoses and include all pediatric cancers. A recent analysis showed that 80 percent of all patients who lacked an FDA-targeted therapy were rare cancer patients.

In addition, of the 3,994 clinical trials in phases 1, 2, and 3 from January 1, 2012, to January 1, 2017, almost 75 percent did not include a rare cancer by name. While rare cancer affects every population, translational research and commercial drug development has traditionally neglected small patient populations. Each subtype of cancer requires a targeted therapy in order to save a life or to significantly improve lifespan.

What is the Department's plan to ensure there are adequate investments for treatments for rare cancer patients and what can Congress and this Committee do to help?

Response: HHS, through the National Institutes of Health (NIH), and including the National Cancer Institute (NCI), remains committed to supporting research to advance the understanding of all cancers, including rare cancers, and to inform the development of targeted cancer therapies for rare cancers and rare subtypes of cancers, including pediatric cancers.

NIH-supported developments in understanding the specific genes, proteins, and other unique molecular characteristics driving certain cancer subtypes have shown that cancer is made up of a

collection of hundreds, if not thousands, of subtypes defined by these characteristics. As such, "cancer" is now considered to be a collection of rare cancer subtypes. This evolved understanding of cancer is reflected in NCI's current clinical trials portfolio and investments in translational and basic research, including several initiatives in the intramural Center for Cancer Research (CCR).

Increasingly, clinical trials are examining targeted therapies based on molecular subtypes. For example, NCI's National Clinical Trials Network (NCTN) is currently supporting trials assessing therapies to treat gliomas with certain genetic alterations[4] and pancreatic cancers with specific gene alterations.[5,6] NCI also supports trials that are dedicated to patients with rare tumors, including the NCTN-supported DART (Dual Anti-CTLA-4 and Anti-PD1-Blockade in Rare Tumors) Trial[7] and the Rapid Analysis and Response Evaluation of Combination Anti-Neoplastic Agents in Rare Tumors (RARE CANCER) Trial,[8] which is supported by NCI's Experimental Therapeutics Clinical Trials Network.

To ensure that researchers have a strong pipeline of therapy candidates to consider for use in clinical trials, NCI supports several initiatives to support the preclinical stage of development of therapeutics to treat rare cancers, including the NCI Experimental Therapeutics (NeXT) Program and the Pediatric Preclinical Testing Consortium (PPTC). The first step in identifying new therapeutic targets, however, is elucidating the basic biological mechanisms that give rise to cancers. To further these research efforts, NCI supports the development of resources for broad use across the cancer research community.[9] These resources include cell lines, organoid models, patient derived xenograft (PDX) models, biospecimens, and other biological samples.

The Rare Tumor Patient Engagement Network, launched in FY 2018 and part of NCI's CCR, leverages the resources of the NCI intramural research program and the NIH Clinical Center to bring together investigators, patients, and advocacy groups to study rare tumors. Under the umbrella of this effort, NCI launched the My Pediatric, Adolescent, and Adult Rare Tumor (MyPART) Network, a collaboration of scientists, patients, family members, advocates and healthcare providers to find treatments for rare cancers. Additionally, the NCI Comprehensive Oncology Network Evaluating Rare CNS Tumors (NCI-CONNECT) program aims to advance the understanding of rare adult central nervous system (CNS) cancers by establishing and fostering patient-advocacy-provider partnerships and networks to improve approaches to care and treatment; several clinical studies and trials are currently open through NCI-CONNECT.[10]

Because of these and similar investments, the U.S. Food and Drug Administration (FDA) has approved a number of therapies in recent years for patients with rare cancer subtypes and related conditions. For example, in May 2021, the FDA granted accelerated approval to sotorasib (Lumakras) for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with alterations in the *KRAS G12-C* gene, a mutation which is present in only 13.8 percent of

[4] www.clinicaltrials.gov/ct2/show/NCT00887146
[5] www.clinicaltrials.gov/ct2/show/NCT04858334
[6] www.clinicaltrials.gov/ct2/show/NCT04548752
[7] www.clinicaltrials.gov/ct2/show/NCT02834013
[8] www.clinicaltrials.gov/ct2/show/NCT04449549
[9] www.cancer.gov/research/resources/
[10] www.cancer.gov/rare-brain-spine-tumor/refer-participate/clinical-studies

NSCLC patients.[11] Similarly, the FDA approved selumetinib (Koselugo) in 2020 for the rare tumor condition neurofibromatosis type 1, in patients over the age of two, as the first approved treatment for this condition. In 2018, the FDA granted accelerated approval to larotrectinib (Vitrakvi) for adult and pediatric patients with solid tumors with a neurotrophic receptor tyrosine kinase (NTRK) gene fusion. NTRK gene fusions are prevalent in nearly all cases of certain rare cancer subtypes, including secretory carcinoma of the breast or salivary gland and infantile fibrosarcoma.[12]

Product development for rare cancers can be aided by advancements in several important areas where FDA and other government agencies have active programs. Improving our understanding of the genetic and biologic underpinnings of rare cancers is critical, and efforts to broaden basic and translational research is foundational to achieve the goal of highly effective treatments. With improved understanding of the biology of a rare cancer, precision medicine can identify patients who are most likely to respond to a treatment through improved biomarker development using in vitro diagnostic tests. As such, biomarker development is an area that holds promise to produce highly effective drugs that can demonstrate efficacy in smaller trials. Because enrollment of patients to clinical trials in a rare cancer can be challenging, expanding trial accrual outside of U.S. academic centers is imperative, and efforts to conduct trials out in the communities where patients live through "decentralized trials" is an important opportunity. Barriers in the U.S. to decentralized trial conduct can be identified and addressed, and may include challenges with interstate medical licensing, telemedicine and equitable access to digital technology. Rare cancer patient accrual to clinical trials can also be greatly expedited by supporting multinational trials, and efforts to support global regulatory interaction to standardize and harmonize regulatory requirements is one area that could be fruitful. Expanding our source of evidence outside of trials is also important, particularly for rare cancers. Scanning routine healthcare for uses of existing treatments that could be repurposed as effective treatments for rare cancers is an opportunity. Efforts to improve interoperability in electronic health records systems is one way that we may learn more from patients receiving routine healthcare through leveraging so called "real-world data." Support and development of rare cancer registries is another area that could yield valuable information to assist product development.

HHS will continue to support research efforts that reflect the scientific understanding of the many subtypes of cancers, including work that will enable the development of therapies for rare tumor subtypes. We appreciate your continued support, and that of your colleagues, for this important research.

Question 12:

Rare cancers account for 380 of 400 distinct forms of cancer and almost 1/3 of all diagnoses and include all pediatric and primary brain cancers. Over 550,000 Americans are diagnosed with a rare form of cancer every year. With evolving medical science, we know each subtype of cancer requires a targeted therapy – and frequently several of them -- in order to save a life or to significantly improve lifespan, and data is required for each cancer to inform where targeted therapies can be used.

[11] ascopost.com/news/january-2021/prevalence-of-kras-g12c-somatic-mutations-by-cancer-type-race-and-sex/
[12] www.ncbi.nlm.nih.gov/pmc/articles/PMC6859817/

Molecular diagnostics and forms of precision medicine are an essential part of determining the form of cancer and which treatment is the best option. However, it is my understanding that only a small percentage of cancer patients are currently eligible to have these molecular diagnostics reimbursed when they are provided at the time of diagnosis. Can you tell me what CMS is doing to expand these reimbursements to ensure more cancer patients can receive these vital diagnostics?

Response: It is important to spur innovation in therapeutics and medical technology in order to improve health outcomes, particularly for patients with complex illnesses such as cancer. CMS looks forward to working with Congress and other stakeholders as we continue to examine payment policies and work to facilitate affordable access to innovative diagnostics and treatments.

Question 13:

Manufacturers of affordable generic medicines are now paying millions of dollars in penalties on prescription drugs that have not been subject to a price increase. These unpredictable, onerous penalties – totaling $1.6 billion over 10 years – make it challenging to continue production of low-margin generics and threaten patient access to life-saving medicine. I introduced legislation to fix the Medicaid Generics Penalty – the Protecting Access to Affordable Medicines Act (H.R. 2868).

Does the Administration plan to ensure the sustainability of the generics market and access for patients by addressing the Medicaid Generics Penalty?

Response: Competition in the market has helped control the growth in spending on prescription drugs. Generic drugs and biosimilars have a role to play in containing the cost of expensive therapies by creating competition. Like President Biden, I believe we must do all we can to lower the costs of prescription drugs and make them more accessible for Americans who depend on these medications for their health.

Question 14:

I understand FDA stopped conducting foreign facility inspections during COVID-19. I'm concerned that this practice, and FDA's recent admission in their "Resiliency Roadmap" that the Agency does not plan to resume foreign inspections in 2021, will result in avoidable drug shortages that will negatively impact patients. What more can FDA do to ensure applications for drugs move through the FDA approval process and avoid unnecessarily delayed approval of medicines? Is FDA making the most of the tools available to them, including remote inspections, to mitigate the impact of delayed foreign inspections?

Response: I commit to do everything I can to ensure that safe and effective therapies get to market as efficiently as possible. While FDA paused all on-site surveillance domestic inspections in March 2020 due to the COVID-19 pandemic, FDA investigators continued mission critical inspections and other activities to ensure FDA-regulated industries are meeting applicable FDA requirements. FDA also later began resuming domestic surveillance inspections in July 2020. To date, FDA has not experienced a significant impact on its ability to take actions on drug and biologic applications.

FDA prioritizes inspections and other oversight work based on risk and the agency's public health priorities. The *Resiliency Roadmap* describes the FDA's general approach to this risk calculation and the criteria that are considered as the agency prioritizes its work. Potential shortages of needed medications and inspections to support applications related to a product that could prevent or alleviate such a shortage are criteria included in the risk analysis. FDA continued to conduct mission-critical inspectional work, including at foreign facilities, throughout the pandemic when necessary to protect the public health. The Agency is also working to optimize its use of remote options and other alternative approaches to strengthen our oversight while some foreign inspections are not possible.

Specifically, FDA has been employing other tools to evaluate facilities, as appropriate, such as requesting records and other information or reviewing trusted foreign regulator inspection records under existing Mutual Recognition Agreements. These tools have been, in many cases, successful to allow the Agency to take actions on applications.

In April, 2021, FDA issued a guidance for industry, Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency. This guidance outlined the FDA's commitment to use additional tools to support regulatory decisions and oversight of facilities. This guidance describes FDA's policy on using such evaluations to support decisions on pending applications. FDA uses a risk-based approach in determining when remote evaluations are appropriate.

FDA intends to meet its user fee obligations including where a facility assessment is needed, whether the assessment involves an inspection or FDA can rely on alternative tools, such as remote interactive evaluations, to support an application decision. FDA recently performed an analysis of user fee metrics across the prescription drug and generic drug programs that demonstrate FDA has been able to take on-time actions to evaluate and close out these drug applications more than 90% of the time, meeting the review program performance levels agreed to by FDA and industry. FDA makes this information available on its website. The *Resiliency Roadmap* for FDA Inspectional Oversight also provides information about FDA's commitment and accomplishments in evaluating facilities during the pandemic. As described in that document, of the approximately 13,500 product applications submitted between March 2020 through March 2021, only 68 application decisions were affected by delays in inspections. Of these, only seven application decisions were considered critical to FDA's mission to protect the public health.

I will work with FDA to ensure the Agency uses every appropriate tool to get critical safe and effective therapies to market as efficiently as possible.

Question 15:

The FDA recently stated that the Agency would not resume foreign facility inspections in Fiscal Year (FY) 2021. Given the significant backlog of medical product applications at FDA, I'm concerned that the continued delay of foreign inspections will result in shortages for lifesaving healthcare products. Why is FDA not planning to resume foreign inspections this year, and what

is FDA's plan to use the $500 million appropriated by Congress in the recent COVID-19 relief package to work down the backlog of facility inspections?

Response: FDA received $73.5 million to address delayed inspections due to COVID-19. This includes $35.1 million to the Office of Regulatory Affairs (ORA) for recovery activities, including inspection modernization and hiring staff to conduct delayed inspections. The ORA used this funding to improve the quality and consistency of data collected during inspections enabling more robust and reliable analytical capabilities. It allowed for the continued automation and harmonization of manual processes leading to more immediate and actionable information reducing time to plan and assign inspections. The funding also allowed the ORA programs to hire additional medical product investigators to engage in inspection and investigation operations providing greater oversight of regulated industry.

There is no doubt that the pandemic has had an impact on FDA inspectional work but as of the end of March 2021 (See *Resiliency Roadmap*), only 48 human drug applications, of the large number of applications received, had been delayed because of a pending inspection, and only six of these were considered mission critical. FDA intends to complete the six mission critical inspections by the end of FY21 and will be working to resolve any application decisions that were delayed as expeditiously as feasible within the risk-based framework employed by the agency. FDA continues to employ maximum flexibility in using alternative inspectional tools, including requesting records and other information, and using information from trusted foreign regulatory partners through mutual recognition agreements and other confidentiality agreements, to support regulatory decisions.

The continuing global pandemic presents significant challenges to FDA's return to the agency's foreign oversight work. Foreign inspection trips must now account for known quarantine requirements as well as the prospect of unknown confinement due to a positive COVID-19 test or a change in travel restrictions. In addition, reduced access to healthcare in foreign countries remains a concern. FDA continues to adapt to the challenges imposed by the COVID-19 pandemic and will use all its oversight tools to help ensure the safety and quality of FDA-regulated products. Although inspections are critical to FDA oversight, they are part of a robust and multi-pronged approached to overseeing the safety and quality of FDA-regulated products.

Question 16:

The Consolidated Appropriations Act of 2021, which was enacted in December 2020, included $3 million in funding to establish the first of its kind Social Determinants of Health (SDOH) Pilot Program at the CDC. This program, similar to authorizing legislation I have cosponsored, will award competitive grants to state, local, territorial, or Tribal jurisdictions to create Social Determinants of Health Accelerator Plans to address negative social determinants of health at the community level.

The CDC is in the process of issuing these grants to fulfill this provision of the end of year appropriations package and recently announced a notice of funding opportunity for communities to receive up to $125,000 to support multisector action plans that address the social determinants of health by accelerating action in state, local, territorial, and tribal jurisdictions that lead to

improved chronic health conditions among Americans experiencing health disparities and inequality.

Addressing health equity and social determinants of health has also been highlighted as a top priority of the Biden Administration. Last month, President Biden included a request for $153 million for the CDC Social Determinants of Health Program in the FY 2022 Budget Request to support states and territories to improve health equity and data collection for racial and ethnic populations – a $150 million increase of what was initially included in the December appropriations package. I strongly support this request, and I know other colleagues on the Committee do as well.

How will you work with the CDC as it advances SDOH initiatives through this funding opportunity? How do you envision the $153 million in funding for this program being used?

Response: HHS agrees that addressing Social Determinants of Health (SDOH) is very important for the health and wellbeing of the nation and that addressing SDOH requires engagement and coordination across HHS as well as with other Departments within the federal government.

HHS is in the process of developing a strategic approach to address SDOH to advance health and well-being over the life course. CDC is playing an important role in this process. Efforts will require working across government agencies to modernize public health and its infrastructure in a way that takes stock of SDOH, such as inadequate housing, lack of access to healthy water, and racial discrimination, as well as the resulting trauma that adversity may have on emotional and physical well-being.

CDC's approach will consider both the social and structural conditions that impact health and contribute to disparities and inequities with a framework targeting action in several key areas: data and surveillance, evaluation and evidence building, partnerships and collaborations, community engagement, infrastructure and capacity, and policy. CDC anticipates awarding up to 20 grants to accelerate actions in state, local, tribal, and territorial jurisdictions that prevent and reduce chronic diseases among people experiencing health disparities in late summer FY 21.

With the additional $150 million requested, CDC will award funds to additional jurisdictions to develop SDOH accelerator action plans, fund communities to implement and evaluate action plans, and continue to build the SDOH evidence based through a targeted research agenda, including providing internal grants within CDC, and improved data collection. Additionally, CDC will continue to leverage and coordinate efforts currently underway across the agency to ensure that drivers of health inequity are addressed in our scientific and intervention planning, implementation, and evaluation activities.

The Honorable Doris O. Matsui (D-CA)

Question 17:
CMS created the Transitional Drug Add-on Payment Adjustment (TDAPA) to support payment and patient access to new therapies introduced to the End-Stage Renal Disease (ESRD) Prospective Payment Systems (PPS). When initially introduced, the TDAPA was only available

for new drugs outside of the existing ESRD PPS functional category. These new drugs would receive an add-on payment outside the bundle until CMS gathered sufficient claims data to incorporate the new drugs into the bundle and, subsequently, adjust the base payment rate to reflect the price of the new drug.

CMS has since expanded TDAPA eligibility to include new ESRD-related drugs and biologics that fit within an existing functional category. CMS does not require new ESRD-related drugs to meet substantial clinical improvement criteria for TDAPA eligibility. I am concerned this may encourage the uptake of new drugs that could increase Medicare spending while offering no clinical improvement for the patient.

Secretary Becerra, is review of TDAPA policy for new drugs in an existing functional category warranted to ensure that beneficiary dollars are spent only on new ESRD-related drugs that improve patient care or outcomes?

Question 18:

Following the conclusion of the TDAPA add-on payment, the ESRD PPS bundled payment base rate is not updated to reflect the cost of the new drug in existing functional categories. However, providers may still need to provide these new drugs, as patients have been using them during the duration of the drug's TDAPA eligibility. The new drug may be priced differently than other drugs in an existing functional category that is not reflected in the current bundled payment rate.

Secretary Becerra, in future rulemaking cycles, will CMS consider revising ESRD bundled payment policies to appropriately reimburse for new drugs in an existing functional category that do bring additional clinical value to patients?

Response to Questions 17-18: The Transitional Drug Add-on Payment Adjustment (TDAPA) is a payment adjustment under the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) for certain new renal dialysis drugs and biological products. The TDAPA helps ESRD facilities to incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provides additional payments for such associated costs, and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative. We will take your concerns into consideration as we continue to examine and refine the TDAPA policy.

The Honorable Peter Welch (D-VT)

Question 19:

During the campaign, President Biden made a pledge to leverage a $50 billion investment over the course of his Presidency through a new HHS program called ARPA-Health (ARPA-H), specifically enumerating an initial focus on four areas: Amyotrophic Lateral Sclerosis (ALS), Alzheimer's Disease, Diabetes and Cancer, because in his words, "…they are all contributing factors to immune system irregularities that no one is spending money on."

Mr. Secretary, I strongly support this investment, especially in the four areas the President focused on. Will you ensure that ALS is a major part of the President's ARPA-H effort over the next four years, following the President's stated goal?

Response: Fostering breakthroughs to benefit people with ALS is a priority for this administration. The Advanced Research Projects Agency for Health (ARPA-H) will be established to tackle problems that are currently considered intractable and that, if addressed, could have an outsized impact. In addition, ARPA-H programs will build and develop capabilities and platforms that are broadly applicable to a wide range of diseases and conditions, which may include ALS, cancer, Alzheimer's disease, and diabetes. The goal is for ARPA-H to support promising opportunities to address conditions that fall in the gap between fundamental research in biology and medicine, typically funded by the National Institutes of Health (NIH) and other Federal agencies that support biomedical research; and the research, development, and marketing of specific products that are the focus of the commercial sector.

Question 20:

In the Medicare Part D program, there are payments made to Part D sponsors, including rebates and pharmacy price concessions. These payments are known as Direct and Indirect Remuneration (DIR). When DIR fees are applied at the point-of-sale of a drug to a Medicare beneficiary, they are used to reduce the cost of the drug. However, today the majority of pharmacy DIR fees are applied after a drug is dispensed to a beneficiary. These fees are clawed back from pharmacies a year or longer after a drug is dispensed to a beneficiary, and the fees collected by plans and their pharmacy benefit managers (PBMs) are never used to reimburse or otherwise reduce the cost of a drug for a Medicare beneficiary.

Mr. Secretary, as we look at efforts to reduce the out-of-pocket cost of prescription drugs, will you work with Congress on solutions to address pharmacy DIR fees to support stability for specialty and community pharmacy and lower drug costs for seniors?

Response: Community pharmacies are critical to our nation's health care system and have been especially important during the pandemic. It can be hard for these pharmacies to predict retroactive DIR fees. We must do all we can to ensure that Americans can access important health care services, including from local pharmacies in their communities. I look forward to working with Congress to ensure that community pharmacists have predictability and to lower drug prices for patients and families.

Question 21:

I have been concerned with the challenges that the senior living community has faced throughout the duration of the pandemic. With two million seniors in Vermont and across the country residing in senior living and assisted living facilities, I know that operators across the country have been struggling. They have faced increased costs, workforce challenges, and difficulty admitting new residents due to COVID-19 restrictions, which have all compounded their financial difficulties.

Mr. Secretary, can you confirm that these facilities will receive increased support from HHS and its Provider Relief Fund in a timely manner to ensure they remain operational?

Response: Thank you for raising this important issue. I appreciate the care being given to seniors across the nation in a number of settings, including assisted living facilities.

As you know, to respond to the urgent needs of the nation's health care providers in the wake of COVID-19, Congress established the Provider Relief Fund (PRF) – an investment to stabilize the U.S. health care system facing unprecedented financial losses. In addition, Congress also appropriated an additional $8.5 billion for providers and suppliers of rural Medicare, Medicaid, and Children's Health Insurance Program (CHIP) services. HHS appreciates the support of Congress, state and local governments, health care providers, and countless others in this unprecedented coalition to defeat this virus.

HHS is committed to distributing PRF payments as quickly and equitably as possible while utilizing effective safeguards to protect taxpayer dollars. In order to distribute PRF funding as rapidly as possible at the beginning of the pandemic, HHS began by making automatic payments to providers who billed Medicare on a fee-for service basis. In June 2020, HHS began making payments to Medicaid and CHIP providers, dentists, and assisted living facilities as well. In October 2020, HHS opened Phase 3 of the PRF to all eligible providers based on actual lost revenues and incurred expenses attributable to coronavirus, as well as to behavioral health providers who had not been eligible previously.

With a number of facilities being particularly susceptible to lost revenues or increased health care expenses as a result of the pandemic, HHS has obligated approximately $13 billion in PRF payments to long-term care facilities and senior housing, including assisted living facilities, custodial care facilities, nursing homes, and skilled nursing facilities. These payments cover lost revenues and increased costs to maintain safe environments for residents and staff.

To promote transparency in the PRF program, HHS also plans to release detailed information about the methodology utilized to calculate Phase 3 payments. Providers who believed their Phase 3 payment was not calculated correctly according to the methodology will be given an opportunity to request a reconsideration. All PRF Phase 3 reconsiderations are subject to the availability of funds.

HHS appreciates the care being given to communities across the nation and recognizes that, in doing so, some providers still have difficulties meeting their financial responsibilities. As HHS continues to distribute funds, your feedback informs our ability to administer the PRF in a manner that bolsters the health care system and helps providers experiencing COVID-related financial hardships during this crisis.

The Honorable Kurt Schrader (D-OR)

Question 22:
During this ongoing Public Health Emergency (PHE), many drugs have been on shortage due to supply chain challenges. Providers and patients across the health care delivery system experienced delayed or unavailable needed medications. Thankfully, the FDA allowed notable

flexibilities for compounding pharmacies to step up and fill the need for patients who could not access their medications.

As you may be aware, Medicare has an inconsistent policy on how it reimburses for compounded medications. For example, for hospitalized patients who need compounded medications from bulk drug ingredients, Medicare Part A covers these products; however, even when drugs are in shortage, Medicare Part D plans are not allowed to reimburse for prescriptions that are compounded from bulk drug ingredients. Beneficiaries pay out-of-pocket for these prescriptions and it's a financial barrier that many seniors faced this past year.

Would you be willing to work with Congress to better align Medicare Part D's compounding from bulk drug substances' reimbursement policy for seniors when manufactured drugs are on shortage?

Direct verbiage from the letter to HHS, FDA and CMS is below:

"Patients need coverage for drugs that must be compounded due to shortages. Patients covered by Medicare Part D have a financial hurdle to obtain their medication if it must be compounded by a pharmacist. CMS allows Part D health plans to cover a compounded drug only when the drug's components meet the definition of a Part D drug. However, Medicare does not currently reimburse Part D plans for bulk drug substances and inactive ingredients when used in a compounded drug. In other words, CMS will reimburse a pharmacy for crushing tablets to try to incorporate them into a suspension, but will not reimburse the same pharmacy for using the pure ingredients to make the same suspension. To ensure patients with autoimmune conditions that benefit from compounded medications including hydroxychloroquine continue to have access to these therapies, we request that CMS, on a temporary basis during the COVID-19 pandemic, require Medicare Part D plans to reimburse pharmacies for drugs that must be compounded from bulk drug substances due to shortages when manufactured products are unavailable."

Response: HHS is committed to ensuring that patients have affordable access to the prescriptions they need, particularly during public health emergencies. The global pandemic has highlighted the vulnerabilities of the global supply chain for many products, including prescriptions, and it is critical that HHS continue to work to improve and expand domestic supply chain capabilities. We are also working with colleagues across the federal government to examine policies to reduce barriers and increase access to health care services, including prescription medications. I look forward to continuing to work with Congress on this issue.

Question 23:

Biologic medicines treat some of the most serious conditions such as cancer, diabetes, and inflammatory diseases. Treating these conditions also represents a significant cost burden to the Medicare Part B program and the patients it serves. Biosimilar medicines are approved by FDA to be as safe and effective to previously approved reference biologic products that have gone off patent. This represents the opportunity for high-value competition with savings estimates up to $100 billion over the next five years.

What role do you see high-value products like biosimilars playing in the Medicare program in helping to ease Medicare spending and reduce patient cost?

Question 24:
Since biosimilars have entered the United States market, CMS has worked to reverse polices within the Medicare Part B program that would have proven to undermine this nascent market and limit fair competition in areas where [drug] spending has been the highest.

Do you see value in further policy interventions to support a robust competitive biologics market through incentives/policies that support greater access for all patients within the Medicare program to affordable, high-quality, biosimilar medicines?

Question 25:
Biosimilars are expected to be available in the Medicare Part D marketplace (at the pharmacy counter) as soon as this year, which is good news for patients. As we have seen with biosimilars in Medicare Part B, a key challenge that has stood in the way of achieving a more robust competitive biologics marketplace, is a lack of incentives directed at biosimilars to support greater patient access to these safe, effective, and affordable medicines. I'd like to work with you on ways to prepare the Part D program for biosimilar entry, so we'll see successful uptake of biosimilar competition and reduce patient out of pocket cost.

Will you commit to working with myself and this Committee on ensuring policies are in place for biosimilars in the Medicare Part D program that support all patients have equal access to these important medicines?

Question 26:
What additional steps do you believe should be taken or will be needed to ensure all patients who require treatment have immediate access to high-quality, affordable biosimilar biologic medicines?

Response to Questions 23-26: Prescription drug costs are too high for American patients and families. From the meetings I have had with Members of Congress, I have seen that lowering drug prices is a priority on both sides of the aisle. I agree that patient access to lower-cost generics and biosimilars is important. Competition in the market has helped control the growth in spending on prescription drugs, and generics and biosimilars certainly have a role to play in creating competition for reference products. I look forward to working with Congress to lower the cost of prescription drugs.

Question 27:
In December 2018, the FDA announced that it would begin a process to investigate additional regulatory pathways for the lawful sale of hemp-derived CBD products, including as dietary supplements or food. In the intervening two and a half years, the agency has made several pronouncements, but there have been no actions taken to move the process forward. In the meantime, United States hemp farmers and businesses have struggled mightily from the regulatory inaction, and many states have enacted their own laws to address this growing market.

This has led to a confusing patchwork of laws, while bad actors continue to take advantage of the ongoing regulatory uncertainty.

When should we expect the FDA to take action on this growing challenge?

Response: FDA recognizes the significant interest in cannabidiol (CBD). The agency is committed to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived products.

The Honorable Tony Cárdenas (D-CA)

Question 28:
I am pleased the HHS budget increases funding for the NIH. I am particularly interested in the work of NIH's National Center for Complementary and Integrative Health. Advancing research on whole person health will help prevent disease and improve our healthcare system. What actions from Congress would be helpful to advance the work of this Center and support other efforts focused on whole person health at HHS more broadly?

Response: Whole person health is an area of research that focuses on health as a biopsychosocial process involving the whole person. This area includes understanding the interconnections between various organs and systems of the body, and the impact of single or multicomponent interventions on physiological, behavioral, and social systems. The hope is that by deepening our scientific understanding of the connections that exist across all domains of human health, we can better understand how conditions interrelate, define multicomponent interventions that address these problems, and improve how we support patients through the full continuum of their health experience, including the return to health.

This type of research is novel and challenging. It will require the development of new methods to study complex systems, including big data and artificial intelligence. It will also require collaboration between specialized clinicians, researchers, and data scientists. A key challenge for the National Center for Complementary and Integrative Health (NCCIH) is to support these scientific investments without compromising existing programs. With whole person health now central to NCCIH's new Strategic Plan, we are planning to continue increasing our support for this important emerging field of research

The field of whole person health is still in its infancy, but NCCIH is working to develop partnerships within and outside of the NIH to advance this field of research. These partnerships will help support research, generate scientific interest, disseminate key findings, and implement novel interventions. While these partnerships will be helpful, a larger culture shift within the biomedical community will also be needed—from an organ-specific disease model to a whole person care model. Partnerships within the NIH and across HHS focused on whole person health will help facilitate this culture shift.

Question 29:

I am also pleased to see historic investments in the budget related to behavioral health. We know the pandemic has significantly impacted the mental health of our communities, including young people. Could you please expand upon how HHS will support the social, emotional, and mental well-being of youth and specifically how HHS will ensure that services are culturally and linguistically responsive?

Response: This Administration shares your commitment to making quality mental health services available to all Americans, including our nations' seniors. Americans are experiencing increased mental health challenges and greater barriers to receiving necessary behavioral health care. The FY 2022 budget provides $2.9 billion for SAMHSA's mental health activities, an increase of $1.1 billion over FY 2021 enacted. These investments will develop the behavioral health infrastructure, expand suicide prevention activities, support the success of 988 crisis services, address children's mental health, and increase community-based mental health programs that provide services to the nation's most vulnerable populations.

Question 30:

Emergency Medicaid is a primary source of funding emergency care for people who are ineligible for Medicaid because of their immigration status, which leaves out millions of people from many green card holders and DACA recipients and TPS holders to undocumented immigrants. Only a few states have opted to clarify that this program covers COVID-related care, which creates confusion in communities that are disproportionately uninsured. HHS must provide clarity around this in order to address the inequities in access and provide a uniform policy that allows everyone in the United States to have a clear source of COVID-related care. In order for the country to effectively address and contain this pandemic and others in the future, testing and treatment, including vaccines, must be accessible to everyone. That is why on March 19th, 2021, I authored a letter to HHS and CMS requesting guidance to states clarifying that emergency Medicaid will provide coverage for COVID-19 testing, treatment, and vaccinations for all individuals, regardless of immigration status. Will HHS commit to issuing guidance or taking other administrative action related to emergency Medicaid to ensure it's clear to states that all individuals, regardless of immigration status can access COVID-19 testing, treatment, and vaccinations at no cost to them?

Response: CMS is committed to protecting the health and safety of all Medicaid beneficiaries. CMS has issued and will continue to issue guidance to states regarding access to COVID-19 testing, treatment and vaccinations both for the uninsured and for all individuals who qualify for Medicaid coverage.

Question 31:

Current CMS policies can delay Medicare beneficiaries' access to innovative medical technologies approved by the FDA. Regulatory proposals currently under consideration at CMS, including the Medicare Coverage of Innovative Technology program and "adjunctive" Continuous Glucose Monitors (CGM) coverage expansion proposal, seek to address this gap, particularly for devices that have FDA Breakthrough Device designation and, in cases such as adjunctive CGM, devices that are covered by commercial insurers and where lack of CMS coverage means that beneficiaries are threatened with loss of access as they age into Medicare. Will HHS commit to work to ensure Medicare beneficiaries have access to the most innovative,

FDA-approved technologies that their doctors determine would be in their best interest and provide the greatest care?

Response: HHS is committed to Medicare coverage that provides an appropriate balance of support for innovation with necessary protections for Medicare patients. HHS looks forward to working with Congress and other stakeholders as we examine policies to facilitate affordable access to innovative new treatments.

The Honorable Robin Kelly (D-IL)

Question 32:
Secretary Becerra, thank you again for testifying before the Committee. I would like to ask about the issue of maternal health and maternal mortality in the United States.

As noted in the Administration's budget request, the United States has one of the worst rates of maternal mortality among developed countries in the world. In 2017, the United States recorded a maternal mortality ratio of 17.4 deaths per 100,000 pregnancies, ranking last among industrialized countries.[13] The numbers are far worse for Black women. In the same year, Black mothers experienced a maternal death ratio of 37.1 deaths per 100,000 pregnancies, more than twice the rate of white mothers. The causes of death vary, but it's clear there are widely inequitable outcomes for maternal health in the United States.

I fully support your request to increase investments in maternal health. The HHS funding proposal requests increased funding for Maternal Mortality Review Committees, or "MMRCs", rural maternal health care, implicit bias training for clinicians and health workers, and state pregnancy medical home programs. Many of these proposals have also been priorities for the Energy and Commerce Committee, and I believe these provisions are critically important to addressing the maternal health crisis.

Secretary Becerra, improving maternal health outcomes requires accessible, quality pre-conception, prenatal, delivery, and post-partum care. How could the investments the Administration has requested improve maternal health care and narrow these persistent inequities we see in maternal health outcomes?

Question 33:
Last Congress, the House passed the Maternal Health Quality Improvements Act in an overwhelmingly bipartisan fashion. The bill included grants for implicit bias training, similar to the proposals in the budget request, as well as additional provisions to address rural maternal health and training for health care providers. Unfortunately, this bill did not become law last Congress, but I continue to believe these policies are critically important.

[13] The Commonwealth Fund, *Maternal Mortality in the United States: A Primer* (Dec. 16, 2020) (www.commonwealthfund.org/publications/issue-brief-report/2020/dec/maternal-mortality-united-states-primer#:~:text=The%20most%20recent%20U.S.%20maternal,after%20the%20day%20of%20birth.).

a. Can you discuss the value of implicit bias training for health care providers, especially in the context of maternal health?

b. What are additional policies the Committee should be considering in order to effectively address our maternal health crisis?

Response to Questions 32-33: Studies over the past 20 years found a correlation between provider implicit bias and lower quality of care. Often, implicit bias can lead to a negative evaluation of a person based on characteristics such as race or gender. Research has shown that provider bias can contribute to disparities in health outcomes, often influencing patient-provider communication, diagnosis and treatment decisions. Implicit bias training among maternal health care providers can reduce health disparities and improve maternal health outcomes. Implicit bias training can help providers recognize their individual biases and provide evidence-informed training in implementing tools and approaches to address bias in maternal health care practices, especially in areas that experience poor maternal health outcomes. The COVID-19 pandemic has laid bare inequities within our society and how social and economic conditions impact an individual's health and well-being. I intend to take a department-wide approach to the advancement of equity, consistent with President Biden's charge to federal departments and agencies, and this would include examination of ways to address the social determinants of health.

The United States has the highest maternal mortality rate among developed nations, with an unacceptably high mortality rate for Black and American Indian/Alaska Native women. Addressing this critical public health issue is a major priority of the Biden-Harris Administration. Building on HHS's longstanding efforts to improve maternal health, the President's FY 2022 Budget provides more than $200 million in discretionary funding to reduce maternal mortality and morbidity by implementing evidence-based interventions to address critical gaps in maternity care service delivery and improve maternal health outcomes. This includes increased funding to CDC's Maternal Mortality Review Committees and the Health Resources and Services Administration's (HRSA) Rural Maternity and Obstetrics Management Strategies program as well as other increases across HHS programs. As with all HHS public health work, collecting good data will be critical to this effort. In addition to the discretionary resources proposed for maternal health and reducing maternal mortality, the budget also includes $3 billion over five years to invest in maternal health and reduce the maternal mortality rate and end race-based disparities in maternal mortality.

Question 34:

Can you tell me what steps the Department is taking to increase the assistance made available to the senior living industry since for many operators, they are only eligible for assistance from the Provider Relief Fund and not PPP? Do you foresee being able to fulfill all of the applications for assistance or some portion? What should these operators expect from HHS in the form of additional assistance to ensure vulnerable seniors are cared for in safe facilities?

Thank you, Secretary Becerra. I look forward to working together to improve maternal health in America and reduce our unacceptable rates of maternal mortality, especially among Black women.

Response: Thank you for raising this important issue. I appreciate the care being given to seniors across the nation in a number of settings, including assisted living facilities.

As you know, to respond to the urgent needs of the nation's health care providers in the wake of COVID-19, Congress established the Provider Relief Fund (PRF) – an investment to stabilize the U.S. health care system facing unprecedented financial losses. In addition, Congress also appropriated an additional $8.5 billion for providers and suppliers of rural Medicare, Medicaid, and Children's Health Insurance Program (CHIP) services. HHS appreciates the support of Congress, state and local governments, health care providers, and countless others in this unprecedented coalition to defeat this virus.

HHS is committed to distributing PRF payments as quickly and equitably as possible while utilizing effective safeguards to protect taxpayer dollars. In order to distribute PRF funding as rapidly as possible at the beginning of the pandemic, HHS began by making automatic payments to providers who billed Medicare on a fee-for service basis. In June 2020, HHS began making payments to Medicaid and CHIP providers, dentists, and assisted living facilities as well. In October 2020, HHS opened Phase 3 of the PRF to all eligible providers based on actual lost revenues and incurred expenses attributable to coronavirus, as well as to behavioral health providers who had not been eligible previously.

With a number of facilities being particularly susceptible to lost revenues or increased health care expenses as a result of the pandemic, HHS has obligated approximately $13 billion in PRF payments to long-term care facilities and senior housing, including assisted living facilities, custodial care facilities, nursing homes, and skilled nursing facilities. These payments cover lost revenues and increased costs to maintain safe environments for residents and staff.

To promote transparency in the PRF program, HHS also plans to release detailed information about the methodology utilized to calculate Phase 3 payments. Providers who believed their Phase 3 payment was not calculated correctly according to the methodology will be given an opportunity to request a reconsideration. All PRF Phase 3 reconsiderations are subject to the availability of funds.

HHS appreciates the care being given to communities across the nation and recognizes that, in doing so, some providers still have difficulties meeting their financial responsibilities. As HHS continues to distribute funds, your feedback informs our ability to administer the PRF in a manner that bolsters the health care system and helps providers experiencing COVID-related financial hardships during this crisis.

The Honorable Nanette Diaz Barragán (D-CA)

Question 35:

For 30 years, the CDC's National Breast and Cervical Cancer Early Detection Program has provided lifesaving breast and cervical cancer screening and diagnostic services to low-income, uninsured, and underinsured women. The program also provides public education, outreach, patient navigation, care coordination, and quality assistance to increase breast cancer and cervical cancer screening rates and reach underserved, vulnerable populations.

Unfortunately, at current funding levels the program serves fewer than 15 percent of the estimated number of eligible women for breast cancer screening services, and less than 7 percent of eligible women for cervical cancer screening. The program is currently funded at approximately $197 million even though it is authorized to be funded at $275 million.

Could you discuss the Administration's views regarding the importance of preventive cancer screenings, and would you be able to commit to request full funding for the National Breast and Cervical Cancer Early Detection Program at $275 million in the President's budget?

Response: Preventive cancer screenings are a priority for HHS and the Administration because screening saves lives. The CDC's National Breast and Cervical Cancer Early Detection Program has served more than 6.0 million women and provided more than 15.6 million breast and cervical cancer screening examinations. Even with this success, we know that many women are still not being screened according to screening recommendations. We will continue to support CDC as they implement evidence-based strategies at the interpersonal, organizational, community, and policy levels to get more women screened and connected to treatment if they are diagnosed with cancer.

Question 36:

The nation's Community Health Centers are working diligently each day to treat patients in underserved communities, while also playing a major role in the COVID-19 vaccination effort.

Your department recently released $1 billion to health centers from the American Rescue Plan for capital infrastructure projects. However, a recent needs assessment by Capital Link, a HRSA partner, found that health centers need $17.5 billion over the next five years to maintain and expand services.

Do you support additional infrastructure funding for health centers? If so, will that be reflected in the upcoming Biden administration budget?

Response: The Biden administration recognizes and supports the additional infrastructure needs of health centers, as demonstrated by the commitment to funding health center capital infrastructure in Build Back Better. In addition, HRSA administers the Health Center Loan Guarantee Program that enables health centers to access lower cost financing for capital projects by providing Federally backed guarantees for these loan requests. Currently, HRSA has approximately $860 million in loan guarantee authority available for health centers.

Question 37:

The Department of Health and Human Services has the responsibility of advancing the health and well-being of the American people including Americans' oral health. HHS oversees a range

of programs with oral health care components. Oral health plays a critical role in overall health, and while HHS conducts vitally important work in a wide range of health-related government programs through its operating divisions such as the Centers for Medicare & Medicaid Services and the Centers for Disease Control and Prevention, the topic of oral health must be addressed more thoroughly at senior levels on an agency-wide basis.

a. What is the oral health expertise of those who directly reports/senior level reports to the Secretary?

b. How many dental experts are employed by HHS, in particular, at senior levels?

c. What resources does HHS dedicate to oral health research and publications?

Response to a-c: Thank you for your leadership on this important issue. Oral health is a critical part of overall health and I look forward to working with you on these issues. President Biden supports making dental coverage a standard benefit in Medicare. I know this is an important issue to you, and I look forward to working with you on the legislation needed to expand access to dental care in Medicare. With a FY 2021 budget of $19.5 million, CDC's Division of Oral Health (DOH) focuses on improving oral health and achieving health equity, which is when every person has the opportunity to attain their full health potential. The majority of DOH funds (54%) support oral health programs in 20 states and one territory. Approximately 36% of the budget supports staff, contracts, and other operational costs. The remaining 10% support surveillance and research efforts, as well as any other innovative or pilot projects. For example, CDC monitors disease burden through national surveys and supports periodic state-level data collection among awardees. CDC also conducts research, analysis, and translation of national and state data on oral disease burden, dental care service use, preventive services, and cost-effectiveness, and contributes to the scientific knowledge regarding oral health and disease with surveillance reports and journal articles, such as the 2019 Oral Health Surveillance Report. CDC has also made strategic investments to build practice-based evidence through piloting State-level oral health and other chronic disease program collaborations.

As of May 12, 2021, CDC's Division of Oral Health had four dentists, three of whom are dental officers, plus three vacancies for dental officers. In addition, CDC more broadly had two dentists on staff—one full-time and one part-time—as participants in CDC's Dental Public Health Residency training program. These staff have expertise in evidence-based interventions that support oral health such as dental sealants and community water fluoridation; implementing state programs to improve oral health; oral health data and economics; dental infection prevention and control guidelines; and policy and communications strategies.

Question 38:

I have recently introduced the COVID Vaccine Transportation Access Act (H.R. 3013) which requires 100 percent FMAP for the ride to and from the vaccine site. This is in addition to the 100 percent FMAP that is provided for the vaccine and for the provider to administer it. There is

evidence from Non-Emergency Medical Transportation (NEMT) benefit managers that only a tiny percentage of eligible Medicaid beneficiaries — among the most vulnerable patients — are getting the transportation benefit to the vaccine sites.

Many mass sites are drive-thru and an enormous barrier for many Medicaid beneficiaries without cars or someone to drive them. I hope as the Department writes the guidance for the 100% FMAP, that the Department will also consider adopting this policy through regulation.

Can you bring me up to date on the Department's position on including non-emergency transportation in the 100% FMAP for vaccines and their administration in the Medicaid program?

Response: State Medicaid agencies must ensure necessary transportation for beneficiaries to and from providers of covered services. This non-emergency medical transportation (NEMT) assurance requirement is critical to ensuring Medicaid beneficiaries are able to access the services to which they are entitled. States have flexibilities with respect to the design of certain aspects of their NEMT programs, including how NEMT is covered; these flexibilities determine, in part, the federal matching rates they receive for such services.

CMS has taken many actions to ensure that state and territorial Medicaid agencies have the tools they need to identify the issues that need to be considered and addressed in order to provide coverage and payment for vaccine administration in the Medicaid program, and is available to provide technical assistance as they continue to plan and prepare for the widening distribution of COVID-19 vaccines.

I look forward to continuing to work with you to ensure that lack of transportation is not a barrier to Medicaid beneficiaries' access to vaccination against COVID-19.

Question 39:

On January 1st, the Centers for Medicare and Medicaid Services (CMS)'s hospital price transparency rule went into effect.

What steps do you plan to take to ensure that hospitals are complying with the rule, and do you believe a $300/day enforcement penalty should be strengthened so hospitals take the compliance of this rule more seriously?

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

Hospital price transparency helps people know what a hospital charges for the items and services it provides. CMS expects hospitals to comply with all federal requirements, including those regarding price transparency. CMS will provide additional implementation and enforcement details regarding hospital price transparency requirements in future rulemaking.

Question 40:

Assisted living providers serve an aging population, which on average is age 85 and older. These individuals are more likely to die of COVID-19 and the cost of PPE, overtime, and hero pay for senior caregivers on the front lines have amounted to $15 billion in losses and expenses.

The Provider Relief Fund was intended to help these assisted living providers keep their doors open during this crisis, but I have been informed that providers have had to wait a long time for provider relief fund allocations while some providers have been wrongly denied.

Additionally, I have been informed that providers who anticipated a specific amount of relief based on the government's own frequently asked questions, instead received a much lower amount because HRSA modified the publicly disclosed formula and created an "alternative method."

Can you please outline this alternative method, and is HHS providing an appeals process for these assisted living providers if they disagree with the allocation?

Response: Thank you for raising this important issue. I appreciate the care being given to seniors across the nation in a number of settings, including assisted living facilities.

As you know, to respond to the urgent needs of the nation's health care providers in the wake of COVID-19, Congress established the Provider Relief Fund (PRF) – an investment to stabilize the U.S. health care system facing unprecedented financial losses. In addition, Congress also appropriated an additional $8.5 billion for providers and suppliers of rural Medicare, Medicaid, and Children's Health Insurance Program (CHIP) services. HHS appreciates the support of Congress, state and local governments, health care providers, and countless others in this unprecedented coalition to defeat this virus.

HHS is committed to distributing PRF payments as quickly and equitably as possible while utilizing effective safeguards to protect taxpayer dollars. In order to distribute PRF funding as rapidly as possible at the beginning of the pandemic, HHS began by making automatic payments to providers who billed Medicare on a fee-for service basis. In June 2020, HHS began making payments to Medicaid and CHIP providers, dentists, and assisted living facilities as well. In October 2020, HHS opened Phase 3 of the PRF to all eligible providers based on actual lost revenues and incurred expenses attributable to coronavirus, as well as to behavioral health providers who had not been eligible previously.

With a number of facilities being particularly susceptible to lost revenues or increased health care expenses as a result of the pandemic, HHS has obligated approximately $13 billion in PRF payments to long-term care facilities and senior housing, including assisted living facilities, custodial care facilities, nursing homes, and skilled nursing facilities. These payments cover lost revenues and increased costs to maintain safe environments for residents and staff.

To promote transparency in the PRF program, HHS also plans to release detailed information about the methodology utilized to calculate Phase 3 payments. Providers who believed their Phase 3 payment was not calculated correctly according to the methodology will be given an

opportunity to request a reconsideration. All PRF Phase 3 reconsiderations are subject to the availability of funds.

HHS appreciates the care being given to communities across the nation and recognizes that, in doing so, some providers still have difficulties meeting their financial responsibilities. As HHS continues to distribute funds, your feedback informs our ability to administer the PRF in a manner that bolsters the health care system and helps providers experiencing COVID-related financial hardships during this crisis.

The Honorable Lisa Blunt Rochester (D-DE)

Question 41:
Given the enormous economic, social, educational, and mental health consequences of the COVID-19 pandemic on children and youth, a multi-pronged response strategy is needed to set forth an ambitious agenda to help children not simply recover but thrive in the long-term. How are you working across all of the agencies within your department, as well as with other departments, to most effectively implement and align the health, education, tax and social policies included in the American Rescue Plan that are focused on addressing the needs of children, youth and their families?

Response: HHS is committed to interagency collaboration and coordination and leads several existing interagency councils and working groups, especially as it relates to programs funded by the American Rescue Plan and other pandemic relief funding authorized by Congress. Within our Department, the Administration for Children and Families (ACF), Office of Early Childhood Development (ECD) leads coordination, collaboration, and communication with federal agencies and other Departments around early childhood to improve the health and well-being of young children and their families. We have several existing interagency workgroups that include political and career leaders who have committed to working together to increase our collective impact and improve outcomes for children and families across the country. As interagency partners, we developed resources to encourage interagency and cross-sector partnerships and examples of specific actions that states may consider taking to support the implementation of the ARP Act and comprehensive strategies that advance more equitable early childhood systems at the state and local level (see: https://www.acf.hhs.gov/ecd/arp-funds-equitable-ec). We are also committed to the importance of children and their caregivers having access to high-quality resources that equitably support social-emotional development and mental health. We will continue to leverage our early childhood federal interagency workgroups to identify areas to strengthen alignment and coordination across our programs. These topics are also integrated in ACF's Strategic Plan (see: https://www.acf.hhs.gov/about/acf-strategic-plan-2022) and ACF's Equity Information Memorandum (see: https://www.acf.hhs.gov/policy-guidance/equity-action-prioritizing-and-advancing-racial-equity-and-support-underserved

Question 42:
How do you plan to coordinate with other agencies and departments to implement other major children's initiatives, such as the proposed American Families Plan, that require cross-departmental alignment to maximize impact?

Response: As stated previously, HHS is committed to interagency coordination and leads several existing interagency councils and working groups, especially as it relates to programs funded by the American Rescue Plan and other pandemic relief funding authorized by Congress. We plan to leverage our early childhood federal interagency workgroups, including the Early Childhood Health and Well-being Leadership Group to identify areas to strengthen alignment and coordination across our programs. We will also coordinate with other related interagency groups convened by ASPE working on economic mobility and addressing equity that can inform priority actions.

Question 43:
Medicaid is a critical payer for many children and covers upwards of 40 percent of all births. Given the added stressors of the pandemic, what opportunities do you see within the Centers for Medicaid and CHIP Services and CMMI to incentivize states and providers to test value-based payment models that holistically address SDOH for children and families?

Response: HHS is taking a department-wide approach to the advancement of equity, consistent with President Biden's charge to federal departments and agencies, and this includes examining ways to address the social determinants of health. The CMS Innovation Center is currently testing the Accountable Health Communities Model, which evaluates whether systematically identifying and addressing the health-related social needs of Medicare and Medicaid beneficiaries through screening, referral, and community navigation services will impact health care costs and reduce health care utilization. HHS looks forward to working with Congress to address these critical issues across the department.

Question 44:
I am the co-lead of legislation, the Telehealth Modernization Act, that would permanently remove restrictions on the use of telehealth, particularly for Medicare beneficiaries. My bill, for example, would permanently enable seniors to access telehealth services from their homes. How is HHS working to ensure Medicare beneficiaries have continued access to the telehealth flexibilities they've benefited from throughout the public health emergency?

Response: Telehealth is an important tool to address health equity and improve access to health care. Health care should be accessible, no matter where you live. HHS continues to examine the telehealth flexibilities developed for the current public health emergency and determine how we can build on this work to improve health equity and improve access to health care. I look forward to working with Congress to determine which flexibilities can be continued administratively and what may need to be done through legislation.

The Honorable Angie Craig (D-MN)

Question 45:
Mr. Secretary, each year over 50,000 Americans die from colorectal cancer, the second leading cause of cancer death in the country. Congress has provided over $70 million to the CDC's Colorectal Cancer Control Program (CRCCP) to increase colorectal cancer screening rates. And

last year, 24 members of this subcommittee cosponsored H.R. 1570, the Removing Barriers to Colorectal Cancer Screening Act, that was enacted into law. These are critical first steps in addressing the surprise out-of-pocket costs that Medicare patients face in completing their colorectal cancer screening. But there is more work to be done.

The US Preventive Services Task Force (USPSTF), the Centers for Disease Control (CDC), and the American Cancer Society, have consistently documented the importance of colorectal cancer screening. Importantly, USPSTF's recommendation supports flexibility in the methods and tests used in recommended colorectal cancer screenings, acknowledging that the best test is the one that gets done.

Under current CMS policy, some Medicare beneficiaries may be subject to a cost-share following a colorectal cancer screening depending on the exact sequence of screening events, despite clear Congressional intent in eliminating cost-sharing as a potential barrier to receiving these essential services.

If a patient chooses a non-invasive cancer screening method and receives a positive result, then a follow-up colonoscopy is required to complete the screening, which too often results in an out-of-pocket cost for the patient. Current policy penalizes those who choose USPSTF recommended, accessible, non-invasive screening options. Similarly, some patients with Affordable Care Act plans, depending on the plan and state, also face out-of-pockets costs for completing preventive screening.

Exacerbating this issue is the fact that colorectal cancer affects the most vulnerable populations, taking a disproportionate toll on Black, Indigenous and Latino communities. Black Americans have the highest rates of colorectal cancer of any major racial or ethnic group in the U.S. Due to several factors including lack of access to early, preventive screening, they are 20 percent more likely to be diagnosed with colorectal cancer and 40 percent more likely to die from it than most other groups. Latinos are often diagnosed at later stages than white people and are even less likely to get screened than white and Black individuals. American Indians also have higher incidence and mortality rates than white people. Access to early screening saves lives.

There are many difficult issues that factor into racial and ethnic disparities in colorectal cancer screening, but financial obstacles in Medicare and Affordable Act plans are an easy fix.

I would like you to clarify whether your Department has the ability and willingness to take administrative action to resolve this discrepancy in the way ACA plans and Medicare cover tests and procedures associated with preventing and catching colorectal cancer. Do you have the authority to and will you address these gaps in coverage by issuing guidance or taking other administrative action to remove these cost-shares and increase accessibility for all?

Response: We know cancer as a disease for which there are stark inequities in access to cancer screening, diagnostics and treatment across race, gender, region, and resources. The Biden-Harris Administration is committed to ensuring that every community in America – including those living in rural, urban, and Tribal communities – has access to cutting-edge cancer diagnostics, therapeutics, and clinical trials.

With regard to Medicare, CMS prioritizes expanding access to essential preventive health care services, including cancer screenings. Medicare covers a broad range of colorectal cancer screening tests, including Cologuard® Multitarget stool DNA, screening fecal occult blood test, screening flexible sigmoidoscopy, screening barium enema, screening colonoscopy and most recently, blood-based biomarker tests if they meet certain criteria, including specified test performance characteristics. We will be further addressing this issue by implementing section 122 of the Consolidated Appropriations Act, 2021, waiving Medicare coinsurance for certain colorectal screening tests, through future rulemaking.

Under the Affordable Care Act, most private health plans are required to cover certain preventive services that have strong scientific evidence of their health benefits, and plans are not allowed to charge a patient a copayment, co-insurance, or deductible for these services when they are delivered by a network provider. Plans covered by these rules must offer coverage of a comprehensive range of certain preventive services that are recommended by physicians and other experts without imposing any cost- sharing requirements. This includes services given a "grade" of A or B by the USPSTF, an independent panel of scientific experts that ranks preventive services based on the strength of the scientific evidence documenting their benefits. HHS, together with the Departments of Labor and the Treasury have issued several rounds of guidance to clarify the scope of coverage required for recommended colorectal cancer screenings. Specifically, ACA Frequently Asked Questions (FAQs) have clarified that plans and issuers required to cover preventive colonoscopies without cost sharing may not impose cost sharing for the cost of a polyp removal during the colonoscopy, anesthesia services performed in connection with a colonoscopy, any required specialist consultation prior to the screening procedure, any pathology exam on a polyp biopsy, or bowel preparation medications prescribed for the procedure.

I look forward to working with partners across the federal government, along with Congress and other stakeholders, to examine ways we can increase access to services for the prevention, diagnosis, treatment, and survival of cancer.

The Honorable Lori Trahan (D-MA)

Question 46:
Thank you for your leadership in ensuring the nation's hospitals receive needed resources as they continue to serve on the frontlines of the pandemic. Your appointment to Secretary sends a clear message that the Department, once again, will prioritize access to affordable, quality health care for Americans.

Emerson Hospital is a full-service, regional medical center in Massachusetts that provides advanced medical services to more than 300,000 people in 25 towns across the Commonwealth. The facility is a 179-bed hospital with more than 300 primary care doctors and specialists, and their core mission has always been to make high-quality health care more accessible to those who live and work in their community. To further this mission, Emerson has outpatient Urgent Care centers in communities across my district.

In November 2020, Emerson Hospital submitted their Tranche 3 Provider Relief Fund application. When the team at Emerson Hospital reached out to HRSA for a status update a short time after, they were informed that their application was complete and that they should be hearing back soon. By March 2021, Emerson still had not heard back, and so our team reached out with an inquiry to yours. Your wonderful team at the Department informed my office that they had received all the necessary documents to look into Emerson's Tranche 3 application.

Unfortunately, your team informed us this month that HHS determined that the documentation submitted by Emerson Hospital was not sufficient to ensure their reported quarterly revenue and expenses were based on patient care only. Your team informed us that according to their records, Emerson Hospital reported $258,352,359 in revenue from patient care on their application. To determine the amount of lost revenue, HHS calculated 5.25 percent of the revenue from patient care, amounting to $13,582,227.40 in adjusted losses. Since Emerson Hospital had already received a payment in excess of the calculated Phase 3 payment, HHS did not make an additional payment to the provider.

Emerson was never contacted for additional details or documents to include in their application – and were told it was complete. The hospital had heard nothing about the 5.25% average hospital loss calculation, nor of any other hospital in which HHS stated that the documentation did not support the lost revenue as it relates to patient care. Based on Emerson Hospital's calculations, they were expected to receive $15.5 million in tranche 3 of PRF disbursement.

Considering that Emerson Hospital was previously falsely informed that their application was complete, I am respectfully asking that your team takes all of this into consideration and reviews their application materials once more. Like many hospitals across the nation, these resources will be fundamental in Emerson Hospital's survival through the pandemic. Thank you for your consideration of this request.

Response: HHS recognizes that some providers are still struggling to meet their financial responsibilities while continuing to provide care during the COVID-19 pandemic. Additional information on future Provider Relief Fund distributions will be published on HHS' Provider Relief Fund webpage, at www.hhs.gov/providerrelief, as soon as it becomes available.

The Honorable Lizzie Fletcher (D-TX)

Question 47:
In the American Rescue Plan Act, Congress provided $4.5 billion for the Low Income Home Energy Assistance Program (LIHEAP) to help the millions of people who are struggling to pay their heating and cooling bills during this pandemic.

When the bill was passed, estimates of state allocations were circulated by leadership that were based on a 50-50 split between the "old" LIHEAP allocation formula – which is static and emphasizes primarily heating costs – and "new" formula – which incorporates both heating and cooling costs and is structured dynamically to account for changes in fuel costs, state population and other factors. However, the state allocations just announced by HHS are significantly different from those estimates. For example, Texas is getting $116 million less than expected.

What was the methodology applied by HHS in distributing this round of funding based on the language in the American Rescue Plan?

Response: The methodology applied by HHS in distributing this round of funding based on the language in the American Rescue Plan (ARPA) consisted of the following:

(1) Determining the distribution at the total appropriated by the FY21 Continuing Appropriations Act (FY21 CAA) + ARPA (i.e., $8,250,304,000, which includes the $3.5 million set aside for T&TA and the $5,236,804,000 to be run through the 1981 methodology); and
(2) Backing out the distribution of the $3,750,304,000 appropriated by P.L. 116-260.
According to this methodology, Congress directed $3.01 billion to be awarded through the 1984-Formula. This figure comes from $760 million from P.L. 116-260 + $2.25 billion from ARPA. This amount obviated the $1.975-billion-inflation-and-removal method by causing states and tribes to receive more than $1.975 billion. This is because of because of the following:

- The relevant language in P.L. 116-260 called for appropriating funds (including LIHEAP) "for the fiscal year ending September 30, 2021[(i.e., fiscal year 2020)]"; and
- The relevant language in ARPA called for ARPA LIHEAP funds to be made "[…i]n addition to amounts otherwise available, there is appropriated for fiscal year 2021[…] $4,500,000,000[…] for additional funding to provide payments under section 2602(b) of the Low-Income Home Energy Assistance Act of 1981 (42 U.S.C. 8621(b))[…]".

Question 48:
In section 203 of the FY21 Omnibus, Congress changed the definition of "Medicaid shortfall" under Section 1923(g) of the Social Security Act. As states begin their work on the FY22 disbursement for Disproportionate Share Hospital payments, CMS has yet to conform its regulations to this change in law.

Could you provide an update on when CMS will act to conform its regulations under section 2923(g) to the change in law so that states can proceed with their work appropriately and reliably?

Response: Medicaid Disproportionate Share Hospital payments help hospitals provide care to low-income patients and the uninsured, and I know that this pandemic has placed significant pressure on safety net health care providers. I look forward to working with you and other members of Congress to ensure CMS is supporting safety net providers and the work they do on behalf of their patients. I will ensure that states and providers have the guidance they need to administer and participate in the Medicaid program, while meeting these changes in Medicaid DSH requirements that take effect October 1, 2021.

The Honorable Cathy McMorris Rodgers (R-WA)

Question 49:
I recently had a call with a pediatric psychiatrist at an inpatient mental health facility in Washington state. She said that prior to the pandemic, she would have seasonal patients, but

school closures have led to patients coming in year-round. I also spoke to her about the dangers of social media on our children's mental health. How will this Administration prioritize mental health, especially when it comes to children, and what research initiatives are underway to highlight the impact that big tech companies are having on our children?

Response: The Administration shares your concerns regarding the impact of COVID-19 on our children. The Substance Abuse and Mental Health Services Administration (SAMHSA) staff has been working throughout the pandemic to understand how children's development (including social emotional development and learning) has been impacted by school closures, as well as other consequences of COVID-19, such as loss of social connections, death of family members, and in some cases homelessness and food insecurity brought about by job losses. We are monitoring the impacts on children's cognitive, affective and behavioral health, and we are working with our grantees to ensure that, in communities across the country, children's mental health needs are being addressed. We are working especially hard with child and family-serving providers (including school personnel) to ensure that they are prepared to help children cope with the mental and emotional impacts of COVID when they return to school; to increase the availability of, and access to, mental health supports; and to raise awareness about the importance of children's mental health and wellbeing.

The Administration also remains concerned by and fully committed to understanding the potential impact of problematic technology and digital media use among infants, children, and teens. The National Institutes of Health (NIH) is actively seeking opportunities for synergistic collaborations and for supporting research in this space.

For example, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) explores, from infancy through adolescence, the impact of the type, duration, and timing of exposure to and usage of technology and digital media on healthy development across multiple domains (e.g., neurocognitive, behavioral, linguistic, social-emotional, and physical) and individuals from diverse backgrounds and subpopulations. The NICHD 2020 Strategic Plan[14] highlights research to understand the developmental impact of early and/or prolonged exposure to technology and digital media as a priority, demonstrating the institute's support and interest in receiving incoming investigator-initiated research applications that focus on this topic.

Later this year, NICHD will release a funding announcement focused on the Impact of Technology and Digital Media (TDM) Exposure/Usage on Child and Adolescent Development. This funding announcement was developed as a result of a successful, two-day *Media Exposure and Early Child Development* workshop that NICHD held in 2018, together with the NIH Office of Behavioral and Social Sciences Research (OBSSR), the National Science Foundation (NSF), Children and Screens, the Society for Research in Child Development (SRCD), and the American Psychological Association (APA).

Research funding from NICHD continues to support scientific advancements in understanding the impact of digital media and technology on infant, child, and adolescent development across

[14] www.nichd.nih.gov/sites/default/files/2019-09/NICHD_Strategic_Plan.pdf

domains of functioning (e.g., physical, social-emotional, cognitive) and risk for problematic media use.

The National Institute on Drug Abuse (NIDA) has also been monitoring both the emerging literature and the anecdotal evidence about the potential dangers of social media on our children's mental health. Social media's alleged addiction liability is a particularly salient concern for NIDA.

Significant scientific advances in this area continue as a result of the NIH-supported Adolescent Brain and Cognitive Development (ABCD) Study, the largest long-term study of brain development and child health in the United States. The ABCD study is following the impact of multiple biological, psychological, environmental, and social factors on the developmental trajectory and overall health outcomes of over 12,000 children, ages 9-10, over a period of 10 years. Using cutting-edge technology, scientists are exploring how childhood experiences interact with each other and with a child's changing biology to affect brain development and social, behavioral, academic, health, and other outcomes. For example, a recent study surveyed a portion of this cohort early in the COVID-19 pandemic and found that the mean total daily screen use doubled relative to pre-pandemic estimates (7.7. vs 3.8 hours/day) and that despite the gradual reversal of quarantine restrictions, screen use may have remained persistently elevated.[15] A previous study found social media activity was linked to brain network maturation processes in ways that could help explain mixed consequences for psychopathology and cognitive performance.[16] And another ABCD study found that more screen time in young adolescents may be associated with poorer mental health, academic, and sleep outcomes, but improved quality of peer relationships, highlighting the complexity of this issue.[17]

NIDA will continue to pursue this line of research and participates in the recently constituted "Center of Excellence on Social Media and Mental Wellness Committee" led by SAMHSA for the purpose of identifying new opportunities for interagency collaborations and supporting research related to the impact of social media on youth.

Question 50:

During your confirmation hearing, you told Senator Daines that when it comes to laws related to abortion, "my job will be to make sure that I am following the law." The Hyde Amendment, which is current law, makes it illegal to use taxpayer dollars to fund elective abortions with limited exceptions.

a. Will you enforce the Hyde Amendment?

Response: The Hyde Amendment is a discriminatory policy that reduces access to health care. Everyone, no matter where they live, how much money they make, or how they are insured, should have access to the health care they need. Ultimately, Congress passes laws and so the Hyde Amendment still exists in the law and HHS will continue to follow the law.

[15] jamanetwork.com/journals/jamapediatrics/fullarticle/2785686
[16] www.ncbi.nlm.nih.gov/pmc/articles/PMC6487868/
[17] www.ncbi.nlm.nih.gov/pmc/articles/PMC8425530/pdf/pone.0256591.pdf

b. A January 2021 poll found that nearly 60 percent of Americans oppose taxpayer funding of abortion.[18] Do you agree that taxpayers should not be forced to fund elective abortions?

Response: As HHS Secretary, my role is to implement the law. The Department will follow all applicable laws as they relate to abortion and any other issue.

Question 51:

Committee Republicans sent a letter to the Vice President on April 22, 2021, asking questions about Office of Refugee Resettlement (ORR)'s operations related to the management, care, and treatment of unaccompanied children (UC) and related matters given the historic surge in UC referrals ORR is experiencing. I want to thank you for the response that you sent this week on behalf of the Vice President. However, the response did not fully address all of the questions in our April 22 letter. When can we expect a complete response to our letter?

Response: ORR's top priority is focused on critical mission efforts regarding the health, safety, and well-being of all children referred to ORR care. ORR has worked to ensure children do not spend more time in U.S. Customs and Border Protection (CBP) facilities than necessary, which are only intended for short-term processing and holding. With this mission focus, ORR continues its effort to expand state-licensed funded capacity through the expansion of existing facilities, grant awards to new programs, and updated measures to reactivate beds that were offline due to COVID-19 guidance. We are available to provide additional information related to the program.

Question 52:

How many children does the ORR currently have in its care?

Response: As of Wednesday May 12, 2021, ORR has 20,614 UC in its care.

Question 53:

What is ORR's current permanent bed capacity? How does that compare to ORR's capacity prior to the COVID-19 pandemic?

Response: ORR's state licensed operational bed capacity disaggregated by state (data as of 5/12/21):

Operational Bed Capacity	**State**
1062	Arizona
394	California
11	Colorado
24	Connecticut
413	Florida

[18] The Knights of Columbus, *Americans' Opinions on Abortion* (Jan. 2021) (https://www.kofc.org/en/resources/news-room/polls/kofc-americans-opinions-on-abortion012021.pdf).

338	Illinois
32	Indiana
60	Kansas
37	Maryland
121	Michigan
66	New Jersey
1398	New York
25	Oregon
132	Pennsylvania
7	South Carolina
8	Tennessee
3764	Texas
123	Virginia
9	Washington
20	West Virginia

ORR's Long Term Foster Care operational bed capacity disaggregated by state (data as of 5/12/2021):

LTFC Operational Bed Capacity	**State**
101	Arizona
71	California
18	Massachusetts
2	Maryland
60	Michigan
44	New York
5	Oregon
118	Texas
21	Virginia
29	Washington

Question 54:

How many influx or emergency intake sites does ORR currently have online? How many beds do those sites add to ORR's network?

Response: On May 12, 2021, ORR had 13 EIS programs open, which combined for a total 14,284 operational beds.

Question 55:

The Trump Administration left two influx facilities in warm status for surges in referrals of unaccompanied children (UC) like the very one that HHS is currently experiencing. HHS re-activated one of the facilities – Carrizo Springs in Texas – but as of May 12, 2021 it has yet to re-activate Biscayne Bay (formerly Homestead) in Florida. Instead, HHS has stood up new

influx facilities and emergency intake sites in multiple states across the U.S. These decisions have consequences, such as children remaining in overcrowded U.S. Customs and Border Protection (CBP) border patrol facilities for longer than the 72 hours allowed by law.

a. Why hasn't HHS opened Biscayne Bay, which would provide additional capacity to the ORR network?

Response: ORR did not activate Biscayne Bay ICF due to the immediate need for additional bed capacity and the longer timeline that activating Biscayne presented. As a result, ORR issued a notice to terminate the Homestead Memorandum of Understanding on April 9, 2021. The Job Corps site was kept in warm status per ORR's agreement with the Department of Labor (DOL) for access to the Job Corps building. ORR maintained the site until it could be transferred back to DOL.

b. What criteria does ORR use to determine whether to reactivate a facility that has been kept in warm status?

Response: ORR may activate and open an influx care facility when ORR's operational capacity is at or exceeds 85 percent for a period of three days (as per ORR Policy Guide Section 7.2.2). ORR closely monitors and reviews several variables: UC referral numbers, trends, and projections; DHS referral and ORR initial placement timelines; COVID-19 infection rates and impact on staffing and bed capacity; and total operational bed capacity, including state-licensed capacity availability and projections. Most of these variables are challenging to predict with certainty. However, ORR's plans with respect to reactivating a facility in warm status, are guided by child welfare principles, where a child's best interest – timely placement in a safe, child-friendly, least restrictive setting – is prioritized. ORR's priority is to unify UC with vetted sponsors as safely and quickly as possible following their arrival at an Emergency Intake Site, Influx Care Facility, or standard care provider facility.

Question 56:

How much money does the federal government spend per month to keep Biscayne Bay in warm status?

a. On average, how much has it cost the federal government to stand up the new influx facilities that HHS has stood up in the past few months?

b. On average, how much money does the federal government spend to keep one of the new influx facilities up and running?

Response to a-b: As of May 12, 2021, the average monthly cost in warm status for Biscayne ICF was $650,000.

The cost per day per bed of an EIS facility varies with a range from $700 to $2000 per bed per day. The cost per day per bed at a standard facility is $360. While HHS recognizes that the cost of temporary facilities is more expensive than ORR standard

network of care provider programs, EIS facilities fill an essential need to provide immediate emergency services and comprehensive care for children. The alternative would be for children to remain in DHS custody in facilities that do not have specialized care for children or provide any child-friendly services. ORR still prefers to place children at a standard program and has prioritized increasing the standard and permanent bed capacity. To expand its standard capacity, ORR works closely with the grants and contracts teams to issue competitive grants and contracts. ORR consistently seeks to prioritize both standard bed capacity needs and child welfare while being a good steward of taxpayer funds.

Question 57:

In order to ensure that ORR facilities provide a safe environment for the children in its care, ORR imposes requirements for preventing and addressing potential dangers, including an examination of the background and qualifications of facility employees who have direct contact with the children, and minimum staff-to-child ratios. Recent reports note that the administration is not requiring FBI background checks for caregivers working at emergency intake sites, which could compromise the safety of the children in ORR's care.

a. Why isn't HHS requiring FBI background checks for caregivers?

b. How many new staff, contractors, or volunteers has ORR onboarded in the past four months?

c. How many caregivers started working at an ORR facility before the required background checks were completed?

d. How many caregivers still have not completed the required background checks before working at an ORR facility?

Response a-d: ORR expects EIS to be in compliance with the requirements of Field Guidance #13, including background check requirements. Field Guidance #13 states that only EIS federal personnel, or personnel who have been cleared through a fingerprint-based, federal background check are permitted to supervise direct care staff. Staff and volunteers who provide direct care must pass FBI public record criminal background checks for deployment at EIS. ORR will ensure receipt of background checks required of influx care facilities for EIS staff within 30 days of an EIS opening. Staff and volunteers who provide direct care may not have unsupervised contact with unaccompanied children until all background checks have been completed. ORR may waive or modify background check requirements on a facility to facility basis.

Question 58:

What are the current staffing ratios for each of the influx care facilities and emergency intake sites?

a. What were the ratios for the influx care facilities and emergency intake sites when they first opened?

b. Given how quickly those facilities were stood up, and the staffing challenges that ORR has faced, have those ratios been adhered to since in each facility the entire time they have been open and accepting children into its care?

Response a-b: Staffing ratios require one (1) Youth Care Worker for every eight (8) children during waking hours and one (1) Youth Care Worker for every 16 children during sleeping hours, as well as clinical ratios tied to ORR's cooperative agreements (which is typically one (1) clinician for every 12 children, though individual programs may have separate agreements with their ORR Project Officers for higher ratios).

Staffing ratios have been adhered to in each facility while they have accepted children into its care. The appropriation statutes require that the Secretary apply FSA Exhibit 1 standards to unlicensed facilities that the Secretary determines are applicable for any grant or contract for a facility that remains in operation for more than six consecutive months. EIS are unlicensed facilities and therefore subject to the same congressional appropriation restrictions described above.

Question 59:

The National Institute of Health (NIH) has acknowledged that the osteopathic medical education community is woefully underrepresented in NIH-funded research, as well as NIH advisory councils and study sections. Congress raised this issue with the NIH in 2019 through the Joint Explanatory Statement for the FY20 Labor, Health and Human Services, Education, and Related Agencies. At the time, NIH wrote to Congress saying "NIH is dedicated to strengthening and diversifying the biomedical research workforce. This includes fostering opportunities for physician-scientists with osteopathic medical degrees, a group of researchers NIH recognizes is underrepresented in the biomedical research workforce."

a. What is the current state of NIH funding for colleges of osteopathic medicine and physician-scientists with osteopathic medical degrees?

b. What is the current state of representation by researchers with osteopathic medical degrees on NIH advisory boards and study sections?

c. Since acknowledging the underrepresentation of researchers with osteopathic medical degrees in 2019, what has NIH done to direct funding to colleges of osteopathic medicine and physician-scientists with osteopathic medical degrees?

d. Since acknowledging the underrepresentation of researchers with osteopathic medical degrees in 2019, what has NIH done to increase representation of physician-scientists with osteopathic medical degrees on NIH advisory councils and study sections?

e. There is a precedent for NIH having special programs to address disparities in research funding to underrepresented states, male/female Principal Investigators, young investigators, institutions, and others. Describe how the NIH plans to expand research capacity and grant support for dramatically underrepresented DOs and colleges of osteopathic medicine.

Response to a-e: The National Institutes of Health (NIH) is dedicated to strengthening and diversifying the biomedical research workforce. This includes fostering opportunities for physician-scientists with osteopathic medical degrees, a group of researchers NIH recognizes as being underrepresented in the biomedical workforce. As part of this effort, NIH continues to address recommendations described in a 2014 report focused on the physician-scientist workforce from the NIH Advisory Committee to the Director.[19] As the report notes and NIH agrees with, "findings which lead to advances in practice are driven largely by the work of investigators with a variety of degrees, of whom those with clinical training contribute essential knowledge and skills." The report explicitly listed D.O.s among the physician-scientist workforce that it recommended be sustained and strengthened.

In fiscal year 2020, the NIH funded 71 grant awards to osteopathic medical schools, totaling $42.6 million.

In addition, D.O.s and researchers with other degrees who are employed at osteopathic medical schools served on a National Advisory Council (NAC)[20], Initial/Integrated Review Group (IRG), or Special Emphasis Panel (SEP).[21] Please note the following:

- Members are recorded as described in the U.S. General Services Administration FACA database.[22]
- Members could serve on more than one committee per year.
- Degree information is based on what the reviewer entered when they joined the committee.
- The FY is determined by the date the committee met, not the FY of the applications being reviewed.

The following is a breakdown of the number of D.O.s that participated on these panels for FY2020:

Fiscal Year	D.O. Degree			Other Degree		
	IRG	NAC	SEP	IRG	NAC	SEP
2020	10	2	13	18	0	33

[19] acd.od.nih.gov/documents/reports/PSW_Report_ACD_06042014.pdf

[20] NACs perform the second level of peer review of grant and cooperative agreement applications; provide advice and recommendations on matters of significance to the policies, missions, and goals of the Institute and Center (IC) they advise; provide oversight of research conducted by each IC's intramural program; and serve as a forum whereby interested members of the public, in open session, may hear and comment on issues relevant to the overall mission of the IC.

[21] IRGs and SEPs – provide scientific and technical merit review, which is the first level of peer review of research grant applications and contract proposals. IRG members are appointed for multi-year terms of service. At any given meeting, there are also usually a number of temporary members present to provide the expertise needed. SEP Membership is fluid, with individuals designated to serve for individual meetings rather than for fixed terms of service.

[22] www.facadatabase.gov/FACA/apex/FACAPublicGovtwideReports

The National Center for Complementary and Integrative Health (NCCIH) along with other NIH Institutes and Centers (ICs), has specific opportunities for clinician-scientists, which includes D.O.s, who conduct research across a wide range of complementary and integrative health approaches. Examples of such programs include, but are not limited to:

- Mentored Clinical Scientist Research Career Development Awards.
- K12 career development award program.
- Academic Research Enhancement Award (AREA) program.

Physicians with a D.O. degree represent an important component of the medical community. They straddle the complementary, integrative health, and allopathic medical communities and have historically been connected to NCCIH through the practice of osteopathic manipulation. Osteopathic manipulation is a full-body system of hands-on techniques to alleviate pain, restore function, and promote health and wellbeing. This promising intervention is of interest to NCCIH, and the Center makes every effort to ensure that D.O.s have representation on its advisory council. NCCIH currently has 2 members with a D.O. degree on its 18-member council.

f. Describe what is being done to proportionately include DOs in top leadership positions at the NIH?

g. Osteopathic methods have been shown to be an effective alternative to opioid pain management. What are the NIH plans for expanding research in osteopathic techniques?

h. Does the NIH have any additional program ideas that could "level the playing field" for DOs and colleges of osteopathic medicine in medical research? What would it take for NIH to create an Osteopathic Diversity Program Consortium?

Response to f-h: NIH acknowledges that physicians with a Doctor of Osteopathic Medicine (D.O.) degree represent an important component of the medical community. They straddle the complementary, integrative health, and allopathic medical communities and have historically been connected to the National Center for Complementary and Integrative Health (NCCIH) at NIH through the practice of osteopathic manipulation. Osteopathic manipulation is a full-body system of hands-on techniques to alleviate pain, restore function, and promote health and wellbeing. This promising intervention is of interest to NCCIH. Recently, NCCIH released a funding opportunity for research on force-based manipulations, an area that encompasses osteopathic manipulation.[23] The Center also has specific opportunities for clinician-scientists, which includes D.O.s, who conduct research across a wide range of complementary and integrative health approaches. However, D.O.s are not limited to these opportunities or to NCCIH as a potential granting institution. D.O.s are free to work with their institutions to apply to any relevant funding opportunity announcement from any NIH Institute or Center. While NCCIH sees the value of osteopathic manipulations, the Center does not receive many grant applications to support investigators with a D.O degree or from osteopathic medical schools. The applications the Center does receive are funded at a rate comparable to

[23] grants.nih.gov/grants/guide/rfa-files/RFA-AT-21-006.html

those received to support investigators with an M.D. degree or from traditional medical schools.

NIH job announcements for physician-scientists include language specifically noting that accredited Doctor of Osteopathic Medicine degrees are qualifying for these positions, indicating to potential applicants that they would meet educational requirements.

i. An overwhelming number of DOs go into primary care addressing the shortage of over 100,000 primary care clinicians. Given the effort to shift to preventative care occurring in primary settings, how is the NIH directing more funding to primary care research?

Response: NIH conducts and supports primary care research (PCR) within intramural and extramural programs. The PCR portfolio is integrated across the NIH Institutes and Centers (ICs) to allow for effective research across diseases and populations and translation of evidence for improved health outcomes. Much of NIH's PCR portfolio is captured within the health services research portfolio, which is tracked and made publicly available through NIH's Research, Condition, and Disease Categorization (RCDC) system. NIH's PCR has 4 broad themes: 1) primary care services for specific diseases, body systems, and populations; 2) implementation of care practices and coordination; 3) integration of specialty care services into primary health care; and 4) disparities in primary health care research.

j. Most clinical and biomedical research is directed to urban and suburban patient populations resulting in health disparities further highlighted by the COVID-19 pandemic. What can the NIH do to direct research to rural and medically underserved areas in order to more accurately represent our overall patient population?

Response: NIH is committed to supporting rural health research. From 2015-2020, NIH more than tripled its investment in rural health research, from $192 million to $728 million. While a variety of NIH Institutes and Centers support rural health research related to their respective missions, the National Institute of General Medical Sciences (NIGMS) has a particular focus on building the capacity for rural and medically underserved communities to conduct research.

One of NIGMS's core capacity-building programs is the Institutional Development Award (IDeA), which was authorized by Congress in 1993 to broaden the geographic distribution of NIH funding. The IDeA program builds research capacity at academic institutions in states that have historically received a low level of NIH support, helping institutions compete successfully for additional research funding while also serving the research needs of medically underserved communities in IDeA states. The IDeA program currently consists of several well-established funding initiatives, including the Centers of Biomedical Research Excellence (COBRE), the IDeA-state Networks of Biomedical Research Excellence (INBRE), and the IDeA Networks for Clinical and Translational Research (CTR). IDeA-CTRs, in particular, support statewide or multi-state regional networks that address chronic, infectious, and behavior health challenges that disproportionately affect these often rural or economically-disadvantaged

communities, bringing together several institutions to provide the human and infrastructure resources needed for the conduct of clinical and translational research in such communities.

IDeA initiatives also support a large number of institutions that typically receive limited NIH funding, including colleges of osteopathic medicine (COM). For example, two COMs have received COBRE awards and several more are partners of the INBRE and IDeA-CTR networks. All of the IDeA initiatives increase the capacity for, and broaden participation in, research in IDeA states and jurisdictions, including research that addresses the needs of rural and medically underserved communities. These programs can provide models for building research capacity and participation in rural communities across the country.

The Honorable Brett Guthrie (R-KY)

Question 60:

The Center for Medicare and Medicaid Innovation (CMMI) has cost taxpayers a great deal of money over its first decade.[24] I've recently read about comments in the press from your staff that CMMI should focus less on saving money. Given the dismal fiscal track record of the "Innovation Center" across multiple administrations, I'm not sure how it's possible to place less emphasis on delivering savings to our public health programs and taxpayers.

a. Can you please confirm that CMMI and 402 demonstration projects will pursue savings as the law intends?

b. Will your Budget include any mandatory or nationwide models?

    i. If they're not in the Budget, what type of notice will you commit that Congress will receive if you are to pursue mandatory or nationwide models?

c. Relatedly, what specific processes will you put in place to ensure Congress is consulted on future CMMI models or updates to existing models?

d. What type of information, beyond what is currently available under FOIA, related to CMMI financing and quality will you be providing this Committee?

    i. What does your Department and CMMI plan to do with such information?

Question 61:

Will your Department continue to prioritize models which "on the basis of improvement potential in a hypothetical full rollout across the nation" either:

a. "Reduce avoidable events by at least 10 percent and/or mortality by at least 2 percent;"

[24] Brad Smith, M.Phil., *CMS Innovation Center at 10 Years — Progress and Lessons Learned*, New England Journal of Medicine (Feb. 25, 2021) (https://www.nejm.org/doi/full/10.1056/NEJMsb2031138).

b. "Reduce expenditures by $10 billion annually once expanded nationally;" or

c. "Empower beneficiaries by increasing choice and access?"

d. The above criteria are from a CMMI fact sheet for physician-based models. If you will not use the above criteria, which criteria will you use for prioritizing models?

Question 62:
I will work with you to make sure we are pursuing models that recognize the strides providers have already made and improve our health care system. On April 8th, CMMI announced that it would not solicit any further applications beyond April 2, 2021, for its Global and Professional Direct Contracting Model (GPDC). Numerous provider organizations who intended to participate in the model may no longer be able to participate in the program starting in 2022.

a. Can you explain why the agency decided to halt new applicants so abruptly?

b. Will you commit to reopening the portal for applications and accepting new applicants in the model for a January 1, 2022, start date?

Question 63:
Despite widespread bipartisan support for finalizing the Medicare Coverage of Innovative Technology (MCIT) your Department has now delayed the rule twice, most recently through December 15, 2021.

Will you commit to the bipartisan members in support of finalizing MCIT that you will indeed finalize the rule without additional delays?

Question 64:
Mr. Secretary, can you speak to your plans for the Geographic Direct Contracting Model?

a. Can you speak to how delaying, canceling, or narrowing the scope of the model may impact small and rural providers and the patients they serve?

Question 65:
Mr. Secretary, can you speak to your plans for any of the existing models created during the prior Administration that have not already been canceled?

a. Can you explain recent actions taken by the Innovation Center to cancel or significantly narrow the scope of waivers created by the prior Administration?

b. Will such narrowing of the scope of the waivers affect rural parts of the country?

    i. What type of studies or analysis have been performed before these policy decisions were made?

    ii. If studies or analysis were done before canceling, delaying, or narrowing these

models, were you briefed on them?

Response to Questions 61-65: Innovation is important to advancing goals in health care, and the CMS Innovation Center is integral to the Biden-Harris Administration's efforts to promote high-value care and encourage health care provider innovation. The Innovation Center allows us to test new models to improve patient care, advance health equity, and lower patient costs. The Innovation Center is reviewing its portfolio and learning from the implementation of the Global and Professional Direct Contracting (GPDC) model to inform next steps on this model and strategies for population health, risk-based models Getting feedback from expert stakeholders across the health care system, including Congress, is a critical part of developing and implementing our models, and I look forward to hearing from you as we continue to examine ways to improve our health care delivery system.

With respect to the Medicare Coverage of Innovative Technology rule, CMS is committed to establishing predictable coverage pathways while at the same time ensuring Medicare beneficiaries receive high value care.

Question 66:

Mr. Secretary, I understand that President Biden's American Families Plan proposes to close a "hole in the law" to apply Medicare's 3.8% investment income tax "consistently to those making over $400,000, ensuring that all high-income Americans pay the same Medicare taxes."

a. Speaking on behalf of the programs your Department is responsible for, do you agree with the American Families Plan's policy to make sure those making over $400,000, including government officials, all pay the same Medicare taxes?

b. You may have heard that from 2017 through 2019, as private citizens President Biden and First Lady Dr. Jill Biden avoided paying more than $500,000 in Medicare and ACA payroll taxes on over $13 million in declared corporate profits. Mr. Secretary, how can the Biden Administration claim to stand for seniors in the Medicare program and for the Affordable Care Act if the President himself refused to support the programs with his own tax dollars?

Response: Ensuring the long-term strength of the Medicare program is an important, longstanding issue. It is essential that we protect and strengthen this program for Americans who have spent their lives paying into it. That's why the President's FY 2022 Budget includes the President's American Families Plan Medicare tax reforms that would increase revenues to Medicare and extend the solvency of the Trust Fund by roughly 11 years. I look forward to working with colleagues across HHS, along with Congress and other stakeholders to promote the affordability and sustainability of these programs.

Question 67:

Will you commit to keep the prior Administration's Stark Law and anti-kickback statute reforms in place?

a. Will you commit that you will notify Congress in advance if you plan to alter the Stark Law and Anti-kickback statute reforms?

Response: To implement the statutes enacted by Congress, HHS follows the standard rulemaking policy when issuing regulations, which includes a 60-day public comment period for proposed rules. We look forward to receiving feedback from a variety of stakeholders on proposed rules we release in the future.

Question 68:

Will you commit to fully enforcing the prior Administration's hospital price transparency rule?

a. Keeping in mind recent reports of inconsistent hospital compliance with the rule, will you commit to exploring additional options to bring them into compliance if they do not swiftly comply?

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

Hospital price transparency helps people know what a hospital charges for the items and services it provides. CMS expects hospitals to comply with all federal requirements, including those regarding price transparency. CMS will provide additional implementation and enforcement details regarding hospital price transparency requirements in future rulemaking.

Question 69:

During the pandemic, we saw the importance of strengthening the public health infrastructure to make sure patients could get the right treatment, at the right place, and at the right time. Home oxygen and respiratory therapies played a critical role in helping hospitals manage the surge of patients by allowing some patients with acute conditions to be treated at home with oxygen. Oxygen, positive airway pressure devices, and non-invasive ventilators were essential in treating patients with COVID-19 and transitioning them out of the hospital to the home.

a. How will the HHS help to strengthen the home respiratory benefit in Medicare, especially in rural areas?

b. How will the Department make sure that patients who began receiving these home therapies during the pandemic under relaxed documentation standards are grandfathered into coverage and not be forced into otherwise unnecessary physician visits and testing simply to create a "paper trail" once the pandemic flexibilities are removed?

Response: Thank you for raising this important issue. HHS shares the goal of making sure people can receive care in their homes, including home oxygen and respiratory therapies when appropriate, especially during the pandemic. It is critically important that people are able to get access to care in the most appropriate setting, and we look forward to working with you and other stakeholders as we examine ways to improve home services.

Question 70:
Knowing the physician fee schedule and its impact on the wide variety of physician practices around the country, will you commit to working with this Congress to explore creative but fiscally responsible ways to provide that any future necessary increases to primary care don't disproportionately harm office-based specialists?

Response: Ensuring adequate Medicare payments for primary care and specialty physicians is essential to maintaining beneficiary access to high-quality and affordable health care. I will work to ensure that payments under the Medicare physician fee schedule are implemented in accordance with the law while preserving beneficiary access, and I look forward to working with you and other Members of Congress on this issue.

Question 71:
Secretary Becerra, during your tenure as California's Attorney General, you raised concerns regarding health system consolidation in the state and supported legislation which would have given the CA Attorney General the ability to call a "time out" before a health system attempts to acquire a practice or facility. Can you speak to how you will approach hospital consolidation practices?

a. Which particular federal policies do you believe lead to greater hospital and provider consolidation?

b. What will your Budget and other Department actions propose to do to throttle consolidation based off of government policy arbitrage?

c. How will you continue to build off of Congressional efforts to promote site neutrality and level the playing field among providers?

Response: As you mentioned, this has been a significant focus of my tenure as California's Attorney General, and I will continue to focus on preventing consolidation that increases prices for consumers and patients. Like President Biden, I believe that all Americans should have access to affordable health care, and part of that is identifying solutions to hospital consolidation. I look forward to working with you to tackle this issue and pursue solutions that strengthen our federal programs and protect patients and consumers.

Question 72:
Mr. Secretary, I believe that the so-called "impact table" of the Physician Fee Schedule (PFS) contains room for improvement in informing stakeholders or even CMS itself about the true impact of its policies. Among other things, the PFS impact table blends hospital-based and freestanding providers (rather than disaggregate impacts by site-of-service), does not include all payments (e.g., hospital and ASC technical fees are left out), and does not include all specialties. This committee would be interested in working with you to make the PFS impact table something that is even more meaningful in terms of true impacts to providers across sites-of-service. Notably, such transparency could also help address health system consolidation

concerns if we can better understand on the front-end what the impacts are across various payment regulations (e.g., PFS, ASC, OPPS). Will you commit to work with Congress and medical stakeholders around the country such as physician practices – both big and small and urban and rural - on this issue in the months ahead?

Response: With regard to the Medicare Physician Fee Schedule, I share the Committee's interest in transparency in the published data and understand the desire for more granular information. I look forward to working with Congress and stakeholders to consider suggestions to improve the information that HHS and CMS make available with regard to physician payment for future rulemaking.

Question 73:

We have seen a growth in the private/public partnership program in Medicare Advantage. Over 40% of Medicare beneficiaries are choosing MA and they report high satisfaction with the provider networks, cost savings and coordinated care. There is a lot of interest in what is referred to as "value-based care," which usually means risk-based payments paid to health plans or providers who take financial responsibility for a set of services. Many researchers and health care stakeholders see such payment as the future. As the leading and most successful value-based payment model in Medicare, what role do you see Medicare Advantage having in the future of the Medicare as we work towards modernizing Medicare?

Question 74:

It is no mystery that the Medicare Part A Trust Fund is financially unsustainable. CBO and Medicare Trustees project that the trust fund will become insolvent as soon as 2024, accelerated by the impact COVID-19 on the revenues from payroll taxes that support Medicare. How do you expect the Administration, working with Congress, to tackle this reality that threatens the health coverage and financial security provided by Medicare? Do you expect new revenues or cost saving strategies—or a combination? What work do you believe can be done now to prevent Medicare insolvency and what role do you see Medicare Advantage playing?

Question 75:

Our nation's population is aging: 10,000 new seniors every day, almost a doubling of the population aged 65 and older. This is increasing those eligible for Medicare as well as creating demands this Administration should be preparing for. In Medicare, we are seeing both new enrollees and current beneficiaries choosing Medicare Advantage over Traditional Fee-For-Service Medicare to receive their benefits. Medicare Advantage is showing that it can provide lower consumer costs, offer additional benefits, and achieve better outcomes, like fewer avoidable hospitalizations including for high need, high risk patients for the same or lower cost as FFS Medicare. Do you see Medicare Advantage as an important part of modernizing Medicare while getting better results for our taxpayer dollars? What will you do to protect this public private partnership and keep the program strong?

Question 76:

During the COVID-19 emergency health care utilization for in-person visits to doctors and other health practitioners either stopped or transitioned to telehealth visits almost overnight. Telehealth as an alternative was, and still is, a lifeline for millions of Medicare beneficiaries.

Medicare Advantage was well-positioned to offer video and audio-only visits which enabled continuity of care essential to many thousands and thousands of patients. Yet, many Medicare beneficiaries lack the technology, connectivity, or ability to take advantage of video telehealth visits and used audio-only telehealth visits instead.

Such audio-only visits were accepted by CMS as a billable telehealth visits in FFS Medicare but did not allow health conditions identified during these visits for risk adjustment in Medicare Advantage. The result there may be insufficient data for risk adjustment that is required by CMS in Medicare Advantage. This is likely to also result in long-term consequences in the Medicare Advantage program. Remedies have been suggested to CMS and Congress to address this problem crated by the pandemic. What will your administration do to ensure that Medicare Advantage organizations can continue to meet the annual data collection requirements that assist in accessing health conditions and risks and payment critical to the smooth functioning of Medicare Advantage?

Response to Questions 73-76: Medicare Advantage plays an important role in giving people access to care. Ensuring the long-term strength of the Medicare program, which includes Medicare Advantage, is an important, longstanding issue. It is essential that we protect and strengthen this program for Americans who have spent their lives paying into it. Additionally, telehealth has been and continues to be an important tool to improve health equity and improve access to healthcare. I look forward to working with colleagues across HHS, along with Congress and other stakeholders to promote the affordability and sustainability of our programs and improve access to healthcare through telehealth by building on innovative lessons learned across HHS programs, including Medicare Advantage.

Question 77:

At this point we don't yet have clarity from Chairman Pallone as to how drug pricing will proceed. It seems these decisions could be made by Speaker Pelosi without bipartisan consultation at this Committee. Unfortunately, that is most often a recipe for failure, so we hope House Democrats choose to work with us on bipartisan drug pricing solutions like H.R. 19, which is full of policies focused on lowering seniors' out-of-pocket costs and increasing drug pricing transparency. Unfortunately, we've read numerous press reports that indicate that House Democrats may choose to raid the Medicare program to funnel more money into the Obamacare exchange program.

a. Does the Administration support using Medicare dollars to expand Obamacare?

b. Do you believe it is fair to take dollars from the Medicare program to pay for another Obamacare expansion rather than use those dollars to protect, improve, or sustain the finances of the Medicare benefit for seniors who rely on the program?

Response: The Biden-Harris Administration is committed to building upon the successes of the Affordable Care Act (ACA) and the American Rescue Plan Act of 2021 to provide Americans with access to affordable coverage options. I am committed to identifying opportunities to ensure that all Americans can access the care that they need, as well as the financial assistance they are eligible for under the law.

Question 78:
Do you support the Affordable Care Act and its policies aimed at Americans with disabilities?

a. Mr. Secretary, as you well know the Affordable Care Act banned the use of Quality Adjusted Life Years (QALYS) and similar measures that put a price on a Medicare beneficiary's life. Do you support a similar ban in any drug pricing bill to ensure you or a future Secretary cannot use so-called negotiation to discriminate against patients with rare diseases or those with disabilities?

Question 79:
Mr. Secretary, during the hearing Congresswoman McMorris Rodgers asked if you agreed with the National Council on Disability and the Consortium of Citizens with Disabilities that QALYs discriminate against people with disabilities and that QALYs value disabled lives less than non-disabled lives. Unfortunately, you refused to answer or take a position on the matter. Yes or no, do you agree with these organizations that QALYs discriminate against the disabled and devalue their lives?

a. Can you commit that you will not support legislation in your Budget or otherwise that would import QALYs into the Medicare program or any other federal program under your jurisdiction? If not, why not?

b. Do you concur that five out of the six international reference countries in the Democrats' drug pricing legislation, H.R. 3 (from which the HHS Secretary would base United States drug prices) have QALYs embedded into their existing drug pricing and valuation systems?

    i. If so, do you support removing H.R.3's reliance on international prices with QALYS?

c. Do you agree or disagree with the Consortium of Citizens with Disabilities position that H.R. 3 "relies on international prices to set an upper limit in negotiations? Many of the nations used to create the average international market price rely on QALYs to determine their coverage and prices. CCD is very concerned that these provisions effectively import a QALY-based and discriminatory system from abroad. These systems are discriminatory against people with disabilities and do not have a place in the United States health care system?"[25] If you disagree with their position, please explain what you disagree with and why.

Question 80:
H.R. 3 relies on the United Kingdom, which evaluates the price of a person's life using QALYs, for its rate setting scheme. In their 2019 report to Congress, the National Council on Disability, an independent federal agency, stated "The coverage denials and loss of access to care faced by

[25] Letter from the Consortium for Citizens with Disabilities Health Task Force Co-Chairs to Rep. Frank Pallone, Chairman, House Committee on Energy and Commerce (Sep. 24, 2019) (www.c-c-d.org/fichiers/CCD-Letter-HR-3-Final-9.24.19.pdf).

people with disabilities in (countries using QALYs) illustrate what might happen if the United States made a similar choice."

a. Do you support H.R. 3, and will it be in your Budget?

b. Do you share the concerns of people with disabilities about the use of QALYs and their discriminatory nature?

Response to Questions 78-80: Ensuring that all Americans have access to affordable, quality health care is a top priority for the Biden-Harris Administration, and we will continue working to increase the number of Americans who have affordable care, including those with disabilities. Like President Biden, I believe we must do all we can to lower health care costs, including the costs of prescription drugs and make them more accessible for Americans. I am committed to reducing drug prices and ensuring that beneficiaries have access to the effective and affordable drugs that they need.

Question 81:
Was HHS in the room when discussions were taking place about whether to support the waiver of patent protections under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)?

Question 82:
Were you personally consulted about the decision before it was publicly announced?

Response to Question 81 and 82: HHS is a member of the USTR-led interagency Trade Policy Staff Committee and has been involved in that interagency process.

Question 83:
Officials within the Biden Administration have told the public that patent protections must be waived so that we can vaccinate people across the world and end this pandemic. What projections has HHS done to determine how many more people, globally, will be vaccinated because this action is being taken compared to how many would be vaccinated without waiving patent rights?

Response: The Administration's aim is to get as many safe and effective vaccines to as many people as fast as possible. As vaccine supply for the American people is secured, the Administration will continue to ramp up its efforts – working with the private sector and all possible partners – to expand vaccine manufacturing and distribution. It will also work to increase the raw materials needed to produce those vaccines. The Administration plans to increase vaccine supply and facilitate vaccine delivery through a variety of mechanisms, including vaccine donations, investments to expand domestic and global manufacturing to accelerate new supply to market and build capacity for future preparedness, and investments in country readiness to receive and administer vaccine doses.

Question 84:

Has the agency conducted any analyses to determine how quickly we will get shots in arms by taking this action compared to other actions, such as donating our surplus vaccine doses?

Response: Vaccinating the world as quickly as possible is a top administration priority. As vaccine supply for the American people is secured, the Administration will continue to ramp up its efforts to accelerate production of vaccines and get them to countries in need as fast as possible. We are working with the private sector and all possible partners – to expand vaccine manufacturing and distribution. The United States will also work to increase the raw materials needed to produce those vaccines. The Administration plans to increase vaccine supply and facilitate vaccine delivery through a variety of mechanisms, including vaccine donations, investments to expand domestic and global manufacturing to accelerate new supply to market and build capacity for future preparedness, and investments in country readiness to receive and administer vaccine doses.

Question 85:

Has HHS conducted any studies or analyses to determine how this decision to force patent disclosure and technology transfer will impact the United States response to future outbreaks and pandemics? Do you think private companies are going to want to partner with the federal government, as they did through Operation Warp Speed (OWS), if they know their intellectual property is going to be given away?

Response: Starting in mid-April, the Administration held consultations with interested parties: labor organizations, civil society, public health advocates, public health experts both inside and outside of the government, and vaccine manufacturers. The Administration will continue to work with the private sector and other partners to expand vaccine manufacturing and distribution around the world. This comprehensive effort will not only save lives but also help heal the economy.

The Administration believes strongly in intellectual property protections and the importance of safeguarding American innovation from illicit acquisition. The decision to support a waiver of IP protections for COVID-19 vaccines reflects the extraordinary circumstances of this pandemic. The Administration is committed to working with the World Trade Organization members and will be clear-eyed about potential risks as we enter text-based negotiations.

Question 86:

The Administration has announced that it would support a TRIPS waiver for vaccines only. Many of the advanced technologies associated with the COVID-19 response, such as mRNA technologies, are broadly applicable to cures of the future well beyond the production of vaccines or even COVID-19. The United States leads the world in these advanced technologies. Our competitors, especially China and India, are anxious to catch up.

a. How would you limit the forced transfer of these advanced technologies just to COVID-19?

b. Have you evaluated how forced technology transfers permitted under the proposed TRIPS waiver would affect U.S. competitiveness in advanced life sciences in the future?

c. How would that affect our ability to respond to future pandemics?

Response to a-c: Vaccinating the world as quickly as possible is a top administration priority. The Administration believes strongly in intellectual property protections and the importance of safeguarding American innovation from illicit acquisition. The decision to support a waiver of IP protections for COVID-19 vaccines reflects the extraordinary circumstances of this pandemic. Starting in mid-April, the Administration held consultations with interested parties: labor organizations, civil society, public health advocates, public health experts both inside and outside of the government, and vaccine manufacturers. The Administration will continue to work with the private sector and other partners to expand vaccine manufacturing and distribution around the world. The Administration is committed to working with the World Trade Organization members and will be clear-eyed about potential risks as we enter text-based negotiations. This comprehensive effort will not only save lives but also help heal the economy. The Administration is focused on combatting the current pandemic and preparing to respond to any future biological threat.

Question 87:

Has the Administration evaluated whether the proposed TRIPS waiver would have an impact on the safety and efficacy of the vaccine and medicine supply?

Response: Any products manufactured as a result of a TRIPS waiver would still need to receive relevant regulatory authorizations or approvals before they could be administered to patients. A TRIPS waiver would not change the safety and efficacy standards applied by regulatory authorities.

Question 88:

Manufacturing vaccines involves highly specialized equipment and expertise. In the past year alone, companies have entered into at least 275 vaccines manufacturing and production partnerships around the globe to try to meet the global demand. Not only did existing IP protections enable biopharmaceutical research companies to move quickly and effectively against COVID-19, but they're also the foundation for incentivizing ongoing efforts to ensure that the world can stay ahead of potential variants.

a. Has HHS assessed how the TRIPS waiver will disrupt already strained supply chains? How will the Administration prevent further disruption of vaccine supply chains that are likely to arise out of the waiving of IP?

b. How will the TRIPS waiver address known barriers to vaccine access such as last-mile distribution challenges?

Response to a & b: The United States Government is committed to accelerating progress toward widespread and equitable access to safe and effective COVID-19 vaccines. HHS is working with vaccine manufacturers and with our colleagues at the White House and other agencies to do

everything possible to accelerate production of vaccines, and to get them to countries in need as fast as possible. The Administration plans to increase vaccine supply and facilitate vaccine delivery through a variety of mechanisms, including vaccine donations, investments to expand domestic and global manufacturing to accelerate new supply to market and build capacity for future preparedness, and investments in country readiness to receive and administer vaccine doses.

Question 89:

The Department has committed itself, "to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived (CBD) products." However, FDA enforcement guidance related to CBD products is lacking.

a. Are you committed to releasing risk-based enforcement guidance that would provide Americans the appropriate level of transparency into the science, safety, effectiveness, and quality of products containing CBD?

Response: FDA recognizes the significant interest in CBD. The Agency is committed to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived products.

b. Will you work with this Committee to ensure research and regulatory incentives are maintained to continue scientific innovation of cannabis-derived medicines?

Response: FDA recognizes the potential therapeutic opportunities that cannabis or cannabis-derived compounds could offer and acknowledges the significant interest in these possibilities. FDA's Center for Drug Evaluation and Research (CDER) is committed to supporting the development of new drugs, including cannabis and cannabis-derived drugs, including through clinical trials conducted under investigational new drug applications (INDs) and the process for review and approval of drug applications.

Question 90:

I have heard concerns raised by domestic manufacturers of personal protective equipment (PPE) that money the federal government allocated to the states earlier this year has been used to award contracts to foreign manufacturers, specifically for surgical masks. While a limited domestic availability of PPE would certainly necessitate purchases of PPE from overseas, I am being told that hundreds of millions of surgical masks could be made immediately available from domestic producers.

a. What is the Administration doing to provide transparency into which entities are receiving Federal funds for PPE purchases?

Response: Using supplemental funding, the Strategic National Stockpile (SNS) has vastly increased its inventory of PPE, ancillary medical supplies, pharmaceuticals, and ventilators to meet the national demand. Funds continue to increase production capacity

of PPE and other medical supplies and treatments for acquisition into the Stockpile and to support product distributions to impacted States.

b. Is the Administration currently requiring, or considering a requirement, that domestic manufacturers be prioritized when awarding contracts for PPE using Federal funds unless supplies are insufficient?

Response: In his first week in office, President Biden signed Executive Order 14005, *Ensuring the Future is Made in All of America by All of America's Workers*, launching a whole-of-government initiative to strengthen the use of federal procurement to support American manufacturing. Specifically, Section 1 of EO 14005 states that the federal government "should, consistent with applicable law, use terms and conditions of Federal financial assistance awards and Federal procurements to maximize the use of goods, products, and materials produced in, and services offered in, the United States." Section 1 further states that the federal government "should, whenever possible, procure goods, products, materials, and services from sources that will help American businesses compete in strategic industries and help America's workers thrive."

The SNS has adhered to EO 14005 while using supplemental funding to vastly increase its inventory of PPE, ancillary medical supplies, pharmaceuticals, and ventilators to meet the national demand. Funds continue to increase production capacity of PPE and other medical supplies and treatments for acquisition into the Stockpile and to support product distributions to impacted States.

Question 91:
Have federal funds been used in 2021 to purchase surgical masks from foreign-based suppliers and manufacturers despite the availability of supplies from domestic manufacturers?

Response: HHS follows acquisition regulations and is required to issue awards to the best offeror of products. At the same time, HHS continues to adhere to EO 14005 and the President's commitment to ensuring the future of America is made in America.

Question 92:
What short-term steps is the Department taking to ensure that the domestic surgical mask manufacturing industry is supported throughout the year as Congress and the Administration work together to find long-term solutions to promote and sustain American manufacturing?

Response: The medical supply chain ecosystem is complex, with different private sector players and market dynamics across multiple domains of medical equipment and supplies. HHS is supporting a number of efforts to revitalize and rebuild the nation's domestic manufacturing capacity. Specific efforts include domestic manufacturing of PPE and active pharmaceutical ingredient manufacturing capacity; COVID-19 testing; and, enhanced vaccine production capacity. Each of these domestic manufacturing initiatives meet current, as well as future COVID-19 needs, and seek to create or sustain high-value domestic jobs.

Question 93:

From your perspective, why is it important to maintain an industry of American mask manufacturers, including those who make surgical N95s and other surgical masks, who build and source their products solely within the United States?

Response: HHS follows acquisition regulations and is required to issue awards to the best offeror of products. At the same time, HHS continues to adhere to EO 14005 and the President's commitment to ensuring the future of America is made in America.

Question 94:

President Biden has spoken to the importance of domestic manufacturing partnerships under his Buy American initiative. Are there long-term solutions HHS is considering to support these efforts? Are there additional actions Congress can take to ensure these partnerships are successful?

Response: The medical supply chain ecosystem is complex, with different private sector players and market dynamics across multiple domains of medical equipment and supplies. HHS is supporting a number of efforts to revitalize and rebuild the nation's domestic manufacturing capacity. Specific efforts include domestic manufacturing of PPE and active pharmaceutical ingredient manufacturing capacity; COVID-19 testing; and, enhanced vaccine production capacity. Each of these domestic manufacturing initiatives meet current, as well as future COVID-19 needs, and seek to create or sustain high-value domestic jobs.

Question 95:

On April 15, the EEOC sent a letter, signed by Acting Legal Counsel Carol Miaskoff, to over 40 business groups promising guidance to employers across the country on workplace incentives and the COVID-19 vaccine. Over a month later, the Administration has yet to act on this important issue. Businesses have been asking the EEOC for months to clarify the extent to which employers can offer employees incentives to vaccinate without running afoul of the Americans with Disabilities Act (ADA) and other federal anti-bias laws. Has HHS provided any technical assistance to EEOC on this matter? Do you believe that clarifying workplace incentives could help get more Americans vaccinated? What is the Administration's hesitancy to provide this guidance?

Response: In February 2021, CMS, together with the Department of Labor and the Department of the Treasury, (collectively, the Departments) issued guidance removing barriers to COVID-19 diagnostic testing and vaccinations and strengthening requirements that plans and issuers cover diagnostic testing without cost sharing. The guidance also reinforces existing policy regarding coverage for the administration of the COVID-19 vaccine and highlights avenues for providers to seek federal reimbursement for costs incurred when administering COVID-19 diagnostic testing or a COVID-19 vaccine to those who are uninsured. The Departments will continue to work together to incentivize higher COVID-19 vaccination rates across the country.

Question 96:

According to emails reviewed by the Committee, it is clear the CDC's guidance for reopening schools was heavily influenced by liberal special interest groups. The emails reveal the White House facilitated numerous communications between CDC Director Walensky and the heads of

powerful teachers' unions, the American Federation of Teachers, and the National Education Association. This very close communication, which included personal phone calls to CDC Director Walensky, occurred despite repeated assurances from this Administration that HHS medical guidelines would "follow the science" and be free of political interference. Will you commit to ensuring that political groups do not get to see and provide comment to scientific guidance at the Department of Health and Human Services in advance of the public in the future?

Response: CDC's customary practice is to engage with stakeholders who are end users of the agency's guidance and share draft guidance with them before it is finalized to produce the best possible product. For example, following a robust internal, interagency review, CDC shared their K-12 draft guidance with more than 50 different organizations and stakeholders, including teachers, superintendents, and parents, to address what could be done to strengthen our underlying goal of protecting public health across America's schools.

Question 97:

I am concerned about the lack of transparency around state testing plans. The Trump Administration publicly released two rounds of state testing plans. It appears that these state testing plans are no longer available.

a. Why did the Biden Administration take down these previously publicly-available documents?

   Response: Testing plans were posted online in July 2020 as submitted by state, local, and territorial health departments to reflect testing implementation plans for July – December 2020, utilizing Paycheck Protection Program and Health Care Enhancement Act supplemental funding awarded through the CDC Epidemiology and Laboratory Capacity for the Prevention of Emerging Infectious Diseases (ELC) cooperative agreement. These plans were removed from the website as they were out of date and could mislead the public regarding testing efforts post-December 2020.

b. In addition to the $47 billion the Administration was given in the last Congress for testing, another $50 billion in new funds was just provided in March.

   Do you plan to release the school testing plans that each state was required to submit so that we can know how they will spend their share of the school testing money? If not, why not?

   Response: CDC awarded $10 billion to the 64 state, local, and territorial Epidemiology and Laboratory Capacity for the Prevention of Emerging Infectious Diseases (ELC) cooperative agreement recipients through the Reopening Schools supplement. Recipients were required to provide school screening testing plans, which have been posted online at: https://www.cdc.gov/ncezid/dpei/elc/covid-response/index.html#plans.

Question 98:

Secretary Becerra, one member of our Committee stated that monoclonal antibody therapy is ineffective but the website on the National Institutes of Health (NIH) states, and I quote "In

outpatients with mild to moderate COVID-19 who are at high risk for disease progression, anti-SARS-CoV-2 antibody-based therapies may have the greatest potential for clinical benefit during the earliest stages of infection. For these patients, the Panel recommends administering bamlanivimab plus etesevimab (AIIa) or casirivimab plus imdevimab (AIIa), both of which are available through Emergency Use Authorizations (EUAs) from the Food and Drug Administration (FDA)." Do you agree with the NIH and believe monoclonals work?

Response: I agree with the NIH. FDA has issued EUAs for monoclonal antibody treatments for COVID-19 for the treatment of COVID-19 in adults and pediatric patients. Monoclonal antibodies are laboratory-made molecules that act as substitute antibodies. They can help your immune system recognize and respond more effectively to the virus, making it more difficult for the virus to reproduce and cause harm. I back the FDA's decision to issue these EUAs.

Question 99:

In this budget request, President Biden asked that the budget for the HHS Office for Civil Rights be increased by 24 percent to $47.9 million. Included within this office is a division responsible for overseeing conscience and religious freedom protections. During your confirmation hearing, you said, "I believe deeply in religious freedom…I will not only respect the law when it comes to these issues of religious freedom, but I will enforce them as Secretary of HHS." Will you commit to not reducing the budget of the conscience division?

Awaiting Response: HHS will continue to protect the religious, civil, and constitutional rights of all Americans. This means that we will continue to enforce conscience and religious freedom protections, including receiving complaints, investigating cases, and making findings consistent with the law. Cases are counted regardless of whether OCR has jurisdiction or whether the complaint is meritorious. Increased funding in the FY 2022 Budget helps OCR ensure these priority issues are enforced and would be happy to speak with you about this further.

Question 100:

During your confirmation hearing, you told Senator Daines that, when it comes to laws related to abortion, "my job will be to make sure that I am following the law."

a. Do you agree that it is illegal for a hospital receiving federal funds to force a nurse to assist in an elective abortion procedure against the nurse's conscience-based objections?

b. As you know, it is illegal under the Church Amendment (42 U.S.C. 300a-7). Do you agree that this law is right?

c. Will you enforce this law?

d. Do you agree that health care workers who object to participating in elective abortion should not be forced to do so?

Response a-d: As stated during the confirmation hearings, the Department will follow all applicable laws as they relate to abortion and any other issue. Moreover, HHS OCR

continues to accept and handle complaints filed with HHS, including complaints relating to the Church Amendment and the Weldon Amendment.

Question 101:

The California Department for Managed Health Care mandated that all plans under its authority cover elective abortions, depriving religious organizations, churches, and other employers the option of offering health plans that do not cover elective abortion. It also forced seven health insurance issuers to suspend plans that did not provide elective abortion. On January 24, 2020, the HHS Office for Civil Rights (OCR) determined that California had violated the Weldon Amendment.[26] Nearly a year later, in December 2020, HHS announced that, because California had not complied, HHS would withhold $200 million in federal Medicaid funds from the state for the first quarter in 2021. HHS also announced that it will withhold an additional $200 million every quarter that California is not in compliance.

a. Will you commit to not return the $200 million in federal Medicaid funds from the first quarter in 2021 to California?

b. Have you discussed the issue with your staff?

Response: In my ethics agreement signed on January 17, 2021, and the subsequent authorization issued on March 31, 2021, I have agreed not to participate in any matter involving the State of California that was pending during my tenure as Attorney General. I understand that there has been no litigation on this matter, however, as Attorney General I did issue a public statement on the matter. After consulting with the HHS Acting Designated Agency Ethics Official, I have determined that it is prudent for me to recuse myself from this Medicaid financing matter to avoid even an appearance of impropriety. I trust that the very talented employees of the Department who, at the staff level, handle the vast amounts of work, including specific enforcement and program financing matters, will resolve this matter in a manner that is consistent with the Department's obligations and in the best interest of the American people. If leadership input is required, the Chief of Staff will either handle the case without any input from me or will refer the case to the appropriate person for decision.

Question 102:

On August 28, 2019, the Office for Civil Rights within HHS reported that it had "issued a Notice of Violation letter finding that the University of Vermont Medical Center violated the Church Amendments (42 U.S.C. 300a-7) by forcing a nurse to assist in an elective abortion procedure over the nurse's conscience-based objections."[27]

a. Will you commit to continuing that case until you get a settlement from the hospitals?

b. Will you commit to getting the input of the victims before the case is closed?

[26] Letter from the U.S. Department of Health and Human Services, Office for Civil Rights, to the Honorable Xavier Becerra, Attorney General, State of California, Department of Justice (Jan. 24, 2020) (https://bit.ly/3a6AKmo).

[27] Letter from the U.S. Department of Health and Human Services, Office for Civil Rights, to the University of Vermont Medical Center (Aug. 28, 2019) (https://bit.ly/3ouXEvR).

Response: With regard to the University of Vermont Medical Center matter, as we do with all OCR investigations, HHS took action to ensure the statutes protecting providers are applied in accordance with applicable law. As stated in our letter to the University of Vermont Medical Center, "Based on these subsequent legal developments and concurrent with the Department of Justice filing today, we are withdrawing the August 28, 2019 NOV and will continue to evaluate the underlying complaint. OCR takes seriously its role in protecting the rights of medical providers, including those protected by federal conscience laws.[28]

Question 103:

In 2009, New York nurse Cathy DeCarlo was forced by Mt. Sinai Hospital to assist in a dismemberment abortion. Cathy was opposed to participating in elective abortion. She clearly expressed her objection to the doctor and her nursing supervisor. Though there were other nurses at the hospital willing to participate in abortions, her supervisor insisted that Cathy participate in the abortion at the risk of losing her job and nursing license. After being required to participate in the abortion, Cathy had to wait for three years for the Office for Civil Rights within HHS to address her complaint that the hospital had violated her rights.

a. Do you agree that forcing a nurse like Cathy to participate in an abortion, against her conscience, violates the Weldon Amendment, which is current law?

b. Do you agree with this law: do you believe that forcing a health care provider to participate in an abortion against their conscience is wrong?

Response: HHS OCR continues to accept and handle complaints filed with HHS, including complaints relating to the Weldon Amendment. HHS is committed to protecting the religious, civil, constitutional rights of all Americans under HHS's purview to make sure that we are protecting everyone's rights, including religious conscience rights.

Question 104:

Your Department announced that it will expand its definition of sex discrimination to include gender identify and sexual orientation through an updated enforcement of Section 1557 and Title IX in response to the Supreme Court's Bostock v. Clayton County decision.

a. Do you – and does your Budget include – support protections for doctors, hospitals, and other health care providers who refuse to provide puberty-blocking hormones to children? If not, why not?

Response: Research demonstrates that gender-affirming care can improve the mental health and overall well-being of gender diverse children and adolescents when medically necessary. Health care is between a patient and their health care provider.

[28] Letter from Robinsue Frohboese, Acting Dir. and Prin. Dep., Office for Civil Rights, U.S. Dep't of Health & Human Servs., to David Gacioch (July 30, 2021), at 2, https://www.hhs.gov/conscience/conscience-protections/uvmmc-letter/index.html.

b. Do you - and does your Budget - support allowing Catholic doctors or other religious health care providers to refuse performing irreversible sex change procedures on minors? If not, why not?

c. Will you commit to providing conscience protections for doctors and other medical professionals who refuse to provide abortions or sex change procedures on children in any Medicare for All or Public Option proposal? If not, why not?

   i. If private insurance plans are effectively banned and Medicare for All does not offer clear conscience protections, how do you expect religious doctors and other providers to practice medicine and deliver care?

   ii. Would a policy that effectively removes religious doctors and other medical professionals from the health care work force create health care access problems?

   iii. Can you commit to us that you will undertake a thorough study and survey of health care providers to examine potential access issues before enactment of a Medicare for All proposal?

Response to b-c: HHS will continue to protect the religious, civil, and constitutional rights of all Americans. This means that we will continue to enforce conscience and religious freedom protections, including receiving complaints, investigating cases, and making findings consistent with the law.

Question 105:

There have been reports regarding allegations of neglect and abuse at an ORR facility in San Antonio that is holding more than 1,600 UC. The allegations include sexual abuse, insufficient staffing, children not eating, and those who tested positive for COVID-19 not being separated.

a. Has ORR investigated these allegations?

b. If so, what information can ORR share about these allegations?

c. What, if any, actions have ORR taken in response to these allegations?

Response to a-c: ORR care providers are required to report any child's disclosure of abuse and neglect while they are in ORR care, including any disclosure of abuse and neglect in home country and during their journey to the United States. ORR's broad reporting requirements ensure that care providers report and document any alleged mistreatment of children in ORR care. This includes any reported or observed mistreatment of children by other children.

To ensure that any allegations of abuse at ORR care providers are reported immediately, all staff at ORR care providers, including temporary facilities, are required to report any Significant Incident Reports (SIR) according to guidelines established in ORR's Policy Guide Section 5.8 and must report any allegations of sexual abuse, sexual harassment, inappropriate sexual behavior, or certain employee code of conduct violations via ORR's Sexual Abuse Significant Incident Reports (SA/SIR) in accordance with Policy Guide Section 4.10.2. The staff in ORR care providers must immediately, in accordance with mandatory reporting laws, state licensing requirements, federal laws and regulations, and ORR policies and procedures, report allegations of abuse to local law enforcement, child protective services, and state licensing, as applicable. In addition to following proper reporting procedures, ORR immediately acts to protect alleged victims of abuse and neglect. ORR care providers also refer concerns for human trafficking to the HHS Office on Trafficking in Persons per reporting requirements under the Trafficking Victims Protection Act, which obligates all federal, state, and local officials to report potential trafficking concerns on behalf of foreign national minors (including unaccompanied children) to HHS, specifically OTIP, within 24 hours (22 U.S.C. 7105(b)).

ORR also has a zero-tolerance policy for all forms of sexual abuse, sexual harassment, and inappropriate sexual behavior at all care provider facilities, including secure care provider facilities and long-term foster care providers, and will make every effort to prevent, detect, and respond to such conduct. This is outlined in Section 4 of the UC Policy Guide. A care provider facility must take disciplinary action up to and including termination against any staff member with a substantiated allegation of sexual abuse or sexual harassment against them or for violating ORR's or the care provider facility's sexual abuse-related policies and procedures. Termination must be the presumptive disciplinary sanction for staff who engaged in sexual abuse or sexual harassment. All terminations must be reported to law enforcement agencies and to any relevant licensing bodies. Additionally, any contractor or volunteer who engaged in sexual abuse or sexual harassment must be prohibited from contact with unaccompanied alien children and terminated from the contract or not be allowed to volunteer at the care provider facility. Such incidents must be immediately reported in accordance with Section 4.10. Contractors and volunteers suspected of perpetrating sexual abuse or sexual harassment are removed from all duties requiring contact with children or youth. Care provider facilities must report to ORR all terminations against any staff member with a substantiated allegation of sexual abuse or sexual harassment or any staff member who was terminated for violating ORR's or the care provider facility's sexual abuse-related policies.

ORR published Field Guidance #6 on COVID-19 Intake Procedures for newly admitted UC in November 2020 for ORR-funded programs including standard care provider programs and influx care facilities (ICF). All of ORR's guidance is based on current Centers for Disease Control and Prevention (CDC) guidance and recommendations, that are then adapted for the UC Program. ORR, in collaboration with CDC, continually reviews COVID-19 trends among children in ORR care and the surrounding communities to determine whether and when mitigation strategies should be enhanced, modified, or discontinued. UC test results for COVID-19 must be reported to ORR/Division of Health

for Unaccompanied Children (DHUC) and to state and local public health authorities, as required. In accordance with ORR Policy Guide, section 3.4.6, children held in medical isolation or quarantine continue receiving tailored services when feasible. These services include access to medical, urgent dental, mental health, legal, and educational services. In addition, care providers ensure that medically isolated or quarantined children engage in social interaction with staff and are able to correspond with approved contacts via telephone, video conferencing, and mail, per ORR policy. The provision of these services may involve remote interaction, the use of personal protective equipment (PPE) to protect staff, and mask use by children and staff to help prevent the spread of COVID-19 at the program. ORR care providers continue to supervise children and youth in their facilities, including children and youth in medical isolation or quarantine, in accordance with State licensing requirements and ORR Policy Guide, section 4.4.1.

During the period of time in which the Freeman Expo Center EIS in San Antonio was open, a total of 30 allegations on a range of abuse and/or neglect were reported. Those reports included allegations of verbal abuse, physical abuse, sexual misconduct (including inappropriate sexual behavior and sexual abuse, including between children), neglect, and incidents described as "other". All allegations of abuse and/or neglect at the Freeman Expo Center EIS in San Antonio were reported to the appropriate investigative authorities. The staff identified were dismissed and put on administrative leave while the investigation was pending.

Question 106:

Has ORR received reports of similar allegations at any of its other facilities, both permanent and temporary, since ORR started to experience a surge in UC referrals? If so, please provide the details of those allegations.

Response: ORR care providers report any child's disclosure of abuse and neglect while they are in ORR care, including any disclosure of abuse and neglect in home country and during their journey to the United States. ORR's broad reporting requirements ensure that care providers report and document any alleged mistreatment of children in ORR care. This includes any reported or observed mistreatment of children by other children.

To ensure that any allegations of abuse at ORR facilities are reported immediately, all staff at ORR facilities are required to report any Significant Incident Reports (SIR) according to guidelines established in ORR's Policy Guide Section 5.8 and must report any allegations of sexual abuse, sexual harassment, inappropriate sexual behavior, or certain employee code of conduct violations via ORR's Sexual Abuse Significant Incident Reports (SA/SIR) in accordance with Policy Guide Section 4.10.2. The staff in ORR care facilities must immediately, in accordance with mandatory reporting laws, state licensing requirements, federal laws and regulations, and ORR policies and procedures, report allegations of abuse to local law enforcement, child protective services, and state licensing, as applicable. ORR care facilities also refer concerns for human trafficking to the HHS Office on Trafficking in Persons per reporting requirements under the Trafficking Victims Protection Act, which obligates all federal, state, and local officials to report potential trafficking concerns on behalf of foreign national minors

(including unaccompanied children) to HHS, specifically OTIP, within 24 hours (22 U.S.C. 7105(b)).

Termination must be the presumptive disciplinary sanction for staff who engaged in sexual abuse or sexual harassment. All terminations must be reported to law enforcement agencies and to any relevant licensing bodies. Additionally, any contractor or volunteer who engaged in sexual abuse or sexual harassment must be prohibited from contact with unaccompanied alien children and terminated from the contract or not be allowed to volunteer at the care provider facility. Such incidents must be immediately reported in accordance with Section 4.10. Contractors and volunteers suspected of perpetrating sexual abuse or sexual harassment are removed from all duties requiring contact with children or youth. Care provider facilities must report to ORR all terminations against any staff member with a substantiated allegation of sexual abuse or sexual harassment or any staff member who was terminated for violating ORR's or the care provider facility's sexual abuse-related policies.

Question 107:

According to a recent article in Politico, you have yet to visit an ORR shelter.[29] Have you visited an ORR shelter? If not, why not?

Response: Yes, I have visited a number of ORR UC shelters, including shelters in ORR's state licensed network as well as temporary sites. During these visits I talk with staff and children as appropriate. HHS has a legal and moral obligation to provide safe and appropriate care for all children referred to us by DHS while we work to unite them with a safe and vetted sponsor. I am committed to carrying out this obligation.

Question 108:

What policies and procedures, guidance, and directives have been issued for UC regarding COVID-19, including any screening, testing, and quarantining that happens before UC are transferred to an ORR facility?

a. What about for once they are at an ORR facility?

b. What about if they are transferred from one ORR facility to another?

c. What about before the UC are released from ORR to a sponsor?

d. Are children required to complete any necessary quarantine periods prior to being released to a sponsor? If not, are there policies or agreements in place with their sponsor to ensure that children complete their quarantine period in order to prevent potential community exposure or spread of COVID-19? If so, please explain.

[29] *Becerra's cautious border play rankles White House*, Politico (May 10, 2021) (www.politico.com/news/2021/05/10/becerra-border-immigration-white-house-485931?mkt_tok=ODUwLVRBQS01MTEAAAF8).

Response to a-d: For UC newly admitted to ORR custody (i.e., new intakes), care providers must review all of the child's recent COVID-19 test results (including those from U.S. Customs and Border Protection [CBP] custody), the child's symptom status, and any information about the child's known exposure to COVID-19 while in CBP custody or in transit to the care provider program. After reviewing these items, the care provider will determine which COVID-19 tests must be administered and which procedures must be followed based upon these intake test results. These procedures are outlined in ORR Field Guidance #6, COVID-19 Intake Procedures for Unaccompanied Children Newly Admitted into ORR Custody, which is based on current Centers for Disease Control and Prevention (CDC) guidance, adapted for the UC Program. The only newly admitted children exempted from COVID-19 testing on arrival at an ORR facility are symptomatic children known to be COVID-positive in CBP custody; these children are routed directly to medical isolation (without retesting) where they remain until they meet discontinuation criteria.

ORR policies require the placement of UC with vetted sponsors in a manner that promotes public safety, which includes concerns related to public health. UC who test positive for COVID-19 within or prior to ORR custody must complete a 10-day medical isolation period prior to unification. Children who are exposed as a close-contact to someone with COVID-19 are required to complete a 7-day quarantine period (with negative testing required for discontinuation). Children that are ready for unification with a sponsor before the end of their isolation or quarantine period can be released to their sponsor under certain conditions, including that the child will not travel via commercial or public means and that the sponsor is educated on the need to continue isolation or quarantine on arrival to their destination, in accordance with CDC guidelines.

Aside from the intake process, UC are tested for COVID-19 any time they self-report or are observed to demonstrate COVID-like symptoms. Additionally, children are screened for COVID-like symptoms, including fever, before they are discharged or transferred from an ORR facility. Any fever or COVID-like symptoms at the time of discharge/transfer would result in discharge/transfer delay until the child is evaluated by a medical provider.

In collaboration with CDC, ORR continually reviews COVID-19 trends among children in ORR care and the surrounding communities to determine whether and when mitigation strategies should be enhanced, modified, or discontinued. Additionally, UC test results for COVID-19 must be reported to ORR and to state and local public health authorities, as required.

Question 109:

Mr. Secretary, with so many lives at stake and so many dollars being spent by numerous agencies under your leadership, it is of the utmost importance that your Department lead by example in matters of ethics and good governance. We would like to know how you will handle matters involving your former employer, the State of California, in light of the government ethics regulations, President Biden's Ethics Pledge, your own ethics agreement, and the applicable bar rules you must follow as an attorney.

a. Please specifically address your ethics protocol for dealing with matters relevant to the State of California.

b. When will you take meetings or calls from the state?

    i. What is the specific criteria for deciding whether and how you participate in calls with the State of California?

a. Who is tasked with making sure these protocols are followed and that the criteria is applied to each interaction with the State of California?

a. What procedures are in place to avoid your participation in the various lawsuits the state of California has pending versus the Department?

    i. Relatedly, what procedures are in place to prevent your participation in issues underlying those lawsuits?

b. Which official designee at the Department has been handling matters on which you are recused without the benefit of an Acting Deputy Secretary?

    i. Who decided who your designee would be?

Response (OGC): As Secretary, I provide leadership and direction for the very talented employees of the Department who, at the working level, handle the vast amounts of work, including specific litigation matters. I do not micromanage this work, but I recognize that instances may arise where specific litigation may require leadership attention. Pursuant to my ethics agreement signed on January 17, 2021, and the subsequent authorization issued on March 31, 2021, I have agreed not to participate in any litigation involving the State of California that was pending during my tenure as Attorney General. The Office of the General Counsel tracks all of the Department's pending litigation, including all of those pending against the State of California. For instances where specific litigation requires leadership attention, the cases are screened and those in which I have agreed not to participate do not come before me. Those cases go to the Chief of Staff who will either handle the cases without any input from me or refer the cases to the appropriate person for decision. In the unlikely event a case slips through the screening arrangement, I am committed to self-identifying my recusal obligation and referring the matter to the Chief of Staff for proper disposition, again without input from me.

Question 110:

Will your Budget maintain support for the ban on illegal immigrants receiving health insurance through PPACA exchanges? If not, why not?

Question 111:

Do you support expanding Medicaid to require the use of federal taxpayer dollars to pay for illegal immigrants to receive full Medicaid benefits?

a. Will you allow states to circumvent federal laws prohibiting illegal immigrants from receiving Medicaid benefits?

b. What are your specific plans to enforce such laws?

Response to Questions 110-111: HHS is committed to implementing and enforcing the laws passed by Congress.

Question 112:

Current law requires that certain vaccine doses and administration of those doses are to be covered with no patient cost-sharing. The CARES Act extended that coverage requirement to the COVID-19 vaccine. CMS guidance to payers also provides instructions for payment for vaccine doses and administration, although the federal government is currently directly paying for each individual dose.

a. Going forward, particularly as it relates to potential booster shots for COVID-19, will the federal government continue to pay for each dose of COVID-19 vaccine, or will there be another payment mechanism?

b. Will CMS guidance change to reflect the reality of the current payment situation?

Question 113:

We are encouraged that individuals are receiving vaccines across the country, but I am concerned that the federal government is paying for vaccines for people who have private health insurance. Under current law, commercial payors are supposed to pay for vaccines without any cost-sharing for the individual. Reports suggest that individuals who are receiving vaccines are not providing insurance information, or distribution sites are not collecting insurance information, so that the federal government ends up paying for those vaccinations. There seems to be a lack of enforcement, to ensure that payers are billed when individuals with commercial insurance or Medicare coverage receive the vaccine. In your capacity as HHS Secretary, how can you ensure that payors appropriately cover the costs of vaccines, rather than the federal taxpayer footing the bill?

Response to Questions 112-113: Ensuring that all Americans have access to quality, affordable health care is one of the Biden-Harris Administration's top priorities. The COVID-19 pandemic has underscored the importance of vaccines to preventing the spread of disease, and HHS is committed to removing barriers for patients to get vaccines. HHS is committed to ensuring appropriate and sustainable payment policies are in place, so that Americans can continue to get the care that they need.

Question 114:

Continued investment in research and development of COVID-19 therapeutics is a stated goal of the Biden Administration's COVID-19 response strategy.

a. Why has the Biomedical Advanced Research and Development Authority (BARDA) paused funding for COVID-19 therapeutic research, development, and manufacturing?

Response: Resources from the American Rescue Plan (ARP) have supported investments in therapeutics at HHS. Since January 2021, the federal government has invested in development of multiple therapeutic candidates. We commit to keeping Congress informed of these activities. In addition, information is posted in real-time as products come online and are approved for use. (https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/default.aspx). Development of these candidates have benefited from funding of NIH's ACTIV trials.

b. Prior to this pause in funding, why were grants only offered to antiviral therapeutics, and not a broader range of potential therapeutics including immune modulators?

Response: Since January 2021, the federal government has invested in development of multiple therapeutic candidates. We commit to keeping Congress informed of these activities. In addition, information is posted in real-time as products come online and are approved for use. (https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/default.aspx).

c. What plans are in place for BARDA to support research, development, and manufacturing of COVID-19 therapeutics going forward?

Response: Since January 2021, the federal government has invested in development of multiple therapeutic candidates. We commit to keeping Congress informed of these activities. In addition, information is posted in real-time as products come online and are approved for use. (https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/default.aspx).

Question 115:

The American Rescue Plan (ARP) included $6 billion for research, development, manufacturing, production, and the purchase of vaccines and therapeutics.

a. How much of this funding is being used for therapeutics?

Response: To date, approximately $2.3 billion from the American Rescue Plan (ARP) has supported investments in therapeutics by ASPR or NIH.

b. How much of this funding is being directed by BARDA?

Response: Vaccine and therapeutic activities will be supported by ASPR or NIH under section 2303 of the American Rescue Plan Act of 2021 (ARP).HHS is currently evaluating all COVID-19 supplemental funding sources and determining the specific projects that are best aligned with this appropriation.

c. With respect to therapeutics, how much of this funding do you expect to be directed to production and manufacturing compared to research and development?

Response: Of the $6.05 billion appropriated under section 2303 of the American Rescue Plan Act of 2021 (ARP) to support planned research, development, manufacturing, and procurements costs for COVID-19 vaccines and therapeutics as well as ancillary medical products and supplies, approximately $2 billion will fund vaccine and therapeutic activities supported by ASPR or NIH after evaluating all COVID-19 supplemental funding sources and determining the specific projects that are best aligned with this appropriation. HHS is currently completing this evaluation.

d. How do you anticipate you will prioritize awards and when do you expect to begin releasing funds?

Response: HHS has announced plans to utilize funds from the American Rescue Plan Act of 2021 (ARP) to support the Antiviral Program for Pandemics (APP). The APP, led by NIH and BARDA, is an intensive research program designed to speed development of therapeutics for coronavirus disease 2019 (COVID-19) as well as to build sustainable platforms for targeted drug discovery and development of a robust pipeline of antivirals against viruses with pandemic potential. A key component of the APP is NIH awards for the Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Concern (www.niaid.nih.gov/research/antiviral-drug-discovery-centers-pathogens-pandemic-concern). These Centers, anticipated to receive initial funding in fiscal year (FY) 2022, will conduct innovative, multidisciplinary research to develop candidate antivirals effective against viruses with pandemic potential. NIH will prioritize awards for funding that are judged meritorious via the NIH peer review process, which evaluates and rates the scientific and technical merit of research applications. The AViDD Centers will pursue the development of COVID-19 antivirals, especially those that can be taken in an outpatient setting, as well as antivirals for other specific families of viruses. The specific viral families targeted by the AViDD Centers have high potential to cause a pandemic in the future and include paramyxoviruses, bunyaviruses, togaviruses, filoviruses (including Ebola viruses and Marburg virus), picornaviruses (including enteroviruses and other cold-causing viruses), flaviviruses (including the viruses that cause yellow fever, dengue, and Zika), in addition to coronaviruses.

e. If the funding is not being directed by BARDA, which agency or office within HHS will be managing its administration? priority order for who receives it next?

Response: The Office of the Assistant Secretary for Financial Resources (ASFR) manages the administration of the Department's COVID supplemental resources. Relevant HHS agencies propose and project spending based on their analysis of public health needs and collaborate with HHS and Administration policy officials to determine

the most appropriate use of appropriated resources. Funding determinations are made in a way to maximize the Department's ability to effectively respond to the COVID-19 pandemic and provide the services and resources intended by the American Rescue Plan.

Question 116:

The Department of Defense (DoD) has been evaluating the potential of repurposing several Food and Drug Administration (FDA)-approved therapeutics as treatments for COVID-19. Several of these products have reported very encouraging clinical data that may support the issuance of Emergency Use Authorizations (EUA) by the FDA.

a. To what extent has BARDA been engaged in these efforts?

Response: The Biomedical Advanced Research and Development Authority (BARDA) and DoD work collaboratively on COVID-19 therapeutic development. There are monthly meetings for coordinating all COVID-19 therapeutic development efforts where progress is reported across the US government.

b. Has BARDA reviewed the current and future availability of these products?

Response: Most of the drugs funded by DoD are for the treatment of the hospitalized COVID-19 patient population. Operation Warp Speed (OWS), which determines BARDA funding priorities, has prioritized the treatment of outpatients to prevent hospitalization over therapeutics for the treatment of hospitalized patients. BARDA has not reviewed the current and future availability of many of the DoD funded drugs.

c. Is the Department of Health and Human Services prepared to ensure that sufficient quantities of these medicines are available in the event that they receive and EUA?

Response: If the drugs were given an EUA and there were supply chain issues, the BARDA and ASPR supply chain team would work with the companies to ensure sufficient supply for the U.S. population.

d. Has HHS evaluated the supply chain for these products to ensure that manufacturing of these critical products is to the extent practical resident in the United States itself to ensure the ability of these products to be produced without interruption?

Response: If the drugs were given an EUA and there were supply chain issues, the BARDA and ASPR supply chain team would work with the companies to ensure sufficient supply for the U.S. population.

Question 117:

Over the past 30 years, HHS has supported policies pushing Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID) to close in favor of HCBS residences. In FY2018 alone, five times more federal funding was directed to HCBS's as opposed to ICFs despite the immense challenges in a typical ICF population. Additionally, ICFs are required by

law to deliver more comprehensive medical and therapeutic services. With the current funding policy, individuals with I/DD are finding their options for residential care increasingly limited. ICFs are a federal-state shared program, and if federal funding policies continue to prioritize HCBS over ICF, the federal government is effectively removing the ability of individuals with I/DD – or their guardians – to choose what they determine is the best residential setting to meet their specific needs.

Are you supportive of federal funding specifically for ICFs, and do you agree that a variety of care options are necessary for individuals with I/DD to have their healthcare needs addressed? If so, what next steps should the federal government take to ensure the future of ICFs as a critical component of care options for individuals with I/DD?

Response: Ensuring that all Americans have access to affordable, quality health care is a top priority for this Administration. Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID) serve some of the most vulnerable beneficiaries in our programs, and HHS is continuing to work to ensure that these beneficiaries receive the services they need in the environment that is most appropriate for their situation.

Question 118:

As daily COVID-19 vaccinations slow down, are you and your agencies supportive of the federal government using innovative and effective approaches to get vaccine hesitant populations vaccinated – including the use of ethical Artificial Intelligence (AI) and evidence-based behavioral design to communicate uniquely to unvaccinated individuals, overcoming each person's specific barriers to being vaccinated?

Response: HHS is exploring every opportunity. CDC works with partners at the national, state, local, and community levels through ongoing support for its Vaccinate with Confidence strategy to reinforce confidence in COVID-19 vaccines. The strategy provides a variety of ways to build trust, empower healthcare personnel, and engage communities, including recruitment of vaccine champions, providing resource guides for families on how to talk to one another about getting vaccinated, combatting misinformation by learning how to spot it and respond, and celebrating the decision to get vaccinated through social media platforms. CDC also offers COVID-19 Vaccine Confidence Consults, virtually or by telephone, to state and territorial immunizations programs and tribes that provide technical assistance in identifying barriers to vaccine uptake or confidence in specific populations, effectively communicating about COVID-19 vaccines and answering questions/concerns, addressing COVID-19 vaccine misinformation, increasing vaccine confidence among healthcare personnel, increasing healthcare provider capacity to support vaccine education and confidence, and engaging community partners and trusted messengers in increasing vaccine confidence.

Question 119:

Do you plan to maintain the existing 1332 waiver flexibilities and templates from the prior Administration? If not, why not?

a. What are your plans for 1332 flexibilities?

Response: President Biden has made it clear that his goals for improving the American health care system begin with building on the successes of the Affordable Care Act. HHS is committed to working in partnership with states on policies that improve and expand health insurance coverage in their states, including through applications for section 1332 state innovation waivers.

Question 120:

In 2018, FDA announced an effort to modernize food standards of identity as part of the Nutrition Innovation Strategy. In September 2019, FDA held a public meeting to discuss these efforts.

a. What are the agency's plans for modernizing the food standards of identity, and specifically what changes to existing standards will be made across categories of foods?

b. What is the timeline for resumption and completion of this work?

Response to a-b: FDA's standards of identity (SOI) work is multipronged. First, the Agency is working to modernize the overall framework for establishing and updating SOIs. Second, FDA is working to update individual SOIs as necessary to support innovation. And third, the Agency is examining horizontal approaches to updating SOIs. A horizontal approach allows FDA to make changes across multiple SOIs with one rulemaking, thereby avoiding the resource-intensive approach of updating SOI individually. For example, under a horizontal approach we could allow new technologies and new or novel functional ingredients (e.g., salt substitutes) under multiple SOIs via one rulemaking.

Question 121:

In 2015, Congress directed FDA to establish national licensure standards for wholesale distributors and third-party logistics providers in DSCSA. Licensed entities are also required to report to FDA annually. As of today, these standards are still not public. I have heard some reports of shipments of critical drugs being delayed due to conflicts over licensure. Interoperable exchange of information, verification of authorized trading partners, and potential product access concerns remain without these critical standards.

a. Have these standards been cleared by HHS?

b. Are they now at OMB and, if so, how long have they been awaiting OMB action?

c. Will you ensure these standards are promptly made public?

Response to a-c (FDA): As you are aware, because FDA is currently engaged in the rulemaking process I cannot provide extensive comment on the content of these regulations.

Please see the Unified Agenda of Regulatory and Deregulatory Actions available at: https://www.reginfo.gov/public/do/eAgendaMain for additional information on when we expect the proposed rule will be published for review and comment.

The Honorable Michael C. Burgess, M.D. (R-TX)

Question 122:
The OMB budget request indicates that efforts will be made to invest in FDA's organizational capacity in response to the COVID-19 pandemic and future readiness. I have heard from several drug and biologic companies who are still waiting for site inspections months after their user-fee deadlines. When can companies expect site visits to resume, and will companies have transparency into whether their FDA user-fee agreements will be upheld?

a. Will the FDA commit to using available resources to resume domestic and foreign facility inspections as soon as possible and to begin reducing the site inspection backlog?

Response: FDA is conducting mission-critical inspections whenever needed to protect the public health. In addition, since the week of July 20, 2020, FDA has been resuming prioritized domestic inspections, as described in the FDA statement "Coronavirus (COVID-19) Update: FDA prepares for resumption of domestic inspections with new risk assessment system" issued on July 10, 2020. FDA intends to meet its user fee obligations including where a facility assessment is needed. FDA recently performed an analysis of user fee metrics across the prescription drug and generic drug programs that demonstrate FDA has been able to take on-time actions to evaluate and close out these drug applications more than 90% of the time, meeting the review program performance levels agreed to by FDA and industry. FDA makes this information available on its website. The *Resiliency Roadmap* for FDA Inspectional Oversight also provided information about FDA's commitment and accomplishments in evaluating application-related facilities during the pandemic. As described in that document, of the approximately 13,500 product applications submitted between March 2020 through March 2021, only 68 application decisions were affected by delays in inspections. Of these, only seven application decisions were considered critical to FDA's mission to protect the public health.

The Agency is also working to optimize its use of remote options and other alternative approaches to strengthen our oversight while some foreign inspections are not possible. In April, 2021, the FDA issued a guidance for industry, Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency. This guidance outlined the FDA's commitment to use additional tools to support regulatory decisions and oversight of facilities. This guidance describes the FDA's policy on using such evaluations to support decisions on pending applications. FDA uses a risk-based approach in determining when remote evaluations are appropriate. FDA works directly with facilities to communicate any issues identified through a review of records or other information requested. FDA will notify applicants if the Agency expects to miss a user fee goal date.

Question 123:

I established the Physician-led Technical Advisory Panel (or PTAC) at the Centers for Medicare and Medicaid Innovation, as it is paramount that the physician voice is heard in the creation of quality metrics and new payment models. PTAC has recommended over a dozen models during its existence, yet it has often been ignored. This is deeply concerning to me, and I will continue to make this a priority issue, as this was clearly not the Congressional intent of this law.

How will you leverage the expertise of the PTAC to ensure CMMI is approving models in which providers will want to participate?

Response: Innovation is important to advancing goals in health care, and the CMS Innovation Center is integral to the Administration's efforts to promote high-value care and encourage health care provider innovation. The Innovation Center allows us to test new models to improve patient care, advance health equity, and lower patient costs. Getting feedback from expert stakeholders across the health care system, including the Physician-led Technical Advisory Panel, is a critical part of developing and implementing our models. I look forward to hearing from you as we continue to examine ways to improve our health care delivery system.

Question 124:

Secretary Becerra, you are well aware that an influx of unaccompanied children are crossing our southern border and being referred to the Office of Refugee Resettlement. According to data from the Biden Administration released last week, there are over 21,000 unaccompanied children currently in ORR care. During the initial UAC crisis in 2014, we learned that some children were placed with sponsors who turned out not to be family members, and some who even abused and trafficked the children. As a result, this Committee engaged with ORR to reform the vetting of sponsors. Following those reforms, including background and DNA checks, I felt confident that children were being released to appropriate and safe sponsors. There are now reports that, in an effort to quickly move children out of HHS' care, ORR is placing children with sponsors without proper vetting.

Is this true? If so, why? For how much longer will this practice continue?

Response: ORR evaluates potential sponsors' ability to provide for the child's physical and mental well-being, as required by law. ORR also protects children from smugglers, traffickers, or others who might seek to victimize or otherwise engage the child in criminal, harmful or exploitative activity.

Consistent with ORR's mission and in compliance with requirements found at 8 U.S.C. §1232(c)(3)(A) to perform an independent finding that a potential sponsor has not engaged in any activity that would indicate a potential risk to the child, ORR requires background checks of all potential sponsors, as well as their adult household members in certain circumstances. ORR performs a public records check and sex offender registry check on parents/legal guardians ("Category 1" sponsors) and "Category 2A" sponsors (grandparents, adult siblings, and aunts/uncles/first cousins who were previously a primary caregivers). ORR policy requires fingerprint checks on Category 1 and 2A sponsors where:

- The public records check reveals possibility disqualifying sponsor criteria;

- Where there is a documented risk to the safety of the child;
- The child is especially vulnerable and/or the case is being referred for a home study.

Further, a child abuse and neglect check is needed in cases where the child meets the requirements for a home study, and cases where a special concern is identified.

"Category 2B" sponsors (aunts, uncles, and first cousins without a prior caregiving relationship) and other sponsors ("Category 3") require a public records check, sex offender registry check, and a fingerprint background check in almost all cases. Further a child abuse and neglect check is required for home study cases, and cases where a special concern is identified. In general, ORR's policies regarding sponsor assessments can be found in the ORR UC Policy Guide, available at https://www.acf.hhs.gov/orr/policy-guidance/children-entering-united-states-unaccompanied-section-2.

Question 125:

Under the American Rescue Plan, many states saw drastic reductions in their proportion of federal funding from the Low Income Home Energy Assistance Program appropriated by the American Rescue Plan. Although Congress directed HHS to use an older funding methodology from 1984, it appears this does not account for the entire change. Please explain how HHS interpreted the American Rescue Plan's Section 2911 to arrive at these allocations.

How does this interpretation differ from how HHS interpreted LIHEAP allocations under the CARES Act?

Response: HHS' interpretation of the LIHEAP allocations formula under the American Rescue Plan (ARP) is structurally similar to that of that formula under the CARES Act. The only structural difference is that HHS didn't use the augment-and-back-out process for the 1984-formula portion. That's because that portion exceeded the statutory threshold (i.e., $1.975 billion) under ARP alone (and, consequently, under ARP plus the FY21 Consolidated Appropriations Act (FY21 CAA)).

Other, non-structural differences are as follows:

- Changes to the top-line amounts—specifically the overall appropriation, the training and technical assistance (T&TA) set-aside, and the 1981-/1984-formula split—specified by the regular appropriations act and the CARES Act;
- Changes to the underlying data, consisting of updates to (1) certain elements that underlay the 1984-Formula's state allotment percentages; and (2) the states' and territories' prior year's amounts received;
- Updates to the roster of tribal grant recipients and to the agreement conditions held by certain such recipients; and
- The transfer of funds out of LIHEAP by HHS' Secretary from the FY20 Continuing Appropriations Act (FY20 CAA), upon which the CARES Act's distribution was based.

a. Had Section 2911(1) of the ARP not required $2.25 billion to be allocated using the 1981 formulas, how would that have affected the LIHEAP allocations?

b. Had Section 2911(1) of the ARP not required $2.25 billion to be allocated using the 1981 formulas, how would that have affected the LIHEAP allocations?

Question 126:

In 2015, a U.S. District Judge found that Texas was in violation of the Constitutional rights of children in the state's foster care system. Recently, it was reported that 23 children have died in the state's long-term foster care system since 2019. What oversight and progress has been made at a federal level to address this issue since this ruling in 2015?

Response: The Children's Bureau (CB) regularly monitors states/tribes/territories or jurisdictions for compliance with federal regulations, policies and laws related to child welfare federal funding and policy. There are several mechanisms that CB uses to monitor jurisdictions which include: review and approval of titles IV-E and IV-B state plans, CAPTA state plans, Child and Family Services Reviews which includes reviewing a set of cases for compliance with safety, permanency and well-being, and title IV-E eligibility reviews. Each year states provide an update to their title IV-B state plan and as new legislation is enacted amendments to the title IV-E state plan. As part of the submission of state plans, the Regional Office staff review the written plan and supporting documentation, hold discussions with the jurisdiction to understand the policy and state legislation and determine compliance of the federal regulation. With CAPTA state plans, states are required to have citizen review teams and child fatality review teams in place to review child deaths, near child deaths, and make recommendations to the state on possible changes to their policies and procedures. The CB Regional Offices review these plans and recommendations made including tracking the areas identified as needing improvements in policy or practice. Discussions occur regularly between the jurisdiction to address the state plans/reports/updates. If the jurisdiction is not in compliance with the federal regulations, the jurisdiction is placed on a program improvement plan.

The CB also conducts Child and Family Service Reviews (CFSRs) which is a federal-state collaborative effort to monitor states' conformity with federal requirements and to enhance states' capacity to achieve improved outcomes for all children and families. This includes reviewing a number of in-home and foster care cases, conducting interviews of stakeholders and making a determination of strengths and areas needing improvement related to safety, permanency and well-being. We continue to emphasize the use of data and evidence to identify strengths and areas for improvement in state and court systems. The reviews provide the jurisdiction including the court system with an opportunity to consider evidence of disparities in decision-making, programs and policies that may contribute to inequities in services and outcomes for these children and families. States not in conformity with the national standards are required to complete a program improvement plan. The Regional Offices work with the state during the two-year program improvement plan to monitor progress. States that do not meet the required level of improvement are required to pay a penalty. The Department of Family and Protective Services (DFPS) completed their most recent CFSR program improvement plan with no penalties assessed.

Children's Rights, a national advocacy group from New York City, filed suit against the Governor of Texas, the Texas Health and Human Services Commission, and the DFPS in federal court alleging constitutional claims. The case is currently before Judge Janis Graham Jack

(Senior Judge) of the Corpus Christi Division in the United States District Court, Southern District of Texas.

As part of the findings from December 17th, 2015 memorandum opinion, DFPS was required to establish and implement policies and procedures to ensure that foster children in the permanent managing conservatorship of DFPS are free from an unreasonable risk of harm. A final order was established on January 19, 2018. The Court's orders were established in five categories: General; Screening, Intake and Investigation of Maltreatment in Care Allegations; Organizational Capacity; Preventing Child-on-Child Sexual Aggression; and Regulatory Monitoring & Oversight of Licensed Placements. The Court appointed a Special Master to help the state implement the numerous findings (now court orders) and requires periodic reports from the Special Master and the state. Foster group homes were required to immediately provide 24-hour awake-night supervision to continue to operate. Other orders included requiring DFPS staff to visit with children monthly and separately from their caretaker. It should be noted that CB requires states to report on monthly case worker visits data yearly and Texas has consistently met that requirement with no penalties required. The Special Masters noted in their most recent report (January 2022) that DFPS is making substantial policy and practice improvements towards compliance with the court orders.

The CB Regional Office regularly meets with DFPS to address child welfare program efforts within all the monitoring requirements and to address current initiatives the state is implementing to improve services to families and children to ensure safety, permanency and well-being of children being served by DFPS.

Question 127:

It is no secret that as we are seeing great medical advancements, the Centers for Medicare and Medicaid Services' payments models for novel technologies lag behind private insurers, and often do not adequately reimburse providers. This disincentivizes providers from utilizing these new technologies, many of which may improve outcomes. How will HHS review the adequacy of provider reimbursement for new technologies, and will the agency work to ensure new technologies are not underutilized simply due to these gaps in provider reimbursement?

Response: It is important to spur innovation in therapeutics and medical technology that improves health outcomes. CMS looks forward to working with Congress and other stakeholders as we examine payment policies to facilitate affordable access to innovative new technologies.

Question 128:

The United States has made history by successfully getting the COVID-19 shot into the arms of more Americans than we ever thought possible by this date. However, we are beginning to see vaccination rates slow. Although most Americans receive routine vaccinations from their personal physicians and health providers, the Biden Administration has not yet widely engaged personal physicians or office-based practitioners is distributing the COVID-19 vaccine. Given that majority of Americans trust their family doctors and providers, and most individuals already receive routine vaccines at their provider's office, will the Administration more directly engage physicians in the COVID-19 vaccine distribution?

Response: CDC has engaged in regular communication with clinical societies, such as the American Medical Association (AMA), American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP), to disseminate messaging and answer provider questions related to the COVID-19 vaccines. CDC also disseminates evidence-based health information and public health emergency messages to clinicians through the Clinician Outreach and Communication Activity (COCA) network and the Health Alert Network (HAN) which serves a wide range of clinical professionals, including physicians, nurses, physician's assistants, pharmacists, paramedics, veterinarians, epidemiologists, public health practitioners, and state and local health department officials. In addition, COCA collaborates with national clinician organizations, which in turns allows for extended outreach to a large number of clinicians. For as long as vaccines have been available, there has also been misinformation and concerns. Every new vaccine, regardless of disease, will be accompanied by questions, concerns, and misinformation. We can effectively foster vaccine confidence and address those concerns and misinformation by building trust, which takes dedicated time and effort. Engaging in outreach efforts and partnering with trusted advocates in communities are central to our national and international vaccine confidence efforts.

Question 129:

There are several coverage gaps that exist in covering colorectal cancer tests both in ACA plans and Medicare. Do you have the administrative authority to address these coverage caps and remove cost-sharing, or do you believe that Congressional action is required?

Response: We know cancer as a disease for which there are stark inequities in access to cancer screening, diagnostics and treatment across race, gender, region, and resources. The Biden-Harris Administration is committed to ensuring that every community in America – including those living in rural, urban, and Tribal communities – has access to cutting-edge cancer diagnostics, therapeutics, and clinical trials.

With regard to Medicare, CMS prioritizes expanding access to essential preventive health care services, including cancer screenings. Medicare covers a broad range of colorectal cancer screening tests, including Cologuard® Multitarget stool DNA, screening fecal occult blood test, screening flexible sigmoidoscopy, screening barium enema, screening colonoscopy and most recently, blood-based biomarker tests if they meet certain criteria, including specified test performance characteristics. We will be further addressing this issue by implementing section 122 of the Consolidated Appropriations Act, 2021, waiving Medicare coinsurance for certain colorectal screening tests, through future rulemaking.

Most private health plans, including those offered through the Marketplaces, are required to cover certain preventive services that have strong scientific evidence of their health benefits, and plans are not allowed to charge a patient a copayment, co-insurance, or deductible for these services when they are delivered by a network provider. Plans covered by these rules must offer coverage of a comprehensive range of certain preventive services that are recommended by physicians and other experts without imposing any cost- sharing requirements. This includes services given a "grade" of A or B by the USPSTF, an independent panel of scientific experts that ranks preventive services based on the strength of the scientific evidence documenting their benefits. HHS, together with the Departments of Labor and the Treasury have issued several

rounds of guidance to clarify the scope of coverage required for recommended colorectal cancer screenings. Specifically, ACA Frequently Asked Questions (FAQs) have clarified that plans and issuers required to cover preventive colonoscopies without cost sharing may not impose cost sharing for the cost of a polyp removal during the colonoscopy, anesthesia services performed in connection with a colonoscopy, any required specialist consultation prior to the screening procedure, any pathology exam on a polyp biopsy, or bowel preparation medications prescribed for the procedure.

I look forward to working with partners across the federal government, along with Congress and other stakeholders, to examine ways we can increase access to services for the prevention, diagnosis, treatment, and survival of cancer.

Question 130:

When the Ryan White Clinic Act was signed into law, PrEP did not yet exist. Today, PrEP is a unique and critical tool in preventing HIV/AIDs, and the Trump Administration leaned into its importance with the "Ready, Set, PrEP" program to provide PrEP to uninsured individuals. Is it your understanding that under the current statute, the Ryan White Clinic Act bars HRSA grantees from providing PrEP?

Response: The Ryan White HIV/AIDS Program (RWHAP) legislation provides grant funds to be used for care and treatment of people diagnosed with HIV, thus prohibiting the use of RWHAP funds for PrEP medications and the related medical services such as physician visits and laboratory costs, except for targeted HIV testing. The RWHAP legislation does, however, allow RWHAP recipients and providers to provide services such as risk reduction counseling and targeted HIV testing, which should be part of a comprehensive PrEP program.

The Health Resources and Services Administration (HRSA) strongly encourages RWHAP recipients and providers to leverage the RWHAP infrastructure to support PrEP services within the parameters of the RWHAP legislation. RWHAP recipients and providers are uniquely positioned to support PrEP programs. As community leaders in HIV prevention, care, and treatment, RWHAP recipients and providers are: 1) connected to people most at risk for contracting HIV; 2) knowledgeable about barriers to accessing HIV care and prevention services; and 3) experts in antiretroviral medications used for HIV. These are just a few of the skills that make RWHAP recipients and providers especially equipped to support, establish, and implement PrEP programs supported with non-RWHAP funds.

In addition, the HRSA Health Center Programs' primary focus in the Ending the HIV Epidemic in the U.S. initiative is on expanding outreach, care coordination, and access to Pre-Exposure Prophylaxis (PrEP)-related services to people at high risk for HIV transmission through selected health centers in the identified jurisdictions. In FY 2020, the first year of the Initiative, HRSA provided $54 million in resources to 195 health centers that received Health Center/Ryan White Program funding and/or were located in close proximity to a Ryan White Program where no jointly funded health center currently existed in the target jurisdiction

The Honorable H. Morgan Griffith (R-VA)

Question 131:

In December 2018, the FDA announced that it would begin a process to investigate additional regulatory pathways for the lawful sale of hemp-derived CBD products, including as dietary supplements or food. In the intervening two and a half years, the agency has made several pronouncements, but there have been no actions taken to move the process forward. In the meantime, U.S. hemp farmers and businesses have struggled mightily from the regulatory inaction, and many states have enacted their own laws to address this growing market. This has led to a confusing patchwork of laws, while bad actors continue to take advantage of the ongoing regulatory uncertainty. When should we expect the FDA to take action on this growing challenge?

Response: FDA recognizes the significant interest in CBD. The agency is committed to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived products.

The Honorable Gus Bilirakis (R-FL)

Question 132:
Medicare Advantage is a critical choice for seniors' health care today serving approximately 42 percent or more than 26 million seniors across the country. I, along with my E&C colleague, Congressman Veasey, joined Congresswoman Val Demings and Congressman Mike Gallagher to co-lead a letter recently sent to you, submitted for the record, signed by 70 bipartisan Members in support of protecting and strengthening Medicare Advantage for the millions of seniors it serves including more than 116,000 seniors in my district that rely on the program. We represent districts where the majority – over 50 percent – of seniors chose to enroll in MA. There are 90 Congressional Districts like ours, as well as Puerto Rico, that represent 7.2 million seniors enrolled in the program. Beneficiaries consistently report high satisfaction with the quality of care under the program and cost savings, including the clinical care model and additional benefits not available in Medicare Fee-for-Service, such as care coordination and transportation to provider offices.

Will you commit to protecting this important choice for seniors enrolled in Medicare Advantage in Florida and across the country?

Response: HHS is committed to providing affordable, high-quality coverage to all beneficiaries. We are committed to making sure that beneficiaries will continue to have access to a wide selection of Medicare Advantage plans and affordable premiums. We are committed to making sure that Medicare Advantage will continue to provide high quality care for beneficiaries and value for taxpayers. HHS appreciates your observations as we consider future policies that affect the program, we look forward to continuing to work with Congress and other stakeholders to ensure a strong Medicare Advantage program.

Question 133:
Each year, the U.S. cruise industry supports over 463,000 jobs accounting for $24.4 billion in wages. In Florida, cruising supports over 149,000 jobs annually accounting for $8.1 billion in wages and 8.3 million passengers embark creating over $9 billion in direct spending. Given the

disappointing April jobs report, getting Americans back to work is mission critical and cruising should not be left behind in that effort.

a. In October, the CDC provided industry with a roadmap to becoming operational again and recently indicated that ships may be able to resume sailing from Florida ports in mid-July. Do you still envision that July timeline for a resumption of service?

b. While I understand and appreciate the Administration has stated it is not supportive of vaccine passports, it has also indicated an interest in establishing certain technology standards that may impact the decisions businesses and other large employers (including government entities) consider as the country returns to normal. What can we expect these standards to address and when does the Administration expect to release them?

Response to a-b: CDC is actively working with the cruise industry and other stakeholders to meet the goal of cruise resumption by the summer timeline. With respect to technology standards and representing individuals' vaccination history digitally and on paper, the Biden-Harris Administration has maintained that solutions in the market should be secure, privacy protective, and based on open, industry standards. The Administration has also highlighted the importance of such solutions being accessible to all with respect to health equity considerations (such as pricing, language, disability access, etc.).

Question 134:

I want to raise an issue that Congresswoman Sewell and I have been working on to address risk adjustment for audio-only telehealth in the Medicare Advantage program. During the height of the pandemic, nearly half (43 percent) of primary care visits in Medicare were conducted virtually, with many seniors lacking access to broadband technology or the comfort or ability to utilize video-based calls. As a result, they depended on audio-only telehealth services. Unfortunately, CMS does not allow audio-only visits to count for MA risk adjustment purposes, in direct contrast to the Marketplace where CMS allows audio-only visits to be counted. This raises concerns about the ability to fully document all telehealth encounters for MA risk-adjustment and equitable and consistent policy across programs under your leadership. This is an urgent issue because MA plans must file their bids for plan year 2022 on June 7th and the Senate has not yet confirmed the Administrator at CMS. As Secretary, you have the authority to address this matter.

a. Absent a permanent Administrator at CMS, what steps do you plan to take to address this matter and ensure that seniors are treated the same as those enrolled in individual plans through the marketplace?

b. Can I get your commitment to issue immediate guidance allowing audio-only encounters to be used in Medicare Advantage risk-adjustment?

Response: Telehealth is an important tool to improve health equity and improve access to health care. HHS continues to examine how telehealth, including in the Medicare Advantage program, can be used to improve health equity and improve access to health

care.

Question 135:
Health providers have been reporting COVID-19 data for a year now to both the states and HHS.

Are there any plans from HHS to streamline these data reporting requirements?

Response: Efficiency and minimizing burden on data providers (e.g., health care) and our state and local partners are priorities of CDC's public health surveillance work. Generally, COVID-19 data are first reported to state and local jurisdictions, which then provide record-level anonymized data to CDC so the agency can build a national picture of COVID-19 using data from across jurisdictions. For instance, health care providers report COVID-19 cases to state and local public health departments (which require this reporting under state and local law), and these jurisdictions then send record-level anonymized case data to CDC through CDC's National Notifiable Diseases Surveillance System. This allows for the streamlined flow of data from the origin of a case report to the state and then to CDC without requiring the health care provider or laboratory to report to multiple sources. Laboratory result data works in a similar way—laboratories and testing entities report testing results to state and local jurisdictions, which then relay these data (without personal identifiers) to CDC. Reporting of COVID-19 public health surveillance data directly to federal agencies (e.g., aggregate COVID-19 hospitalization data reported as a CMS requirement) is generally the exception rather than the rule, and CDC works with state and local public health agencies to ensure they have prompt access to these data sent to the CDC.

Making the data reporting process less burdensome on providers is a focus of CDC's Data Modernization Initiative (DMI). For instance, DMI has allowed the rapid scale up of electronic case reporting (eCR) of COVID-19 cases during the course of the pandemic. eCR is an innovation that allows a COVID-19 case to be reported automatically from an electronic health record to the state or local public health department, rather than requiring a health care provider to fill out and send a case report form to the health agency. The result is faster, more complete data for public health, and less burden and work on our frontline healthcare workers. At the dawn of the pandemic, virtually no health care providers had this capability; as of May 8, 2021, DMI investments allowed CDC to expand this innovative reporting capability to more than 7,600 health care facilities across the United States.

Question 136:
Under the Trump Administration, HHS engaged in an initiative called Patients Over Paperwork that sought to reduce regulatory burden on health providers and update regulations such as Stark.

Does HHS plans to continue those efforts?

Response: HHS is always looking for ways to improve our programs, including by finding ways to reduce improper payments, improve patient outcomes, and increase affordable access to care while limiting provider burden.

Question 137:

The COVID-19 pandemic has highlighted the importance of ensuring that Medicare beneficiaries have timely and robust access to hearing and balance related services. The World Health Organization recently noted that social isolation resulting from COVID-19 lockdowns has heightened the importance of ear and hearing care, highlighting that rehabilitation can help ensure that those affected, and society at large, avoid the adverse consequences. However, outdated and unnecessary Medicare restrictions limit seniors' access to this necessary care. This is especially important now as emerging evidence indicates a link between long-term hearing problems and COVID-19 infection. Medicare, however, currently only covers diagnostic tests performed by audiologists to assess hearing and balance when ordered by a physician, while treatment services are not covered. Yet, audiologists' scope of practice includes auditory and vestibular treatment and neurological monitoring and are Medicare-covered benefits when provided by other practitioners. Most private health plans allow for direct access to audiology services, as do other public payers, such as Medicaid. These unfair restrictions prevent Medicare beneficiaries from accessing care in a timely manner, imposing unnecessary costs on the health care system, and increasing consumer costs. I am an original cosponsor of H.R. 1587, the Medicare Audiologist Access and Services Act, that would fix these problems and provide Medicare beneficiaries increased access to hearing and balance related services provided audiologists.

a. During your tenure in the House, you championed legislation to ensure Medicare beneficiaries had direct access to diagnostic and treatment services provided by audiologists, which as I noted they currently lack. Why did you support that legislation?

b. Given that emerging research appears to link COVID-19 infection with certain long-term health problems such as tinnitus, or ringing in the ears, how important will it be to ensure that there are a sufficient number of health professionals such as audiologists to diagnose and treat such conditions?

c. Would you commit to reviewing the Department's existing authorities to ensure Medicare beneficiaries have timely and robust access to hearing and balance services provided by audiologists?

Response: CMS agrees that it is important for Medicare beneficiaries to have access to medically necessary services. Current law limits Medicare coverage of audiology services furnished by audiologists to hearing and balance assessment services. HHS is committed to expanding access while working within the confines of the law, and looks forward to working with Congress on these issues in the future.

Question 138:

According to the National Institutes of Health a rare disease is defined as a condition that affects fewer than 200,000 Americans. This distinction, defined by Congress through the passage of the Orphan Drug Act (ODA) in 1983, applies to as many as 7,000 rare diseases and between 25-30 million people in the United States. When considered together, rare diseases are quite widespread. Despite this reality, rare diseases were historically considered "orphan" because companies were not able to incur the financial burdens of a clinical trial to create a therapy for

such a small population of affected individuals. The Orphan Drug Act was designed to provide additional incentives to encourage companies to develop new drugs for rare diseases.

Regulatory incentives implemented by the ODA have improved the environment for therapeutic development. However, clinical trial programs for rare disease treatments continue to face challenges, including an incomplete understanding of the effects of rare disease on patients, due to small patient populations and the limitations of currently available treatments. Often this basic and valuable information and understanding is gained through the process of conducting clinical trials. This research is of great value to these rare disease communities, whether or not the trial results in the optimal outcome of a newly approved therapy, because they provide valuable information regarding the natural history of a disorder and could direct future investigators toward a cure.

It is clear from the evidence that the COVID-19 pandemic has made it extremely difficult for drug innovators to engage patients in clinical trials than under normal circumstances. As a result, it can be exceedingly challenging, or in some cases nearly impossible, to recruit enough patient participants to fulfill the needs of a traditional clinical trial. This is especially true for rare disease. For some companies struggling to fund these trials, these delays can be devastating. Withdrawing from the trial is often the most prudent financial option, though it comes at quite a cost to the patients waiting for the information.

For the millions of Americans with rare diseases, for whom the promise of clinical investigations and pharmaceutical innovation holds the possibility of a better, longer life, will you commit to working with the FDA, NIH, and members of Congress to identify ways to ameliorate the COVID-19 impact on rare disease innovation?

Response: The Department of Health and Human Services is committed to advancing equity across the health care system, including access to clinical trials and treatments for patients from minority populations with rare diseases. Specifically, NIH is committed to working with the FDA and members of Congress to identify ways to reduce the impact of the COVID-19 pandemic, particularly with respect to rare disease research and therapeutic development and innovation.

Research on specific rare diseases is supported by NIH Institutes and Centers (ICs) based on where a particular rare disease falls within their mission, with the National Center for Advancing Translational Sciences (NCATS) being the home of the Office of Rare Diseases Research (ORDR). NCATS is focused on finding ways to speed the development of treatments for multiple diseases simultaneously, in collaboration across NIH ICs, with the goal of ultimately helping more patients more quickly.

There are over 7,000 rare diseases, affecting approximately 30 million Americans. Based on a recent NCATS pilot study,[30] rare diseases result in an estimated $400 billion per year in total direct medical costs, similar to annual direct medical costs for cancer, heart failure, and Alzheimer's disease. For the millions of people living with a rare disease, the novel coronavirus

[30] https://ncats.nih.gov/news/releases/2021/nih-study-suggests-people-with-rare-diseases-face-significantly-higher-health-care-costs

disease COVID-19 presented extra challenges, from potential reduced access to needed medical care to possible heightened anxiety and stress. In 2020, the NIH-supported Rare Diseases Clinical Research Network (RDCRN)[31], in addition to continuing its existing research, launched a survey to find out how the COVID-19 pandemic impacted individuals with rare diseases, their families and caregivers. Preliminary results[32] indicated the pandemic negatively affected rare disease patients in several ways including, access to regular health care, treatment for the rare disease, and special diets.

To enable research to continue to the fullest extent possible during the pandemic, the NIH has also directly worked with grant awardees, including small businesses, to offer flexibilities to help mitigate the effects of the COVID-19 pandemic for all research. This included both no cost and funded extensions to allow researchers to continue their work. In addition, administrative supplements for unanticipated costs due to the impact of COVID-19 were awarded, often to allow extended enrollment of patients in clinical trials or for travel costs for clinical research participants.

In addition to these flexibilities, NCATS continued during the pandemic to foster as much research and research-related activities that address rare diseases.

We also have a long-standing commitment to supporting innovation in clinical development programs to help bring safe and effective drugs to patients more efficiently. Although the COVID-19 pandemic accelerated the use of innovative trial designs, FDA's policy development in this area long preceded the current public health emergency. FDA recognizes that there are emerging shifts in how diseases, specifically rare diseases, are diagnosed, prevented, and treated, and in the development of therapeutics. FDA is working on multiple fronts to provide guidance on innovative approaches to drug development, such as complex, innovative trial designs, master protocols, decentralized trials, trials utilizing real world data and evidence (RWD/RWE), modelling, and simulation. Our engagements with stakeholders have supported innovative trial designs as part of the COVID-19 pandemic response. These designs improve clinical trial efficiency and may optimize product development for other diseases, including rare diseases.

FDA continues to promote innovation in clinical trial design and conduct, and to encourage the utilization of advanced technologies. The Agency is already working in many ways to facilitate pharmaceutical development and improve the overall clinical trial enterprise. FDA is also leveraging the importance of strong national and global partnerships in collectively advancing scientific knowledge to ultimately benefit patients. The Agency is invested in helping advance innovations, such as decentralized clinical trials and the use of digital health tools that have the potential of making clinical trials more efficient and may allow for wider inclusivity of diverse populations. Further, recognizing the value of innovative designs, FDA is committed to continuing the Complex Innovative Designs Meeting Program, which provides applicants accepted into the program with additional meetings with FDA to discuss proposed innovative designs.

Question 139:

[31] https://ncats.nih.gov/rdcrn
[32] https://www.rarediseasesnetwork.org/news/2021-02-10-COVID19-survey-preliminary-results

Private practice physical therapists and other therapy providers are facing a trifecta of payment cuts in January 2022. First, CMS is scheduled to further reduce therapist payment under the Medicare fee schedule to pay for the E/M increase; second, the return of the 2 percent sequester; and third, CMS is scheduled to implement an additional 15 percent cut to therapy services when therapy services are provided in-part by a physical therapist assistant or occupational therapy assistant.

Therapy assistants play a vital role in the delivery care, especially in small outpatient therapy businesses and in rural and underserved areas. On top of this 15 percent cut, Medicare regulations still require overly burdensome direct supervision rules for therapy assistants in the outpatient clinics. As a Member of Congress who represents these small business owners, I am concerned about the combined impact this looming cut will have on access to care, as well as to the financial viability of therapy small businesses—especially because of the ongoing economic impact of the pandemic.

I therefore have two suggestions.

a. I urge CMS to provide support and flexibility to small therapy businesses by modifying the supervision requirements for physical therapist assistants from direct to general supervision in private practice settings via the 2022 Medicare Physician Fee Schedule (MPFS) rulemaking. At a minimum, I urge CMS to permanently allow direct supervision of physical therapist assistants to be satisfied through virtual means.
b. I recommend CMS exempt rural and underserved areas from the pending Medicare payment differential for services furnished in whole or in-part by physical therapist assistants. This could be achieved by either creating a class-specific geographic index or establishing incentive payments for RVU data collected from rural physical therapists to offset the physical therapist assistant payment reduction in rural areas.

Which one of these suggestions can you commit to pursuing? I look forward to hearing how CMS acts in order to protect access to community-based physical therapy care that is provided in small-business settings.

Response: Increasing beneficiary access to care in rural and underserved areas is consistent with our longstanding interest in increasing beneficiary access to Medicare-covered services in rural and underserved areas. We solicited comments on direct supervision by interactive telecommunications technology. This information will allow us to consider safety and program integrity issues in the context of virtual supervision, and to what degree and on what basis this flexibility could be continued following the public health emergency. We will consider this and other information as we determine future policy regarding use of communication technology to satisfy direct supervision requirements as well as the best approach for safeguarding patient safety while promoting use of technology to enhance access.

Regarding the payment reductions for therapy services furnished in whole or in part by therapy assistants required by Medicare statute, we intend to monitor the implementation of the therapy assistant modifiers, including any changes to access to outpatient therapy services.

Question 140:
For the first time since the 1938 Food, Drug, and Cosmetics Act passed, the FDA has proposed to treat homeopathic drugs the same as new pharmaceutical drugs, requiring a new drug application. Constituents of mine who safely use homeopathic medicines are very concerned that they are already losing access to these products. Is FDA aware of this issue and, if so, what is the Agency doing to address it?

Response: The homeopathic drug industry has grown significantly since FDA issued Compliance Policy Guide (CPG) 400.400 in 1988. This growth, and the increased population exposure that it signifies, contributed to FDA's enhanced focus on the safety of homeopathic drugs in recent years and the withdrawal of the CPG. Since the issuance of CPG 400.400 in 1988, FDA has encountered multiple situations in which drug products labeled as homeopathic ("homeopathic drug products") posed a significant risk to patients, even though the products, as labeled, appeared to meet the conditions described in CPG 400.400. Upon further review, FDA determined that CPG 400.400 was inconsistent with its risk-based approach to regulatory and enforcement action generally and therefore did not reflect the Agency's current thinking.

FDA wants to clarify for both consumers and industry how it assesses the potential safety risks of these products. That is why, in 2017, FDA issued a draft guidance discussing its intent to apply a risk-based enforcement approach to homeopathic drug products; the Agency issued a revised draft in 2019 in response to public comments. This is an area that FDA takes very seriously, as there are many homeopathic drug products being sold in the U.S. market, none of which are approved by FDA. The risk-based approach to regulatory and enforcement action for homeopathic drug products in the revised draft guidance is sensitive to the different levels of risk presented by different types of homeopathic products.

Question 141:
Data illustrates that seniors are the most at-risk population for death and serious illness from COVID-19. According to the CDC, 80.9 percent of all COVID-19 deaths have occurred in people aged 65 and older. Residents of assisted living facilities are particularly at risk because they, on average, are aged 85, suffer from multiple chronic conditions, and require assistance with daily living activities such as eating, bathing, dressing, and taking medications which cannot be socially distanced. While thankfully vaccines are now helping to keep residents and caregivers safe, many facilities continue to struggle with immense financial burdens. Of the $175 billion appropriated, so far only $1 billion has been sent to assisted living providers (0.5 percent of all Provider Relief Fund dollars). While the Provider Relief Fund did allocate over $12.5 billion to skilled nursing facilities, these relief funds did not go to assisted living providers. Since the beginning of the public health emergency (PHE), senior living and senior support providers have incurred billions in expenses or losses related to the acquisition of additional personal protective equipment and other infection prevention and control supplies, as well as additional support for their workforce. The financial strain they are experiencing is further exacerbated by lost revenue due to record-low occupancy rates as the move-in of new residents was slowed, and in many cases halted, due to the PHE; these losses are long-term, compounding, and unsustainable.

Will HHS commit to providing a fair and equitable allocation of remaining Provider Relief Fund resources to the frontline caregivers and operators that have received comparatively little relief to date, such as assisted living providers, Alzheimer's/memory care centers, and senior congregate care facilities?

Response: HHS is working on approaches to distribute Provider Relief Fund (PRF) funding as quickly and equitably as possible while maintaining effective safeguards for taxpayer dollars. HHS is considering feedback from Congress and stakeholders, as well as operational lessons learned from prior PRF payments, as part of this process. The PRF also continues to provide claims reimbursement to healthcare providers for COVID-19 testing, treatment, and vaccine administration services for the uninsured, and COVID-19 vaccine administration for the underinsured. Additional information on future distributions will be published on HHS' Provider Relief Fund webpage, at www.hhs.gov/providerrelief, as soon as it becomes available.

Question 142:

Important protections for individuals with serious disabilities who rely on complex rehabilitative manual wheelchairs will expire on June 30, 2021. It is only fair that the temporary policy approved in 2019 become permanent before June 30th so that users of complex rehabilitative manual wheelchairs will have the same benefits as complex rehabilitative power wheelchair users. By making this policy permanent, there will be equal access for the people with disabilities who depend on this technology.

Will you please provide the Committee with an update on this important matter?

Response: It is critical to ensure that Medicare beneficiaries have access to the durable medical equipment they need. CMS is actively reviewing public comments submitted to the agency on related rulemakings, including engaging in future rulemaking, and will update interested stakeholders and suppliers when more information is available.

Question 143:

Can you commit to assessing patient access concerns related to products that bring crucial clinical benefits to patients, under the Medicare hospital outpatient and ambulatory surgical center payment systems, related to the packaging of previously separately paid drugs into ophthalmic procedures where the products are furnished in a low percentage of such procedures?

Response: HHS is committed to assessing and addressing barriers to patient access across our department, including within the Medicare program. We will take your concerns into consideration as we continue to explore and evaluate packaging policies that apply under the Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System.

Question 144:

When therapeutics are the first line of defense and a critical area for people dying with lung inflammation, why did BARDA pause Area of Interest 9.3 Immunomodulators on June 3, 2020, especially when immunomodulators target this late stage of Acute Respiratory Distress Syndrome? What happened to that critical area of interest designed to target the cytokine storm?

Response: BARDA has not received funding to support advanced research and development of immunomodulators to address late stages of COVID-19. The area of interest under the Broad Agency Announcement was closed due to lack of funding.

Question 145:

As we seek to learn from the COVID-19 response, the United States must be ready with rapid response capabilities to protect us from future pandemic surprises, but many pandemic threats (e.g., coronaviruses) are predictable, and so we must also prepare for the most likely pandemic threats.

a. What is the Administration's plan to develop tests, treatments, and vaccines in preparation for those pathogens which most likely will cause future outbreaks?

   Response: The American Rescue Plan Act of 2021 provided $6.05 billion for research, development, manufacturing, production, and the purchase of vaccines, therapeutics, and ancillary medical products and supplies to prevent, prepare, or respond to COVID-19 or any disease with pandemic potential. Of this amount, HHS allocated $850 million to the SNS to procure supplies to respond to the COVID-19 pandemic.

b. How should we stockpile for the most likely countermeasures to be needed as mitigation?

   Response: The Budget includes $905 million for the SNS to make meaningful investments across a number of portfolios necessary to ensure readiness for future public health emergencies. Funds would also be used to support SNS's ongoing storage and distribution needs, which were expanded and modified to meet the demands of the COVID-19 pandemic. These activities are separate from on-going COVID response activities which have largely been supported by supplemental appropriations.

Question 146:

FDA recently released guidance for industry on Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency. According to the guidance, "A remote interactive evaluation does not constitute an inspection for purposes of section 510(h)(3) of the FD&C Act. However, FDA will use information gathered via a remote interactive evaluation to determine the scope, depth, and timing of a future inspection."

a. Can FDA provide clarity on timelines for remote interactive evaluations?

b. Can FDA clarify the timing between remote interactive evaluations and scheduling inspections?

c. Will the agency provide information on prioritization or criteria for conducting remote interactive evaluations?

Response to a-c: There is no doubt that the pandemic has had an impact on FDA inspectional work but as of the end of March 2021, only 48 human drug applications, of the large number of applications received, had been delayed because of a pending inspection, and only six of these were considered mission critical. FDA intends to complete the six mission critical inspections by the end of FY21 and will be working to resolve any application decisions that were delayed as expeditiously as feasible within the risk-based framework employed by the agency. FDA considers public health need, including actions related to drugs that treat a serious disease for which there is no substitute, in its risk-based approach to planning inspectional work.

FDA also uses establishment inspection information from capable foreign regulatory authorities under Mutual Recognition Agreements (MRAs). In addition, FDA collaborated with our trusted capable foreign regulatory authority partners to expand the use of MRAs to include sharing third country reports in order to increase the scope of influence of the MRA during the pandemic. This approach provides additional information regarding a facility's conformance with regulatory requirements that FDA can use to inform decisions related to drug approvals and shortages.

Question 147:

FDA is currently experiencing a backlog in foreign and domestic inspections of facilities where drugs are manufactured, processed, packed, or held due to the COVID-19 public health emergency. These backlogs are resulting in delays for drug approval and development for rare disease patients.

a. How does the agency plan to address the significant backlog?

b. Can FDA provide clarity on timelines for addressing the inspections backlog?

c. Will FDA use or adopt the existing Mutual Recognition Agreements in place?

Response: There is no doubt that the pandemic has had an impact on FDA inspectional work but as of the end of March 2021, only 48 human drug applications, of the large number of applications received, had been delayed because of a pending inspection, and only six of these were considered mission critical. FDA intends to complete the six mission critical inspections by the end of FY21 and will be working to resolve any application decisions that were delayed as expeditiously as feasible within the risk-based framework employed by the agency. FDA considers public health need, including actions related to drugs that treat a serious disease for which there is no substitute, in its risk-based approach to planning inspectional work.

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The Honorable Billy Long (R-MO)

Question 148:
Secretary Becerra, I think that we can all agree that reopening the country and the economy safely is a top priority. Over the course of the last year, there has been talk of reopening when viral spread is nearly done, which has now shown to be highly unattainable due to the Coronavirus' propensity to mutate. Then came multiple therapies, including successful monoclonal antibodies, but those require visiting a clinic or hospital setting. Then through the miracles of science, biotechnology provided the world with multiple vaccines to the virus. However, the demand for the vaccine has begun to level off and it is clear, much like the yearly flu vaccine, there has to be more if we are going to reopen without the fear of death and sickness spreading.

Last year, multiple companies began investigating the possibility of broad, oral antiviral medications, which do not require refrigeration or hospitals and also present a potentially affordable alternative for patients, for patients suffering from the coronavirus. I understand that several of these options have begun to present successful data not unsimilar to that of the monoclonal antibodies to the FDA.

The concept that patients, vaccinated or not, could have access to oral medications that drastically reduce the chances of hospitalizations due to the coronavirus and nearly eliminate the changes of death is a remarkable one. Please keep this Committee, the Congress, and the public well informed of the work in this area, as with the goal of reopening the country and the world safely is a thought we all have daily, we will be keeping a close eye.

Response: I will keep you up to date on these developments. I will note that FDA has created a special emergency program for possible coronavirus therapies, the Coronavirus Treatment Acceleration Program (CTAP). The program uses every available method to move new treatments to patients as quickly as possible, while at the same time finding out whether they are helpful or harmful. FDA continues to support clinical trials that are testing new treatments for COVID so that we gain valuable knowledge about their safety and effectiveness. The CTAP dashboard provides a snapshot of development of potential COVID-19 therapeutics. Given the urgent nature of the pandemic and the number of companies and researchers developing COVID-19 related therapies the dashboard can change frequently. You can find more information about the program here: https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap.

Question 149:
Secretary Becerra, can you commit to me that the FDA will do everything in its power to approve these therapies that meet the necessary safety thresholds so that ASPR and BARDA can make sure supply of these medications make it to patients all over the United States and the rest of the world?

Response: Yes, ensuring that these drugs are safe and effective while also available to Americans is a priority for me.

Question 150:
Given the executed MRA between FDA and EMA with respect to recognizing drug inspections conducted by foreign regulatory authorities, what barriers are preventing FDA from considering novel inspection approaches to address pre-approval inspections?

Response: I am aware of concerns raised that the COVID-19 pandemic has hindered FDA's ability to conduct inspections of medical product facilities. I am committed to working with FDA to find ways to modernize the inspections program and to incorporate novel approaches to these important inspections.

While the COVID-19 pandemic strained FDA's ability to perform traditional foreign inspections, as I understand it, the Agency has worked to improve inspection capabilities within the current public health environment. I agree that we must apply the lessons learned during this public health emergency to our work going forward.

I continue to work to ensure that safe and effective therapies get to market as efficiently as possible. While FDA paused all on-site surveillance domestic inspections in March 2020 due to the COVID-19 pandemic, FDA investigators continued mission critical inspections and other activities to ensure FDA-regulated industries are meeting applicable FDA requirements. FDA also later began resuming domestic surveillance inspections in July 2020. To date, FDA has not experienced a significant impact on its ability to take actions on drug and biologic applications.

FDA has also been employing other tools to evaluate facilities, as appropriate, such as requesting records and other information or reviewing trusted foreign regulator inspection records under existing Mutual Recognition Agreements. These tools have been, in many cases, successful to allow the Agency to take actions on applications.

FDA pre-approval requirements and practices vary in some respects from those that are followed by the European Union (EU), with which FDA has executed a MRA. Since July 2019, the FDA and the European Union have been actively engaged in evaluating how to implement the US-EU MRA for consideration of pre-approval inspections.

I will work with FDA to ensure the Agency uses every appropriate tool to get critical safe and effective therapies to market as efficiently as possible.

Question 151:
When considering novel inspection approaches, and in times when foreign inspections are not feasible due to the inability to travel, is the FDA open to using technology to perform virtual inspections in lieu of an in-person pre-approval inspection? What barriers are preventing FDA from considering this approach?

Response: During this worldwide public health emergency, FDA has used a variety of tools to oversee facilities that manufacture FDA-regulated products. These tools include record requests in advance of or in lieu of a drug facility inspection, relying on information from trusted regulatory partners, and remote interactive evaluations (such as remote livestreaming video of

operations, teleconferences and screen sharing). The Agency has used some or all of these approaches to evaluate facilities for human and animal medical products during the public health emergency when inspections of drug facilities were not possible due to travel or quarantine restrictions.

Inspections are an important tool to keep Americans safe, and are part of a set of tools used for regulatory oversight. As part of the wide variety of tools we have deployed during the COVID-19 pandemic, remote interactive evaluations have informed the FDA's regulatory decision-making, contributed to ensuring drug quality and helped determine the scope, depth and timing of future inspections. By necessity, the Agency has adapted by conducting more remote interactive evaluations throughout the public health emergency and are continuing to expand their use as appropriate.

FDA recognizes that remote interactive evaluations do not replace inspections, and that there are situations where only an inspection is appropriate based on risk and history of compliance with FDA regulations. Within the exceptional context of a global pandemic, the Agency sees remote interactive evaluations as part of a necessary strategy to evaluate medical product facilities by using all available approaches to ensure the medical products we regulate are safe, effective and of high quality. FDA is open to using technology to perform virtual facility assessments where appropriate. On April 14th the Agency released guidance to describe how we will request and conduct voluntary remote interactive evaluations at facilities where drugs are manufactured, processed, packed, or held; facilities covered under FDA's Bioresearch Monitoring (BIMO) program; and outsourcing facilities registered under section 503B of the FD&C Act for the duration of the COVID-19 public health emergency. More info on this guidance can be found at this website: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remote-interactive-evaluations-drug-manufacturing-and-bioresearch-monitoring-facilities-during-covid.

The Honorable Larry Bucshon, M.D. (R-IN)

Question 152:
Secretary Becerra, as you know, FDA's Center for Tobacco Products is funded entirely by industry user fees that can be used on a range of activities, including the review of premarket tobacco product applications (PMTAs) as well as enforcement.

All tobacco products, including electronic nicotine delivery system (ENDS) products or e-cigarettes, that were not on the market prior to August 2007 need to have submitted PMTAs last year, which FDA is currently reviewing.

The most recent data from the National Youth Tobacco Survey showed an alarming increase in use of disposables over the past year, up nearly 1,000% among high school e-cigarette users and more than 400 percent among middle school users.

This concerning increase is likely due in large part to FDA effectively carving flavored disposables out its 2020 guidance document describing how the agency will prioritize

enforcement against ENDS products that are being marketed absent FDA authorization or for which the manufacturer has not submitted a premarket application.

In that same guidance document, however, FDA explained that it would also prioritize enforcement against manufacturers of products who have failed to take adequate measures to prevent minors' access. This is clearly the case for most if not all of such products, particularly those still marketing flavors appealing to minors. While FDA did send warning letters to ten manufacturers of particularly popular brands, the market is still flooded with such products, the overwhelming majority of which are likely not the subject of a premarket application pending at FDA.

Do you agree that FDA should immediately prioritize enforcement activities against manufacturers of disposable ENDS products? How specifically, does the agency plan to take action against these same manufacturers who are now marketing synthetic nicotine products, in an effort to further skirt FDA regulation?

Response: Preventing youth use of tobacco products is an important priority for HHS. ENDS remain the most commonly used tobacco product by youth. Examples of FDA enforcement action against manufacturers of disposable ENDS products that violate the law are:

- In September 2020, FDA issued a warning letter to XL Vape LLC (doing business as Stig Inc.), a popular disposable e-cigarette brand among youth, for the unauthorized sale of their ENDS products
- In July 2020, FDA issued warning letters to companies, including Puff Bar, for the unauthorized sale of flavored disposable e-cigarettes
- FDA has refused admission into the U.S. hundreds of shipments of ENDS products, including disposables, worth nearly $2 million for violations of the FD&C Act.

FDA is concerned about increasing reports of ENDS that purportedly contain exclusively synthetic nicotine (nicotine not derived from tobacco) and the efforts of companies marketing such products to take advantage of what they perceive to be a loophole in the law to evade FDA jurisdiction and regulation. The Agency is working to address this problem to ensure these products are properly regulated.

Question 153:

Secretary Becerra, each year over 50,000 Americans die from colorectal cancer, the second leading cause of cancer death in the country. Congress has provided over $70 million to the CDC's Colorectal Cancer Control Program (CRCCP) to increase colorectal cancer screening rates. And last year, 24 members of this subcommittee cosponsored HR 1570, The Removing Barriers to Colorectal Cancer Screening Act, that was enacted into law. These are critical first steps in addressing the surprise out of pocket costs that Medicare patients face in completing their colorectal cancer screening. But there is more work to be done.

The US Preventative Services Task Force (USPSTF), the Centers for Disease Control (CDC) and the American Cancer Society, have consistently documented the importance of colorectal cancer screening. Importantly, USPSTF's recommendation supports flexibility in the methods and tests

used in recommended colorectal cancer screenings, acknowledging that the best test is the one that gets done.

Under current CMS policy, some Medicare beneficiaries may be subject to a cost-share following a colorectal cancer screening depending on the exact sequence of screening events, despite clear Congressional intent in eliminating cost-sharing as a potential barrier to receiving these essential services.

If a patient chooses a non-invasive cancer screening method and receives a positive result, then a follow-up colonoscopy is required to complete the screening, which too often results in an out-of-pocket cost for the patient. Current policy penalizes those who choose USPSTF recommended, accessible, non-invasive screening options. Similarly, some patients with Affordable Care Act plans, depending on the plan and state, also face out of pockets costs for completing preventive screening.

Does HHS have the ability and willingness to take administrative action to resolve this discrepancy in the way ACA plans and Medicare cover tests and procedures associated with preventing and catching colorectal cancer. Do you have the authority to and will you address these gaps in coverage by issuing guidance or taking other administrative action to remove these cost-shares and increase accessibility for all?

Response: We know cancer as a disease for which there are stark inequities in access to cancer screening, diagnostics and treatment across race, gender, region, and resources. The Biden-Harris Administration is committed to ensuring that every community in America – including those living in rural, urban, and Tribal communities – has access to cutting-edge cancer diagnostics, therapeutics, and clinical trials.

With regard to Medicare, CMS prioritizes expanding access to essential preventive health care services, including cancer screenings. Medicare covers a broad range of colorectal cancer screening tests, including Cologuard® Multitarget stool DNA, screening fecal occult blood test, screening flexible sigmoidoscopy, screening barium enema, screening colonoscopy and most recently, blood-based biomarker tests if they meet certain criteria, including specified test performance characteristics. We will be further addressing this issue by implementing section 122 of the Consolidated Appropriations Act, 2021, waiving Medicare coinsurance for certain colorectal screening tests, through future rulemaking.

Most private health plans, including those offered through the Marketplaces are required to cover certain preventive services that have strong scientific evidence of their health benefits, and plans are not allowed to charge a patient a copayment, co-insurance, or deductible for these services when they are delivered by a network provider. Plans covered by these rules must offer coverage of a comprehensive range of certain preventive services that are recommended by physicians and other experts without imposing any cost- sharing requirements. This includes services given a "grade" of A or B by the U.S. Preventive Services Task Force, an independent panel of scientific experts that ranks preventive services based on the strength of the scientific evidence documenting their benefits. HHS, together with the Departments of Labor and the Treasury have issued several rounds of guidance to clarify the scope of coverage required for recommended

colorectal cancer screenings. Specifically, ACA Frequently Asked Questions (FAQs) have clarified that plans and issuers required to cover preventive colonoscopies without cost sharing may not impose cost sharing for the cost of a polyp removal during the colonoscopy, anesthesia services performed in connection with a colonoscopy, any required specialist consultation prior to the screening procedure, any pathology exam on a polyp biopsy, or bowel preparation medications prescribed for the procedure.

I look forward to working with partners across the federal government, along with Congress and other stakeholders, to examine ways we can increase access to services for the prevention, diagnosis, treatment, and survival of cancer.

Question 154:

Secretary Becerra, in the No Surprises Act, the IDR entity is prohibited from considering "usual and customary charges". Will CMS abide by its current legal definition of "customary charges" to mean "the uniform amount in which the individual physician or other person charges in the majority of cases for a specific medical procedure or service"?

Response: HHS is working with the Departments of Labor and Treasury to ensure that this critical legislation is implemented effectively and in a timely manner. HHS, along with the Departments of Labor and the Treasury and the Office of Personnel Management, are committed to engaging in a thoughtful rulemaking process to ensure this law is implemented as intended. I look forward to continuing to work with you and other Members of Congress on this shared goal.

Question 155:

Secretary Becerra, the COVID-19 pandemic has revealed some important deficiencies that Representative Kuster and I have introduced legislation to help address. Immunization Information Systems (IIS) are state and locally-based registries that serve as a vital link between public health officials, community providers and individuals, not only in cases of disease outbreaks or emergencies but also during routine vaccination efforts. We have seen during the current pandemic that systems have differing levels of capability in terms of data collection and reporting. The Centers for Disease Control and Prevention provides funding for these systems, but they are used by a wide range of providers, payers, and health programs.

a. How does your department's budget plan support IIS for the duration of the pandemic as well as for routine vaccine data collection and reporting efforts?

b. Also, what are some lessons learned this far that can help inform IIS data modernization efforts?

c. What steps can Congress take to support greater alignment of IIS programs that will strengthen and improve the quality, security, and reliability of the data for COVID vaccines and routinely recommended vaccines across the life course?

Response to a-c: COVID-19 placed unprecedented demands on immunization information and reporting systems. CDC worked with jurisdictions to update and implement new data systems that facilitated data exchange, interoperability, and the

capture of de-identified data for complete and accurate reporting. CDC funded enhancements to jurisdiction immunization information systems or IISs to collect, exchange, and share large quantities of immunization data that were critical for public health decision-making. Jurisdictions improved IIS functionality such as integrating scheduling and/or mass vaccination tools, as well as improving system infrastructure such as increasing the use of cloud hosting and storage and increasing processing bandwidth to accommodate higher volumes of data. CDC established data use agreements with 64 jurisdictions and built an immunization data submission architecture/pipeline to ensure rapid data analysis and reporting to key stakeholders and to the externally facing COVID Data Tracker. Ultimately, epidemiological surveillance is improved because public health officials have access to more accurate vaccination data without the identity of the patients being revealed.

Question 156:
Secretary Becerra, do you think more transparency is needed to understand whether the 340B program is working as intended, and how 340B savings are being used to support patients versus padding profits?

Question 157:
Secretary Becerra, do you think private not-for-profit DSH hospitals should be required to use 340B savings to support patient care and provide charity care much in the same way grantees do?

Question 158:
Secretary Becerra, do you think we should better target the 340B program to hospitals that provide higher levels of charity care to support their efforts to take care of vulnerable patients?

Question 159:
Secretary Becerra, how can this committee work with you to improve the 340B program in a way that helps patients with greatest needs access drugs or healthcare services in an affordable way?

Response to Questions 156-159: The 340B Drug Pricing Program is an indispensable program for our safety-net providers serving some of our neediest populations. I look forward to working with you and other Members of Congress to uphold the law and ensure this vital program is able to support vulnerable communities.

The Honorable Markwayne Mullin (R-OK)

Question 160:
I want to ask you about COVID-19 testing, and about how the Administration plans to spend the $50 billion in funding provided in March. This was on top of extensive previous funds for COVID-19 testing.

a. Of the $47 billion appropriated in the last Congress for testing, how much of those funds remain available?

b. If funds are still available, why are these funds still available? Are there roadblocks to HHS disbursing these funds?

c. In addition to these funds, $50 billion in new funds for testing was just provided in March. So far, the Administration has publicly announced how only $13 billion would be spent ($10 billion for schools, $2.25 billion for screenings to address disparities in testing, and now just under $1 billion for testing in rural areas).

d. Does the Administration have a plan for the remaining $37 billion? If so, what is it?

Response: The American Rescue Plan provides the resources for the Biden Administration to further ramp up testing actions to detect, diagnose, trace and monitor COVID-19 and prevent its spread. Congress appropriated $47.8 billion to HHS for COVID testing, contact tracing, and mitigation, and HHS is in the process of allocating all $47.8 billion for testing, contact tracing, and mitigation activities.

On March 17, 2021, the Administration announced its plans to invest more than $12 billion to expand COVID-19 testing, including funding for school screenings, resources for screenings to address disparities and advance equity, and additional support for asymptomatic and long-term care screening. These measures are part of President Biden's strategy to increase COVID-19 testing nationwide as vaccinations increase.

This announcement follows the Administration's announcement in February 2021 of new actions to expand testing capacity across the country. These activities to expand COVID testing, contact tracing, and mitigation are at different phases of execution. In some cases, planned activities are multi-year by design and will include funding to jurisdictions in future years to support state and local response.

HHS continues to carefully assess how to use the limited resources for the highest priority response activities.

Question 161:

The president has requested $4.3 billion for the Office for Refugee Resettlement. Does this number take into account the influx of migrants due to Biden's border crisis?

Response: The budget request supports the ongoing implementation of critical programmatic reforms enhancing the well-being of children in care, such as bolstering case management services that reduces the time it takes to safely place children with their vetted sponsors as well as expanding the bed capacity of ORR's nation-wide network of care provider programs. The UC Program received an unprecedented number of children in the spring of 2021. On April 28th, 2021, ORR reported a census of nearly 23,000 children in care, and migration trends continue to drive an increase in resource needs for the UC Program. ORR continues to work closely with DHS to track migration trends in order to best predict UC Program needs and resources. The budget request also includes expanding the scope of post-release services and the number of

children who receive them as well as providing services to families who were separated at the United States-Mexico border by the previous administration.

The Honorable Richard Hudson (R-NC)

Question 162:
Given the ongoing delays in Food and Drug Administration (FDA) conducting in-person inspections of pharmaceutical manufacturing facilities due to the pandemic, please answer and provide clarity around the following questions:

a. Please address and outline the impact these delays have had and will have moving forward on patients and the availability of medicines.

b. Please outline explicitly what FDA is doing to ensure the current delays and lack of inspections will not cause future drug shortages.

c. Please explain how FDA is prioritizing resuming foreign inspections and the backlog of affected applications.

    i. Is there a specific criterion applied in this prioritization?

    ii. When does FDA expect to fully resume foreign inspections?

Response to a – c.ii: There is no doubt that the pandemic has had an impact on FDA inspectional work but as of the end of March 2021, only 48 human drug applications, of the large number of applications received, had been delayed because of a pending inspection, and only six of these were considered mission critical. FDA intends to complete the six mission critical inspections by the end of FY21 and will be working to resolve any application decisions that were delayed as expeditiously as feasible within the risk-based framework employed by the agency. FDA considers public health need, including actions related to drugs that treat a serious disease for which there is no substitute, in its risk-based approach to planning inspectional work.

FDA recently issued a report, the *Resiliency Roadmap* for FDA Inspectional Oversight, that fully outlines and provides data through the end of March 2021, on the impacts of the COVID-19 pandemic and its related travel and other restrictions on FDA's inspectional work. It describes how FDA continued to conduct inspections considered critical to the agency's public health mission, and prioritized oversight using a risk-based approach to address or prevent drug shortages. The Roadmap explains this approach and, in Table 6, provides the risk-based prioritization criteria that are considered in making oversight decisions. For decisions about foreign facility inspections, FDA must also take into account Department of State travel advisory information, specific country requirements as well as the public health consequence to determine if a foreign inspection is appropriate. These factors will be balanced with the FDA objective to minimize missed application goal dates and work through the inventory of delayed inspections.

Question 163:
There remain concerns around the growing backlog of drug and device approvals due to Food and Drug Administration's postponement of foreign facility inspections. FDA recently released a report on this topic, "Resiliency Roadmap for FDA Inspectional Oversight," and it states that FDA will not conduct any foreign inspections with U.S.-based staff for the remainder of FY 2021. Can you explain why FDA is unwilling to restart foreign inspections this year, and why FDA is not conducting more remote interactive evaluations, in lieu of in-person inspections, to work through this backlog? What are the main barriers for FDA to resume inspections?

Response: The continuing global pandemic presents significant challenges to FDA's return to foreign oversight work. Foreign inspection trips must now account for known country quarantine requirements as well as the prospect of unknown confinement due to a positive COVID-19 test while on travel or a change in travel restrictions. In addition, reduced access to healthcare for FDA staff in foreign countries remains a concern. Despite these challenges, FDA has conducted all mission-critical oversight work throughout the pandemic, including in foreign countries. FDA has also enhanced its collaboration and reliance on information from trusted foreign regulatory partners through mutual recognition agreements and other confidentiality agreements, to support regulatory decisions.

FDA continues to adapt to the challenges imposed by the COVID-19 pandemic and will use all its tools to help ensure the safety and quality of FDA-regulated products. Although inspections are critical to FDA oversight, they are part of a robust and multi-pronged approach to ensuring the safety and quality of FDA-regulated products.

Question 164:
The Food and Drug Administration (FDA)'s recent report, "Resiliency Roadmap for FDA Inspectional Oversight," states the base-case scenario that FDA will only complete 26% of the outstanding inspections for human and animal medical products in FY 2021. There remain concerns that FDA's inability to work through the backlog of inspections will result in drug shortages and hinder patient access to lifesaving treatments. Section 2304 of the American Rescue Plan Act (H.R. 1319; PL # 117-2) specifically appropriated $500 million to FDA to address delayed or cancelled inspections due to the COVID-19 pandemic. How is FDA using these funds to work through the inspection backlog, and why has FDA stated they will not resume foreign inspections this year?

Response: Using the methodology described in the Resiliency Roadmap, FDA will start a gradual transition to standard operations in July 2021 if current COVID-19 travel and facility access restrictions are lifted, and FDA investigators are available to conduct inspections. This is described in the Roadmap as the "Base-Case Scenario" and it is estimated that 26% of the human and animal medical product surveillance inspections still to be conducted can be completed by the end of September 2021. These figures refer to surveillance inspections which, unlike an inspection related to a potential drug shortage or an issue with patient access to a lifesaving treatment, have not been prioritized or considered to be mission-critical during the COVID-19 pandemic.

For human and animal medical products, FDA has utilized remote tools to either help achieve surveillance targets or prioritize inspections within the site selection models that prioritize facilities for surveillance coverage. Some inspections cannot benefit from remote tools, such as the Mammography Quality Standards Act annual mandate inspections. These inspections constitute 25% of the 3,229 domestic human and animal medical product inspections remaining. For other domestic human and animal medical product inspectional purposes, FDA will continue to use these tools to the maximum extent possible, particularly for lower-risk situations.

FDA received $73.5 million to address delayed inspections due to COVID-19. This includes $35.1 million to the ORA for recovery activities, including inspection modernization and hiring staff to conduct delayed inspections. ORA used this funding to improve the quality and consistency of data collected during inspections enabling more robust and reliable analytical capabilities. It allowed for the continued automation and harmonization of manual processes leading to more immediate and actionable information reducing time to plan and assign inspections. The funding also allowed ORA programs to hire additional medical product investigators to engage in inspection and investigation operations providing greater oversight of regulated industry.

The continuing global pandemic presents significant challenges to FDA's return to foreign oversight work. Foreign inspection trips must now account for known country quarantine requirements as well as the prospect of unknown confinement due to a positive COVID-19 test while on travel or a change in travel restrictions. In addition, reduced access to healthcare for FDA staff in foreign countries remains a concern. Despite these challenges, FDA has conducted all mission-critical oversight work throughout the pandemic, including in foreign countries. FDA has also enhanced its collaboration and reliance on information from trusted foreign regulatory partners through mutual recognition agreements and other confidentiality agreements, to support regulatory decisions.

Question 165:

HHS has supported provider-based Nursing and Allied Health (NAH) training through Medicare passthrough payments for decades. Over the years, these programs have produced thousands of professionals and is playing an essential role in mitigating health care workforce shortages. It has proven to be one of the HHS' most successful work force development programs. It has come to my attention that CMS has pulled back on provider-based NAH Medicare passthrough support through a combination of claw backs, payment modifications, and new audit practices. Can you identify where health care workforce training falls within HHS' current priorities? Specifically, what more can CMS do to not just protect nursing and allied health training, but also expand investment in such programs, especially as we emerge from the current COVID-19 public health emergency?

Response: The pandemic emphasized the significant impact health care workforce shortages have on patient care across the country. The President's FY 2022 Budget supports a strong public health workforce and addresses gaps in the existing public health infrastructure at federal, state, and local levels. In addition, HHS is committed to finding ways to enhance our nation's health workforce, including through programs and initiatives that provide critical training opportunities.

HHS is committed to strengthening the health workforce and connecting skilled providers with communities in need. The President's Budget includes a number of proposals related to healthcare workforce development. For example, the Budget requests an increase of $47.3 million for the National Health Service Corps programs to improve access to quality primary care, dental, and behavioral health in underserved urban, rural, and tribal areas. In addition, the American Rescue Plan Act of 2021 (ARP Act) provided $330 million for programs including the Teaching Health Center Graduate Medical Education. These funds will support community based, ambulatory patient care centers that operate primary care residency programs in family medicine, internal medicine, pediatrics, internal medicine-pediatrics, psychiatry, obstetrics and gynecology, generally dentistry, pediatric dentistry, and geriatrics. Teaching health centers specifically have been shown to attract residents from rural or disadvantaged backgrounds who are more inclined to practice in underserved areas than those from urban and economically advantaged backgrounds. Most recently, using ARP Act funds, HHS established several new health workforce programs, including two programs supporting training activities that aim to reduce burnout and address mental health problems experienced by health care workers. HHS continues to develop the health care workforce in rural areas through the Primary Care Training and Enhancement: Physician Assistant Rural Training Program, among other programs. This particular program increases the number of primary care physician assistants, particularly in rural and underserved settings, and improves primary care training in order to strengthen access to and delivery of primary care services nationally.

Question 166:

The Food and Drug Administration (FDA) recently announced it is investigating numerous reports of infections and contamination issues from reprocessed urological endoscopes. Three deaths – though all outside of the U.S. – are associated with these hospital acquired infections (HAIs). HAIs can lead to longer hospital stays, long-term disability, and high costs for patients and their families. There are a number of improvements needed to address HAIs, but effective cleaning of surgical instruments, like endoscopes, is essential. The Centers for Disease Control and Prevention (CDC)'s "2008 Guideline for Disinfection and Sterilization in Healthcare Facilities" specifically discusses the use of enzymatic detergents to clean medical devices. However, since 2008 there have been immense advances in our understanding of the need for the proper dosage of enzymes in these detergents to effectively reduce the bioburden on devices. This bioburden interferes with the sterilization process by acting as a barrier against the sterilization agents.

What steps will be taken to ensure the CDC examines and, where necessary, re-examines current and relevant research regarding enzymatic detergents used in cleaning critical and semi-critical medical devices. If appropriate based on this current and relevant research, will you commit to appropriately updating CDC guidance?

Response: CDC's "2008 Guideline for Disinfection and Sterilization in Healthcare Facilities", updated in 2019, recommends cleaning patient-care items with water and detergent, or with water and enzymatic cleaners to remove visible organic residue (e.g., residue of blood and tissue) before high-level disinfection or sterilization procedures, including endoscopes.[33] The guidance

[33] https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf

also recommends following manufacturer's guidelines on cleaning and sterilizing devices and that staff ensure any detergents or enzymatic cleaners selected are compatible with the metals and other materials used in medical instruments and that the device is rinsed adequately to remove any cleaning residues that may interfere with further disinfection/sterilization processes. The Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Association for the Advancement of Medical Instrumentation (AAMI) review available evidence and provide advice/guidance on enzymatic detergents. HICPAC developed the "Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC" to provide additional guidance on ways to improve facility-level training and ensuring competency for reprocessing endoscopes.[34] HICPAC is a federal advisory committee chartered to provide advice and guidance to CDC and the Secretary of HHS on infection control and strategies for surveillance, prevention, and control of healthcare-associated infections, antimicrobial resistance and related events in U.S. healthcare settings. National standards organizations like AAMI provide guidance for cleaning and reprocessing used by accrediting agencies to inform their certification processes.[35]

The Honorable Earl L. "Buddy" Carter (R-GA)

Question 167:
Mr. Secretary, in 2017 this Committee was instrumental in the enactment of legislation that would allow consumers to have access to over-the-counter hearing aids. But consumers can't access these low-cost, high-quality hearing aids until FDA establishes a regulation governing these products – the draft regulation was due in August of last year. On a bipartisan basis, my House and Senate colleagues have repeatedly inquired of FDA on the status of this regulation.

During our conversation on May 12th, you told me that you support moving this regulation forward as soon as possible. By what date can we expect this regulation to be issued in a proposed form? If you cannot share a date, please advise me on why the regulation is so delayed and an estimated timeline.

Response: FDA is giving high priority to completing this rulemaking. FDA remains committed to establishing a science-based regulatory category for over-the-counter hearing aids that provides reasonable assurance of safety and effectiveness while promoting access to devices that will help address a significant public health need. As you know, FDA issued the proposed rule "Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids" on October 19, 2021. We received over 1,000 public comments on the proposed rule and the Agency is reviewing them carefully. FDA is working expeditiously to issue the final rule by the current statutory deadline of July 17, 2022.

Question 168:
The COVID-19 pandemic has made clear the need to strengthen the nation's pandemic preparedness position. One key federal asset remains the Strategic National Stockpile, which I'm happy to see the Administration has prioritized for much-needed additional funding in its FY22 budget request. One of the most anticipated threats we face is that of pandemic influenza, and

[34] https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html
[35] https://www.aami.org/st91

we must address existing vulnerabilities to be adequately prepared. To mitigate this risk, the agency must prioritize replenishment and diversification of the stockpile, in addition to adequate funding levels for the SNS.

a. Mr. Secretary, what is the Agency's approach to evaluating the nation's existing stockpile and ensuring that additional funding is used for diversification as well as replenishment of expired critical medical supplies?

Response: Under statutory requirements, HHS is required to annually assess SNS holdings and inventory as part of the SNS Annual Review. HHS is in the process of conducing the review and will provide the findings to Congress upon completion.

b. Mr. Secretary, how is the Agency approaching the need to modernize the SNS in order to be prepared for the next pandemic event?

Response: In his first week in office, President Biden signed Executive Order 14005, Ensuring the Future is Made in All of America by All of America's Workers, launching a whole-of-government initiative to strengthen the use of federal procurement to support American manufacturing. Specifically, Section 1 of EO 14005 states that the federal government "should, consistent with applicable law, use terms and conditions of Federal financial assistance awards and Federal procurements to maximize the use of goods, products, and materials produced in, and services offered in, the United States." Section 1 further states that the federal government "should, whenever possible, procure goods, products, materials, and services from sources that will help American businesses compete in strategic industries and help America's workers thrive."

The SNS has adhered to EO 14005 while using supplemental funding to vastly increase its inventory of PPE, ancillary medical supplies, pharmaceuticals, and ventilators to meet the national demand. Funds continue to increase production capacity of PPE and other medical supplies and treatments for acquisition into the Stockpile and to support product distributions to impacted States.

Question 169:

FDA has stopped most foreign inspections since COVID-19 began. We are now more than one year into the pandemic and FDA still has not articulated when they will resume foreign inspections.

a. Mr. Secretary, what are the main barriers for FDA to resume foreign inspections?

b. Mr. Secretary, why isn't FDA able to work through the backlog of inspections when other developed countries have been able to make progress on this issue?

Response to a-b: The safety of FDA's investigative staff is of upmost importance. FDA evaluates the current travel restrictions and advisories, working closely with the U.S. State Department in making these decisions. Note that foreign inspections continue to be performed by staff in FDA's offices in China and India when possible.

The continuing global pandemic presents significant challenges to FDA's return to foreign oversight work. Foreign inspection trips must now account for known country quarantine requirements as well as the prospect of unknown confinement due to a positive COVID-19 test while on travel or a change in travel restrictions. In addition, reduced access to healthcare for FDA staff in foreign countries remains a concern. Despite these challenges, FDA has conducted all mission-critical oversight work throughout the pandemic, including in foreign countries. FDA has also enhanced its collaboration and reliance on information from trusted foreign regulatory partners through mutual recognition agreements and other confidentiality agreements, to support regulatory decisions.

Question 170:

I'm concerned that FDA is reluctant to embrace technology to address the backlog of facility inspections. FDA published guidance on remote interactive inspections last month, but the Agency says these tools are not equivalent to inspections. Situations such as COVID-19 are exactly the most appropriate time for FDA to use the tools provided to them by Congress to perform remote inspections.

Mr. Secretary, why is the FDA unwilling to use these tools in lieu of inspections?

Response: During this worldwide public health emergency, FDA has used a variety of tools to oversee facilities that manufacture FDA-regulated products. These tools include record requests in advance of or in lieu of a drug facility inspection, relying on information from trusted regulatory partners, and remote interactive evaluations (such as remote livestreaming video of operations, teleconferences and screen sharing). The Agency has used some or all of these approaches in lieu of inspections to evaluate facilities for human and animal medical products during the public health emergency when inspections of drug facilities were not possible due to travel or quarantine restrictions.

Inspections are an important tool to keep Americans safe, and are part of a set of tools used for regulatory oversight. As part of the wide variety of tools we have deployed during the COVID-19 pandemic, remote interactive evaluations have informed the FDA's regulatory decision-making, contributed to ensuring drug quality and helped determine the scope, depth and timing of future inspections. By necessity, the Agency has adapted by conducting more remote interactive evaluations throughout the public health emergency and are continuing to expand their use as appropriate.

FDA recognizes that remote interactive evaluations do not replace inspections, and that there are situations where only an inspection is appropriate based on risk and history of compliance with FDA regulations. Within the exceptional context of a global pandemic, the Agency sees remote interactive evaluations as part of a necessary strategy to evaluate medical product facilities by using all available approaches to ensure the medical products we regulate are safe, effective and of high quality.

On April 14th FDA released guidance to describe how the Agency will request and conduct voluntary remote interactive evaluations at facilities where drugs are manufactured, processed, packed, or held; facilities covered under FDA's Bioresearch Monitoring (BIMO) program; and outsourcing facilities registered under section 503B of the FD&C Act for the duration of the COVID-19 public health emergency. More info on this guidance can be found at this website: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remote-interactive-evaluations-drug-manufacturing-and-bioresearch-monitoring-facilities-during-covid.

FDA intends to make optimum use of its oversight tools, including use of tools that may be alternatives to inspections, such as those described in the agency's April 2021 Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency, Guidance for Industry.

Question 171:
The Qualifying Payment Amount (QPA) is a critical part of the No Surprises Act, as in most cases, it is the basis for calculating a patient's cost sharing responsibility. Additionally, it is one of the explicit considerations of an arbiter in the Independent Dispute Resolution process. In 2019 and 2020, Congress expressly rejected the "benchmarking" approach to surprise medical bills.

Mr. Secretary, will you ensure that physicians' fixed and variable costs, as well as overhead and uncompensated care amounts, will be considered as factors in IDR so the QPA does not become the de facto "benchmark" amount?

Question 172:
The No Surprises Act does not give any additional weight to the QPA in determining a fair payment amount than any of the other considerations listed in the act. If the drafters had intended one consideration to have more weight, they would have stated as much. Some within the healthcare space have encouraged HHS to make the QPA into a benchmark, even going so far as to recommend penalizing arbiters that deviate from the QPA in their final determinations.

Mr. Secretary, do you agree that this concept is outside of the statutory authority granted through the No Surprises Act? Do you agree that it does not comport with Congressional intent?

Question 173:
It is critical that health plans furnish sufficient, timely and accurate information on the Pts in network cost sharing based (with clear delineation of deductible and co-insurance amounts) based on the QPA and that they do so as required under existing regulations via the 835-remittance advice and ANSI remark codes within 30 days of the claim filing. Plan type requirements should also be communicated timely and accurately to the physicians in the 835-remittance advice including whether an ERISA plan is subject to federal or state law; otherwise, compliance by the physicians with the patient protections of the NSA will be futile.

Mr. Secretary, how will you ensure that health plans provide adequate information on network cost sharing?

Question 174:
The NSA statute is clear that no later than 30 days after the claim is submitted to the health plan that the plan must issue an initial payment or denial.

Mr. Secretary, how will you protect physicians' patients in the event that health plans fail to respond to the assertion that the claim is considered de facto accepted by the health plan?

Question 175:
According to a 2020 study from Guidehouse, "25% of rural hospitals nationwide are at a high risk of closing unless their financial situations improve. Of these hospitals, 82% are considered highly essential to their communities." Many of these same financial pressures affect minority and underserved communities in urban areas as well.

a. Mr. Secretary, do you believe your agency has sufficiently considered the effects of regulatory policy on access to care related to the No Surprises Act on these at-risk communities?

b. What safeguards are you building into the data insurers use to calculate the QPA to ensure they accurately reflect the total median amount of their in-network payments?

c. Are you effectively accounting for non-rate-based payments like volume and quality incentives?

d. How do you plan to ensure those already marginalized by our healthcare system aren't further taken advantage of by ever narrowing networks and dwindling access to care?

Response to Questions 171-175: I thank you and other Members of Congress for your leadership to eliminate surprise billing from our health care system by passing the No Surprises Act. Patients and their families deserve the security of knowing that the insurance they buy will be there for them when they need it. Patients who receive emergency care at an out-of-network hospital or with an out-of-network provider should never have to worry about paying large out-of-network bills. HHS is working hard, together with our colleagues at the Departments of Labor, the Treasury and the Office of Personnel Management to implement this critical legislation effectively and in a timely manner. The Departments are committed to engaging in a thoughtful rulemaking process to minimize unintended consequences of the new law. However, as we continue implementation, the Departments will continue to update you and your staff on this critically important law.

Question 176:
The use of spread pricing by pharmacy benefit managers is an egregious practice, especially in the taxpayer-funded Medicaid managed care program. To stop PBMs from playing these pricing games that enable, Medicaid managed care programs could implement a "pass-through" model, which includes a transparent benchmark based on National Average Drug Acquisition Cost (NADAC) and a commensurate dispensing fee like those in Medicaid fee for service programs. Under a pass-through pricing model, PBMs are paid an administrative fee, which is the only

source of revenue under the contract, thus avoiding any costly PBM spread. The Congressional Budget Office (CBO) has estimated this bipartisan policy, which was included in both House and Senate drug pricing reforms last Congress, would save $1 billion over 10 years.

Mr. Secretary, does this Administration support such legislative reform to eliminate spread pricing, provide transparency in drug pricing, and protect taxpayer dollars in Medicaid programs?

Response: Like President Biden, I believe we must do all we can to lower the costs of prescription drugs, increase transparency in drug pricing, and make prescription drugs more accessible for Americans. We are open to any ideas that could help us move toward these goals and we welcome input from stakeholders and the public. I look forward to working with you to make sure Americans have access to the drugs they need at prices they can afford.

Question 177:

Generic injectable overdose agents have been available for several years, and FDA is doing all it can to encourage additional entrants to the market, yet the FTC has previously said "too much transparency can harm competition in the market." The FTC has expressed concern "when information disclosure allows competitors to figure out what their rivals are charging, which dampens each competitor's incentive to offer a low price."

Mr. Secretary, wouldn't requiring a whole host of new reporting requirements, particularly of sensitive business information that would impact competitive dynamics impede companies from wanting to enter the market?

Response: Competition in the market has helped control the growth in spending on prescription drugs. I believe that generic drugs and biosimilars have a role to play in containing the cost of innovative yet expensive therapies by creating competition. Like President Biden, I believe we must do all we can to help lower the costs of prescription drugs and make them more accessible for Americans who depend on these medications for their health.

I commit to addressing substance use disorders, including supporting programs and initiatives across the continuum of prevention, treatment, and recovery support services; working to address stigmatization often associated with these conditions; and strengthening enforcement of this country's mental health parity laws.

Question 178:

Secretary Becerra, as you and your team look for solutions to address increasing health care costs, I want to call to your attention a letter dated November 25, 2020, (attached) addressed to HHS's Food and Drug Administration from numerous doctors of leading academic institutions highlighting a significant cost pressure that hospitals will soon face as a result of a lack of competition in the blood platelet market which impacts hospitals in all of our districts. I've long been a proponent of choice and competition across health care services and would ask that we discuss this matter and what can be done to provide choice and competition in the blood supply market for hospitals in preparation for compliance, without any further delay, with Docket No. FDA-2014-D-1814, "Bacterial Risk Control Strategies for Blood Collection Establishments and

Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Final Guidance," September 2019.

Response: The COVID-19 pandemic has underscored the importance of maintaining an adequate blood supply. FDA is aware of the unique operational and inventory challenges in various hospital settings. FDA's recommendations present blood collection establishments and transfusion services options for complying with FDA's regulations to reduce the risk of bacterial contamination of platelets. I look forward to working with you on these efforts.

The Honorable Neal Dunn, M.D. (R-FL)

Question 179:
As the Administration continues work to fill the FDA commissioner position, I wanted to bring to your attention a concern I have at the FDA related to compounding pharmacies and the patients they serve. Last year, FDA finalized an MOU on interstate distributions of compounded drugs that States have until October 26 of this year to sign. Pharmacy and physician stakeholders and state boards of pharmacy have been raising concerns about the MOU, including concern over FDA not undertaking rulemaking before finalizing the MOU.

It is my understanding that several states, including my home state of Florida, have state laws on confidentiality that would make it impossible for the states to sign and comply with the MOU without a change in the law by the legislature. As you know, pharmacies in states that cannot or will not sign the MOU will be capped at shipping no more than 5 percent of their compounded drugs interstate, jeopardizing access for the patients they serve and causing unnecessary economic damage to the pharmacies. It is my understanding that the major national pharmacy organizations (APC, NCPA, APHA, NASPA), who are assisting state boards of pharmacy in complying, have asked FDA to delay enforcement of the MOU for two years so that these issues at the state level can be resolved.

Is it your intent to direct FDA to give consideration to this request?

Response: Thank you for noting your concerns with the final standard Memorandum of Understanding entitled "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [insert State Board of Pharmacy or Other Appropriate State Agency] and the U.S. Food and Drug Administration" (final standard MOU) and extending the period for states to decide whether to sign the final standard MOU. As of May 12, 2021, FDA provided until October 27, 2021, for states to consider signing the final standard MOU before FDA intends to enforce the statutory five percent limit on distribution of compounded human drugs out of the state in which they are compounded in states that do not sign the final standard MOU (five percent limit). FDA provided this one-year period as we understood, based on comments from stakeholders, that this timeframe should correspond to a full legislative cycle for most states and allow time for states to modify their laws and regulations, if necessary. FDA appreciates the critical role pharmacies play in the U.S. healthcare system, and we recognize the need to preserve patient access to compounded drugs for patients who have a medical need that cannot be met by an FDA-approved drug product.

FDA has received requests to extend the period of time before the Agency intends to enforce the statutory five percent limit. FDA is actively considering the requests for extension of this period. States may sign the final standard MOU at any time, including after the Agency will begin to enforce the five percent limit. FDA plans to continue active, direct engagement with state entities considering signing the final standard MOU to address their questions and concerns.

Question 180:

Last year, in response to the pandemic, CMS issued a series of waivers of Medicare rules. Among the rules waived was the Medicare anesthesia supervision rule – a rule that provides for physician oversight of anesthesia services for Medicare beneficiaries. I have received inquiries from my local Florida anesthesiologists concerned about the permanent waiver of this patient safety requirement.

What is the status of this waiver and what considerations will CMS give to deciding whether to end the waiver or make it permanent?

Response: In response to the COVID-19 public health emergency, CMS issued a blanket waiver of the requirements under 42 CFR §482.52(a)(5) (hospitals), §485.639(c)(2)(CAHs), and §416.42(b)(2)(Ambulatory Surgical Centers (ASCs)) that a certified registered nurse anesthetist (CRNA) be under the supervision of a physician. Under the waiver, CRNA supervision will be at the discretion of the hospital and applicable state law. These waivers have allowed CRNAs to function to the fullest extent of their licensure, and may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. CMS continues to review the need for existing emergency blanket waivers issued in response to the COVID-19 public health emergency, and I look forward to working with you on this issue.

Question 181:

As you are aware, Congress passed the No Surprises Act at the end of 2020 as part of the Consolidated Appropriations Act for Fiscal Year 2022. This policy will hold patients harmless in the event of medical billing disputes between providers and payors. It is important that HHS implement the law's patient protections as Congress intended and that the independent dispute resolution process is balanced and does not benefit one party over the other.

a. The No Surprises Act requires the arbiter for surprise medical bills to weigh all factors evenly, including the median in-network rate. Still, there is concern in the provider community that the Administration could use the rulemaking process to give preference to the median in-network rate, which would act as a de facto price control that would harm doctors and hospitals and is not in line with Congressional intent. Can you commit to following the law and ensuring that all rules and regulations pursuant to the No Surprises Act do not give any favor to the median in-network rate?

b. Evidence from states like New York and Texas that have enacted arbitration/IDR models to resolve surprise medical bills shows that both patients and health care providers have seen reduced costs. Given these successes, what steps are you taking to ensure that the No Surprises Act (which enacts a robust and fair IDR system) will result in the same

outcomes on the federal level?

c. How will you ensure that HHS's rulemaking process does not result in rate-setting, i.e., the federal government setting prices for health care providers, which would inevitably result in reduced access for patients?

d. Congress rejected proposals to institute a "benchmark" that would have let the federal government set prices for health care providers in favor of the IDR process to settle payment disputes. As you know, HHS is tasked with rulemaking and implementation, along with the Departments of Labor and Treasury. What steps are you taking during the rulemaking process to ensure that our nation's health care providers are not negatively impacted by HHS rules and regulations set forth in the law?

e. Can you commit that HHS will undertake a full and transparent rulemaking process for No Surprises Act, including at least a 60-day comment period that allows stakeholders to share their views with the Department?

f. Please detail the work underway at HHS to implement the No Surprises Act.

g. Does HHS expect to meet all statutory deadlines for regulations it is tasked with writing pursuant to the No Surprises Act?

Response: HHS is working collaboratively with the Department of Labor, the Department of the Treasury, and Office of Personnel Management to ensure that the No Surprises Act is implemented in a timely and effective manner, and in accordance with statutory deadlines. The Departments will look to state experiences, among other factors, to help inform upcoming rulemaking. HHS, along with the other Departments, are hard at work implementing the more than 35 provisions included in the No Surprises Act and Title II Transparency Provisions.

Question 182:

The safe resumption of the United States cruise industry is an issue important to my home state of Florida. I am encouraged by some of the recent activity - CDC's April 26th letter is a significant step forward, recognizing that vaccinations are a game changer. It is encouraging that CDC is working toward a shared goal with the industry of resuming sailing by July 15th. Not only are more than 400,000 jobs supported by the US cruise industry, cruising also represents a much loved and much needed vacation ritual for more than 14 million Americans each year. Given vaccination and the state-of-the-art public health standards developed by leading national experts on the Healthy Sail Panel, cruising can resume safely.

However, I worry that if the April 26th letter was a step forward, the May 5th guidance moves us backward. Although CDC acknowledged on April 26th that vaccination makes a difference, the May 5th guidance doesn't carry through that acknowledgement. This guidance would require cruise guests at outdoor swimming pools to wear masks, for example. The same requirement does not apply to land-based swimming pools, even though there is no similar guarantee that

swimmers at your neighborhood pool will be vaccinated. Diners on board cruise ships will have to be masked between courses – local restaurants don't face that same requirement. Basically, cruises will face significantly tougher requirements than land-based resorts, yet cruise passengers will have to be vaccinated and resort guests will not. It seems as though the guidance could be further revised to reflect the more nuanced approach to masking requirements for vaccinated populations that CDC has released for other activities. I understand it takes 90 days to return a ship to service. Cruise lines are moving forward now to meet the July 15th target.

Final guidance is needed so cruise lines know the rules and customers know what they are buying. It is time for clarity and common sense. Can I count on you to work with the cruise industry to address these remaining issues in a timely and transparent way?

Response: CDC is committed to working with the cruise industry and seaport partners to resume cruising following the phased approach outlined in the Conditional Sailing Order (CSO). This goal aligns with the prospective resumption of passenger operations in the United States, as outlined by many major cruise ship operators.[36]

Question 183:

I believe that we can work to lower health care costs through improved transparency and increased competition, not a one-size-fits-all Medicare-for-All, which would kick millions off of private coverage & put the government in charge. The Trump Administration's hospital price transparency rule accomplishes the goal of price transparency and empowering consumers, which will drive competition. However, I am concerned by what I am seeing thus far on the compliance front. I was glad to learn that CMS sent warning letters out to hospitals in violation of the rule.

a. Can you speak to any other efforts to ensure enforcement of the rule & usability of the pricing data?

b. Will you commit to continued enforcement of this rule and to work with Congress should CMS need more authority to make this pricing data more useful for patients and employers?

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

Hospital price transparency helps people know what a hospital charges for the items and services it provides. CMS expects hospitals to comply with all federal requirements, including those regarding price transparency. CMS will provide additional implementation and enforcement details regarding hospital price transparency requirements in future rulemaking.

[36] CDC's Temporary Extension & Modification of Framework for Conditional Sailing Order (CSO) expired on January 15, 2022. CDC recommends that cruise ships operating in U.S. waters choose to participate in CDC's COVID-19 Program for Cruise Ships.

The Honorable Dan Crenshaw (R-TX)

Question 184:
The U.S. response to COVID-19 demonstrated significant vulnerabilities in our nation's preparedness against emerging and unknown threats. While we must work in the coming months to combat COVID-19, there are still very real chemical, biological, radiological, and nuclear (CBRN) threats that continue to put the nation's security at risk. In his worldwide threat assessment testimony, former Director of National Intelligence (DNI) Coats said, "the threat from biological weapons has also become more diverse as bio-warfare agents can be employed in a variety of ways and their development is made easier by dual-use technologies." Rapid advances in technology make it possible to create biological weapons in a lab and increase the risk of re-emergence of threats like smallpox, which killed an estimated 300 million people in the 20th century before it was eradicated.

We can't take our eye off long-standing CBRN threats, or jeopardize preparedness against them, despite HHS' intense focus on COVID-19.

a. Will you commit to ensuring key preparedness and response agencies at HHS – specifically ASPR and BARDA – focus not only on defeating COVID, but also on the full scope of their missions to protect the American public?

   Response: Yes. Supporting continued efforts at broad preparedness for public health and medical threats is critical to ensure we are best protected for whatever threats come next. I am working diligently to ensure programs are supported, as needed, to continue missions.

b. ASPR and BARDA have a proven track record over the last 15 years in developing medical countermeasures (MCMs) against CBRN threats. What will you do to ensure ASPR/BARDA have the resources necessary to continue critical MCM development programs for CBRN threats like smallpox?

   Response: Supporting continued efforts at broad preparedness for public health and medical threats is critical to ensure we are best protected for whatever threats come next. I am working diligently to ensure programs are supported, as needed, to continue missions.

c. How much is currently available at BARDA to support new awards and options in existing development contracts?

   Response: For Fiscal Year 21, Congress provided BARDA with $364.6 million to support advanced research and development of medical countermeasures. We are appreciative of the funding provided and look forward to working with Congress to articulate program needs and requirements for future investments.

d. What products development contracts are in danger of failing because of the interruption due to insufficient funds?

Response: For Fiscal Year 21, Congress provided BARDA with $364.6 million to support advanced research and development of medical countermeasures. We are appreciative of the funding provided and look forward to working with Congress to articulate program needs and requirements for future investments.

Question 185:

In addition to the considerable challenge of managing and controlling the COVID-19 pandemic and preparing for unknown future pandemics you must ensure that we are better prepared for a known threat we face every year: seasonal flu.

The SNS has recognized for a number of years that the flu antivirals stored in the stockpile are well past their expiration date. Although these products have been extended under the DoD/FDA Shelf Life Extension Program ("SLEP"), there are inevitable issues arising from reliance on product labeled as 10-15 years expired. For this reason, the SNS undertook a five-year plan to replace a significant portion of the expired product with fresh, currently approved product and modernize its distribution system with inventory management capabilities leveraging serialized product with track and trace capabilities.

Secretary Becerra, my questions for you relate to your level of commitment to assuring the nation becomes prepared over the next several years to manage the threat posed by influenza.

a. Did the Administration's decision to reprogram money from the SNS's Strategic National Stockpile, Title II—Department of Health and Human Services, ASPR, Preparedness and Response account result in a decision to not make a flu antiviral replenishment purchase for this fiscal year?

Response: Due to the overall appropriated funding level for the SNS in FY21, $705 million, decisions were made on how to best utilize funding and support advancement of requirements to best protect the population. The decision to not utilize funding to procure significant additional quantities of flu antivirals was not a result of any specific funding transfer. Further, many holdings of flu antivirals fall under the FDA Shelf Life Extension Program. Using this program, we are able to ensure best use and holding of product as well as support cost effective measures for overall inventory.

b. Please indicate the time period during which HHS plans to replenish our antivirals stockpile, or if the agency has determined that it is no longer necessary to replenish the aging stockpile?

Response: HHS continues to evaluate a timeline for replenishment of expiring antivirals and the addition of new antivirals to the SNS in light of existing resources and competing priorities. In the meantime, SNS is working closely with FDA to maximize the shelf-life of products currently held by SNS.

c. Please describe and share any discussion and analysis the agency has conducted to assure preparedness in light of the expected recurrence of flu once COVID-19 restrictions have been lifted.

Response: Supporting continued efforts at broad preparedness for public health and medical threats is critical to ensure we are best protected for whatever threats come next. I am working diligently to ensure programs are supported, as needed, to continue missions.

Question 186:

Congress has been asking some questions and E&C Members have expressed an interest from last week's hearing to further address the suspense of AOI 8.3, 9.3 and 9.2 by the advanced development agency BARDA for COVID-19.

Can you provide me with the vaccines that were developed by BARDA since June 2020 versus those BARDA was used to acquisition? In addition, could you provide me with the therapeutics that BARDA developed for COVID-19 versus those BARDA was directed for acquisition since May 2020?

Response: In the spring of 2020, BARDA evaluated, selected and funded Moderna, Janssen, Merck, and Sanofi for development of COVID-19 vaccines. Subsequently, beginning in late spring of 2020, BARDA and DoD's JPEO partnered to develop vaccines and therapeutics, first as part of OWS, and subsequently under the CAG. This was a joint effort with JPEO providing the contracting and legal expertise and BARDA providing the scientific and program management expertise. Negotiations were a joint effort with both JPEO and BARDA involved. Under this partnership, additional advanced development and procurement or just procurement contracts were awarded to Pfizer, AstraZeneca, Janssen, Moderna, Sanofi, and Novavax. In all cases, regardless of whether the contract was directly awarded by BARDA or in collaboration with JPEO, or under the auspices of OWS or the CAG, each contract/project was managed by a BARDA led Project Coordination team supporting clinical, regulatory, manufacturing and delivery.

Question 187:

While we cannot speak to allocation estimates derived by entities outside of HHS, we can explain what is new about the LIHEAP funding allocation methodology in light of the ARP, compared to prior years. Congress typically directs HHS to use a hybrid allocation formula each year which runs part of the funding through the 1981 statutory methodology and part through the 1984 statutory methodology. Up until this year with the receipt of the ARP funding, the amount of funding that Congress directed HHS to run through the 1984 methodology fell below the $1.975 billion statutory threshold for running the 1984 formula. Therefore, in those years, HHS had to inflate each state's 1984 calculations by $1.975 billion in order to run the statutorily required hold harmless calculations that are part of the 1984 methodology. Once the determinations are made as to the hold harmless provisions, HHS removes the $1.975 billion from the 1984 formula portion in order to arrive at the final 1984 allocation amounts for each state. Typically, in such years, several states receive $0 through the 1984 methodology because their portion is reduced to account for the smaller states protected by the hold harmless

provisions. The states that now received a part of the 1984 funding portion because of the ARP funding, as opposed to the FY 2021 appropriation alone, include: Illinois, Indiana, Iowa, Maine, Michigan, Minnesota, New York, Pennsylvania, and Wisconsin.

With the ARP legislation, Congress directed $2.25 billion to be awarded in FY 2021 via the 1984 methodology. Therefore, HHS did not need to run the adjustment procedure in order to carry out that portion of the allocation calculation. The result is that now every state receives some portion of the 1984 funding amount, which means that a few states are receiving less of the 1984 portion than they otherwise would have this year if the 1984 funding amount had been less than $1.975 billion. Those states that saw a decline in what their 1984 funding amount this year would have been if not for this change included Texas, Arizona, Nevada, and Florida."

Further, the funding allocations for the LIHEAP program projected for each state in the American Rescue Plan Act vary significantly from the amounts actually provided to states. This is especially the case in states that rely on the program's funding to reduce the burden of cooling costs. In the American Rescue Plan Act, these states received considerably less than projected under a 50/50 split between LIHEAP's "old" and "new" formulas. These discrepancies are a prime example of the difficulties states face due to the uncertainly and unpredictability of LIHEAP funding, which often leads to states inadequately administering program dollars to their most vulnerable populations.

What was the methodology behind how HHS/ACF allocated ARP LIHEAP funds, and would you please discuss the source of divergence from previous projections?

Response: The methodology behind how HHS/ACF allocated ARP LIHEAP funds consisted of the following:

(1) Determining the distribution at the total appropriated by the FY21 Continuing Appropriations Act (FY21 CAA) + ARPA (i.e., $8,250,304,000, which includes the $3.5 million set aside for T&TA and the $5,236,804,000 to be run through the 1981 methodology); and
(2) Backing out the distribution of the $3,750,304,000 appropriated by P.L. 116-260.
According to this methodology, Congress directed $3.01 billion to be awarded through the 1984-Formula. This figure comes from $760 million from P.L. 116-260 + $2.25 billion from ARPA. This amount obviated the $1.975-billion-inflation-and-removal method by causing states and tribes to receive more than $1.975 billion. This is because of because of the following:

- The relevant language in P.L. 116-260 called for appropriating funds (including LIHEAP) "for the fiscal year ending September 30, 2021[(i.e., fiscal year 2020)]"; and
- The relevant language in ARPA called for ARPA LIHEAP funds to be made "[…i]n addition to amounts otherwise available, there is appropriated for fiscal year 2021[…] $4,500,000,000[…] for additional funding to provide payments under section 2602(b) of the Low-Income Home Energy Assistance Act of 1981 (42 U.S.C. 8621(b))[…]".

The sources of Texas' divergence from previous projections consisted of the omissions of the following:

(1) The hold-harmless provision that held states and territories to 97 percent of their total FY20 awards and ratably reduced those remaining such grant recipients to 100 percent of those respective awards (i.e., the third hold-harmless provision); and

(2) The $1.975M augmentation-and-backout method in calculating the 1984-Formula portion.

HHS uses the $1.975M augmentation-and-backout process to calculate the 1984-Formula portion when the amount to be distributed to states and tribes through that portion falls below $1.975 billion. This wasn't the case of ARP, for which the 1984-Formula alone (and, thus, when combined with CAA) exceeded this threshold. By contrast, the previous projections explicitly omitted the third hold-harmless provision. They also employed the $1.975M augmentation-and-backout method in calculating the 1984-Formula portion because HHS had done so for the CARES Act (wherein the amount set aside for that portion was only $1,428,000,000 after including the amount called-for by the FY20 Continuing Appropriations Act (FY20 CAA)).

a. Are you committed to ensuring that LIHEAP is modernized in ways that ensure it is transparent, predictable, and equitable for all individuals who utilize the program to help make ends meet?

Response: HHS is committed to ensuring that LIHEAP is modernized in ways that ensure it is transparent, predictable, and equitable for all individuals who utilize the program to help make ends meet. HHS plans to ensure that the program is transparent by issuing the following materials:

- The report Reducing the Volatility in Annual State LIHEAP Allocations as a Result of the Statutory Formula, which the House Committee on Appropriations mandated in House Committee Report 116–450;
- The report An Assessment of the Program's Formula and Allocations of Funding Among States and report appendices, that evaluates the program's formula and allocations of funding among states, that was mandated by House Committee Print 38-679; and
- The report mandated by H. Rept. 117-96, which will detail LIHEAP's formula and state allocations from each source of funding for FY 2020 and FY 2021.

HHS believes that the best way to ensure that the program is predictable is by continuing to review the options for reducing volatility in annual state allocations. This will build on the review that HHS conducted on reducing the volatility in annual State allocations as a result of the LIHEAP formula for the report mandated by H. Rept. 117-96.

HHS plans to ensure that the program is equitable by gathering the data announced in LIHEAP DCL 2022-03 that shows the race, ethnicity, and gender of LIHEAP applicant-beneficiaries.

Question 188:

As HHS Secretary, you're housing UACs in large convention centers. As the AG of California, you rejected the Trump Administration's request for small and medium size state-licensed facilities to do the same thing. What changed?

Response: ORR has a legal and moral obligation to safely care for all unaccompanied children referred to ORR care. In addition to high referral rates from DHS in 2021, ORR faced a number of compounding challenges including the COVID-19 pandemic which forced approximately 40 percent of ORR's available bed capacity offline and compounded staffing challenges. Despite these challenges that strained ORR's network of standard bed capacity, ORR leveraged a whole-of-government approach to ensure children were moved quickly and safely out of crowded DHS border facilities.

Question 189:

Regarding the Texas 1115 waiver:

a. If not you, who made the decision to rescind the waiver?

b. What other options did you pursue before pursuing the most dramatic option: rescinding the entire waiver?

c. If Texas resubmits the waiver, can you guarantee that they will be successful?

Response to a through c: The partnership between states and the federal government is central to Medicaid, and the Biden-Harris Administration is committed to working with states to strengthen this vital program. HHS is committed to supporting state innovation and states' ability to test different models that meet the unique needs of their residents and to ensuring open, and timely communication with our state partners. Medicaid is an important source of coverage for many American families. It is important that states' Medicaid section 1115 demonstrations promote the objectives of the Medicaid program and that their Medicaid section 1115 demonstration applications comply with the requirements of section 1115 and its implementing regulations.

I agree that states need certainty and predictability from the federal government, and it's important that HHS continue to work closely with states to help them explore ways to address the unique needs of their residents. We look forward to continuing to work with Texas.

The Honorable John Joyce, M.D. (R-PA)

Question 190:

We have seen the rate of daily vaccination in the United States continue to reach a plateau. By some experts' estimation it could take as long as three months for us to reach herd immunity assuming we keep the current pace. The development of cutting-edge therapeutics and new vaccines to combat variants of COVID 19 will remain critical in the coming months and years. For this reason, Congress has provided BARDA with more resources to this end, however, we

have heard that these activities remain stopped and this funding has not yet made it to the agency. Why is this the case and will your office commit to working with this subcommittee to rectify this matter?

Response: To date, approximately $2.3 billion from the American Rescue Plan (ARP) has supported investments in therapeutics at HHS. Since January 2021, the federal government has invested in development of multiple therapeutic candidates. We commit to keeping Congress informed of these activities. In addition, information is posted in real-time as products come online and are approved for use. (https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/default.aspx). Development of these candidates have benefited from funding of NIH's ACTIV trials.

Question 191:
Have any public health officials from the administration traveled to the border to review the conditions at ORR, CBP, or other border facilities to assess their safety from a public health perspective? If yes, please disclose who, when, and which facilities were visited.

Response: Yes, I have visited a number of ORR UC shelters, including shelters in ORR's state licensed network as well as temporary sites. During these visits I talk with staff and children as appropriate. HHS has a legal and moral obligation to provide safe and appropriate care for all children referred to us by DHS while we work to unite them with a safe and vetted sponsor. I am committed to carrying out this obligation. Since March 2021, the Centers for Disease Control and Prevention (CDC) have worked diligently to monitor COVID-19 cases among UC both on the ground at ORR facilities, including EISs, and remotely. CDC continues to support the implementation of measures to reduce and prevent the spread of COVID-19.

Additionally, United States Public Health Service (USPHS) Commissioned Corps. Officers have deployed to EIS and continue to provide health expertise to support ORR's mission. USPHS officers assist in weekly health and safety meetings with EIS facilities to help quickly elevate and address any health and safety concerns.

The Honorable Paul Tonko (D-NY)

Question 192:
As you know, the 340B Drug Pricing Program enables eligible hospitals across the country — including more than 100 hospitals in my home state of New York — to purchase outpatient pharmaceuticals from drug companies at a discounted rate. These hospitals use the savings to provide greater access to needed drugs and more comprehensive services in their communities.

Like many hospitals throughout the country, 340B hospitals in my district have experienced significant changes in their volume as a result of the COVID-19 pandemic, leading to financial and operational challenges that have altered their payer mix, placing their eligibility for this crucial program at risk. I am concerned how this will impact hospitals in my district such as St. Mary's and their ability to best serve the community. In one survey, 35 percent of hospitals reported their DSH adjustment percentage is going down as a result of service to COVID-19

patients. Twenty-one percent of those surveyed reported they are "extremely" or "very" concerned that they will lose their 340B eligibility.

Is this an issue that HHS is monitoring and will HHS step in if hospitals lose their 340B eligibility?

Response: The 340B Drug Pricing Program is an indispensable program for our safety-net providers serving some of our neediest populations. I look forward to working with you and other Members of Congress to uphold the law and ensure this vital program is able to support vulnerable communities.

The Honorable Kathleen Rice (D-NY)

Question 193:
Mr. Secretary, I am very concerned about the impact of a new policy that in some circumstances limits an individual hospital's Medicaid DSH payments. The new policy modifies the Medicaid DSH cap calculation to remove from the payment shortfall calculation the financial losses and gains for services provided to Medicaid dual-eligible enrollees. In my state, that group mostly consists of Medicare and Medicaid beneficiaries — the poor elderly.

This new policy will result in a steep reduction of critical Medicaid DSH supportive funding for public hospitals in my district and across the state. For example, in my district, Nassau University Medical Center is expected to see a cut of more than $20 million a year. A devastating blow for hospitals that already operate on thin to negative margins.

Mr. Secretary, will you work with me and my colleagues whose public hospitals, the most vulnerable in our districts, are harmed by this policy to find a way to mitigate these unintended consequences?

Response: Medicaid Disproportionate Share Hospital payments help hospitals provide care to low-income patients and the uninsured, and I know that this pandemic has placed significant pressure on safety net health care providers. I look forward to working with you and other members of Congress to ensure CMS is supporting safety net providers and the work they do on behalf of their patients, while complying with the requirements set forth in federal law.

Question 194:
Last year, Congress passed the CARES Act, which allocated $100 billion to the Public Health and Social Services Emergency Fund for the sole purpose of reimbursing healthcare providers for COVID-19-related expenses or lost revenue attributable to the pandemic. We added more funds in subsequent bills to help keep our health system afloat. These resources, referred to as the Provider Relief Fund, served as a lifeline to our hospitals and health systems that were at the epicenter of the national COVID-19 outbreak.

The ongoing pandemic and numerous factors outside of healthcare providers' control are preventing some providers from using their Provider Relief Funds before HHS's June 30 deadline.

Will you consider extending the June 30th deadline? I recommend extending it to 90 days after the public health emergency terminates.

Response: Please note that PRF recipients may use payments for eligible expenses or lost revenues incurred prior to receipt of those payments (i.e., pre-award costs) so long as the funds are to prevent, prepare for, and respond to coronavirus. It is the obligation (or incurred) date that determines whether the expense is an allowable cost, not the date of possession. If the purchase occurred within the period of availability, but the item was received after the period of availability, it would still be considered an allowable cost. The provider will need to maintain adequate supporting documentation to show that the expense is attributable to coronavirus and was incurred within the period of availability. Providers must retain supporting documentation for three years.

Question 195:

The United States has done a tremendous job making the COVID-19 vaccines available to Americans and getting shots in arms, but many Americans have lingering questions about the vaccine. For those people who are hesitant to get the COVID-19 vaccine, trust remains the critical issue, and these people are often most effectively reached by their personal physician. In fact, in a Harris poll from January, a majority of Americans said that family doctors are most trusted to say when it's safe to get the vaccine. These practitioners are also experienced in and optimally positioned to address, contextualize, and correct information fueling vaccine hesitancy that patients might access through their own research.

a. How has the administration engaged with physicians in distributing the COVID vaccines?

b. Are you considering a bigger role for family and personal physicians as we work on reaching Americans who have chosen not to receive the vaccine?

Response to a-b: CDC has engaged in regular communication with clinical societies, such as the American Medical Association (AMA), American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP) to disseminate messaging and answer provider questions related to the COVID-19 vaccines. CDC also disseminates evidence-based health information and public health emergency messages to clinicians through the Clinician Outreach and Communication Activity (COCA) network and the Health Alert Network (HAN) which serves a wide range of clinical professionals, including physicians, nurses, physician's assistants, pharmacists, paramedics, veterinarians, epidemiologists, public health practitioners, and state and local health department officials. In addition, COCA collaborates with national clinician organizations, which in turns allows for extended outreach to a large number of clinicians. For as long as vaccines have been available, there has also been misinformation and concerns. Every new vaccine, regardless of disease, will be accompanied by questions, concerns, and misinformation. We can effectively foster vaccine confidence and address those concerns and misinformation by building trust, which takes dedicated time and effort. Engaging in outreach efforts and partnering with

trusted advocates in communities are central to our national and international vaccine confidence effort.

Note: Responses are provided as of the date of the hearing, May 12, 2021.