April 20, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

Thank you for appearing before the Subcommittee on Health on Wednesday, March 29, 2023, to testify at the hearing entitled, "Fiscal Year 2023 HHS Budget."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Tuesday, May 2, 2023. Your responses should be mailed to Jolie Brochin, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Jolie.Brochin@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Brett Guthrie
Chair
Subcommittee on Health

cc: Anna Eshoo, Ranking Member, Subcommittee on Health

Attachment 1—Additional Questions for the Record

The Honorable Cathy McMorris Rodgers

Question #1

1. Dr. Tabak's current title is Senior Official Performing the Duties of the National Institutes of Health (NIH) Director.

a. How long has Dr. Tabak held this title?
b. What was Dr. Tabak's previous title?

HHS Response
Dr. Tabak has served as the Principal Deputy Director of NIH since 2010. In December 2021, he became the Acting Director of NIH for 210 days, in accordance with the time limitation for an acting officer established by the Federal Vacancies Reform Act of 1988 (FVRA).

c. How long does Dr. Tabak anticipate remaining in this current position, with the current title?

HHS Response
He plans to perform the duties delegated to him until the position of Director, NIH is filled. However, in accordance with the spring-back provision of the Federal Vacancies Reform Act, he will again serve as the Acting Director, NIH, upon the President submitting a nomination for the Director, NIH, position to the Senate.

d. Please explain the legal framework of Dr. Tabak's current position and role under the Federal Vacancies Reform Act,[1] as well as the legal timeline under which Dr. Tabak can maintain his role in its current capacity.

HHS Response
The Federal Vacancies Reform Act of 1998[2] applies to many Senate-confirmed positions in the Executive branch and allows certain officials to perform the duties of those positions when they become vacant in an acting capacity, subject to certain requirements and time limitations. The FVRA permits an acting officer to serve for a 210-day period prior to the submission of a nomination for the position. After that period expires, agency officials may still be delegated the authority to perform the delegable duties of the position but will no longer be the "Acting" official under the FVRA and cannot perform any non-delegable functions or duties of the vacant position.

e. Please explain, under current federal law, any exclusive or nondelegable duties that could not be performed by the "Senior Official at NIH performing the duties of the NIH Director."

[1] The Federal Vacancies Reform Act of 1998, Pub. L. 105-277.
[2] www.gsa.gov/cdnstatic/Vacancies_Reform_Act_1998.pdf

HHS Response
Effective July 15, 2022, Secretary Becerra delegated to Dr. Tabak all of the delegable functions, duties, and authorities of the position of the NIH Director to allow for the continuity of NIH's operations and fulfillment of the delegable duties and responsibilities of the NIH Director position in conformance with the FVRA, sections 3345 through 3349d of title 5, United States Code, for the period of time until the NIH Director position is filled permanently. In keeping with the requirements of the FVRA, Dr. Tabak ceased to be "Acting Director, NIH". Consistent with the Secretary's delegation of authority, Dr. Tabak was delegated all of the delegable functions, duties, and authorities of the position of the NIH Director.

Question #2

2. Recent reporting[3] shows the U.S. government may have double paid for projects at labs in Wuhan, China, for high-risk pathogen research through grants provided by NIH and United States Agency for International Development (USAID), at the expense of potentially tens of millions of U.S. taxpayer dollars. The FY 2024 budget requests $515 million for the HHS Office of Inspector General (OIG), including $117 million for an emergency preparedness, response, and recovery initiative and cybersecurity activities, among other things, and another $5 million to help find and return defrauded and misspent HHS funds.

a. Please explain any efforts or investigations the HHS OIG has considered or initiated related to these reports, either in tandem with USAID or separately.

HHS Response: HHS OIG performed an audit of NIH awards to EcoHealth during Federal fiscal years 2014-2021. The audit identified $8.0 million of funding that NIH awarded to EcoHealth and almost $600,000 that was subawarded to Wuhan Institute of Virology. HHS OIG found $89,171 of unallowable costs claimed by EcoHealth. Unallowable costs claimed by WIV and paid by EcoHealth under the NIH awards totaled $15,089 ($13,037 of unallowable indirect costs due to using an incorrect indirect cost rate and $2,052 due to an invoice that included a duplicate charge for in vitro study costs). During the audit HHS OIG engaged with USAID OIG and other OIGs to discuss any oversight work on EcoHealth and its subrecipients. HHS OIG continues to coordinate with USAID OIG as they monitor this issue.

Question #3

3. A recent JAMA analysis[4] confirmed an alarming trend regarding NIH-funded clinical trials' failures to both appropriately register, and ultimately publish, the results of these federally funded trials. In the FY 2024 budget, the Administration requested $48.6 billion for NIH, of which this is claimed to support over 44,000 research project grants, including over 10,000 new and competing grants. However, this recent analysis indicates the U.S. taxpayer may never see the results of these trials. Specifically for pediatric trials, less than two-thirds of the clinical trials studied were registered in advance on the federal database ClinicalTrials.gov. Just 13% of

[3] CBS News, U.S. government agencies may have been double billed for projects in Wuhan, China, records indicate; probe launched, March 17, 2023.
[4] JAMA Analysis, Dissemination of the Results of Pediatric Clinical Trials Funded by the US National Institutes of Health, Feb. 21, 2023.

finished trials were registered within 12 months of completion and almost half of trials did not have results published four years after completion of NIH funding. A recent HHS OIG[5] audit found that over half of clinical trials funded by the NIH failed to publicly report results during 2019 and 2020. Worse still, the NIH continued to fund new clinical trials by the same researchers who had failed to report findings. Since 2007, trial sponsors have been required under law to register studies on ClinicalTrials.gov within 21 days after the first human subject is enrolled and submit results within a year after the trial is completed. The failure to properly abide by these requirements raises serious concerns around transparency, efficiency, and financial responsibility.

a. Please explain what HHS is doing to enforce and ensure compliance to current reporting and publishing requirements to prevent a waste of our taxpayer funding.

HHS Response

NIH is committed to ensuring that clinical trials are registered and their results made public in a timely fashion.[6] All NIH Institutes, Centers and Offices (ICOs) are united in their commitment to ensure broad and responsible dissemination of information about and from NIH-funded clinical trials through ClinicalTrials.gov.

The NIH policy on the Dissemination of NIH-Funded Clinical Trial Information provides the expectation that all NIH-funded awardees and investigators conducting clinical trials will ensure that such trials are registered with and summary results information is submitted to ClinicalTrials.gov, in accordance with policy requirements.[7,8] The policy took effect for all competing applications and contract proposals requesting support for the conduct of a clinical trial that were submitted on or after January 18, 2017, and for clinical trials initiated by the NIH intramural research program on or after January 18, 2017.

NIH is actively implementing processes to verify compliance with clinical trials registration and results information submission requirements by NIH grantees, including additional enhancements in response to an HHS Office of the Inspector General (OIG) audit published in August 2022.[9] As noted in NIH's comments appended to the OIG audit, NIH has developed a number of activities that enhance NIH's ability to identify noncompliance and take compliance actions against responsible parties that are either late in submitting trial results or do not submit results. There are a range of consequences for noncompliance, as noted in the report, that focus on the grant project.[10]

NIH has worked in close collaboration with partners within the HHS Office of General Counsel and Food and Drug Administration (FDA) to standardize NIH's approach across its ICs for verifying extramural grant recipient compliance with both the NIH Policy and regulatory requirements pursuant to the Food and Drug Administration Amendments Act of 2007, Public Law 110-85. The processes and enhancements NIH has implemented provide a comprehensive and

[5] HHS OIG, The National Institutes of Health Did Not Ensure That All Clinical Trial Results Were Reported in Accordance with Federal Requirements, August 2022.
[6] https://grants nih.gov/policy/clinical-trials/reporting/understanding/nih-policy htm
[7] https://grants nih.gov/policy/clinical-trials/reporting/understanding/nih-policy htm
[8]https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.3_clinical_trials_registration_and_reporting_in_clinicaltrials.gov_requirement htm
[9] https://oig.hhs.gov/oas/reports/region6/62107000.asp
[10]http://grants nih.gov/grants/policy/nihgps/HTML5/section_8/8.5_special_award_conditions_and_enforcement_actions htm

automated system for centralized tracking of registration and results reporting information, enabling NIH to take action upon the notification of a potential violation. To support its process, NIH has enabled new internal quarterly reporting to NIH Institutes and Centers of all NIH grant-funded clinical trials that have not submitted results information to ClinicalTrials.gov by the required deadline. In addition, FDA refers reports of potentially noncompliant clinical trials with an apparent association to NIH, so that NIH can verify if the clinical trial has NIH grant-funding to take further appropriate action.

A March 2023 NIH Open Mike blog reported on analyses of NIH-grant-funded clinical trials for which main results were due in fiscal years 2020, 2021 or 2022.[11] The blog states "after our systems had been implemented, a total of 530 trials had results information due in FY 2020, FY 2021, or FY 2022. Our analyses show that of these trials, 96% had results information submitted to ClinicalTrials.gov (see Table 1). This is in stark comparison to compliance rates before our policies were enacted. But we note that still only a minority of trials (37%) submitted results information on time."

The NIH Intramural Research Program (IRP) developed and published NIH Policy Manual Chapter 3007 (MC 3007), "Clinical Trial Registration and Results Information Reporting."[12] It establishes responsibilities and procedures for registration and results information reporting of IRP-conducted or supported clinical trials to ClinicalTrials.gov and establishes consequences in the event of noncompliance. As of February 14, 2023, since the implementation of MC 3007 in January 2022, all intramural trials that have results expected have submitted results information to ClinicalTrials.gov. The IRP's experience to date with MC 3007 suggests the new policy is an effective tool to facilitate intramural compliance with reporting requirements.

NIH does take its responsibilities in facilitating compliance with these requirements seriously and is working to identify and resolve any instances of noncompliance. At this time, NIH has not withheld any funding due to noncompliance with ClinicalTrials.gov requirements.

Question #4

4. The Office of the National Coordinator for Health Information Technology (ONC) stated in the preamble to the 21st Century Cures Act final rule that it "designed the final rule to operate in a manner consistent with the framework of the HIPAA Privacy Rule and other laws providing privacy rights for patients." If the rules are working as intended, access to Electronic Health Information (EHI) should be consistent with HIPAA and the 21st Century Cures Act and a component of the move towards improved interoperability.

a. Is HHS aware of any electronic health records (EHR) vendors that may be limiting access or the exchange of data in scenarios even where information sharing is otherwise permitted under HIPAA?
b. Please describe any actions HHS is taking to remedy these issues.

HHS Response

HHS policies, as directed by the 21st Century Cures Act, Health Information Technology for

[11] https://nexus.od nih.gov/all/2023/03/24/nih-clinical-trials-reporting-compliance-a-shared-commitment/
[12] https://policymanual.nih.gov/3007

Economic and Clinical Health Act (HITECH Act), and Health Insurance Portability and Accountability Act (HIPAA) seek to prevent inappropriate interference with access, exchange, or use of patients' electronic health information that is permitted by HIPAA Rules and consistent with the patient's privacy preferences. When electronic health information is needed (to, for example, support safe, coordinated care), any limits EHR developers may impose for anti-competitive purposes would be a serious concern that HHS will address where it is identified. Survey data and information blocking claims received by HHS suggest hospitals and potentially other health care providers are not yet reporting possible information blocking as often as they might be experiencing it.[13, 14] HHS continues to promote to health care providers the opportunity to report information blocking they experience and that they should refrain from engaging in it themselves.

The HHS Office of Inspector General (OIG), in close ongoing coordination with other parts of HHS including ONC and the Office for Civil Rights (OCR), has the lead on information blocking enforcement. The 21st Century Cures Act gave the HHS Inspector General authority to investigate any claim that a health IT developer of certified health IT, other entity offering certified health IT, health care provider, health information network, or health information exchange engaged in information blocking.[15] HHS expects to publish the OIG's final rule establishing procedures necessary to use the 21st Century Cures Act authority to investigate information blocking claims and take enforcement action against certain entities. Statutory authority to determine civil money penalties specific to information blocking by health IT developers (such as EHR developers), health information exchanges, and health information networks references violations identified through an OIG investigation.[16] OIG and ONC actively coordinate and will continue to do so to ensure that, in addition to any civil money penalty action taken by HHS through OIG, ONC also takes appropriate action under the ONC Health IT Certification Program (the Program) with respect to any Program-participating EHR vendors (or other Program-participating developers) determined by OIG to have committed information blocking.

Question #5

5. Non-ventilator hospital acquired pneumonia (NV-HAP) is associated with longer hospital stays, higher overall health care costs, and increased morbidity and mortality. It is my understanding that routine oral care during inpatient stays can help prevent such incidents according to numerous studies and initiatives, including the Veteran's Affairs Hospital-Acquired Pneumonia Prevention by Engaging Nurses (HAPPEN) initiative that has been implemented at every VA Medical Center in the nation.

a. Please provide information and describe any efforts underway or being considered by HHS to prioritize the prevention of NV-HAP.

HHS Response

The Agency for Healthcare Research and Quality (AHRQ) supports investigator-initiated research on prevention of healthcare-associated infections (HAIs) through its HAI Prevention Notices

[13] ONC Quickstat "Information Blocking Claims: By the Numbers," available on ONC's website: https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers

[14] https://academic.oup.com/jamia/article/29/9/1489/6597051

[15] 42 U.S.C. 300jj–52(b)(1) as added by section 4004 of the 21st Century Cures Act (Pub. L. 114-255)

[16] 42 U.S.C. 300jj–52(b)(2)(A), as added by section 4004 of the 21st Century Cures Act (Pub. L. 114-255).

program announcements. AHRQ welcomes applications focused on prevention of NV-HAP, though we have not received meritorious applications in this area in recent years.

As part of the AHRQ Safety Program for MRSA Prevention, one of the educational webinars focuses on prevention of both ventilator-associated pneumonia (VAP), and NV-HAP. The webinar includes recommendations for routine oral care, as recommended by the Association for Professionals in Infection Control and Epidemiology (APIC) and the Society for Healthcare Epidemiology of America (SHEA).

Question #6

6. US technical agencies have been relied on for years to ensure the quality and standards of the products used within the United States President's Emergency Plan For AIDS Relief (PEPFAR) program to protect both the patients who rely on these programs and the U.S. taxpayer dollar used to purchase them. Specifically, the Food and Drug Administration (FDA) has maintained the role of ensuring the quality of the medicines used, and, for decades, the Centers for Disease Control and Prevention (CDC) has independently validated all diagnostic HIV tests and the critical algorithms used to ensure accurate HIV diagnosis and disease monitoring in PEPFAR.

a. Is CDC still providing these independent validations of HIV diagnostic tests for PEPFAR?

HHS Response

Yes. CDC conducts and collaborates with global partners on independent evaluations of HIV serological and molecular diagnostics used in PEPFAR programs.

b. Please describe any and all plans for the CDC to no longer provide independent evaluations of diagnostic tests used in PEPFAR, including any plans for CDC to outsource this responsibility to other entities, such as the World Health Organization (WHO) and Africa Centres for Disease Control and Prevention (Africa CDC).

HHS Response

CDC plans to continue to support independent evaluations of HIV diagnostics used in PEPFAR programs. To ensure that evaluations are conducted with the appropriate specimens for specific test under review and to ensure timeliness of the review of all products in the pipeline the evaluations are not completed by a single laboratory. Thus, CDC currently collaborates with the WHO Prequalification (PQ) of *in vitro* Diagnostics department and their network of approved laboratories to ensure that evaluations are conducted in a timely manner and with the appropriate level of quality.

Question #7

7. It is my understanding, based on recent reporting,[6] the Biden administration is launching a $5 billion-plus program to accelerate the development of new coronavirus vaccines and treatments, dubbed “Project NextGen.” The House Committee on Energy and Commerce has not been briefed on this announcement, nor has received direct outreach from the

Administration on this initiative or how this initiative will impact the Administration's current FY 2024 budget requests. In the FY 2024 budget, the Administration requests $20 billion in mandatory funding across the Department of Health and Human Services for pandemic preparedness and response.

a. Secretary Becerra testified in front of the House Committee on Energy and Commerce, Health Subcommittee, on the Administration's FY 2024 budget requests, on March 29, 2023. "Project NextGen" was announced on April 10, 2023, vis a vis reporting by the *Washington Post*. Please explain why this new initiative was not mentioned or raised during the hearing, particularly with members specifically asking questions regarding conflicting accounts between the Administration's funding claims and public reporting on unexpired and unobligated funding.
b. Please explain the planned structure and organization of "Project NextGen," including anticipated leadership and subagency within HHS that will be leading the initiative.
c. According to recent reports, "[a] pot of money was finally created after the White House directed HHS to free up $5 billion for the initiative,"[7] and "[t]he administration said the initial allocation of $5 billion for Project NextGen will be financed through money saved from contracts costing less than originally estimated."[8] Please provide a detailed accounting from which accounts, current programs, or existing contracts was used to subsidize the $5 billion in funding for "Project NextGen."
d. Please explain the potential ramifications the redirection this funding, assumedly planned for other initiatives, programs, and contracts, will have on the currently operating initiatives, programs, and contracts.
e. Please explain how the creation of this new initiative will impact or alter the future of current initiatives, programs, and contracts, including any that may now be duplicative.
f. Please explain if and how the creation of this new initiative will impact the Administration's FY 2024 budget request.

HHS Response

HHS continues to provide timely updates to Committee staff on HHS initiatives and actions related to our ongoing responses to COVID-19, including ongoing investments in research and development for next generation vaccines and medical countermeasures. In order to stay ahead of the rapidly evolving virus that causes COVID-19 (SARS-CoV-2), we need to continue to support the development of a new generation of tools. While our vaccines are still very effective at preventing serious illness and death, they are less capable of reducing infections and transmission over time. New variants and loss of immunity over time could continue to challenge our healthcare systems in the coming years. HHS continues to coordinate actively across the federal government and the private sector to advance the pipeline of new, innovative vaccines and therapeutics from labs to clinical trials to deliver for the American people.

Question #8

8. Families USA helped form a new alliance of organizations called the Consumers First Coalition, which combines the perspectives of consumers, employers, labor unions, and primary care providers to address systemic health care challenges. The Coalition has written your administration as well as this Congress urging us to take on hospital consolidation. They

have proposed a number of specific policies with bipartisan support, including greater enforcement of price transparency rules and site-neutral payment policies to eliminate "site-dependent reimbursement distortions that indirectly incentivize acquisition of non-hospital patient access points...the continuation of this perverse incentive type of market consolidation drives up costs and incentivizes consolidation with no corresponding improvements in quality or access."

As you know, the Obama-Biden and Trump administrations also proposed site neutral payment policies in years past and now a growing chorus of patient stakeholders and organizations like the Consumers First Coalition and governmental institutions like the GAO, the HHS OIG, and MedPAC have proposed further site neutral payment policies in Medicare.

a. Will you commit to support us and work with us on site neutral payment policies to save patients billions of dollars out-of-pocket and deliver on President Biden's promise to address hospital consolidation?

HHS Response:

We understand this is an increasing concern, particularly as consolidation and closures continue to impact cost and access to care. CMS payment policy is set by Congress, and may at times not allow for adjustments to account for differences in facilities where care is received. CMS would be happy to continue to work with Congress to ensure that Medicare payment policy is achieving our shared goal of access to affordable care.

Question #9

9. I was encouraged to see CMS finalize its policy to apply pharmacy price concessions to the negotiated price in all phases of the Part D benefit in its CY2023 MA/Part D rule.

I understand that the estimated total net savings (i.e. cost-sharing *and* estimated premium impact) to beneficiaries totals $26.5 billion over the next 10 years. Your rule confirms that "beneficiaries would see lower prices at the pharmacy point-of-sale and on Plan Finder for most drugs, beginning immediately in the year the proposed change would take effect (2024)," and that "lower point-of-sale prices would directly result in lower cost-sharing costs for non-low-income beneficiaries, and on average we expect these cost-sharing decreases would exceed the premium increases."

a. Do you stand by this analysis from the CMS Office of the Actuary?
b. Do you stand by the analysis from the CMS Office of the Actuary of the prior administration's so-called rebate rule which would have saved patients over $25 billion in net costs over 10 years (i.e. net of cost-sharing and premiums)?
c. Do both of these policies operate from the same principle of requiring rebates – from both the pharmacy and manufacturer perspective – at the point of sale?
d. If yes, what principle or prudential judgment did you exercise to distinguish between these two policies by finalizing one policy that would according to your press release reduce "out-of-pocket costs for prescription drugs starting in 2024" and the other, of which the CMS Office of the Actuary estimated "total beneficiary cost-sharing would decrease and that the decrease in total beneficiary

cost-sharing would offset any increase in premiums across all beneficiaries" regardless of the various assumptions made about behavioral impacts of the rule?

e. If not, please explain your analysis.
f. Can you commit to supporting Congressional efforts to build off of your pharmacy price concessions policy to return rebates to patients at the point of sale?

HHS Response

CMS finalized a policy that requires Part D plans to apply all price concessions they receive from network pharmacies to the negotiated price at the point of sale, so that the beneficiary can also share in the savings. Specifically, CMS is redefining the negotiated price as the baseline, or lowest possible, payment to a pharmacy, effective January 1, 2024. CMS is applying the finalized policy across all phases of the Part D benefit. This policy reduces beneficiary out-of-pocket costs and improves price transparency and market competition in the Part D program. We are happy to provide technical assistance on legislation.

Question #10

10. I want to express my support for CMS proposing and prioritizing the completion of a robust separate expedited pathway for transitional coverage of innovative FDA-approved devices.

While I, along with members from both parties, am discouraged this administration withdrew the Medicare Coverage of Innovative Technologies ("MCIT") rule I have remained hopeful the important goals can still be accomplished through the rebranded "Transitional Coverage for Emerging Technologies" ("TCET") rule.

However, after two years of numerous Congressional inquiries and letters, and several delays from your department, we have not seen a proposed rule or official confirmation of its timing.

Furthermore, I am concerned about speculation that CMS is moving in the wrong direction with this proposed rule by expanding or refining the Coverage with Evidence Development (CED) process as the *only* pathway under TCET.

a. Do I have your commitment that you will publish a proposed rule this month (April 2023), in keeping with your Department's Fall 2022 Unified Agenda, that allows for a separate coverage pathway for new devices without burdensome additional processes and duplicative evidence generation requirements for truly innovative products?
b. If not on schedule, when do you anticipate the rule coming out?
c. When do you expect to release and implement the final rule?

HHS Response

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

concerns in the future.

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

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

Question #11

11. How many FDA-approved breakthrough devices have been approved during this administration?

a. How many of these FDA-approved breakthrough devices have received CMS coding, coverage, and payment?
b. How long is the average expected time between an FDA-approved breakthrough device approval and Medicare coverage?
c. How long is the average span of "Coverage with Evidence Development" (CED) for FDA breakthrough devices that are covered under CED?

HHS Response

Medicare's Coverage with Evidence Development (CED) is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. In making coverage decisions involving CED, CMS decides after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary. Coverage in the context of ongoing clinical research protocols or with additional data collection can expedite earlier beneficiary access to innovative technology while ensuring that systematic patient safeguards, including assurance that the technology is provided to clinically appropriate patients, are in place to reduce the risks inherent to new technologies, or to new applications of older technologies.

The FDA performs a vital and an important role. CMS recognizes the important and related – but different – roles of the respective agencies. The FDA determines whether to approve a new breakthrough device based on a careful evaluation of the available data and pursuant to specific standards. CMS makes national coverage decisions based on whether something is reasonable and

necessary for the treatment of an illness or injury for the Medicare population. In determining the generalizability of the results of the body of evidence to the Medicare population, CMS considers, at minimum, the age, race and gender of the study participants. CMS conducts its own independent review to determine whether an item or service is reasonable and necessary for use in the Medicare population and should be covered nationally by Medicare.

Question #12

12. I have become aware of a concerning lack of transparency surrounding CMS' methods for managing National Coverage Determination (NCD) requests and sharing that information with the public. For example, medical innovators may submit a formal NCD request to CMS, but because there is no specified timeline for CMS to respond to such requests or to provide information regarding the waiting list, they have no visibility into the process or timeline for action on their requests. This lack of transparency ultimately creates uncertainty for medical innovators and the doctors and patients who are waiting for Medicare to decide whether to cover these products.

We were pleased to see, in September of 2020, CMS had posted on its website a dashboard (https://www.cms.gov/files/document/ncd-wait-list.pdf) of NCD requests under review, requests that had been reviewed but not yet opened (referred to as the NCD Wait List), opened with a national coverage analysis (NCA) underway, or finalized within the previous 12 months. This dashboard represents a positive step forward toward transparency of NCD processes. However, the dashboard did not provide complete details regarding the NCDs that were underway or the NCDs that had been finalized, and has not been updated since it was posted to the website in 2020.

a. How can HHS ensure that CMS can provide greater transparency for both requestors and the public regarding the status of NCD requests, prioritization of those requests, and the status of the current waiting list?
b. How many current items are on the NCD wait list at this moment?
c. Does CMS believe it has discretion to review requests on a different timeline than as prescribed by the statute?

HHS Response

Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category). National coverage determinations (NCDs) are made through an evidence-based process, with opportunities for public participation. For NCD requests not requiring an external technology assessment (TA) or Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) review, the decision on the request must be made not later than 6 months after the date the completed request is received. For those NCD requests requiring either an external TA and/or MEDCAC review, and in which a clinical trial is not requested, the decision on the request must be made not later than 9 months after the date the completed request is received. Not later than the end of the 6- or 9-month period, the proposed decision must be made available on the CMS website for public comment. This comment period will last 30 days, and comments will be reviewed and a final

decision issued not later than 60 days after the conclusion of the comment period. A summary of the public comments received and responses to the comments will continue to be included in the final NCD. An Annual Report is issued listing the national coverage determinations made in the previous year and explaining how to get more information on those determinations.

Question #13

13. As you know public policy always involves tradeoffs. What do you see as the relevant tradeoffs involved in your administration's decision to continue with a nationwide vaccine mandate for health care workers?

A nationwide vaccine mandate mean we have fewer qualified health care workers to treat patients. More workers may be vaccinated – and as the CDC has confirmed this does not prevent transmission of COVID-19 now or at the time the mandate was instituted - but that means many of our health care clinicians, administrative staff, cooks, and other health care workers will find work elsewhere depriving many underserved communities of health care workers. We have news stories documenting thousands of health care workers being fired or quitting because of this mandate.

a. How many health care workers have left their job because of the mandate?
b. Have you attempted to quantify the disruptions to care on account of workforce shortages or workforce transitions (e.g. migration of existing workforce to other facilities, industries and the subsequent training of new staff and overall loss of experienced staff) on the quality of care delivered and the availability and access of care, especially in rural and underserved parts of the country?

HHS Response

We know that the COVID-19 vaccine saves lives, and this Administration has made it a priority to continually work to protect our most vulnerable communities across the country. The health care staff vaccination requirement for covered Medicare- and Medicaid-certified providers and suppliers has been enforced in all states since February 20, 2022. To date, most providers and suppliers subject to the requirements surveyed by states have been found to be in substantial compliance with this requirement.

Question #14

14. CMMI recently released three distinct models aimed at addressing drug pricing issues. While the report was light on details and specifics, I am concerned about the direction of all three models, particularly the model aimed at accelerated approval, which could have the unintended consequence of delaying patients' access to important new medicines. I appreciate the concern with companies not completing their clinical trials in a timely manner. But if HHS is not careful, the model could have the unintended result of companies not seeking accelerated approval at all, and patients having to wait longer for promising new therapies. When you look at the possible

model and the IRA together, I am struggling to see why a company with a promising new drug wouldn't then just skip accelerated approval altogether, especially with the potential disadvantages of bringing a drug for a single indication to the market quickly under the IRA. I'm also worried about the effect of a one-size-fits-all $2 generic drug copayment policy which would hamstring health plans from encouraging seniors to use low-cost generic alternatives.

a. Knowing I can count on you to say you will enforce the law, I want to know if you support the policy and bipartisan principles which created the accelerated approval pathway, a pathway that continues to enjoy bipartisan support to this day?
b. Can you commit that before releasing a demo related to accelerated approval that you will study its impact on patient access to new therapies and include in that impact analysis a study of the incentives for new therapies seeking accelerated approval in any rulemaking or model announcements?
c. Do you believe there is a lack of availability of zero dollar or low-priced generic plans for seniors today? If so, what data do you have to support the lack of availability of low-priced generic plans for seniors?
d. Should health plans be allowed to incentivize seniors to choose preferred generics?
e. Can you commit that this model will not be made mandatory or that you will impose any penalties on plans that choose not to participate?

HHS Response

Building on the Inflation Reduction Act, the Secretary of HHS was tasked by the President's Executive Order, "Lowering Prescription Drug Costs for Americans," to consider whether to select for testing by the CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs, including models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that promotes high quality care . The Secretary has selected three models to test, including the Medicare High-Value Drug List Model. This model would allow Part D Sponsors to offer a Medicare-defined standard set of approximately 150 high-value generic drugs with a maximum co-payment of $2 for a month's supply, applying across all phases of Part D coverage up to the out-of-pocket limit. Participation in this model would be voluntary for Part D plans.

While some Part D plans already offer a limited set of low-priced generics, this model would encourage plans to expand their current low copayment drug offerings and provide beneficiaries access to a standardized list of generics with copayments of no more than $2 across participating plans. This could provide beneficiaries with greater predictability and transparency with their drug costs and enable them to more easily access low-cost generics.

The Secretary also selected the Accelerating Clinical Evidence Model, which would test whether targeted adjustments to Medicare Part B payment amounts would give manufacturers an incentive to expedite and complete confirmatory clinical trials. The completion of confirmatory trials on a timelier basis could provide earlier confirmation of clinical benefit based on a validated endpoint,

ultimately leading to timelier post-market safety and efficacy data. Timely generation of evidence is of interest to both CMS and the FDA.

The Model would not change the FDA approval process, would not be directed at discouraging the clinically-appropriate use of products that are approved via the accelerated approval pathway, and would not change the way CMS covers new drugs. Any payment adjustments would be structured in a manner that attempts to avoid penalizing physicians or beneficiaries for choosing (or avoiding) a drug granted accelerated approval. CMS is still exploring the specific approaches to payment adjustments.

CMS continues to develop these models and looks forward to working with Congress and with stakeholders on their development.

Question #15

15. The most recent analysis from your department found that there is an estimated 20+% of payment errors in the Medicaid program. This may be some of the $100b in fraud that was reported by National Health Care Anti-Fraud Association, but it could also be something less insidious, like an underpayment for a service. The issue is we simply don't know what's going on in Medicaid, and we need to be better stewards of the Medicaid program.

For example, the OIG has found a recurring issue of states paying per member per month payments to Medicaid Managed Care Organizations for deceased beneficiaries. The opacity of the Medicaid program is clearly leading to tax payer dollars being spent in inappropriate ways.

a. What is HHS doing to correct this high PERM rate?
b. What is HHS doing to prevent further per member per months for deceased beneficiaries?

HHS Response

The vast majority of improper payments are not fraud, and improper payment estimates are not fraud rate estimates. Improper payments are payments that do not meet CMS program requirements, such as insufficient or missing documentation associated with the payment or payments where insufficient information was provided to determine whether a payment was proper. Most improper payments involve situations where a state or provider missed an administrative step.

The federal-state partnership, central to the success of the Medicaid program, depends on clear lines of responsibility and shared expectations. States are responsible for accurately determining eligibility for all individuals applying for or receiving benefits in accordance with federal regulations, and CMS provides states with guidance and technical assistance to ensure states comply with federal requirements.[17]

CMS uses the Payment Error Rate Measurement (PERM) program to measure improper payments and produce state and national improper payment rate estimates in Medicaid. CMS continues to

[17] 42 CFR § Part 435

implement a robust state-specific PERM corrective action plan (CAP) process that provides enhanced technical assistance and guidance to states, including coordinating with states as they develop a corrective action plan to address each error and deficiency identified during the PERM cycle.

In addition to PERM, CMS addresses improper payments through a number of strategies and corrective actions. For example, CMS works with states through the Medicaid Eligibility Quality Control program to design and conduct pilots to evaluate the processes that determine an individual's eligibility for Medicaid benefits. In addition, CMS has enhanced a number of data systems to more accurately measure and strengthen program integrity and Medicaid financial management efforts. CMS also provides ongoing guidance, education, and outreach to states on federal requirements for Medicaid provider screening and enrollment and shares Medicare provider enrollment data to assist states and territories with meeting Medicaid screening and enrollment requirements. More information on the mitigation strategies and corrective actions that CMS is taking to address Medicaid improper payments is available in the Department of Health and Human Services Agency Financial Report Fiscal Year 2022 at: https://www.hhs.gov/sites/default/files/fy-2022-hhs-agency-financial-report.pdf.

In addition, the President's FY 2024 Budget includes a proposal to enhance CMS's ability to take meaningful actions to protect beneficiaries and enforce requirements, making Medicaid managed care compliance tools more effective and consistent with similar authorities in fee-for-service. Currently, CMS has inadequate financial oversight and compliance tools in Medicaid managed care, lacking maximum flexibility to disallow and defer individual or partial payments associated with contracts with managed care organizations, prepaid inpatient health plans, and prepaid ambulatory health plans. CMS's only recourse when it identifies compliance failures is to withhold all federal financial participation under the contract, an untenable compliance option given potential beneficiary harm and disruption to the state's Medicaid program. This proposal conditions federal match in Medicaid managed care plan contract capitation payment amounts on a service-by-service basis and provides CMS with additional enforcement options.

Question #16

16. We've heard from a wide variety of stakeholders – everyone from local leaders to providers to patient advocates – who are concerned by the so-called "IMD Exclusion" and its archaic rules that limit residential facilities from offering more than 16 beds for such care.

a. Under the current and prior administrations, more than 30 waivers have been granted to waive the IMD Exclusion, which I believe is a positive step in the right direction. If we're waiving the law for so many states though, with implementation varying by state, don't you think it makes sense to standardize things by lifting the IMD Exclusion in statute?
b. As Secretary, you signed off on processes for states to apply for section 1115 waivers to waive the IMD Exclusion for Qualified Residential Treatment

Programs, or QRTPs. Do you believe that Congress should act to codify that decisions and allow for states to lift the Exclusion for QRTPs?

HHS Response

Strengthening behavioral health care is a top priority for the Biden-Harris Administration. CMS has worked within the confines of the law to provide states with flexibility to increase access to services for individuals residing in IMDs. As you noted, CMS has approved Medicaid section 1115 demonstrations that allow state Medicaid programs to pay for services provided to individuals with serious mental illness or serious emotional disturbance or substance use disorder who are short-term residents in an IMD. Similarly, managed care organizations are permitted to reimburse up to 15 days per month of treatment in IMDs as an in-lieu of service—that is, a service that is not included under the state plan, but is a clinically appropriate, cost-effective substitution for a similar, covered service.

Children in foster care should receive the medical care that they need and to which they are entitled, without disruption, in a safe and nurturing setting that fosters their growth and development. CMS is committed to ensuring children with unique health needs receive high-quality care in the most appropriate setting permissible under the law, and CMS has worked within the confines of the law to provide states with flexibility to increase access to these services.

HHS looks forward to working with Congress on this issue moving forward, and we are always willing to provide technical assistance to Congress on important health care issues.

Question #17

17. I'm worried about a growing trend that we're starting to see in prescribing trends of antipsychotic drugs for seniors and people with disabilities, especially in nursing homes and other congregate care settings. To be clear, antipsychotics are an important drug for many Americans in managing their mental health needs. But it is not certain that some who are being prescribed these drugs actually need them, and instead are just being sedated. This issue has been noted both by the GAO and the OIG.

a. What is HHS doing to increase oversight of this issue?
b. Does HHS need additional authorities from Congress to further protect seniors and people with disabilities from potentially abusive prescribing practices?

HHS Response

CMS is committed to reducing the unnecessary use of antipsychotic drugs in nursing homes and holding facilities accountable for failures to comply with federal requirements, and CMS is continuing to implement several efforts to address this issue.

All nursing homes are required to ensure residents are free from unnecessary medications. On every standard survey and on relevant surveys conducted in response to complaints, surveyors review medical records to confirm that the clinical indication for any prescribed medicine, including antipsychotics and other psychotropics, is thoroughly documented. CMS has also implemented specific enforcement remedies—such as denial of payment for new admissions or

per day civil money penalties—for nursing homes that have continued to have high levels of antipsychotic medication use among long-stay nursing home residents, known as "late adopters."[18] And that have also had a history of noncompliance citations with federal requirements related to antipsychotic medication use and dementia care. Such facilities will be subject to this enhanced enforcement if it is determined to not be in substantial compliance with certain requirements at specific severity levels during any survey.

Most recently, earlier this year, CMS announced its intent to conduct audits to identify facilities with patterns of erroneous Minimum Data Set (MDS)[19] coding of residents with a diagnosis of schizophrenia. Currently, quality measurements regarding the use of antipsychotic medications among nursing home residents exclude residents with schizophrenia.[20] When nursing home residents are given erroneous schizophrenia diagnoses, they are subject to poorer quality care and unnecessary antipsychotic medications, both of which can be dangerous. Additionally, this inaccurate MDS coding misleads the public by misrepresenting the nursing homes' rate of antipsychotic usage in the posted quality measure.

Question #18

18. I'm concerned by a pending Medicaid rule, titled "Streamlining Eligibility and Enrollment". The Office of the Actuary cited potential costs for the rule at over $60 billion over the first five years. Some unofficial estimates that we've seen show that the final costs of the rule could come out at $200b over ten years. This, of course, could trigger as much as an additional $50-$100b in additional state spending. All the while, States are required to have balanced budgets.

What's more is that this rule comes at a time when States are in the midst of unwinding the Families First and Coronavirus Response Act's continuous coverage requirements, which could take over 14 months to unwind. Adding these costs to States while unwinding occurs could be detrimental to a successful unwinding.

a. Will you commit to not finalizing this rule until after unwinding is done?
b. What in the budget would help states in relieving the pressure of having an additional $50 billion in added costs over 10 years?

HHS Response

In September 2022, CMS issued a proposed rule[21] that includes several provisions aimed at simplifying the enrollment process and maintaining continuity of coverage for eligible beneficiaries, including children and individuals dually enrolled in Medicare and Medicaid, many of whom are over 65 and/or have a disability. CMS estimates that this proposed rule would remove

[18] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO19-07-NH.pdf
[19] https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/nhqimds30
[20] https://www.cms.gov/files/document/qso-23-05-nh.pdf
[21] "Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment, and Renewal Processes" (CMS-2421-P) https://www.federalregister.gov/documents/2022/09/07/2022-18875/streamlining-the-medicaid-childrens-health-insurance-program-and-basic-health-program-application

barriers to enrollment and increase the number of eligible individuals who obtain coverage and are continuously enrolled in Medicaid and CHIP. Recognizing that most states will require up to 12 months to implement the changes proposed in this rule, we sought public comment on making the final rule effective 30 days after publication with full compliance required 12 months later. The comment period for the proposed rule closed on November 7, 2022. CMS is taking into consideration comments received for final decision making.

The Honorable Brett Guthrie

Question #19

1. CMS has recently announced even further steps to limit access to accelerated approval drugs in Medicare Part B by proposing to slash payments to providers prescribing these therapies.
    A. The FDA bases its decision on approving an Accelerated Approval drug on studies that demonstrate a drug's effect on a surrogate or intermediate clinical endpoint, **and studies must be "adequate and well controlled**" as required by law. Do you believe the FDA's clinical review teams aren't appropriately assessing whether these studies are adequate and well-controlled and therefore lacking the ability to judge whether the drugs are "safe and effective"?

    B. The Consolidated Appropriations Act of 2023 includes changes to the Accelerated Approval pathway, including giving the FDA the authority to start post-approval confirmatory trials before an approval is granted. Shouldn't we be focusing more on ensuring these changes to statute are effectively implemented and trusting FDA to follow the letter of the law before moving forward with these reimbursement changes at CMS?

HHS Response

The FDA performs a vital and an important role. CMS recognizes the important and related – but different – roles of the respective agencies. The FDA determines whether to approve a new medical product based on a careful evaluation of the available data and a determination that the medical product is safe and effective for its intended use but does not consider the specific needs of the Medicare patient populations. CMS conducts its own independent review to determine whether an item or service is reasonable and necessary for use in the Medicare population and should be covered nationally by Medicare.

Question #20

2. Please confirm that, where a manufacturer elects MBPRO, the manufacturer may calculate ASP by reference to the sales and discounts considered in the determination of the non-value-based BP.

    A. If the manufacturer may not do so, please explain why not?
    B. If the manufacturer may do so, please confirm that CMS will immediately issue guidance clarifying that this is so.

C. If CMS will not do so, please explain why not.

HHS Response

Earlier this year, CMS issued guidance on Average Sales Price (ASP)[22] reporting for manufacturers of drugs and biologicals reporting multiple best prices under the Medicaid Drug Rebate Program. The guidance stated that for the purposes of ASP data reporting, rebates paid to states under the multiple best prices reporting option, that are associated with value-based purchasing (VBP) arrangements that meet the definition of such an arrangement at 42 CFR § 447.502, are considered a Section 1927 rebate for the purposes of Section 1847A(c)(3) of the Social Security Act, and thus such rebates should not be included in the calculation of the manufacturer-reported ASP for the drug. Section 1847A(c)(3) lists in parentheses those discounts that do not need to be included in the computation of ASP, such as rebates under Section 1927. We reiterate that only those VBP rebates that are paid to states that meet the definition of a value-based purchasing arrangement under § 447.502 for purposes of the multiple best price option are exempt from ASP.

Question #21

3. CMS has come under fire for its restrictive policy for recently approved therapies by the FDA to treat Alzheimer's disease. We are aware of additional CMS policies through Star Ratings that would also restrict patient access to products that could be approved by FDA. Can you describe how you will address the disconnect between FDA approval and CMS restricting access to Medicare beneficiaries moving forward to ensure today's seniors have access to innovative medications?

HHS Response

The FDA performs a vital and an important role. CMS recognizes the important and related – but different – roles of the respective agencies. The FDA determines whether to approve a new drug or biological based on a careful evaluation of the available data and a determination that the drug is safe and effective for its intended use. In general, CMS makes national coverage decisions based on whether something is reasonable and necessary for the diagnosis or treatment of an illness or injury for the Medicare population. In determining the generalizability of the results of the body of evidence to the Medicare population, CMS considers, at minimum, the age, race and gender of the study participants. CMS conducts its own independent review to determine whether an item or service is reasonable and necessary for use in the Medicare population and should be covered nationally by Medicare. To date, there has not been an antiamyloid mAb that has been approved by the FDA for the treatment of AD based upon evidence of efficacy from a direct measure of clinical benefit.

Question #22

4. In response to my Question for the Record from the May 12, 2021 hearing (which I received nearly two years later) I asked the following three questions:

   A. Which particular federal policies do you believe lead to greater hospital and

[22] https://www.cms.gov/files/document/part-b-asp-data-reporting-guidance-clarification-medicaid-drug-rebate-program-multiple-best-prices.pdf

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?

Your response stated: "…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."

I am so glad that after our 2021 hearing, President Biden issued his Executive Order on Promoting Competition in the American Economy in which he identifies hospital consolidation as a problem that has "left many areas, particularly rural communities, with inadequate or more expensive healthcare options," and charges you to "identify and advance any additional administrative actions necessary to further policies" and to "identify any potential legislative changes necessary to further the policies" in the Executive Order.

D. Now that it has been nearly two years since this directive was issued, what administrative actions have you identified and advances to address hospital consolidation?
E. And what legislative changes have you identified which will address hospital consolidation?

HHS Response

In addition to lowering costs and increasing access to care, CMS's ongoing efforts to increase transparency across the health care system will help to incentivize competition, improve consumer experience, and realize additional savings across the health care system, including for patients. Lack of accessible information on prices makes it challenging for consumers to shop for services and limits competition. Over the past several years, CMS has implemented—and is continuing to implement—numerous complementary policies to promote transparency across the health care system, including the hospital and health plan price transparency rules and the implementation of the No Surprises Act.

With respect to Medicare site neutral payments, CMS payment policy is set by Congress, and may at times not allow for adjustments to account for differences in facilities where care is received. We understand this is an increasing concern, particularly as consolidation and closures continue to impact cost and access to care. CMS would be happy to provide technical assistance on any legislation you draft to modernize Medicare payment policies.

The Honorable Morgan Griffith

Question #23A

A. On November 28, 2022, Health and Human Services issued a proposed rule, as required under Section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act,

to better align 42 CFR Part 2 ("Part 2") with the Health Insurance Portability and Accountability Act (HIPAA). This rule is long overdue since the CARES Act was signed into law during the 116th Congress. When do you anticipate issuing this final rule?

HHS Response

The HITECH Act gives an individual a right to direct a covered entity to transmit an electronic copy of their protected health information in an electronic health record to any entity or person designated by the individual, and applies the HIPAA right of access reasonable, cost-based fee limitation to this type of right of access request.

In the HIPAA Privacy Rule Notice of Proposed Rulemaking (NPRM) to Support, and Remove Barriers to, Coordinated Care and Individual Engagement NPRM, the Department proposed to implement these provisions of the HITECH Act.

The Department is carefully reviewing all comments received during the comment period and your expressed concerns to ensure that the final rule implements the congressional requirement and protects privacy in a manner that does not place unreasonable burdens on providers or harm patients.

Question #23B

B. For more than a decade, China has been one of the largest producers of active pharmaceutical ingredients (APIs) in the world. It is estimated that Chinese manufacturers make up around 40 percent of all APIs used worldwide, and that China and India are the source of approximately 80 percent of the APIs imported to the United States. Even before the COVID pandemic in 2019, the Department of Defense acknowledged in testimony before the U.S.-China Economic and Security Review Commission, that "the national security risks of increased Chinese dominance of the global API market cannot be overstated."

    a. Given how important domestic drug manufacturing is to ASPR's National Health Security Strategy, what is the department doing to further incentivize the domestic supply and production of API and medical countermeasures?

HHS Response

With funds appropriated though COVID-19 supplementals, ASPR is investing in domestic manufacturing of several important medical supplies, including API. As an example, on May 18, 2020, BARDA awarded Phlow Corp. a contract (75A501200C00092) to address the near-term threat of drug shortages of essential medicines for hospitalized COVID-19 patients, to establish a Strategic Active Pharmaceutical Ingredient (API) Reserve (SAPIR), and to build U.S.-based advanced large scale commercial manufacturing capabilities to supply domestic self-sufficiency for manufacturing of critical APIs and finished essential medicines to prevent future drug shortages. This work is intended to strengthen U.S. national health security interests by enhancing the nation's supply chain resiliency for essential medicines, including those used for COVID-19 patients, and ensuring that the United States has the necessary API reserve and U.S.-based manufacturing capabilities to meet the nation's needs for patient care in national emergency situations. These initial efforts have proven successful and Phlow has met all the contractual milestones.

To build and sustain a domestic advanced pharmaceutical manufacturing ecosystem, additional HHS investments through the ASPR Office of Industrial Base Management and Supply Chain (ASPR-IBMSC) have been directed at developing and deploying innovative manufacturing technologies, as well as establishing new partnerships to improve the responsiveness and resilience of the domestic pharmaceutical supply chain. These investments to address API and key starting material supply chain vulnerabilities include domestic direct, biologically derived production of APIs and antibiotics and fine chemicals or catalysts whose use are more prevalent in U.S. pharmaceutical production.

The FY2024 President's Budget includes a $400 million Pandemic Preparedness and Biodefense request. The $400 million requested will ensure we are able to maintain the capabilities built and used extensively during the COVID-19 pandemic to strengthen the domestic manufacturing base. In addition, the $400 million requested will ensure HHS has ready resources to immediately scale up manufacturing of vaccine and therapeutic prototypes at the first indication of an outbreak. The requested funding would also accelerate advanced development and additional manufacturing of medical countermeasures for clinical trials and, when appropriate, patient care as part of an emergency response. If appropriated by Congress, the Department will develop specific spend plans as funds are allocated to programs across HHS.

b. As part of the administration's biomanufacturing initiative, is HHS assessing the role synthetic biological manufacturing processes can play in mitigating API supply chain vulnerabilities?

HHS Response: IBMSC and BARDA are partnering to establish a biomanufacturing consortium. One of the first projects that this consortium will undertake will define, develop and validate synthetic biological manufacturing pathways for drug substances that have been previously off-shored and deemed critical for acute care of patients.

c. As part of the PAHPA reauthorization, are there new authorities needed to further help acquire, construct, or alter non-federally owned facilities to better allow ASPR to support efforts to develop net new domestic manufacturing capacity for medical countermeasures, including their API? If so, why is such authority needed?

HHS Response

Yes, ASPR is seeking construction authority to further support efforts to develop net new domestic manufacturing capacity for medical countermeasures. Construction authority was previously provided to ASPR as part of various COVID-19 supplemental legislation. ASPR has used this authority to support the physical construction of domestic manufacturing facilities. Once the COVID-19 funds have been expended, ASPR loses construction authority. It is important to have construction authority, as requested in the FY 2024 President's Budget, to sustain the work we have started and to expand this work to other parts of the public health supply chain as appropriate.

Question #23C

C. I am a strong supporter of the community health centers that do great work in my district and across the country. I am concerned about reports from community health centers that pharmacy benefit managers are taking predatory actions against health centers by effectively forcing them to sign unfair contracts that divert the savings generated from drug discounts under the 340B program. Health centers are effectively forced into signing these contracts that basically pick their pocket by including provisions which put savings from the 340B program into the pocket of PBMs. Whatever people think about the 340B program, I think we can all agree that we don't need big PBMs being predatory middlemen to scoop up discounts intended for safety net providers.

    a. Does HHS have the legal authority to address this matter, or is this an issue requiring legislation from this committee/Congress?

HHS Response

The 340B statute does not explicitly address pharmacy benefit management programs and does not provide HRSA with explicit regulatory authority to address this matter.

The Honorable Robert E. Latta

Question #24A

A. As the PHE winds down, we must ensure that Medicare beneficiaries, many of whom are considered high-risk, have continued access to therapeutics to treat or prevent severe COVID. Medicare Advantage Part D plans have realized the savings associated with these treatments, as patients have avoided costly hospitalizations. However, as direct copay assistance ends, I'm concerned that stand-alone Part D plans, who do not directly benefit from savings on the medical side, will begin restricting access to such therapeutics. What will HHS do to ensure that copays for COVID therapeutics remain affordable for beneficiaries?

HHS Response

CMS is committed to providing beneficiaries access to the therapeutics they need. There is no change in Medicare coverage of treatments for those exposed to COVID-19 once the PHE ends, and in cases where cost sharing and deductibles apply now, they will continue to apply. Generally, the end of the COVID-19 PHE does not change access to oral antivirals, such as Paxlovid and Lagevrio. For individuals enrolled in a MA plan, the plans must cover treatments that Traditional Medicare covers, but they may require the individual to see a provider who is in the MA plan's network and may have different cost sharing than Traditional Medicare.

CMS has also permitted Part D sponsors to pay pharmacy claims for dispensing fees of U.S. government-procured Emergency Use Authorization (EUA) oral antiviral drugs for treatment of COVID-19 without enrollee cost- sharing. Additionally, the agency has strongly encouraged Part D sponsors to pay dispensing fees for these drugs that may be higher than a sponsor's usual

negotiated dispensing fees, given the unique circumstances during the COVID-19 PHE. This flexibility will continue following the end of the COVID-19 PHE while U.S. Government-procured product remains available.

In addition, on December 29, 2022, the Consolidated Appropriations Act, 2023 was enacted (Pub. L. 117-328) and revised the definition of a covered Part D drug to temporarily (upon enactment and through December 31, 2024) include oral antiviral drugs approved under an EUA from the FDA, on the basis of the COVID-related Emergency Use Authorization declaration published in 2020. Oral antiviral drugs for COVID that meet the statutory definition of a covered Part D drug and are not procured by the US government must be covered by Part D plans as a formulary product or through the formulary exception process.

Question #24B

B. Based on outcomes data during the Public Health Emergency is there any reason to believe that the supervision waiver for CRNAs impacted patient health and outcomes beyond increasing access to timely care?

HHS Response

Under the COVID-19 Public Health Emergency (PHE), CMS currently waives the requirement that a certified registered nurse anesthetist (CRNA) must be under the supervision of a physician, instead permitting CRNA supervision at the discretion of the hospital or Ambulatory Surgical Center (ASC) and state law. This waiver applies to hospitals, CAHs, and ASCs. These waivers allow CRNAs to function to the fullest extent of their licensure when this is occurring consistent with a state or pandemic or emergency plan.

CMS will end this emergency waiver at the end of the PHE, which is expected to be on May 11, 2023, but states may apply to waive the requirement. To apply for an exemption in a state, based on the standards set forth in the final rule published on November 13, 2001, the Governor of the state must send a request to CMS. In the letter, the Governor of the state must attest that they consulted with the State Boards of Medicine and Nursing about issues related to access to and quality of anesthesia services and concluded that it is in the best interest of the citizens of the state to opt-out of the current supervision requirements and that the opt-out is consistent with state law.

Question #24C

C. Before both the Senate and House L-HHS Appropriations Subcommittees you repeatedly said FDA is waiting for a confirmatory trial for lecanemab (Leqembi). However, CMS does provide a way for coverage during accelerated approval, through a randomized clinical trial. Leqembi has completed its confirmatory trial which was quickly published in the *New England Journal of Medicine* and has since been submitted to the FDA with a

Fast Track, Priority Review and Breakthrough Status designation from the FDA and PDUFA date of 7/6/23. The American Academy of Neurology (AAN) and over 200 Alzheimer's researchers and providers have supported coverage of Leqembi, even though there was previous skepticism regarding coverage of Aduhelm. Mr. Secretary, what additional evidence or science is needed for CMS to move forward? I encourage you to work expeditiously to resolve any outstanding obstacles that are preventing coverage of a treatment that can provide hope for those that are currently suffering.

HHS Response

Alzheimer's disease is a devastating illness that affects millions of Americans and their families. CMS is committed to helping people get timely access to treatments and improving care for people with Alzheimer's disease and their families. CMS has a responsibility to ensure that people with Medicare have appropriate access to therapies that are reasonable and necessary for use in the Medicare population.

The FDA performs a vital and an important role. CMS recognizes the important and related – but different – roles of the respective agencies. The FDA determines whether to approve a new drug or biological based on a careful evaluation of the available data and a determination that the drug or biological is safe and effective for its intended use. In general, CMS makes national coverage decisions based on whether something is reasonable and necessary for the diagnosis or treatment of an illness or injury for the Medicare population. In determining the generalizability of the results of the body of evidence to the Medicare population, CMS considers, at minimum, the age, race and gender of the study participants. CMS conducts its own independent review to determine whether an item or service is reasonable and necessary for use in the Medicare population and should be covered nationally by Medicare. As of the hearing date, there has not been an antiamyloid mAb that has been approved by the FDA for the treatment of AD based upon evidence of efficacy from a direct measure of clinical benefit.

Question #24D

D. What are the Administration's plans for the next Medicare DMEPOS Competitive Bidding Program round? The most recent round (Round 2021), was the first time CMS implemented safeguards to protect the program's integrity. However, the Agency did not move forward with 13 product categories due to it not achieving the expected savings. What will happen with all 16 product categories after the end of Round 2021?

HHS Response

Round 2021 of the DMEPOS Competitive Bidding Program began on January 1, 2021, and extends through December 31, 2023. CMS competed 16 product categories in 130 competitive bid areas in Round 2021 of the DMEPOS Competitive Bidding Program, although the product category for non-invasive ventilators was removed in April 2020 due to the COVID-19 public health emergency. Of the remaining 15 product categories that were bid for Round 2021, 13 of the product categories have been in previous rounds of the Competitive Bidding Program, while 2 were competed for the first time in Round 2021. There were 130 competitive bid areas resulting in over 2,000 competitions. CMS received and has reviewed over 49,000 bids.

The Competitive Bidding Program has been an essential tool to help Medicare set appropriate payment rates for DMEPOS items and save money for beneficiaries and taxpayers while ensuring patient access to quality items. CMS will continue to evaluate the results of Round 2021 and will go through notice and comment rulemaking when proposing changes that will further improve the DMEPOS Competitive Bidding Program so it will continue to help Medicare set market based prices, save money for beneficiaries and taxpayers, and limit fraud and abuse in the Medicare program while ensuring access to quality items.

Question #24E

E. Mr. Secretary, what are your thoughts on using pharmacogenomic (genetic) testing to improve medication selection for those that suffer from major depressive disorder?

HHS Response

Pharmacogenetic testing is a potentially promising approach to improving treatment selection for people with mental illnesses including major depressive disorder. The National Institute of Mental Health (NIMH) is working to advance research in this and related areas.

Effective treatments – including medication and psychotherapy – exist for depression, but treatment selection remains a significant challenge because it relies largely on trial-and-error approaches, with each treatment approach requiring up to three months to determine its effectiveness. Therefore, there is an urgent need for accurate, fast, easy-to-use, and widely accessible biomarkers – including but not limited to genetic biomarkers such as risk gene variants – that can improve treatment selection by predicting an individual's response to different treatment options. NIMH currently supports research to identify such biomarkers to improve treatment selection for depression, as well as other serious mental illnesses and neurodevelopmental disorders. Additionally, as part of the Precision Psychiatry Initiative proposed in the FY 2024 President's Budget Request, NIMH is prepared to expand and accelerate biomarker development research specifically focused on depression.

Question #24F

F. Can you provide this Committee with an update as to where things stand on OTC pediatric fever-reducing products and will you work with us and continue discussions on the availability of OTC pediatric products as we prepare for the reauthorization of the Over-The-County Monograph Drug User Free Program?

HHS Response

FDA is happy to provide updates concerning the availability of over-the-counter (OTC) pediatric products as Congress prepares for the reauthorization of the Over-the-Counter Monograph Drug User Fee Act (OMUFA) program.

FDA understands the temporary issue with availability of acetaminophen and ibuprofen was due to

a significant surge in demand during an unprecedented peak in viral respiratory illnesses, including a large RSV outbreak, peak flu season, and the ongoing COVID-19 pandemic. It is the Agency's understanding that the manufacturers were using allocation strategies to meet demand (i.e., adjusting the distribution to ensure an adequate supply throughout the market). As a result, not all distributors and pharmacies were able to keep in-stock levels to their usual levels.

There are multiple manufacturers of nonprescription acetaminophen and ibuprofen oral suspension and chewable tablets as well as prescription ibuprofen oral suspension which were reported to be in short supply in late 2022. The manufacturers all reported continuing full production; however, they also reported unprecedented increased demand. In response, they reported increasing production to 24 hours a day, 7 days a week to continue to get product out into distribution and onto pharmacy and hospital pharmacy shelves to meet demand.

FDA continues to offer our assistance on steps to further increase supply, such as expediting review of submissions for new manufacturing sites, suppliers, or other components to increase production. In early 2023, FDA also published guidance on compounding of certain ibuprofen oral suspension products by outsourcing facilities to help increase supply in hospitals, health systems, and pharmacies.

In addition to publishing the guidance on compounding of certain ibuprofen oral suspension products to help increase supply, we also reached out to our international regulatory contacts on supply status in their countries, and all of them were experiencing increased demand as well. We continued efforts with the manufacturers that were making products for the U.S. market to increase supply to meet demand.

FDA is monitoring in-stock rates at the pharmacy/retail level as well as the manufacturers' reported production, inventory, and rate of filling orders for distributors that supply the retail sector and hospitals. All of these data sources are showing supplies are currently meeting patient needs and consumer demand.

Question #24G

G. Mr. Secretary, I want to emphasize something right off the bat: both you and I have a shared goal of protecting the health care of seniors enrolled in Medicare. With that said, certain pieces of your recent Plan Year 2024 Medicare Advantage Advance Notice alarmed me. Eliminating and collapsing over 2,200 diagnosis codes – which previously had been included in the Medicare Advantage Risk Adjustment calculation (used to determine overall health of the over 30-million seniors who choose to enroll in MA plans) – has been raised by doctors at the American Medical Association, the Medical Group Management Association, and many others as concerning.
    a. Will you please elaborate on the process your team used to evaluate which codes should be eliminated?
    b. Are physician coding practices and tendencies factored into your decision not to phase in potential coding eliminations?
    c. Have over 2,200 diagnosis codes ever been eliminated from the MA Risk Adjustment calculation without some sort of phase-in period? How many

codes were eliminated/collapsed annually in the risk adjustment model on average over the past five years?

HHS Response

As required by law, CMS adjusts payments to health plans offering MA to reflect the expected health care costs of enrollees based on health status and demographic characteristics through a process known as "risk adjustment." This ensures CMS pays more for enrollees with greater health care needs and reduces incentives for plans to favor healthier beneficiaries. CMS routinely makes a series of routine technical updates, improvements, and recalibrations to the MA risk adjustment model to reflect more recent utilization and cost patterns and to ensure MA payments accurately reflect the costs of care for MA enrollees. In February, CMS proposed routine technical updates to improve the accuracy of MA payments in the 2024 Advance Notice. CMS received public feedback on these proposals, and will take this feedback into account when finalizing the 2024 Rate Announcement.

Question #24H

H. The COVID-19 pandemic further exposed and exacerbated the inequities that impact access to healthcare for millions of Americans. When people can take control of their everyday health through direct access to safe and effective over- the-counter medicines, whether it's to quit smoking or manage their allergies, they not only stay healthier, but also save on healthcare costs. In fact, studies show that for every dollar spent on over-the-counter medicines, it saves the U.S. healthcare system $7.33. However, for this to remain true, we must have efficient processes, rooted in science, that permits FDA to make new and effective over- the-counter medicines available to Americans without lengthy and unnecessary delays. Does FDA have all the necessary authorities and appropriate staff capabilities to efficiently handle the pipeline of applications for over-the-counter products?

HHS Response

For nonprescription new drug application (NDA) drugs, FDA is working to finalize rulemaking regarding nonprescription drugs with an additional condition of nonprescription use (ACNU). Nonprescription drugs are used by consumers without the supervision of a health care professionals and require the consumer to be able to determine they have the condition for which the drug is to be used, and to appropriately use the drug. FDA issued a proposed rule in June 2022, which proposed that when FDA finds that labeling alone is not sufficient to ensure that the consumer can appropriately self-select and use a drug product in a nonprescription setting, an applicant may submit an application proposing an ACNU that a consumer must successfully fulfill to obtain the nonprescription product. For example, an applicant could propose an ACNU that requires a consumer to respond with specific answers to a set of questions on a self-selection test available by a phone "app" or an automated telephone response system to purchase the nonprescription product. If finalized, this rule would provide additional options for switching prescription drugs to nonprescription status. This is expected to increase access to nonprescription products.

For over-the-counter (OTC) monograph drugs, FDA continues to make large strides in OMUFA implementation using the resources provided by OMUFA I. For example, FDA issued four draft guidances for industry to aid stakeholders with recommendations regarding various aspects of the

OMUFA program. These guidances include: Over-the-Counter Monograph Order Requests (OMORs): Format and Content (April 2023), Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program (November 2022), Providing Over-the-Counter Monograph Submissions in Electronic Format (September 2022), and Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs (February 2022). In addition, on May 2, 2023, FDA posted five additional deemed final orders, completing the process of posting 33 deemed final orders for 32 different monograph therapeutic categories and one for non monograph conditions. All of the deemed final orders can be found on OTC Monographs@FDA. The deemed final orders for the monograph therapeutic categories provide the OTC monograph conditions for each therapeutic category as of the date of enactment of the CARES Act. Such deemed final orders provide of the conditions under which a drug is generally recognized as safe and effective (GRASE) for each therapeutic category. As we begin planning for OMUFA II, we will continue to work with the industry to identify resource gaps so that Americans can continue to access safe and effective OTC monograph drugs without the need for a prescription.

The Honorable Dan Crenshaw

Question #25A

A. CMS recently issued an Informational Bulletin related to state funding streams for the Medicaid program and health care related taxes.

- Can you explain why CMS felt the need to release this bulletin, and whether CMS is trying to revive the Medicaid Fiscal Accountability Rule, which was withdrawn in 2021?

Question #25B

B. I'm all for transparency but let me be clear: Texas is already required to report the sources of income for our 1115 waiver. This is providers getting together to offset the cost of Medicaid for our communities.

- Does this informational bulletin articulate a change in CMS policy?
- Has CMS ever approved "health care related tax arrangements involving the redistribution of Medicaid payments among the providers subject to the tax?"
- Although CMS may not like voluntary provider tax mitigation arrangements, does CMS hold statutory authority to address these agreements?

HHS Responses for A and B

In February 2023, CMS issued an informational bulletin reiterating federal requirements concerning health care-related taxes and hold harmless arrangements involving the redistribution of Medicaid payments. This guidance, which does not establish new policy, was issued as a reminder in response to questions received from several states about complying with section 1903 of the Social Security Act (42 U.S.C. 1396b(w)(4)(C)(i).). CMS recognizes that health care-related taxes often finance critical programs that pay for care provided to Medicaid beneficiaries and shore up the

health care safety net, and it will continue to approve permissible health care-related taxes that meet federal requirements and remains committed to working with states.

Question #25C

C. Last year, in your testimony to the Committee you voiced your support of ARPH-H with a 'focus on cancer and other deadly diseases.' Last year, ARPA-H received $1.5 billion. This year, you are seeking another $1 billion for an overall budget of $2.5 billion. Under the Director, the four ARPA-H focus areas are defined as:

- Health Science Futures (Accelerating research across areas)
- Scalable Solutions (geography/manufacturing)
- Proactive Health (prevention programs)
- Resilient Systems (weather, climate change)

None of these focus areas specifically address cancer research, cures, or deadly diseases. In fact, per the ARPA-H website, Resilient Systems is *defined as: 'Developing capabilities, business models, and integrations to weather crises such as pandemics, social disruption, climate change, and economic instability. Resilient systems need to sustain themselves between crises – from the molecular to the societal – to better achieve outcomes that advance American health and wellbeing.*

- What does this mean in terms of healthcare innovation or cancer and cures research?
- Is this just another way to mislead the taxpayers in order to fund climate change vs. cancer, diabetes, or other deadly diseases?
- Has the ARPA-H mission changed? If so, when were you going to be transparent with the American People?

HHS Response

The mission of ARPA-H is to accelerate better health outcomes for everyone by supporting the development of high-impact solutions to society's most challenging health problems. ARPA-H expects that projects funded in all four ARPA-H focus areas will address a variety of diseases and disorders, including cancer, Alzheimer's, and diabetes. ARPA-H is organizing its portfolio in a disease-agnostic way to take advantage of synergies across scientific innovation areas. For example, investments in advanced manufacturing techniques have the potential to accelerate diagnosis and treatment for multiple diseases.

The Resilient Systems Office focuses specifically on enhancing the robustness of systems that affect health outcomes, such as electronic health records systems, public health systems, supply chains, clinical research systems, biophysical systems, and technologies that facilitate communication between patients and clinicians. Technological advances in the resilience of today's systems will enable the healthcare ecosystem to remain responsive to patient needs even when faced with unexpected events or disruptions such as hurricanes, pandemics, or cyberattacks.

Question #25D

D. As of today, there are 24 full time employees listed on the website–

- What percentage of ARPA-H employees are working remotely versus in-person?
- What types of projects are these 24 full-time people working on?
- When do you expect to begin work on ARPA-H projects that align with the primary mission of innovation, health transformation and cancer and other diseases?

HHS Response

As of March 29, ARPA-H employs approximately 52 full-time Federal employees. To ensure robust representation of ideas and experiences from across the United States, ARPA-H has implemented recruiting efforts that expand beyond the Washington, DC region. As such, ARPA-H utilizes telework policies to stay competitive with the private sector and support a diverse workforce across the country. Like the Department, ARPA-H believes that organizational health and organizational performance should be the foundation for future operational decisions as we continue to increase meaningful in-person work. As always, our north star will continue to be delivering on our mission which means building on the innovations and technology that we have put to work over the last three years to ensure we are enhancing the health and well-being of all Americans.

Question #25E

E. ARPA-H is designed to address specialized research "that cannot readily be accomplished through traditional research or commercial activity." The omnibus legislation from last year outlines some key guidance on site selection, and your recent request for proposal includes a strategy for selecting two additional core sites, with a hub-and-spoke strategy.

- What steps is HHS taking to ensure that the site and partnership applications are considered solely on their merits?

HHS Response

ARPA-H has released a Request for Consortium Agreement (RCA) to solicit proposals for their customer experience and investor catalyst hub sites. The RCA describes ARPA-H's approach and evaluation criteria to identify the unique locations for these hubs. The evaluation criteria will be based off 4 factors:

- Factor 1 – Technical Solution
- Factor 2 – Depth and Breadth of Hub-and-Spoke Network
- Factor 3 – Management of the Consortium
- Factor 4 – Cost/Price Reasonableness

ARPA-H will select for award proposers whose proposal conforms to the RCA requirements

and is determined, based on evaluation, to be most advantageous to the government. The site proposals will solely be considered on how their merits fit the evaluation criteria.

Question #25F

F. In your response to Congresswoman Castor in Questions for the Record for an April 27, 2022 FY23 Budget Hearing, you allude to repurposing other HHS funds to run the OCCHE.

- "In addition, funds will be dedicated for staffing who will manage contracts, cooperative agreements, grant programs, and fellowship administration. Without appropriated funds, OCCHE has relied on details from other HHS operating divisions. This funding would allow the office to focus on medium and long-term goals such as developing climate resilience grant language and related training resources for use across operating divisions and federal agencies."
- Before receiving appropriations, where did HHS divert funding from to run OCCHE?
- What was the total amount of diverted funds?

HHS Response

The Office of Climate Change and Health Equity has been resourced by flexible, no-year funding sources, the Secretary's Initiatives and Innovations funding from the General Departmental Management appropriation, and a mix of reimbursable and non-reimbursable details from HHS operating divisions totaling $1.1M in FY 2021 and $1.6M in FY 2022.

The Honorable Mariannette Miller-Meeks

Question **#26A**

A, The President's Budget calls for countless new programs and funding streams. However, the President's Budget calls for no consolidations or closings of existing programs. This is a significant departure from past precedent for either party. President Obama's FY17 Budget included a whole section of cuts, consolidations, and closings. Does OMB believe there are no existing programs that could be cut or consolidated to enhance efficiency?

HHS Response

HHS has processes in place to assess and mitigate potential duplication and overlap of programs, and to ensure coordination across Operating and Staff Divisions. For example, through HHS performance processes Operating and Staff Divisions come together on a routine basis to collaborate on specific programmatic areas where they have shared equities. Instead of consolidating programs, HHS works to identify and strengthen handoffs between programs to elicit the highest operational efficiency.

Question #26B

B The Centers for Disease Control and Prevention has come under public scrutiny following its public failures during the pandemic. Many have understandably criticized the agency, citing mission creep in the agency and a lack of focus in preventing communicable diseases. The CDC performs vital functions, yet many believe it needs to be right-sized and refocused. However, the President's budget not only doesn't cut or eliminate a single program at the CDC, it doesn't call for a single decrease in any CDC program. Do you believe there is any way to find programs that could be consolidated or shifted from the CDC to make the agency more efficient in its response to public health threats?

HHS Response

With supplemental funding, CDC and its partners have stabilized the foundation for the U.S. public health system, which, in late 2019, was in a weakened condition after years of underinvestment. Thanks to supplemental funding over the past three years, Americans today are better protected from public health threats.

CDC's FY 2024 request is the responsible budget for where we are now. It will enable the Agency to bolster its public health core capabilities—data, lab, workforce, and global and domestic preparedness—to maintain and further expand upon the critical capacities we've built using base and COVID supplemental funding. This request also includes increases to address the ongoing consequences of COVID-19 such as mental health, suicide, ACES, opioid addiction, and violence. This budget also works to make up for the progress lost in routine vaccination during COVID – vaccines continue to be one of our greatest public health tools and getting back on track is imperative. As always, CDC increases include support to federal, state, and local partners who work on the front lines to respond to these significant health challenges.

Americans expect us to protect them from public health threats. If funding cuts are made, the progress we've made will halt, we will backslide to a pre-pandemic state of readiness, and will again be underprepared for the next threat. We already face tough choices about which programs and partners to fund; additional cuts will have an even greater, negative impact on our ability to support states, localities, and tribal and territorial partners. Without continued ongoing investments, CDC will not be able to sustain these critical capacities, build on progress to date, and ensure health security for Americans.

Question #26C

Secretary Becerra, in its March 15th Medicare Drug Price Negotiation Program Initial Guidance, CMS stated the agency "is considering whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development." Please detail how the agency is assessing the Negotiation Program's potential impact on orphan drug development and what potential actions the agency could undertake to protect future rare disease drug development.

HHS Response

CMS supports continued drug innovation and believes it is vitally important that beneficiaries have

access to innovative new therapies. We are striving to implement the Negotiation Program in a thoughtful way that both improves drug affordability and accessibility for people with Medicare and supports innovation.

The law requires CMS to exclude certain orphan drugs approved or licensed when identifying qualifying single source drugs, referred to as the orphan drug exclusion. To be considered for the orphan drug exclusion, the drug or biological product must (1) be designated as a drug for only one rare disease or condition by the FDA and (2) be approved by the FDA only for one or more indications within such designated rare disease or condition. As noted in the initial guidance, we are still considering whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development. The agency will continue to keep Congress and stakeholders updated as we move forward.

The Honorable Troy Balderson

Question #27

1. One concern I have with your budget request is that you continue to throw more and more taxpayer money at problems without new initiatives or programming that will cause actual change. This past winter, Central Ohio experienced a measles outbreak. 85 children got sick, and 35 had to be hospitalized. The Columbus Health Department said the spread was mostly driven by a lack of vaccination in the community.

   In 2019, 23 percent of parents opposed schools requiring certain vaccinations. That number has grown to 35 percent today. I believe this change is partly due to the mistrust surrounding your agency as a whole and of the COVID-19 vaccination mandates led by your department and the Biden administration. You lied to the American people about the value of natural immunity and about transmission amongst the vaccinated. You rushed to mandate vaccines without fully researching or conducting long-term studies on their side effects.

   Over the past three years, you received 1 billion dollars for vaccine confidence activities. In this year's budget, you request 317 million additional dollars for Domestic Immunization efforts at the CDC. How specifically do you plan to use this additional money to restore trust in our normal vaccination regimens?

HHS Response

A strong vaccination recommendation from a healthcare provider is a leading factor in vaccine acceptance. Members of medical and health-focused professional associations act as influential messengers to their patients and community members by sharing culturally competent vaccine information to increase confidence and uptake of the vaccine. CDC builds alliances with and funds professional and medical associations that represent physicians of color and serve racial and ethnic minority groups. For example:

- 505,547 clinicians have been reached through new strategies and resources.
- 967 healthcare organizations have been reached through new strategies and resources.

- 150 trainings have been provided for clinicians or individuals affiliated with healthcare organizations.

Additionally, CDC has worked with over 500 partners, including:

- **Pima County Health Department – (Tucson, AZ)** is in the process of completing a needs assessment to identify drivers of COVID-19 and flu vaccine hesitancy, influential messengers, and community acceptable approaches. Pima has trained 79 influential messengers, administered 700+ COVID-19 vaccinations/600+ flu vaccinations to members in their community, and created culturally and linguistically appropriate messaging and campaigns. They have also created and funded Community Action Groups to help increase vaccine uptake in their target populations.
- **Houston County Board of Health's (Houston County, GA)** H-CHAMP program creates, develops, and empowers ambassadors (influential messengers) from within the community to spread the word about upcoming vaccine events, to dispel the myths about vaccination, and to reduce barriers to vaccination. Some highlights of the program have been determining social drivers associated with low coverage rates and working with Faith-Based Organizations to hold vaccine events and disseminate information on the safety, efficacy, and importance of vaccination.
- **National Hispanic Medical Association (NHMA)'s Gulf Coast Chapter (LA)** partnered with Ochsner Health Hispanic employee resource group to better understand the reasons behind COVID-19 vaccine hesitancy in the Hispanic community in the Greater New Orleans area. They conducted focus groups and interviews to understand barriers and developed actionable interventions to increase vaccination rates in the local Hispanic community.
- **Association of American Indian Physicians (AAIP),** which advocates for pursuing excellence in Native American health care, planned an educational session titled "Traditional Approaches to COVID-19" for the 2022 Cross Cultural Medicine Workshop open to health care professionals, practitioners, and students.

Question #28

2. Much of the public agrees that our agencies need to return to their original, intended purposes and prepare for future pandemics, instead of focusing on COVID-19 at the expense of the litany of other diseases and health challenges facing Americans. Your budget requests 20 billion additional dollars in mandatory funding for pandemic preparedness, on top of increases of hundreds of millions for the relevant agencies. What percentage of resources and offices will continue to be dedicated to COVID?

HHS Response

COVID-19 was a focus of many components within HHS as we worked to protect the health of all Americans during the pandemic. This will continue to be the case as long as there is need and

resources to respond.

Question #29

3. During the FDA's Rare Disease Day last month, Commissioner Califf committed to speeding solutions for rare disease patients and voiced concerns that there are still thousands of rare diseases that lack drug treatment. However, the overly narrow scope of the orphan drug exemption in the Inflation Reduction Act, or IRA, would discourage investment into additional orphan indications for existing therapies. These additional indications are often diseases without any current therapies available. If science proved a medicine had more uses, that medicine could become subject to future price controls.

   How is HHS ensuring that the IRA's orphan drug exemption does not disincentivize future research of orphan drugs3 for rare diseases without current treatment options?

HHS Response

CMS supports continued drug innovation and believes it is vitally important that beneficiaries have access to innovative new therapies. We are striving to implement the Negotiation Program in a thoughtful way that both improves drug affordability and accessibility for people with Medicare and supports innovation.

The IRA requires CMS to exclude certain approved or licensed orphan drugs when identifying qualifying single source drugs, referred to as the orphan drug exclusion. Section 1192(e)(3)(A) of the Social Security Act (42 U.S.C. 1320f-1(e)(3)(A)) describes a drug that qualifies for the orphan drug exclusion as "[a] drug that is designated as a drug for only one rare disease or condition under section 526 of the Federal Food, Drug, and Cosmetic Act and for which the only approved indication (or indications) is for such disease or condition." As noted in the initial guidance, we are still considering whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development. The agency will continue to keep Congress and stakeholders updated as we move forward.

The Honorable John Joyce

Question #30

1. Nearly 800,000 people in the United States have End Stage Renal Disease, with over 550,000 needing dialysis, a procedure to remove waste products and excess fluid from the blood, to live. [1]. This process must take place several times a week, and cannot be missed, even in times of national emergency. In the recent past, patients have been transported in order to receive treatment, including being flown from U.S. territories to the mainland. In recent years, the Strategic National Stockpile (SNS) contracted with dialysis platforms that relied on potable water sources in order to deliver care in or near disaster zones either in-home or in a temporary outpatient care facility. Since inclusion of dialysis machines in the SNS can help prepare the U.S. to care for patients needing dialysis during future emergencies, what steps are you taking to ensure these devices are included in the SNS or that the Administration for Strategic Preparedness and Response is prepared to provide dialysis care during disasters and

public health emergencies?

https://usrds-adr.niddk.nih.gov/2021/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities

HHS Response

The SNS currently has no requirement or resources available to procure and stockpile deployable dialysis machines. However, ASPR does have the HHS emPOWER Program (emPOWER) that is at the forefront of innovating and harnessing the power of federal health data, artificial intelligence, and federal-to-community level partnerships to protect health and save lives, including aiding those individuals who are dependent on dialysis machines. emPOWER is a partnership between ASPR and the Center for Medicare and Medicaid Services (CMS) that provides federal data, mapping, and AI tools to help communities protect the health of at-risk Medicare beneficiaries, including individuals who rely on electricity-dependent durable medical and assistive equipment devices, or essential health care services (i.e., facility-based dialysis, home oxygen tank services, home health care services, and at-home hospice services).

In a disaster or emergency, authorized state or territorial public health authorities that meet certain requirements may submit a disclosure request for official review and approval of a minimum necessary HHS emPOWER Emergency Response Outreach Individual Dataset to support critical life-saving assistance and response outreach public health activities. The dataset includes limited individual level data and healthcare provider and supplier information for Medicare beneficiaries who have a claim for one or more types of electricity-dependent durable medical equipment and certain cardiac implantable devices and or one or more of the above-mentioned types of essential healthcare services. The dataset has been used by public health authorities to activate emergency plans and communications, deploy response assets and resources, and conduct life-saving outreach with authorized partners in the event of emergencies and disasters.

Question #31

2. One of the goals of this administration is to address health disparities, but we can't begin to do that without establishing a stable Medicare payment system. Physicians need support as they care for historically marginalized populations, especially in rural communities and small towns. The current Medicare system can penalize physicians for caring for the most vulnerable populations because the cost of care is higher. For example, CMS quality and value measures need to be risk adjusted, because patients with complicated conditions and comorbidities are likely to have increased costs associated with their care. What is CMS doing to ensure a stable Medicare payment system so physicians are not unfairly penalized for treating patients with more complicated conditions?

HHS Response

The Biden-Harris Administration is committed to protecting and strengthening Medicare so that Americans of every generation can count on it, and ensuring that providers receive appropriate payments is a critical part of our efforts. Ensuring adequate payment rates for physicians and other

health care professionals is essential in maintaining patients' ability to access high-quality and affordable health care. CMS is required to base payments for services under the physician fee schedule on the relative resource costs involved in furnishing a service, and the fee schedule is subject to statutory budget-neutrality requirements. CMS does not have the legal authority to implement increases in payment outside of budget neutrality without additional action taken by Congress.

However, CMS recognizes that there can be challenges and additional costs associated with the care provided to patients with complex medical needs and marginalized populations. In recognition of these challenges, the Calendar Year (CY) 2020 Medicare Physician Fee Schedule (PFS) final rule established a Complex Patient Bonus, which is added to a provider's Merit-based Incentive Payment System (MIPS) final score and based on the overall medical complexity and social risk for the patients treated by a clinician or group. CMS intends for this bonus to serve as a short-term strategy to address the impact patient complexity may have on MIPS scoring while we continue to work with stakeholders on methods to account for patient risk factors. Additionally, the CY 2023 PFS proposed rule contained a request for information on risk indicators within the complex patient bonus formula to continue to align with CMS's approach to operationalizing health equity. The agency appreciates stakeholder responses to this request for information and may consider this information to inform future rulemaking.

Question #32

> 3. The Medicare program has been focusing on ways to advance quality care through measurement. While we all can support this initiative, there are problems with the current system. For instance, the reporting requirements are incredibly burdensome, and many of the measures CMS requires for reporting are irrelevant to physicians and their patients. Further, CMS mandates reporting, or physicians are penalized. What is CMS doing to ensure a diversity of payment models that work for small and large physician practices as well as those in different specialties and communities nationwide?

HHS Response

The Innovation Center plays a critical role in implementing the Quality Payment Program, which Congress created as part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). In fall 2021, the CMS Innovation Center set a strategic goal for its next ten years: to transform the health system into one that achieves equitable outcomes through high quality, affordable, person-centered care. As part of this, the Center is committed to designing models that are inclusive of a variety of providers who care for underserved populations, ultimately increasing beneficiaries' access to high-quality care.

Additionally, on September 6, 2022, CMS posted a Request for Information (RFI), titled Make Your Voice Heard: Reducing Burden and Increasing Efficiencies. CMS is committed to engaging with partners, communities, and individuals across the health system to understand their experiences with CMS policies and programs, particularly how existing and proposed CMS policies and programs impact the experience of healthcare. The CMS Office of Burden Reduction & Health Informatics (OBRHI) was established to serve as a focal point and champion for burden

reduction, national standards and interoperability, and to engage our customers to inform solutions. This work is focused on advancing efficient, equitable, and quality healthcare across all CMS programs, including Medicare, Medicaid, the Children's Health Insurance Program (CHIP), the Marketplace, and CMS Innovation Center models. The information received supports the CMS effort to increase the understanding of how our work serves to support stakeholders.

With respect to the quality measures in use, CMS has worked to align quality measures to reduce burden and drive quality improvement and care transformation. CMS has developed a "Universal Foundation" of the key quality measures to be aligned across all programs (to the degree applicable and feasible) in order to reduce inconsistency and promote a focus on important quality issues. CMS started by identifying measures for the Universal Foundation's adult and pediatric components. In addition to these, metrics are necessary, for example, to assess care in specific populations or settings, such as to promote specialty care in the clinician value-based purchasing program, the Merit-based Incentive Payment System (MIPS). For MIPS measures, we are also transitioning the framework of MIPS to incorporate MIPS Value Pathways, which will focus on streamlined subsets of measures related to a specific specialty or medical condition, offering a connected assessment of quality of care, and with less burden on practitioners.

Question #33

4. The United States needs to be prepared for the next infectious disease outbreak. A critical component of being prepared is ensuring that we are actively conducting monitoring and surveillance of these pathogens at both the hospital and community setting. How will

   HHS ensure the correct diagnostic testing is being done to quickly identify infectious pathogens?

HHS Response

Disease surveillance is currently led by CDC. However, ASPR's Biomedical Advanced Research and Development Authority (BARDA), Detection Diagnostics and Devices Infrastructure (DDDI) Division is funding development of leading-edge diagnostic products for informing individualized care of patients in response to future biological incidents across the spectrum of diagnostic needs. Use cases being addressed include home-use molecular tests and point-of-care molecular testing platforms, both to bring testing closer to the patient and enable test-to-treat care scenarios. Also included are pathogen family tests and next generation sequencing based threat agnostic testing, to make diagnostic testing available faster. Contingent on availability of funding, BARDA/DDDI is interested in working in collaboration with IBMSC to ensure test manufacturing capabilities for these and other critical testing technologies are available domestically and able to produce needed tests quickly during a biological incident.

In addition, the Administration's *National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security* includes plans to speed up the availability of diagnostic tests, both in terms of type and

quantity, of tests for current and future pandemics. Congressional support for the plan is essential to its success. In this plan increased variant identification, both in disease surveillance and for informing care for specific patients will become more available. Specific objectives are established in this plan to make testing available more quickly both for new emerging diseases and emerging SARS-CoV-2 variants. Due to the shorter development time for molecular test technologies, the plan includes investment in domestic capability to manufacture the newly emerging molecular tests that are appropriate for use in non-laboratory settings, including homes, making them much more widely available.

Question #34

5. The COVID-19 pandemic has exhausted the misuse and overprescribing of antibiotics which has consequently increased the spread of antimicrobial resistance in the United States and around the world. Recent examples of resistance include the eye drop recall and the alarming spread of Candida auris – a deadly fungal infection – in hospitals. Unfortunately, diagnostic tests are not adequately being utilized prior to the prescription of an antibiotic. How will HHS help support efforts to decrease empiric antimicrobial therapy and encourage enhanced utilization of diagnostic tests?

HHS Response

Through the 2020-2025 National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), HHS is working with federal, state, and local partners to implement a suite of complementary actions to combat antibiotic resistance. The National Action Plan for CARB includes two goals particularly relevant to appropriate antibiotic use. Goal 2 supports antibiotic stewardship, which guides appropriate antibiotic use and thereby reduces the opportunities for resistance to develop. Goal 3 supports the development and appropriate use of diagnostic tests to provide the right antibiotic at the right time in the right dose.

CDC, AHRQ, and CMS support the development, evaluation, and implementation of high-quality antibiotic stewardship programs across a variety of healthcare settings. CDC's Core Elements of Antibiotic Stewardship offer providers and facilities a set of key principles to guide efforts to improve antibiotic use and, therefore, advance patient safety and improve outcomes; this guidance has been tailored for hospitals, outpatient settings, nursing homes, and resource-limited settings. The AHRQ Safety Program for Improving Antibiotic Use was developed to help clinicians in hospitals, doctors offices, and long-term care apply the Four Moments of Antibiotic Decision Making and concepts derived from the Comprehensive Unit-based Safety Program (CUSP) to improve antibiotic stewardship by selecting the optimal antibiotic regimens, routes of administration, and durations. AHRQ and partners assessed the Safety Program's impact on patient safety culture and antibiotic prescribing practices across a total of 1,304 participating sites throughout the United States, including 476 units from 402 acute care hospitals, 439 long-term care facilities, and 389 ambulatory care centers. Results indicate that the Safety Program aided participating sites to develop and enhance their AS activities and to reduce antibiotic prescribing. At the end of each intervention, a toolkit was developed that contained materials developed for each cohort as well as additional information to allow sites that did not participate to recreate the Safety Program at their own facilities. CMS works closely with CDC in the development of its antibiotic stewardship program requirements as well as the interpretive guidelines that support

these regulations. Through its published rules and guidance, CMS has strongly encouraged healthcare facilities to use CDC's Core Elements of Antibiotic Stewardship as a basis for establishing antibiotic stewardship programs in Medicare-participating facilities. In 2022, CMS published updates to interpretive guidance for hospital requirements under the Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction Final Rule, which revised the regulatory requirements for hospitals related to infection prevention and control and antibiotic stewardship programs.

CDC, AHRQ, NIH, and FDA are working under the National Action Plan for CARB to fund research to better understand the appropriate use of diagnostic testing to address bacterial or fungal infections, and to use that evidence to promote the appropriate use of new and existing diagnostics that determine the presence, severity, or antimicrobial susceptibility or resistance of bacterial or fungal infections in human clinical care. For example, CDC used data from their Gonococcal Isolate Surveillance Project to guide updates to the 2020 gonorrhea treatment recommendations published in the Morbidity and Mortality Weekly Report. These data were used in determining recommended treatment regimens and for test-of-cure testing recommendations.

HHS agencies continue to monitor the implementation of these activities to understand their impact and develop additional proposals to support appropriate antibiotic use, including through improved diagnostic testing. For example, the FY2024 President's Budget includes a proposal for CDC to advance laboratory science through shortening the time to develop diagnostic tests, evaluating and implementing new detection technologies, increasing the number of tests results available per day, ensuring the quality of test results, improving laboratory safety and efficiency, and developing uniform quality practice standards for CDC and other public health labs. AHRQ supports research to determine appropriate integration of approved diagnostics into clinical care. For example, AHRQ is currently funding several research projects aimed at diagnostic stewardship which helps avoid overtreatment of cultures that do not represent infection. AHRQ supports this research with funds earmarked for combating antimicrobial resistance.

Question #**35**

6. **As we know, the Public Health Emergency ends on May 11, however many private payers have indicated through their current COVID-19 policies that they will no longer cover and reimburse COVID tests administered at point of care – meaning in pharmacies, urgent care centers and physician office labs. Point of care testing is essential for Test to Treat models and ensuring that patients receive the right treatment in a timely manner. Does HHS plan to work with private payers to ensure beneficiaries have access to COVID testing at point of care post-PHE and further integrate into routine medical care for respiratory illnesses?**

HHS Response

The requirement for group health plans and health insurance issuers offering group or individual health insurance coverage to cover COVID-19 tests without cost sharing, both for over-the-counter and laboratory tests, will end at the end of the Public Health Emergency (PHE). However,

plans and issuers are encouraged to continue to provide this coverage, without imposing cost sharing or medical management requirements, after the PHE ends.

Question #36

7. As the fentanyl crisis continues to grip the nation, how is your department ensuring that providers have access to all unbiased tools—such as definitive urine drug testing—to determine what medications or controlled substances patients are taking?

HHS Response

SAMHSA administers the Drug Testing Advisory Board (DTAB), which is a board of experts that works together to advise the Assistant Secretary for Mental Health and Substance Use on the agency's Federal Drug-Free Workplace Programs and drug testing laboratory certification program. These activities collectively regulate federal employee and applicant drug testing. Although the Federal Workplace Drug Testing Program primarily regulates federal workplace drug testing, this program, in consultation with DTAB, benefits drug scientific drug testing standards used in other contexts, such as clinical drug testing.

SAMHSA also provides support to providers through the Providers Clinical Support System (PCSS) program in an effort to train health professionals to provide effective, evidence-based, medication-assisted treatments to patients with opioid use disorder in primary care, psychiatric care, substance use disorder treatment, and pain management settings. For example, the PCSS offers trainings and technical assistance for primary care providers on how to interpret urine drug screening results and how to conduct office-based substance use treatment.

Additionally, HHS, in conjunction with the Department of Labor and the states, enforces the Mental Health Parity and Addiction Equity Act to ensure comparable benefits to substance use disorder treatment as compared to those for medical/surgical treatment. As highlighted by the 2022 MHPAEA Report to Congress and the FY 2021 Enforcement Fact Sheet, this includes efforts to ensure comparable access to urine drug testing.

Question #37

8. How are HHS and CMS ensuring that Medicare beneficiaries have broad access to definitive drug testing services, which is the only objective tool clinicians have available to detect fentanyl and other illicit substances?

Question #38

9. Are you aware that the Medicare Administrative Contractors are proposing detrimental policy changes that would negatively impact access to definitive urine drug testing services

for beneficiaries in treatment for substance use disorder? Why is CMS allowing these policies to proceed in the middle of a national drug abuse epidemic?

Question #39

10. Six of the seven Medicare Administrative Contractors in recent months have proposed Local Coverage Determinations (LCDs) that would dramatically reduce access to definitive drug testing, which is only objective tool available to clinicians to detect whether their patients have ingested fentanyl and many other illicit substances that cannot be tested or detected by other means. Will you commit that CMS will review these draft LCDs and instruct the MACs to remove them if they are found to be procedurally or clinically inappropriate?

HHS Responses 37-39

Under the Medicare statute, Medicare Administrative Contractors (MACs) are authorized to develop Local Coverage Determinations (LCDs) in the absence of national policy or as long as the LCDs do not conflict with a national policy. The MACs issue LCDs to provide the evidentiary-based coverage criteria within their jurisdictions to assist providers in submitting proper claims for payment. Several MACs proposed LCDs for urine drug testing related to four codes that are based on the number of different drug classes that are tested. The MACs proposed to reduce the number of drug classes to the middle range of these four codes.

CMS requires that the MACs follow the LCD development process, including opportunities for public comment and input from the local medical community, as described in Chapter 13 of the Medicare Program Integrity Manual (PIM).[1] Part of that process requires that the MACs considered all comments received. As a result of the public comments received, some MACs have rescinded their proposed LCDs and the other MACs are doing the same.

Question #40

11. In December 2022, Congress provided BARDA with an additional $200 million in funding to be used by September 30, 2023. The agreement encouraged BARDA to "engage in public-private partnerships to support advanced research and development of innovative platform technologies and medical countermeasure (MCM) programs focused

    on, but not limited to, vaccines, therapeutics, and other MCMs for emerging infectious diseases, including novel pathogens and viral families with pandemic potential."

    - How is this additional money being spent by BARDA?

HHS Response

The FY23 additional funding will advance the development of MCMs across BARDA's threat areas, many of which are considered pathogens of pandemic potential such as influenza virus and filovirus. The additional funding will also support transformative science & technology to

strengthen national and global health security through BARDA Ventures as well as help BARDA maintain a world-class workforce that continues to respond to the COVID-19 pandemic as well as numerous public health emergencies and outbreaks caused by Chemical, Biological, Radiological and Nuclear (CBRN) threats and pandemic influenza. As part of BARDA's FY23 initiatives, the agency is focused on implementing strategies that support U.S. readiness for future biothreats and leverage technologies capable of rapidly pivoting to address new threats. This includes supporting the use of therapeutic platforms and the development of host-directed MCMs to address a broad swath of pathogens. Pursuing both approaches is critical as host-directed MCMs provide value, especially early in a response to an emerging infectious disease, as they can reduce morbidity and mortality while direct acting products are developed against a new threat. Many of these investments are cross-cutting or threat agnostic and therefore would work to prepare the nation against a variety of biological threats.

The Administration's 2022 *National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security* (Strategy) details a coordinated approach to address the challenges from biological threats. Implementation of the strategy aims to rapidly make and equitably deploy safe and effective vaccines against any pathogen family, at timescales and quantities necessary to contain and control a potential nationally or internationally significant biological incident. In addition, implementation of the Strategy aims to establish innovative and agile domestic therapeutic research, development, manufacturing, and delivery capabilities that yield a range of safe and effective therapeutics, available before or readily created during a nationally or internationally significant biological incident. The Strategy aims to realize ambitious timelines in the development of novel countermeasures, both for vaccines and therapeutics.

HHS will work with other departments and agencies to enhance vaccine and therapeutic capacity and capability and will drive towards achieving transformational bold outcomes, recognizing the need for sufficient resources and aggressive action to achieve these objectives.

- What is the administration doing to advance therapeutics that could address COVID-19 and its variants?

HHS Response: As part of the COVID-19 response, BARDA supported the advanced development and procurement of therapeutics. BARDA screened existing monoclonal antibodies developed for other coronaviruses and supported the development of new targeted monoclonal antibodies using platform technology that had previously been used to successfully license monoclonal antibodies for other diseases. BARDA advanced two targeted monoclonal platform candidates identified in screening through manufacturing, non-clinical, and Phase 2 and Phase 3 clinical trials. BARDA issued advanced purchase agreements for additional monoclonal antibody candidates, which were critical to encouraging companies to develop these products. BARDA supported clinical trials aimed at re-purposing immune modulators and other host-targeted therapeutics for the treatment of hospitalized COVID-19 cases. BARDA leveraged an advance purchase agreement with Merck for molnupiravir to provide Merck assurance of a purchase upon successful development and achieving Emergency Use Authorization (EUA). The program also supported monoclonal antibody and antiviral procurement to ensure access until the commercial

market was established. As a result of BARDA's efforts, 10 therapeutics achieved Food and Drug Administration (FDA) Emergency Use Authorization (EUA) while 23.6 million treatment courses of COVID-19 therapeutics have been shipped to providers across the U.S.

As seen with COVID-19, hospitalized patients have few treatment options when suffering from acute respiratory distress syndrome (ARDS) or acute lung injury (ALI). BARDA is continuing to support host-targeted therapeutics that can treat or prevent ARDS of any cause, which will better prepare the nation against COVID-19 for the next respiratory pandemic. BARDA currently has an open Broad Agency Announcement (BAA) area of interest (AOI) focused on immunomodulators or therapeutics targeting lung repair. This AOI seeks to develop immune modulators or other host-directed therapeutics promoting tissue repair that can prevent, treat, and/or improve clinical outcomes of ALI/ARDS caused by the pandemic or seasonal influenza and other respiratory viral infections.

As part of Project Next Gen, BARDA is supporting the Administration to accelerate the development of COVID-19 next generation MCMs to include therapeutics such as long-acting monoclonal antibodies. BARDA currently has two open AOIs for its BAA focused on COVID-19 monoclonal antibodies for both treatment and pre-exposure protection for individuals that may not be able to mount an adequate immune response or for individuals whom vaccination is not recommended. In addition, BARDA recently released new Flexible and Strategic Therapeutics (FASTx) AOIs in the BAA and EZ-BAA seeking proposals to advance cost-effective, quickly adaptable therapeutic platforms to treat viral infections, including COVID-19.

The Administration's 2022 *National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security* (Strategy) details a coordinated approach to address the challenges from biological threats. Implementation of the strategy aims to rapidly make and equitably deploy safe and effective vaccines against any pathogen family, at timescales and quantities necessary to contain and control a potential nationally or internationally significant biological incident. In addition, implementation of the Strategy aims to establish innovative and agile domestic therapeutic research, development, manufacturing, and delivery capabilities that yield a range of safe and effective therapeutics, available before or readily created during a nationally or internationally significant biological incident. The Strategy aims to realize ambitious timelines in the development of novel countermeasures, both for vaccines and therapeutics.

HHS will work with other departments and agencies to enhance vaccine and therapeutic capacity and capability and will drive towards achieving transformational bold outcomes, recognizing the need for sufficient resources and aggressive action to achieve these objectives.

- What is the administration doing to ensure that the development and approval of therapeutics is equal to vaccines?

HHS Response: The Administration is committed to the continued development and approval of MCMs, including vaccines and therapeutics, that address COVID-19. BARDA also supports the

development of additional vaccines and therapeutics to address pandemic influenza, chemical/biological/radiologic/nuclear threats and emerging infectious diseases. BARDA will continue to make investments to advance the development of these MCMs through its public private partnership model. In addition to providing funding, BARDA has subject matter experts with decades of experience that work hand in hand with industry partners to help expedite MCM development. If you have constituents interested in speaking with BARDA, BARDA has a program called TechWatch that facilitates conversations with companies about their product, technology or capabilities to explore potential partnering opportunities. BARDA encourages all interested companies to request a meeting.

The Honorable Michael Burgess

Question #41

Information Blocking/Information Sharing

1. The vision of the bipartisan 21st Century Cures Act was to enable health care data to be exchanged easily and electronically, relieving provider burdens imposed by fax machines and paper records and enabling providers to focus on patient care. In practice, electronic health records (EHR) companies can still act as gatekeepers, only allowing information to be shared on their terms by leveraging providers requirements to share patient data. EHR vendors write into their contracts that only certain provider personnel can have access to their systems, putting their own intellectual property concerns above facilitating patient care.

    - Are you concerned that there are loopholes in the current information blocking rules that continue to permit bad behavior by EHR vendors?
    - How does HHS plan to step up enforcement activities and finalize rules to give the law teeth?

HHS Response

Health IT developers under the ONC Health IT Certification Program (Program) are subject to conditions and maintenance of certification requirements, including provisions that limit their restrictions on certain communications about their EHR technology and related practices. Additionally, health IT developers of certified health IT are subject to the information blocking regulations, which outline specific exceptions that are reasonable and necessary activities that do not constitute information blocking. For example, restrictions related to intellectual property may constitute information blocking unless they meet the requisite conditions under the Licensing Exception.

ONC maintains a web-based feedback portal for submitting concerns and complaints about health IT developers' practices. One selection is specifically for submitting reports of information blocking as required by the 21st Century Cures Act and another is for submitting general concerns about health IT developers' actions under the Program, the latter of which is within ONC's oversight authority.

The 21st Century Cures Act gave the HHS Inspector General authority to investigate any claim that a health IT developer of certified health IT, other entity offering certified health IT, health care provider, health information network, or health information exchange engaged in information blocking.[23] HHS expects to publish our Office of the Inspector General (OIG) final rule establishing procedures necessary to use the 21st Century Cures Act authority to take enforcement action against EHR vendors, certain other developers and sellers of health information technology, and health information networks or exchanges. This rule will add the Cures Act authority to impose civil monetary penalties for information blocking to the regulatory framework for imposition and appeal of penalties under laws addressing other types of serious misconduct, such as filing false Medicare claims or paying kickbacks for steering patient referrals.

Question #42

Physician Owned Hospitals

2. Can you clarify your rationale for changing the interpretation behind the intent of the statute?

    - Did AHA or FAH communicate with any CMS staff through official or unofficial channels about this issue?
    - With hospital consolidation a key policy concern, why is CMS implementing policy to reduce competition?

HHS Response

Congress limited the ability of physician-owned hospitals to expand. CMS is required under the law to establish a process for physician-owned hospitals to apply for an exception from the expansion prohibition. CMS welcomes feedback on that process and is happy to work with you to provide technical assistance on legislation you draft related to this issue.

Cybersecurity

3. Mr. Secretary, I appreciate the work we have done together to strengthen cybersecurity for medical devices with the new premarket authorities for FDA that were included in last year's omnibus legislation. I was also pleased to see HHS partner with the Healthcare and Public Health Sector Coordinating Council (HSCC) to recently publish a report on legacy medical technologies and provide actionable strategies for manufacturers and health care providers to implement as part of their shared responsibility in the clinical environment.

Question #43

A. Recently, FDA issued guidance indicating that, beginning October 1, 2023, the agency will consider issuing "refuse to accept" notices for medical devices that do not

[23] 42 U.S.C. 300jj–52(b)(1) as added by section 4004 of the 21st Century Cures Act (Pub. L. 114-255)

include the required premarket cybersecurity elements, as set forth in the omnibus legislation. Does FDA plan to issue an updated final premarket guidance on cybersecurity of medical devices before this date? If not, what guidance will control?

HHS Response

FDA is grateful to Congress for providing FDA with explicit cybersecurity regulatory authorities for medical devices in Section 3305 of the Food and Drug Omnibus Reform Act (FDORA), which added section 524B to the Federal Food, Drug, and Cosmetic Act (FD&C Act). As we experience an increase in cyber threats across health systems, and from other nations including China, the new authorities are critical to help ensure patients have access to devices that are safe, and for safeguarding the Healthcare and Public Health Critical Infrastructure Sector and our national security.

FDORA states that the amendments to the FD&C Act shall take effect 90 days after the enactment of this Act, so the new premarket cybersecurity requirements became effective on March 29, 2023. Understanding it will take time for industry to transition to compliance with the new requirements, FDA issued a guidance for immediate implementation: Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices Under Section 524B of the FD&C Act[24] on March 29, 2023. The guidance explains that the Agency generally intends not to issue "refuse to accept" (RTA) decisions for premarket submissions for cyber devices that are submitted before October 1, 2023, solely because information required by section 524B of the FD&C Act may be deficient. Instead, FDA will work collaboratively with sponsors of such premarket submissions as part of the interactive review or deficiency process. As FDA implements the new provisions, we are working to provide clarity and transparency for those who will be complying with the new requirements.

Please note that the RTA process is an administrative acceptance process to assess whether the submission contains the sufficient information to allow for the substantive review of the submission to begin. While FDA does not intend to refuse to accept submissions that are missing the documentation required under section 524B, the requirements under section 524B of the FD&C Act are being incorporated into Center for Devices and Radiological Health's (CDRH) review of submissions for cyber devices and we are seeking this information interactively.

To further provide guidance to manufacturers on how to address the requirements in section 524B of the FD&C Act, the Agency released a frequently asked questions webpage[25] and updated the help text for cybersecurity documentation in the voluntary eStar submission templates[26]. These resources point to our existing final guidance documents, primarily the 2014 guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" and the 2016 guidance "Postmarket Management of Cybersecurity in Medical Devices." The Agency will continue to keep the public updated as it implements the new statutory provisions. We are working to finalize the 2022 draft update to the premarket cybersecurity guidance "Cybersecurity in Medical

[24] Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act | FDA
[25] Cybersecurity in Medical Devices Frequently Asked Questions (FAQs) | FDA
[26] https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program

Devices: Quality System Considerations and Content of Premarket Submissions" and it is on the A-List of priorities for FY2023.[27]

The cybersecurity team in FDA's CDRH engages with sponsors of medical devices and encourages those with questions about considerations they should take into account with respect to cybersecurity for marketing their devices to contact us. Additionally, FDA has several mechanisms for manufacturers to obtain feedback on potential premarket submissions. For general questions on cybersecurity policy or the requirements under section 524B of the FD&C Act, there are two mailboxes people can contact: CyberMed@fda.hhs.gov and OPEQ_Cybersecurity@fda.hhs.gov. For more specific feedback on submission documentation prior to making an application to the Agency, CDRH routinely reviews presubmissions under the Q-Submission Program[28]. During the submission review process, CDRH also strives to be interactive with manufacturers to seek information during the review process prior to issuing deficiencies or final decisions to the extent possible.

Question #44

B. What does HHS see as the next step to raise cybersecurity awareness and defenses across the entire health sector?

HHS Response

The cybersecurity threat landscape continually evolves. The government and the private sector can always do more to keep pace with and protect themselves from these threats. HHS encourages the Healthcare and Public Health (HPH) sector to increase the awareness of cyber threats among their employees, stakeholders and the public by adopting best practices aimed at reducing susceptibility to threats posed by bad actors. In addition, HHS encourages cybersecurity personnel and the entire HPH sector workforce to avail themselves of federal resources that provide tactical information identifying the specific tactics, techniques and procedures to mitigate threats from bad actors. Through various programs, HHS is working diligently with our sector partners and federal partners at CISA and the FBI to increase the information provided to the sector which can be used to combat cyber threats and improve cybersecurity awareness.

Through our public-private partnerships and Healthcare and Public Health (HPH) sector engagements, feedback from stakeholders shows that these efforts have significant impact in improving the sector's cyber health. To improve and expand cybersecurity awareness and education, HHS, via the 405(d) Program recently released the Health Industry Cybersecurity Practices (HICP) 2023 edition which aims to provide organizations with recommendations and best practices to prepare and fight against cybersecurity threats that can impact patient safety. In addition, the HHS 405(d) Program launched a free cybersecurity education platform called "Knowledge on Demand". The platform includes five cybersecurity awareness trainings that align with the top five cybersecurity threats outlined in the landmark 405(d) HICP publication. To improve sector defense, the Health Sector Cybersecurity Coordination Center (HC3) continues to release alerts tailored to the HPH sector focused on current and emerging threats. These alerts not

[27] CDRH Proposed Guidances for Fiscal Year 2023 (FY2023) | FDA
[28] Q-Submission Guidance - Level 2 Update (fda.gov)

only include information on how to detect, prevent, and resolve these threats but also mitigations which are specific to healthcare's unique needs. HC3 has also been working directly with the sector and CISA on tabletop exercises to show the importance of preparing for cyber incidents and how best to recover. Additionally, the HHS Healthcare Threat Operations Center (HTOC), which is currently comprised of HHS, the Defense Health Agency, and the Department of Veterans Affairs, is developing plans for expanding services and maturing and improving its processes to share real time information amongst the federal healthcare community. Lastly, HHS is working with the Health Sector Coordinating Council (HSCC) Joint Cybersecurity Working Group to develop a five-year strategic plan that aims to address HPH sector cybersecurity and resilience.

Rare Disease Drugs

Question #45

4. The European Medicines Agency's approval process incorporates a risk versus benefit analysis that considers patient preference information including patient risk of uncertainty of clinical benefit in exchange for earlier access to a potentially effective drug. Do you think it's important that rare disease patients' voices are being heard through the inclusion of patient experience data in FDA's benefit-risk framework for drug approval?

HHS Response

FDA recognizes the importance of the patient and expert clinician perspective to inform drug development and regulatory decision-making. FDA incorporates the patient perspective in many ways, through patient listening sessions that focus on patient experiences, perspectives, and needs related to their health or a disease; patient focused drug development meetings that characterize the most significant symptoms of their condition and the impact of the condition on daily life and patients' approaches to treatment; and through public advisory committees that solicit independent expert advice where patients and expert clinicians often provide their expertise on rare diseases and conditions, which informs regulatory decision-making.

Patient experience data is an important part of the review process. Specifically, FDA reviewers assess a product's benefits and risks based, among other things, on data from patients. As part of FDA's Patient Focused Drug Development Program, the agency has developed a series of four methodological patient-focused drug development (PFDD) guidance documents[29] to address how stakeholders can collect and submit patient experience data from patients and caregivers. This series of guidance documents is intended to facilitate the advancement and use of systematic approaches to collect and use robust and meaningful patient and caregiver input that can better inform medical product development and regulatory decision making. For patient experience data, this usually takes the form of Patient-Reported Outcomes (PROs) or other types of Clinical Outcome Assessments (COAs). In clinical trials, PROs or COAs can be primary, secondary, or supportive endpoints. In addition, patient experience data can provide contextual or supporting information (e.g., tolerability, patient priorities or concerns).

Patient experience data can help inform critical aspects of a drug development program, and

[29] FDA Patient-Focused Drug Development Guidance Series for Enhancing the Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making | FDA

benefit-risk assessment more broadly. For example, patient experience data collected early in the development program can help identify unmet patient needs and define the target patient population. Patient experience data can also inform the assessment of the clinical relevance of the study endpoints, that is, to help identify endpoints that measure or predict clinical outcomes of importance to patients. FDA has recently discussed the use of patient experience data in benefit-risk management in its September 2021 draft guidance for Industry, "Benefit-Risk Assessment for New Drug and Biological Products".[30]

Patient Preference Information (PPI) may be useful to sponsors at various stages of drug development, including informing the therapeutic context, identifying endpoints, and informing benefit-risk assessment. If available, PPI could be considered within the context of FDA's assessment of the drug's efficacy and safety to the patient population, although it would not, for example, overcome lack of substantial evidence of effectiveness.

Finally, in 2019 FDA and EMA co-developed an ICH reflection paper on Patient Focused Drug Development, receiving endorsement of the ICH Assembly that same year. This paper identified the opportunity to enhance medical product development through effective inclusion of the patient's perspective. The reflection paper calls for future development of two new internationally harmonized ICH guidelines. One would address what to measure in a clinical trial, including refining the set of important impacts and concepts from patients, to select, modify or develop COAs that can demonstrate change and define endpoints and meaningful change. The other proposed guideline would discuss systematic approaches to designing, conducting, analyzing, and presenting patient preference studies to supplement information about the assessment of a product or inform drug development and related decisions. FDA expects that ICH guideline work in one of these identified areas will begin within the next year.

NSA/Price Transparency

Question #46

5. As you know, one goal of the No Surprises Act is to help drive down the cost of health care by increasing financial transparency for patients, providers, and payors. But the vast majority of the transparency provisions haven't been enacted, namely the Advanced Explanation of Benefits and Good Faith Estimate. These two policies can greatly help patients by making them aware of costs and potentially less expensive care options, before a procedure or test is given or ordered.

    - When does CMS plan to enact and enforce these important patient transparency provisions so innocent people can avoid getting a surprise medical bill in the first place?

[30] https://www.fda.gov/media/152544/download. This draft guidance, when finalized, will represent the current thinking of FDA on this topic. FDA updates guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://fda.gov/regulatory-information/search-fda-guidance-documents.

- We have seen that having a coordinated internet-based tool available at the point of care is the best way to ensure accurate, up to date cost information is between patients, providers, and payors. This can also minimize the burden on providers and plans to meet standards for real-time information surrounding the expected costs.

- How can Congress and the Biden administration help communicate the availability of these price transparency tools, given that the technology does exist?

HHS Response

Health plan price transparency helps consumers know the cost of a covered item or service before receiving care. Due to the Transparency in Coverage final rules, as of July 1, 2022, group health plans and issuers of group or individual health insurance are generally required to post pricing information on the internet for certain covered items and services. This pricing information can be used by third parties, such as researchers and software application developers to help consumers better understand the costs associated with their health care. In addition, another disclosure requirement, under which plans and issuers must make price comparison information available with respect to an initial list of 500 items and services, went into effect on January 1, 2023. This disclosure requirement is intended to provide additional access to pricing information and enhance consumers' ability to shop for the health care that best meets their needs. Starting January 1, 2024, plans and issuers must make price comparison information available with respect to all covered items and services. This information must be made available through an internet-based self-service tool and in paper form, upon request. Typically, consumers receive an Explanation of Benefits after receiving care, which details the prices charged by the provider, the plan's contracted or negotiated rates, consumer cost-sharing obligations, and other information. With the pricing information required by the Transparency in Coverage rules, consumers will have access to this type of information before receiving care and can use it to compare prices and better estimate potential out-of-pocket costs.

Additionally, pursuant to section 204 (of Title II, Division BB) of the Consolidated Appropriations Act of 2021 (CAA), insurance companies and employer-based health plans must submit to the Departments of Labor, Health and Human Services, and the Treasury (the Departments) information about prescription drugs and health care spending. The CAA also requires collection of information about spending on health care services and premium paid by members and employers. The Departments of Labor, Health and Human Services, and the Treasury published regulations implementing this rule on November 23, 2021 and have published updated instructions and Frequently Asked Questions, as well as holding frequent webinars, to ensure compliance with these reporting requirements. As required by the CAA, with this data the Departments will publish findings about prescription drug pricing trends and the impact of prescription drug rebates on patient out-of-pocket costs.

Regarding the Advanced Explanation of Benefits (AEOB) requirements, the Departments received feedback from the public about the challenges of developing the technical infrastructure necessary for providers and facilities to transmit the data to plans and issuers that the good faith estimates and the AEOB require. In September 2022, the Departments released an Request for Information (RFI) that seeks information and recommendations on transferring data from providers and facilities to plans, issuers, and carriers. That RFI also sought comment on ways in which plans could leverage

work already undertaken for compliance with the Transparency in Coverage self-service price comparison tool to comply with the AEOB provision. The Departments intend to undertake notice and comment rulemaking in the future to implement the AEOB requirements including establishing an appropriate data transfer standard. Until that time, the Departments will defer enforcement of the requirement that plans and issuers must provide an AEOB.

APIs/Manufacturing

Question #47

6. The United States is not currently at the forefront of drug manufacturing. For more than a decade, China has been one of the largest producers of active pharmaceutical ingredients (APIs) in the world. It is estimated that Chinese manufacturers make up around 40 percent of all APIs used worldwide, and that China and India are the source of approximately 80 percent of the APIs imported to the United States. Even before the COVID pandemic in 2019, the Department of Defense acknowledged in testimony before the U.S.-China Economic and Security Review Commission, that "the national security risks of increased Chinese dominance of the global API market cannot be overstated."

Question #47A

A. Given how important domestic drug manufacturing is to ASPR's National Health Security Strategy, what is the department doing to further incentivize the domestic supply and production of API and medical countermeasures?

HHS Response

With funds appropriated though COVID-19 supplementals, ASPR is investing in domestic manufacturing of several important medical supplies, including API. As an example, on May 18, 2020, BARDA awarded Phlow Corp. a contract (75A501200C00092) to address the near-term threat of drug shortages of essential medicines for hospitalized COVID-19 patients, to establish a Strategic Active Pharmaceutical Ingredient (API) Reserve (SAPIR), and to build U.S.-based advanced large scale commercial manufacturing capabilities to supply domestic self-sufficiency for manufacturing of critical APIs and finished essential medicines to prevent future drug shortages. This work is intended to strengthen U.S. national health security interests by enhancing the nation's supply chain resiliency for essential medicines, including those used for COVID-19 patients, and ensuring that the United States has the necessary API reserve and U.S.-based manufacturing capabilities to meet the nation's needs for patient care in national emergency situations. These initial efforts have proven successful and Phlow has met all the contractual milestones; however, additional funds will be required to sustain these efforts going forward.

To build and sustain a domestic advanced pharmaceutical manufacturing ecosystem, additional HHS investments through the ASPR Office of Industrial Base Management and Supply Chain (ASPR-IBMSC) have been directed at developing and deploying innovative manufacturing technologies, as well as establishing new partnerships to improve the responsiveness and resilience of the domestic pharmaceutical supply chain. These investments to address API and key starting material supply chain vulnerabilities include domestic direct, biologically derived production of APIs and antibiotics and fine chemicals or catalysts whose use are more prevalent in U.S. pharmaceutical production.

The FY2024 President's Budget includes a $400 million Pandemic Preparedness and Biodefense request. The $400 million requested will ensure we are able to maintain the capabilities built and used extensively during the COVID-19 pandemic to strengthen the domestic manufacturing base. In addition, the $400 million requested will ensure HHS has ready resources to immediately scale up manufacturing of vaccine and therapeutic prototypes at the first indication of an outbreak. The requested funding would also accelerate advanced development and additional manufacturing of medical countermeasures for clinical trials and, when appropriate, patient care as part of an emergency response. If appropriated by Congress, the Department will develop specific spend plans as funds are allocated to programs across HHS.

Question #47B

B. How is HHS coordinating with the Department of Defense to leverage its DPA- Title III authority to prioritize grants, loans or other financial incentives to build domestic manufacturing capacity with the goal of mitigating a future public health emergency?

HHS Response: As of the date of this hearing, HHS/ASPR was working to establish an independent DPA Title III capability with the directive of incentivizing domestic capacity for the production of medical countermeasures (MCMs) that support the national defense. Once established and authorized, the HHS DPA Office will offer HHS with its own internal capability to expand, onshore, maintain, create, and sustain domestic MCM production capacities by pursuing projects that focus on scaling emerging technologies, commercializing R&D investments, and sustaining critical production capabilities to strengthen domestic public health supply chains and ensure a more robust response to a future public health emergency.

Question #47C

C. It is my understanding that HHS is working to establish a DPA Title III program as a legacy program to the U.S. International Development Finance Corporation (DFC) – DPA Loan program, which expired on March 26, 2022. What is the status of consolidating Industrial Base expansion (IBx) and DPA-related activities into a new program? What is the timeline and number of grants or loans envisioned for such program in supporting a domestic medical manufacturing base? What actions is such program taking to support domestic API manufacturing?

HHS Response: As part of the February 2023 ASPR reorganization, the Office of Industrial Base Management and Supply Chain (IBMSC) was formally established within ASPR. Two of the offices within IBMSC are the Advanced Manufacturing Technologies (AMT) Office and the Defense Production Act (DPA) Office. The AMT group leads the API/ Essential Medicines domestic manufacturing program. As funding becomes available, we anticipate that this program will grow, and can then utilize the DPA Title III (once those authorities are in place). HHS' DPA Office will leverage available authorities within Title III of the DPA to invest in the expansion of domestic MCM production capacities. HHS' DPA Office is currently focusing on program establishment while supporting the development of the ASPR Strategic Plan to ensure that HHS' DPA Office is positioned to enable investment in domestic MCM production capacities expansion to improve the resiliency of domestic public health supply chains and strengthen the

domestic public health industrial base. HHS' DPA Office plans on issuing predominantly grants and purchases/purchase commitments. HHS' target for full completion of Title III program establishment is Q2 of 2024.

Question #47D

D. HHS and the DFC announced last week a $410 million loan to the National Resilience through the Defense Production Act Loan Program to support the manufacturing and delivery of vaccines and critical medicines. Do we expect additional loans or funding from this program?

HHS Response: The DoD and DFC concluded this program at the end of March 2023 and no additional loans or funding from this program are anticipated.

Question #47E

E. As part of the administration's biomanufacturing initiative, is HHS assessing the role synthetic biological manufacturing processes can play in mitigating API supply chain vulnerabilities?

HHS Response: IBMSC and BARDA are partnering to establish a biomanufacturing consortium. One of the first projects that this consortium will undertake will define, develop and validate synthetic biological manufacturing pathways for drug substances that have been previously off-shored and deemed critical for acute care of patients.

Question #47F

F. The FY24 budget request includes $400 million for pandemic preparedness and biodefense against emerging threats. How will this proposed funding advance ASPR's permanent industrial base management capabilities in conjunction with Defense Production Act and Emergency Support Function authorities?

HHS Response: ASPR is investing in securing a strong domestic manufacturing base to produce essential products such as medical equipment, pharmaceuticals, vaccines, and personal protective equipment. Since the beginning of the COVID response, ASPR has supported over 87contracts to build and sustain domestic manufacturing of critical medical supplies and to produce medical countermeasures on U.S. soil. In addition, with ASPR's reorganization in February 2023, ASPR established the Industrial Base management and Supply Chain (IBMSC) Office to ensure we have dedicated, full-time staff devoted to addressing this long-term challenge. We are requesting funds in the 2024 President's Budget to support this office and their important work.

The $400 million requested in the FY24 President's Budget for this work, will also ensure we are able to maintain the capabilities built and used extensively during the COVID-19 pandemic to strengthen medical countermeasure development and manufacturing. Funds could also support purchasing domestically made product for inclusion in the SNS, reducing reliance on foreign production. The $400 million Pandemic Preparedness and Biodefense request will ensure BARDA

has ready resources to immediately scale up manufacturing of vaccine, diagnostic and therapeutic prototypes at the first indication of an outbreak. The requested funding would also accelerate advanced development and additional manufacturing of medical countermeasures for clinical trials and, when appropriate, patient care as part of an emergency response.

If appropriated by Congress, the Department will develop specific spend plans as funds are allocated to programs across HHS.

Question #47G

G. As part of the PAHPA reauthorization, are there new authorities needed to further help acquire, construct, or alter non-federally owned facilities to better allow ASPR to support efforts to develop net new domestic manufacturing capacity for medical countermeasures, including their API? If so, why is such authority needed?

HHS Response: At the beginning of the pandemic, many products were manufactured outside of the United States. With significant supplemental investments from Congress, ASPR is building a program to ensure we have personal protective equipment and critical supplies manufactured in the United States moving forward. COVID-19 supplemental legislation also included language that allowed ASPR to support the physical construction of domestic manufacturing facilities. These construction authorities have been used to support the construction of new factories nationwide for COVID-19 related medical supplies. Once the COVID-19 funds are expended, the construction authority ends. It is important to have construction authority to sustain the work we have started and to expand this work to other parts of the public health supply chain.

In addition, the $400 million requested in the FY24 President's Budget for Pandemic Preparedness and Biodefense, will also ensure we are able to maintain the capabilities built and used extensively during the COVID-19 pandemic to strengthen medical countermeasure development and manufacturing. Funds could also support purchasing domestically made product for inclusion in the SNS, reducing reliance on foreign production. The $400 million Pandemic Preparedness and Biodefense request will ensure BARDA has ready resources to immediately scale up manufacturing of vaccine, diagnostic and therapeutic prototypes at the first indication of an outbreak. The requested funding would also accelerate advanced development and additional manufacturing of medical countermeasures for clinical trials and, when appropriate, patient care as part of an emergency response.

Question #48

DEA/Mental Health

I am very concerned that our deepening mental health crisis in this country is being exacerbated by a lack of access to mental and behavioral health care, in part due to our mental health provider shortage. Telemedicine has proven to be an effective method for getting patients across the country clinically appropriate and life-saving care, but I understand there is a need for guardrails to allow for continued effective prescribing. On February 24, DEA's proposed

rulemaking was released in consultation with the Department of Health and Human Services, entitled "Telemedicine Prescribing of Controlled Substance When the Practitioner and the Patient Have Not Had a Prior In- Person Medical Evaluation." I believe this proposed rulemaking does not take into account the three-year history of effective prescribing of controlled medications via telemedicine for behavioral and mental health. Therefore, I have the following questions about the proposed rulemaking:

The Administration in the proposed rulemaking acknowledges that there is a shortage of mental health providers, and that mental health treatment can largely be done through audio-only and video telemedicine examinations to allow for visual cues to assist in prescribing when mental health medications are involved.

Question #48A

A. As such, could you explain the rationale that HHS and the DEA utilized when requiring a patient have an in-person examination after an initial 30-day dosage when being prescribed Schedule III – V non-narcotic medications and buprenorphine?

HHS Response: SAMHSA and the DEA are currently working together to consider the comments received and cannot comment on the active rulemaking process.

Question #48B

B. Did you specifically consider whether requiring an in-person examination after only an initial 30-day dosage for mental and behavioral health treatments is medically necessary?

HHS Response
SAMHSA and the DEA are currently working together to consider the comments received and cannot comment on the active rulemaking process.

Question #48C

C. Specifically, could you explain the rationale for requiring an in-person examination for patients who have already begun treatment via telemedicine and wish to continue via telemedicine?

HHS Response
SAMHSA and the DEA are currently working together to consider the comments received and cannot comment on the active rulemaking process.

Question #48D

D. For those patients who live in a mental health provider shortage area, how will this new proposed rulemaking impact their ability to access care if they are unable to secure an in-person visit within 30 days of receiving an initial prescription?

HHS Response

SAMHSA and the DEA are currently working together to consider the comments received and cannot comment on the active rulemaking process.

Heart Transplant Selection Criteria Oversight

Question #49

7. In 2018, the United Network for Organ Sharing (UNOS) made significant changes to heart transplant selection criteria to reduce waitlist times, among other reasons. However, it is my understanding that some in the heart transplant community are raising questions about the impact these changes may have had on physician practice patterns.

A. How is HHS's Health Resources and Services Administration (HRSA) monitoring long-term changes in both clinical outcomes and quality of life post- transplant?

B. What data has HRSA collected or received via UNOS regarding the impact of the heart transplant selection criteria, and what does the data indicate with respect to the change in heart transplant selection criteria?

C. What role is HRSA playing in oversight of these changes?

D. How will HRSA work with UNOS to make appropriate adjustments to the system to help improve patient outcomes and quality of life while maintaining shorter wait times?

HHS Response

The Organ Procurement Transplantation Network (OPTN) develops and implements policies approved by the OPTN Board of Directors. On March 22, 2023, HRSA announced a multi-year OPTN Modernization Initiative designed to improve effectiveness across the organ donation, procurement, and transplantation system. The Initiative is intended to strengthen accountability, equity, and performance in the organ donation and transplantation system through a focus on five key areas with the following goals:

- Technology – ensure that the system is reliable, secure, patient-centered, user-friendly, and reflective of modern technology functionality. There is a continuous focus on improved IT system functionality and security, while ensuring continuity of services, protecting patient safety, and accelerating innovation in line with industry-leading standards.
- Data Transparency and Analytics – ensure data is accessible, user-friendly, and patient-oriented. The modernization process provides easily accessible, high-quality, and timely data to make informed patient, donor, and clinical decisions; measure and evaluate program performance; inform oversight and compliance activities; and support the advancement of scientific research
- Governance – The OPTN Board of Directors is high-functioning and has greater independence; represents the diversity of communities; and delivers effective policy development.

- Operations – The OPTN is effective and accountable in its implementation of organ policy, patient safety and compliance monitoring, organ transport, OPTN member support, and education of patients, families, and the public.
- Quality Improvement and Innovation – The OPTN promotes a culture of quality improvement and innovation across the network by leveraging timely data and performance feedback, collaborative learning, and strategic partnerships

HRSA will continue to focus on meeting the needs of patients and families by strengthening and providing equitable access to transplantation, improving safety and health outcomes, and empowering patients and providers with the data needed to make informed, shared decisions.

The Honorable Larry Bucshon

Question #50

1. **VALID**

   According to recent media [fiercebiotech.com] reports, the Oncology Center of Excellence has teased the release of an upcoming "pilot project" that would "bypass" the regulatory standards for new cancer medicines currently requiring the use of a companion diagnostic. As described, the pilot would enable the use of unapproved tests meeting a *minimum* standard rather than require the use of an FDA-approved test that has been proven to support the safe and effective use of a new cancer therapy. I would like to better understand the FDA's plans given that Congress spent last year trying to reach bipartisan consensus on diagnostic regulatory reform (the VALID Act) at the FDA's request. Specifically, in its technical assistance to Congress, HHS stated that high-risk tests have a greater potential to cause patient harm if an undetected inaccurate result occurs and therefore these tests, such as companion diagnostics, should be subject to premarket review. Can you please explain in detail how the pilot project either compliments or conflicts with the VALID Act framework, and how FDA will ensure this project protects cancer patients from lower quality tests?

HHS Response

FDA is deeply appreciative of your sponsorship of the VALID Act. Diagnostic test reform remains one of FDA's top legislative priorities for reauthorization of the Pandemic and All-Hazards Preparedness Act, as a modern oversight framework that is specifically tailored to tests would better position ourselves for the future – whether it is preparing for the next pandemic or realizing the full potential of diagnostic innovation. FDA continues to support legislation to establish a modern regulatory framework for all in vitro diagnostic tests and stands ready to continue working with Congress on a modern oversight framework for tests, such as the VALID Act.

With the goal of helping to improve the performance of some tests in certain circumstances, FDA intends to announce a pilot program to provide greater transparency regarding minimum performance characteristics (MPCs) that certain tests for oncology biomarkers should meet if the tests are to be used in connection with oncology drug treatment decisions. The pilot program will

only apply to circumstances where a test is needed to identify the intended patient population of an oncology drug product for which no satisfactory alternative exists; such a test uses a technology previously used in an FDA-authorized companion diagnostic; the accuracy of such a test can be supported by a well-validated reference method, comparator, or materials; and the anticipated benefits of the drug are so pronounced as to outweigh the risks of approval without contemporaneous approval of a companion diagnostic. By requesting performance information for such tests from drug manufacturers, and posting recommended MPCs on the FDA website, the agency will be providing information to labs that they may use as they develop certain types of tests that identify specific biomarkers used for selecting certain cancer treatments. This pilot program may be one helpful initial, but limited, step in reducing the safety risks of using LDTs that are not properly validated to identify treatments for patients with cancer.

The pilot program is not a substitute for legislation to establish a modern regulatory framework for all in vitro diagnostic products, which as noted above would be specifically tailored to tests and would better position FDA for the future.

While the goals of this pilot program are separate and independent from considerations of a new statutory framework that would apply to all in vitro diagnostic tests, the goals of each could be complementary. For example, MPCs developed through the pilot program could be leveraged to support in vitro clinical tests (IVCT) development and facilitate the subsequent preparation of premarket submissions under the VALID Act. Further, MPCs developed through the pilot could be leveraged to support the establishment of mitigating measures (MMs) under the VALID Act and MMs may make certain tests eligible for the technology certification pathway.

Question #51

2. **No Surprises Act**

There seems to be a lack of sufficient oversight, which was mandated in the No Surprises Act ("NSA") statute to the Tri Departments (TDs):

A. The NSA expressly rejected the concept of a federal benchmark payment standard. Instead, the NSA listed 7-8 mandatory factors that all had to be considered by the Independent Dispute Resolution Entities ("IDREs" or adjudicators) in making the final payment standard decision. Why then have the TDs twice attempted to benchmark the final payment to the median allowed amounts as of 1/31/2019 (qualifying payment amount or "QPA") in two separate (and now vacated) final rules?

B. The final rule states that the initial payment by a health plan must be one that the plan reasonably believes to be payment in full for the services rendered. EDPMA member surveys show that the post NSA allowed amounts for the two highest level E&M codes (CPT 99284, 99285) have declined over -50% versus pre-NSA allowed amounts. What is the CMS plan to audit initial payments to determine if the health plans are in compliance with the rule making?

C. What is the current status of the QPA audits which were confirmed by CMS to be underway as early as June 2022 and when will the results be made public? Note: The Tri Departments have stated publicly that QPA issues regarding calculation and use of "ghost rates" cannot be adjudicated in the NSA IDR process; and instead those issues must be brought exclusively to CMS for resolution.

D. The federal law and regulations mandate that the QPAs receive an inflation adjustment. In December 2022, the IRS issued the following regulation for the CPI-U adjustment www.irs.gov/pub/irs-drop/n-23-04.pdf. The adjustment is required to be made annually and is cumulative. What, if anything, have the Tri Departments done to assure that the mandatory CPI-U adjustments have been made?

E. In the CMS listening session on Jan. 5, 2023, multiple stakeholders stated that plans who are adjudicated the loser have not paid per the IDRE decision. What is CMS plan to enforce the terms of the Independent Dispute Resolution Process? What are the enforcement strategies?

F. In October 2021, it was predicted that there could be roughly 17,000 disputes per year in the Independent Dispute Resolution process. After an almost five- month delay in opening the IDR portal on 4/15/22, there was a large backlog of claims filed. The most recent NSA IDR report (released December 2022) showed by the end of September 2022, more than 90,000 disputes had been filed with CMS. How did the agency calculate the original 17,000 number and what explanation is offered as to how the Agency underestimated the number?

HHS Response

CMS is committed to implementing the No Surprises Act (NSA) consistent with the law. Pursuant to the NSA, certified Independent Dispute Resolution (IDR) entities are required to consider the qualifying payment amount (QPA), if submitted, as one of a number of factors when selecting between the offer submitted by a plan or issuer and the offer submitted by a facility or provider or provider of air ambulance services when determining the total out-of-network payment rate for items and services subject to the federal IDR process. The QPA for a given item or service is generally the median contracted rate on January 31, 2019 for the same or similar item or service, increased for inflation.

On February 6, 2023, a federal district court in Texas vacated portions of a Final Rule applicable to IDR disputes involving items or services furnished on or after October 25, 2022, and IDR payment determinations were paused until revised guidance could be drafted. On March 17, 2023**,** certified IDR entities were instructed to resume making payment determinations for disputes involving items or services furnished **on or after** October 25, 2022. Certified IDR entities have now resumed processing all payment determinations. The standards governing a certified IDR entity's consideration of information when making payment determinations for disputes involving items or services furnished on or after October 25, 2022 are provided in the August 2022 final rules, except that HHS, the Department of Labor, and the Department of the Treasury (the Departments) have instructed certified IDR entities not to apply the regulatory provisions vacated by U.S. District

Court for the Eastern District of Texas in *Texas Medical Association, et al. v. United States Department of Health and Human Services et al.,* Case, No. 6:22-cv-372 (February 6, 2023). As of March 17, 2023, the Departments have completed the necessary updates to the Federal IDR portal and Federal IDR process guidance documents to reflect these revised payment determination standards.

Through the IDR process, regulations issued by the Departments require that the losing party remit payment within 30 days of a payment determination. If the prevailing party believes that the non-prevailing party is not complying with the IDR process payment requirements, they should contact the No Surprises Help Desk to submit a complaint. While states are generally responsible for enforcing provisions of the NSA that apply to state-regulated insurers and providers, CMS will directly enforce any NSA provision (or provisions) that a state fails to substantially enforce.

The Departments are actively investigating complaints that we have received about timely payment and are working to determine what is causing payment delays. We believe that at least one of the factors relates to how plans ingest information after a payment determination and then work through their business processes to make the ultimate payment. Until very recently, certified IDR entities would email payment determinations to disputing parties. On March 17, 2023, we released an update to the Federal IDR system so that the payment determination notices will now come from the IDR portal – this should remove a number of the manual steps for plans to correlate the information that is part of a payment determination with the appropriate provider. We are continuing to investigate all of the complaints that we have received about timely payment to determine if there are other issues or actions that we need to take.

Additionally, CMS is conducting QPA audits to ensure that plans are complying with requirements related to the calculation and disclosure of the QPA. The NSA requires the Departments to submit a report to Congress for each year in which audits were conducted. The Departments are actively conducting QPA audits as required under the statute and intend to produce the reports to Congress required in the law.

Through December 5, 2022, there were over 160,000 disputes submitted for resolution through the IDR portal, nearly 10 times greater than the Departments initially estimated. During that time, non-initiating parties challenged the eligibility of over 68,000 disputes for the Federal IDR process. As detailed in the Departments initial report on the first two calendar quarters of the IDR process, many claims are ultimately determined ineligible. That report details the reasons claims were determined ineligible.

When initially estimating the expected usage of the Federal IDR process, the Departments did not have data on how many claims would be submitted through the Federal IDR process. In the absence of such data, the Departments relied on the experience of New York State in estimating the use of the Federal IDR process. For purposes of this analysis, the Departments assumed that, going forward, New York State will continue to see 1,000 IDR cases each year and that the number of Federal IDR cases will be proportional to that in New York State by share of covered individuals in the private health coverage market. Based on this analysis, the Departments estimated that approximately 17,000 claims for Nonparticipating Providers or Nonparticipating Emergency Facilities would be submitted to the Federal IDR process each year. With respect to air ambulance services, the Departments assumed that 10 percent of out-of-network claims for air ambulance

services would be submitted to the Federal IDR process, which would result in nearly 4,900 air transport payment determinations in the Federal IDR process each year. The Departments sought comment on both of these estimates.

Question #52

3. Large increases in non-refundable fees, IDRE fees, and discretionary batching fees:

    - CMS announced the 600% increase in non-refundable administrative fees for both sides in the IDR, from $50 to $350 for each party. The NSA statute permits the Tri Departments to assess an administrative fee which is reasonably calculated to address the costs in operating the IDR system. What data supports the increase? What lead to the announcement of the 600% increase when approximately 60 days previous the Agency announced that the fee would remain at $50 for 2023?

HHS Response

The No Surprises Act requires the Departments to establish the IDR administrative fee at a rate where the total amount of fees paid is estimated to be equal to the amount of expenditures estimated to be incurred by the Departments in administering the Federal IDR process. There is a very high volume of disputes being submitted for resolution, which led to increased Federal administrative costs. Through December 5, 2022, there were over 160,000 disputes submitted for resolution through the IDR portal, nearly 10 times greater than the Departments initially estimated. During that time, non-initiating parties challenged the eligibility of over 68,000 disputes for the Federal IDR process. IDR entities have had to perform a substantial amount of outreach and analysis to determine whether a submitted dispute is eligible for the Federal IDR process. Assessing the information received and making an eligibility determination can be a time-consuming process for IDR entities, but an eligibility determination must be made before a dispute can proceed to IDR. Cases can be ineligible for a number of reasons. Some common reasons include: incomplete documentation, lack of compliance with applicable timelines, non-completion of open negotiation, incorrect batching and incorrect jurisdiction (federal vs State). These issues are detailed in our first report on the IDR process and the amended 2023 fee guidance. In order to address these issues, the Departments have engaged a contractor and government staff to conduct pre-eligibility reviews, which have also led to increased Federal costs. The Departments are also considering additional policy and operational improvements, including through rulemaking, to improve the process for determining the eligibility of disputes and ultimately increase the speed with which certified IDR entities render payment determinations. We plan to adjust the administrative fee as operational requirements change over time.

Question #53

4. State and federal jurisdiction issues:

    - How is CMS auditing the enforcement of the NSA where the jurisdiction is shared between the state and federal government?
    - What are the remedies to parties who receive no response from state officials to questions regarding enforcement?

HHS Response

Enforcement under the No Surprises Act is done collaboratively between Federal and State Partners. The Department of Labor and the Treasury Department generally have primary enforcement authority over private sector employment-based group health plans. The IRS has jurisdiction over certain church plans. HHS also has primary enforcement authority over non-federal governmental plans, such as those sponsored by state and local government employers. OPM has jurisdiction over Federal Employee Health Benefit (FEHB) plans, which are federal governmental plans. While states are generally responsible for enforcing provisions of the NSA that apply to state-regulated insurers and providers, CMS will directly enforce any NSA provision (or provisions) where CMS determines the state is failing to substantially enforce the NSA.

To aid in CMS's assessment of the state's authority and intention to enforce each applicable provision, in June 2021, CMS asked each state to complete a written survey providing its assessment of whether the state has the authority and intends to substantially enforce these new requirements. The survey includes descriptions of each applicable provision's requirements. Based on these responses, and communication with states, CMS sent letters to each state that specified CMS's understanding of the PHS Act provisions, as extended or added by the CAA, 2021, that each state is enforcing either directly or through a collaborative enforcement agreement, and the provisions that CMS is enforcing. These letters also communicate whether the federal independent dispute resolution process and the federal patient-provider dispute resolution process apply in each state, and in what circumstances. These letters can be accessed here: https://www.cms.gov/cciio/programs-and-initiatives/other-insurance-protections/caa

CMS Regulations at 45 CFR Part 150, describe numerous circumstances in which, based on information that indicates there is a reasonable question as to whether a state may be failing to substantially enforce, CMS may investigate to confirm whether a state is or is not substantially enforcing a provision of Title XXVII of the PHSA. These regulations also set forth the process by which CMS monitors whether a state is substantially enforcing a provision of Title XXVII of the PHSA, and the steps that CMS can take to begin federal enforcement if the agency obtains information that suggests a state is not substantially enforcing a provision of Title XXVII of the PHSA.

The Honorable Earl L. "Buddy" Carter

Question #54

1. Secretary Becerra – Absent a transplant, patients with end stage renal disease (ESRD) must receive regular dialysis treatments to sustain their lives. In addition, patients with ESRD often have one or more hospitalizations each year. They suffer from multiple comorbidities, including diabetes, depression, and heart disease, requiring specialty care and multiple medications. Congress recognized ESRD patients' vulnerability, and that the availability of Medicare coverage creates strong incentives for private insurers to discourage their enrollment. To protect ESRD patients and their right to elect the

coverage that best meets their needs and that of their families, Congress created the MSPA. It also limited the time period for which private insurers are the primary payer for care delivered to ESRD patients to up to 30 months. Unfortunately, in a June 2022 ruling, the Supreme Court narrowly interpreted the law, creating a loophole that allows private insurers to evade the MSPA protections for ESRD patients, and we've seen employers and insurers are starting to take advantage of it. Last year, I joined in introducing the Restore Protections for Dialysis Patients Act to close the loophole, and we have since revised the legislation to further clarify the bill's intent. We appreciate CMS' work to offer Congressional offices feedback and technical assistance on legislative drafts. Secretary Becerra – Can you please assure me that CMS will provide that assistance as soon as possible on the Restore Act to avoid any delay in reintroducing this important legislation.

HHS Response

HHS agrees that it is critical to preserve and increase access to high quality, affordable health care, including services to treat ESRD. As always, HHS appreciates the opportunity to provide technical assistance to Congress on important health care issues.

Question #55

2. Secretary Becerra – Last year, Congress passed the Lymphedema Treatment Act, which will provide much needed relief to the millions of Americans who are suffering from lymphedema. However, I am concerned about the Medicare implementation process, which is not very transparent, and in particular, that patients who need custom-fit supplies will have access to those items. Can you commit to work with me to ensure that this coverage will be implemented properly, so these patients are able to receive the treatment they need?"

HHS Response

The Consolidated Appropriations Act, 2023 newly established Medicare coverage of certain lymphedema compression treatment items. The statute requires the implementation of this provision by January 1, 2024. CMS will implement the Lymphedema Treatment Act through notice and comment rulemaking with a 60-day comment period on the proposed rule. CMS welcomes stakeholder feedback on its implementation of this provision of the law during rulemaking and throughout the implementation process.

Question #56

3. Secretary Becerra, HHS has proposed extensive discretion in settling on a "maximum fair price" for certain drugs. In your recent proposed guidance, CMS proposed to require that every element of the negotiation process remain secret and goes as far as to require manufacturers to destroy any notes on the process. How is this consistent with your support for transparency in government and ensuring that the public can trust that CMS's decisions are in the best interests of current and future patients?

HHS Response

The law requires that CMS must determine which information submitted to CMS by a manufacturer of a selected drug is proprietary information of that manufacturer. Information that is deemed proprietary shall only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Medicare Drug Price Negotiation Program. CMS intends to implement a confidentiality policy that is consistent with existing requirements for protecting proprietary information, and that strikes an appropriate balance between (1) protecting the highly sensitive information of manufacturers and ensuring that manufacturers submit the information CMS needs for the Negotiation Program, and (2) avoiding treating information that does not qualify for such protection as proprietary. In the initial guidance released for the Negotiation Program, CMS is seeking comment on the confidentiality policies.

Question #57

4. We know that many experts recognize misaligned incentives in the current payment system may lead PBMs to favor medicines with high list prices and larger rebates or discounts. But, did you know that when PBMs faced exposure over their rebating practices, PBMs shifted their compensation models to focus on administrative or other fees? And those fees have typically remained tied to list prices. So, even in cases where health plans maybe receiving a substantial portion of rebates from PBMs, PBMs may still have an incentive to favor high list prices. In doing so, the current PBM compensation model is causing patients to face a higher financial burden for their prescription drugs. It's all a shell game. In my view, PBMs should not tie their compensation to the price of a medicine. *Secretary Becerra* - Do you agree that PBMs should be reimbursed based on the services they are providing in a fair and predictable manner?

HHS Response

The Departments of HHS, Labor, and the Treasury will be releasing a report which will include information on the impact of prescription drug rebates, fees, and other remuneration on premiums and out-of-pocket costs. The department looks forward to continuing to work with you on reforms to eliminate unnecessary costs in our health care system.

In April 2022 CMS finalized a policy that requires Part D plans to apply all price concessions they receive from network pharmacies to the negotiated price at the point of sale, so that the beneficiary can also share in the savings. Specifically, CMS is redefining the negotiated price as the baseline, or lowest possible, payment to a pharmacy, effective January 1, 2024. CMS is applying the finalized policy across all phases of the Part D benefit. This policy reduces beneficiary out-of-pocket costs and improves price transparency and market competition in the Part D program.

Question #58

5. Due to the complexity of the pharmacy practice, many pharmacy students undertake a residency in a hospital. According to federal regulation, pharmacy residency programs operated by hospitals that are affiliated with or owned by a health system or academic medical center are required to be directly controlled by those hospitals (42 C.F.R. §413.85). These hospitals receive pass-through payments from Medicare. However, due to a lack of clarity and Medicare Administrative Contractors' (MACs) inconsistent

interpretation of what is needed to meet the "direct control" requirement, hospitals and affiliated health systems need greater clarity from the Department of Health and Humans Services and the Centers for Medicare and Medicaid Services (CMS) to ensure compliance. Secretary Becerra – Can hospitals share or contract for administrative functions the health systems, without violating 42 CFR §413.85(f)(1)(i)-(v)? What documentation would assist CMS in confirming that the hospital retains control of the residency program?

HHS Response

Under Medicare regulations, Pharmacy Residency Programs must meet certain requirements in order to claim pass-through payments from Medicare. These regulations (42 CFR § 413.85) require providers to meet a number of requirements with respect to training costs, curriculum, instruction, and program administration. Specifically, with respect to program administration, the regulations state that the operator must "control the administration of the program, including collection of tuition (where applicable), control the maintenance of payroll records of teaching staff or students, or both (where applicable), and be responsible for day-to-day program operation. (A provider may contract with another entity to perform some administrative functions, but the provider must maintain control over all aspects of the contracted functions.)" For example, staff and student W-2 forms must be issued by the hospital, not by a related academic institution or home office. Hospital-employed staff, not staff employed by an educational or related institution, must be responsible for controlling, managing, and operating the program financially and administratively on a daily basis, such as, but not limited to, enrollment, collection of tuition, human resources matters, and payroll. While §413.85(f)(1)(iii) states that a provider may contract with another entity to perform some administrative functions of day to day operations, the provider must maintain control over all aspects of the contracted functions. The hospital cannot have an arrangement with an educational institution where there are certain functions for which the hospital has no involvement and no oversight. If educational institution personnel are involved, hospital staff must have final decision making authority.

The January 12, 2001 final rule provides additional guidance on what "direct control" of the curriculum means. Although the accrediting agency often dictates which courses and the order of the courses that must be completed by each student, to the extent where there is some flexibility provided by the accrediting body, it must be the hospital, not another educational institution deciding upon the order of the coursework, and the manner its students will accomplish the coursework that will allow the program to be accredited. In addition, there may be certain courses that are unique to the hospital, and the hospital decides what those courses are and when they are taught. Furthermore, control of the curriculum means the hospital actually provides all of the courses, or, with respect to the basic courses required for completion of the program (e.g., English 101), the hospital arranges for an outside organization to provide those academic courses necessary to complete the course work. (See 66 FR 3364).

Question #59

6. Over the past decade, well over 100 hospitals have closed, negatively impacting patients, healthcare professionals, and communities across the United States, and this crisis has only been exacerbated over the past three years with the COVID-19 Public Health Emergency. It is no coincidence most of these hospital closures have occurred in areas with the lowest Medicare Area Wage Index rates, including my state of Georgia. As you

know, the Medicare Area Wage System adjusts how much Medicare pays hospitals in each region based on wage data self-reported by hospitals. Over the past 20 years, this CMS-created system has experienced a rapidly growing divide between hospitals in the bottom and top quartiles. In 2007, the lowest AWI hospitals had AWI of 0.77 and the highest AWI hospitals had AWI of 1.53. This year, the lowest AWI hospitals have AWI of 0.65, and the highest AWI hospitals have AWI greater than 1.89. Secretary Becerra – Do you support policies, such as establishing a permanent national minimum AWI, to prevent this negative feedback cycle that is devasting low-AWI hospitals?

Question #60

7. To address the escalating crisis of annually declining Medicare AWI rates for low-AWI hospitals, I have worked with a bipartisan group of my colleagues to introduce and advance legislation to establish a reasonable national minimum Medicare Area Wage Index floor of 0.85. This legislation would increase Medicare reimbursement rates for approximately 800 hospitals in the bottom quartile of reimbursement rates. Secretary Becerra – Do you support a permanent legislative solution to address the flaws in the Medicare Area Wage System and help prevent future hospital closures?

Question #61

8. Over the past four years, the annual Medicare payment rules for hospitals have provided additional assistance for hospitals in the bottom quartile of AWI-based reimbursement rates. This Low Wage Index Hospital Policy has been a vital lifeline for more than 800 low-AWI hospitals in 24 states across the nation. I was joined by a bipartisan group of colleagues in sending a letter to you requesting that the Low Wage Index Hospital Policy be renewed again in the upcoming fiscal year 2024 Medicare Hospital Inpatient Prospective Payment Systems proposed rule. Secretary Becerra – Do you support continuing this important payment policy to help save rural hospitals and other low-AWI hospitals in FY24?

HHS Response 59-61

Section 1886(d)(3)(E) of the Social Security Act (42 U.S.C. 1395ww(d)(3)(E)) requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.

To help mitigate wage index disparities between high wage and low wage hospitals, in the FY 2020 Hospital Inpatient Prospective Payment System (IPPS) final rule, CMS adopted a policy to increase the wage index values for certain hospitals with low wage index values (the low wage index hospital policy). This policy was adopted in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. CMS also indicated its intention that this policy would be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. As CMS undertakes the rulemaking process for the FY 2024 IPPS rule, the agency will consider all stakeholder comments after the release of a proposed rule. Additionally, CMS is happy

to work with you to provide technical assistance on any legislation you draft related to the Medicare Area Wage Index.

Question #62

9. I am concerned about a new nationwide policy that requires prior approval for a Medicare beneficiary to use ambulance non-emergency medical transportation (NEMT) to dialysis. This policy is tough on low-income End Stage Renal Disease (ESRD) patients in my district that qualify for Medicaid and Medicare (dual eligibles) that need transportation to and from life-sustaining dialysis services. My district has a diabetes prevalence of 12 % compared to 8% nationally — 50% higher than the national average. First, with my colleagues, Reps. Cardenas, Bishop and others, we asked CMS to not implement this policy until there was a way for the low-income dialysis patients to access alternative transportation through Medicaid. CMS went ahead and implemented it nationwide during the COVID emergency. At the end of the last Congress, we co-sponsored legislation we plan to reintroduce to address this problem because the administration has not been responsive to our concerns. On March 27, 2023, we received a response that confirmed that the legislation is needed and I hope I can count on your support to see our legislation enacted as soon as possible. We would greatly appreciate a response regarding the steps the agency plans to take to address our concerns.

HHS Response

The Medicare ambulance services benefit for non-emergent ground ambulance transport is generally limited to the following requirements: (1) there is a medically necessary transportation of the beneficiary to the nearest appropriate facility that can treat the patient's condition and any other methods of transportation are contraindicated meaning that traveling to the destination by any other means would endanger the health of the beneficiary and (2) the beneficiary's condition must require both the ambulance transportation itself and the level of service provided in order for billed services to be considered medically necessary. At this time, there is no statutory authority to expand the Medicare ambulance benefit or Medicaid non-emergency medical transportation (NEMT) benefit. CMS has provided technical assistance to your staff related to legislation that would assist certain dually eligible beneficiaries in accessing NEMT under Medicaid. CMS would be happy to continue to provide technical assistance to your staff regarding that legislation.

In addition, CMS issued a proposed regulation, published in the Federal Register on September 7, 2022, that would make it easier for people to enroll in and retain their Medicaid coverage. Several proposals would simplify the processes for Medicare beneficiaries to enroll in Medicare Savings Programs and full-benefit Medicaid coverage. The comment period closed on November 7, 2022, and we are in the process of reviewing comments and drafting the final rule.

The Honorable Richard Hudson

Question #63

1. An October 2022 GAO Report found the SNS currently has serious gaps in the recommended quantity of medical countermeasures. It cited both budgetary restraints and a lack of communication with private partners that was hindering an appropriate response. What has HHS done so far and how will HHS continue to ensure public-private partnerships are able to succeed in providing necessary medical countermeasures, including vaccines, therapeutics, and PPE for the nation?

HHS Response: ASPR appreciates the review conducted by GAO and is actively working to address the findings included in this report. Because the report was limited release and includes sensitive information, we would be happy to brief you and your staff on specific details.

One of the most important findings in this report is the clear gap between requirements and funding levels. With the re-launch of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) in 2022, ASPR is working on finalizing several budget and strategy documents that will align requirements with full resource requests. We anticipate delivery of these critical reports to Congress in the near-term and look forward to providing follow-on briefings as needed.

Question #64

2. The Government Accountability Office (GAO) released a report updating the status of the approximately $4.6 trillion that the federal government provided to assist the national response and recovery from the COVID-19 pandemic. The report indicated that, as of January 31, 2023, the federal government had obligated a total of $4.5 trillion and expended $4.2 trillion, or 98 and 90 percent of the total funds provided, respectively. At the recent hearing, I asked about the remaining unexpired unobligated balances. A Bloomberg report from the White House indicated over 98% of the funds had been committed, leaving about $4.5 billion from the Public Health and Social Services Emergency Fund. This information, provided directly from the White House, contradicts the GAO report, which states that the Public Health and Social Services Emergency Fund received approximately $345.7 billion, with total obligations at $325.1 billion and an Unexpired Unobligated Balance of $20.6 billion. This discrepancy creates a gap in funding reporting of more than $16 billion. I would like to follow up on your promise to provide clarity to the Committee, seeing that Bloomberg is getting these numbers before us. Please provide an accurate, up-to-date accounting of the remaining unexpired unobligated balances for COVID-19 Relief Funding for the Public Health and Social Services Emergency Fund.

    - Please specify the programs or initiatives involved in the remaining $16 billion discrepancy in the unexpired unobligated balances.
    - Please supply evidence explaining the discrepancy between the GAO's reported $20.6 billion in unexpired unobligated balances under the Public Health and Social Services Emergency Fund and the White House-provided figure of $4.5 billion under the same fund.

HHS Response
Congress has appropriated nearly $346 billion to the Public Health and Social Services Emergency Fund (PHSSEF) to support HHS's coronavirus relief efforts. The Government Accountability Office (GAO) reported in February 2023 that $20.6 billion remained unexpired and unobligated as of January 31, 2023. By March 27, 2023, $20.4 billion remained unexpired and unobligated within the PHSSEF appropriation.

Unobligated balances reported by the GAO are higher than amounts reported as uncommitted because agencies routinely commit funds before obligating them. For example, an agency would typically commit funds while negotiating a contract with a manufacturer or another provider to secure those dollars for negotiation of goods or services in good faith. The agency would not obligate those same funds until the contract is actually signed by the government.

Question #65

3. At the hearing, Secretary Becerra welcomed the idea of working together, specifically on communicating to retailers and consumers about which ENDS products are lawfully being marketed pursuant to FDA's regulatory and enforcement policies. In your annual report to Congress on Tobacco Regulation Activities, there was nothing identifying any meaningful action to clarify and enforce against ENDS products unlawfully on the market. We are interested in an updated and user-friendly list on the FDA website of ENDS products by brand that have received either a premarket authorization or are the subject of a pending application. The overwhelming majority of products currently on the market are not the subject of a pending application or litigation with the agency, particularly when it comes to flavored disposable products that minors are increasingly using in the absence of meaningful FDA enforcement actions. What are the agency's specific plans for updating the list on the website, making it more user-friendly and an approximate timeline? Will the Agency commit to regularly updating this list so retailers and the public have transparency regarding which products are lawfully being marketed?

HHS Response
FDA is committed to sharing information that is useful to industry, including retailers, and the public. FDA appreciates that many retailers seek to comply with the law and not sell tobacco products that are illegal.

Generally, a tobacco product may be legally marketed in the United States if: 1) it was commercially marketed in the United States as of February 15, 2007 (referred to as "pre-existing tobacco products"); or 2) it is not a pre-existing tobacco product and it has received a marketing order from FDA to market a new tobacco product.

To date, no valid pre-existing electronic nicotine delivery systems (ENDS) have been identified, and unless the e-cigarette is the subject of a marketing granted order (MGO), the product is on the market illegally.

To date, FDA has issued marketing granted orders for 23 tobacco-flavored e-cigarette products and devices. FDA provides a publicly available list of MGOs so that retailers, consumers, and others may know which products may be legally marketed: https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders.

FDA posts marketing granted orders for all pathways (e.g., PMTA, MRTP, SE, etc.) and works diligently to update those lists as orders are issued. However, we recognize that we can do more to make it easier for retailers to locate marketing granted orders on our website. Towards that goal, we are currently developing a searchable public database of all tobacco products that have a positive marketing order, which will be useful to retailers. CTP is also creating a comprehensive webpage for all enforcement activities for products that are illegally marketed without FDA authorization, routinely reaching out to industry trade groups and other industry stakeholders to keep them apprised of the development of new enforcement priorities and updates, enhancing FDA's Tobacco Product Marketing Order webpage, and developing a searchable public database of all tobacco products that have an FDA marketing order. This work has already been initiated, and the new web content has been posted, starting in spring 2023.

Question #66

4. I remain concerned about the threat of and the nation's preparedness to combat public health security threats. In fact, a recent GAO report found the Strategic National Stockpile (SNS) contained most of the recommended medical countermeasures but did not contain those countermeasures in the recommended quantities. Moreover, many of the countermeasures in the SNS, such as those for smallpox and pandemic influenza have gone through multiple shelf-life extension approvals. There are concerns that, while they may be safe to deploy, large amounts of these countermeasures are either close to or past their effective date. A related concern is that the pandemic influenza countermeasures may not be effective against the high-pathogenic H5N1 avian influenza strain that is currently circulating in bird populations all over the world, threating agricultural and medical communities.

HHS Response: Thank you for sharing your concerns.

Question #67

5. In response to my inquiry regarding the FY23 HHS Budget, you indicated that "SNS plans to procure a limited quantity of influenza antivirals in FY22 using appropriated funding. These planned procurements will support the following recommendations included in the FY 2021 SNS Annual Review: Procure additional quantities of oral antivirals, including oral suspensions, for treatment in all populations to meet the requirements of 54,000,000 for adults, and 31,000,000 for pediatrics." (QFR response provide by Sec. Becerra to Rep. Hudson on December 16, 2022, but noted the responses are provided as of the date of the initial hearing on April 27, 2022). Please confirm that additional oral antivirals were procured for treatment in **ALL** populations.

HHS Response
In FY 2022 SNS spent $30M to procure Baloxavir. Additional information about Baloxavir can be found at https://www.cdc.gov/flu/treatment/baloxavir-marboxil.htm.

Question #68

6. My understanding is that the pandemic influenza countermeasures in the stockpile have gone through multiple rounds of shelf-life extensions and were originally designed to work against a different strain of the virus than is currently circulating. Please outline HHS's efforts to prepare for the threat of avian influenza and 2023-2024 flu season to ensure the SNS replenishes its stockpile with non-shelf-life extended antivirals. Please clarify whether it is HHS's position that the pandemic influenza countermeasures currently stored in the SNS will be effective against the H5N1 strain currently circulating, and the verified data, reports, tests, and studies to support that decision. If there remain questions around efficacy, please outline HHS' plans to restock the SNS with effective flu countermeasures, particularly considering the FY24 budget requests an increase of
$47 million for pandemic influenza.

HHS Response

ASPR supports efforts for a response to a pandemic influenza event and has Tamiflu/oseltamivir in the SNS which is suitable for use in children under 5 years and pregnant women in the event of a pandemic influenza outbreak. Safety and efficacy are always priorities when working with Food and Drug Administration (FDA) to determine shelf-life extensions. While the majority of the SNS influenza antivirals were originally purchased by SNS using funds provided in 2005 under a pandemic influenza supplemental, SNS has worked closely with the FDA to extend the expiration dates of many of the influenza antivirals held by the SNS. The most recent extension of expiration dates for influenza antivirals held by SNS was granted in April 2022. SNS antivirals such as Tamiflu/oseltamivir that have been granted dating extensions by the FDA are considered safe to use in children, pregnant women, and other adults. ASPR notes SNS does not stockpile influenza vaccine. Furthermore, the $47M increase for pandemic influenza supports additional investments on BARDA's mRNA vaccine platform technology to support 2021 American Pandemic Preparedness Plan (APPP) goals and cover increasing sustainment costs for manufacturing capacity for pandemic response readiness, and is unrelated to the antivirals stockpiled by SNS.

The Honorable Diana Harshbarger

I am very concerned that our deepening mental health crisis in this country is being exacerbated by a lack of access to mental and behavioral health care, in part due to our mental health provider shortage. Telemedicine has proven to be an effective method for getting patients across the country clinically appropriate and life-saving care, but I understand there is a need for guardrails to allow for continued effective prescribing.

On February 24, 2023 the U.S. Drug Enforcement Administration's (DEA's) proposed

rulemaking was released in consultation with the U.S. Department of Health and Human Services, entitled "Telemedicine Prescribing of Controlled Substance When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation."

I believe this proposed rulemaking does not take into account the three-year history of effective prescribing of controlled medications via telemedicine for behavioral and mental health. Therefore, I have the following questions about the proposed rulemaking:

Question #69

1. The Administration in the proposed rulemaking acknowledges that there is a shortage of mental health providers, and that mental health treatment can largely be done through audio-only and video telemedicine examinations to allow for visual cues to assist in prescribing when mental health medications are involved.

A. As such, could you explain the rationale that HHS and the DEA utilized when requiring a patient have an in-person examination after an initial 30-day dosage, when being prescribed Schedule III – V non-narcotic medications and buprenorphine?
B. Did you specifically consider whether requiring an in-person examination after only an initial 30-day dosage for mental and behavioral health treatments is medically necessary?
C. Specifically, could you explain the rationale for requiring an in-person examination for patients *who have already begun* treatment via telemedicine and wish to continue via telemedicine?

D. For those patients who live in a mental health provider shortage area, how will this new proposed rulemaking impact their ability to access care if they are unable to secure an in-person visit within 30 days of receiving an initial prescription?

E. The proposed rule focuses almost entirely on the impact on patients and providers, but the roles and responsibilities of pharmacists related to this proposed rule are very unclear. Did HHS provide guidance to DEA on any clinical considerations for this rule, particularly pertaining to pharmacists and pharmacies? With so many new requirements for practitioners seeking to prescribe controlled substances, is it your understanding that pharmacists will be responsible for ensuring that practitioners and patients meet these requirements prior to dispensing a controlled substance?

F. Did HHS and/or DEA consider the impacts that instituting in-person visit requirements would have on those who are unable or opt not to see a provider in- person? Are there concerns that these patients may seek to find their

medications on the black market or the Internet, since their access to the regulated drug supply chain will be disrupted?

HHS Response
SAMHSA and the DEA are currently working together on the final rule and cannot comment on the active rulemaking process.

Question #70

2. In testimony given by the Center for Democracy & Technology's President and CEO Alexandra Reeve Givens at the Committee's hearing on privacy, we heard about the increasing practice of data mining mental health information and activity on telehealth platforms for purposes of data brokerage and targeted advertising.

A. What are the FTC and HHS currently able to do to prevent and mitigate such commercialization of this type of information?

HHS Response
HHS administers and enforces the HIPAA Privacy, Security, and Breach Notification Rules ("HIPAA Rules"), which establish national standards for the protection of individuals' medical records and other individually identifiable health information (collectively, "protected health information" or PHI) by "covered entities" (health plans, health care clearinghouses, and health care providers that conduct certain health care transactions electronically, like billing insurance); set national standards for protecting the security of electronic PHI; and require notification following a breach of unsecured PHI.

If a covered entity engages a telehealth platform vendor to help it carry out its health care activities and functions, the telehealth platform vendor is considered a "business associate" and the covered entity must have a written business associate contract or other arrangement (called a "business associate agreement") with the telehealth platform vendor to ensure that the vendor will appropriately safeguard PHI. The business associate agreement also serves to clarify and limit, as appropriate, the permissible uses and disclosures of PHI by the business associate. A business associate may use or disclose PHI only as permitted or required by its business associate agreement or as required by law. A business associate is directly liable under the HIPAA Rules and subject to civil and, in some cases, criminal penalties for making uses and disclosures of PHI that are not authorized by its business associate agreement or required by law. A business associate also is directly liable and subject to civil penalties for failing to safeguard electronic PHI in accordance with the HIPAA Security Rule.

The HIPAA Rules expressly prohibits covered entities and their business associates from selling PHI to third parties, or using or disclosing PHI for marketing activities, without an individual's authorization. OCR has authority to investigate impermissible uses and disclosures of PHI by telehealth platforms that meet the definition of a covered entity (*e.g.*, a health care provider that bills insurance for health care) or business associate.

In December 2022, OCR issued a bulletin addressing potential impermissible disclosures of electronic PHI (ePHI) by HIPAA regulated entities to online technology tracking vendors that collect and analyze information about how internet users are interacting with a covered entity's website or mobile application. The bulletin explains what tracking technologies are, how they are

used, and what steps regulated entities must take to protect ePHI when using tracking technologies to comply with the HIPAA Rules. *See*: https://www.hhs.gov/about/news/2022/12/01/hhs-office-for-civil-rights-issues-bulletin-on-requirements-under-hipaa-for-online-tracking-technologies.html.

Question #71

3. The harms to consumers, who are also patients, as a result of this commercialization was highlighted in testimony given before the Committee on March 1, 2023, but can you also speak to:

A. The harm this commercialization is doing to the providers in our healthcare system?
B. What is the cost of commercialization to our providers?
C. What is the cost of preventing against such commercialization?

HHS Response

The HIPAA Privacy Rule limitations on the sale of PHI require a covered entity to develop, and train workforce members on, the policies and procedures for compliance. HHS estimates provider burden for compliance with the HIPAA Privacy, Security, and Breach Notification Rules, but does not estimate at a granular level of the cost for training workforce members about the Privacy Rule's provisions on the sale of PHI.

Question #72

4. The HIPAA Privacy NPRM titled "Proposed Modifications to the HIPAA Privacy Rule relating to Support, and Remove Barriers to, Coordinated Care and Individual Engagement" set to be finalized in 2023 contains provisions that are highly likely to increase the commercialization of PHI through provisions like applying the Patient Rate to third-party directives — many of which will go to entities not covered by HIPAA.

   A number of associations — such as the American Academy of Family Physicians, the Association of Health Information Outsourcing Services, and the Health IT Leadership Roundtable Committee in its February 2023 White Paper — have all expressed concern about the increased utilization of the third-party directive and the associated risks to both patients and providers.

A. How will HHS be able to effectively curb this practice and protect patient health data?

The HITECH Act gives an individual a right to direct a covered entity to transmit an electronic copy of their protected health information in an electronic health record to any entity or person designated by the individual, and applies the HIPAA right of access reasonable, cost-based fee limitation to this type of right of access request.

In the HIPAA Privacy Rule Notice of Proposed Rulemaking (NPRM) to Support, and Remove Barriers to, Coordinated Care and Individual Engagement NPRM, the Department proposed to implement these provisions of the HITECH Act. The Department is carefully reviewing all comments received during the comment period and your expressed concerns to ensure that the final

rule implements the congressional requirement and protects privacy in a manner that does not place unreasonable burdens on providers or harm patients.

Question #73

5. HHS currently has two proposed rules and one pending rule that would make changes to the HIPAA privacy rule. However, there is no harmonization between the rules, and in some instances, the rules are in direct conflict with each other.

A. How does HHS plan to move forward with these rules?

HHS Response: The Department carefully reviews all comments received during the public comment periods to proposed rulemakings before making determinations on final rules. In addition, the Department will ensure that any final rule does not create conflicting requirements.

B. What is the agency doing to ensure there is no undue harm done to patients and the providers who handle the protected health information of patients?

HHS Response: The Department will carefully consider public comments as it deliberates on final rule policies to ensure that it implements statutory requirements and protects privacy in a manner that does not place unreasonable burdens on providers or harm patients.

C. For example, what will HHS do to rein in the practice of many commercial third- parties who currently take advantage of existing loopholes in the NPRM to gain a patient's protected health information without an authorization?

HHS Response: The 2021 NPRM has not made any changes to current law, as it is only a proposed rule that has not been finalized.

The HITECH Act gives an individual a right to direct a covered entity to transmit an electronic copy of their protected health information in an electronic health record to any entity or person designated by the individual. If an individual directs that their protected health information be transmitted to a third party, in a "clear, conspicuous, and specific" manner, a covered entity is required to follow the HITECH Act and HIPAA Privacy Rule requirements with regard to taking action on the individual right of access. The HITECH Act and HIPAA Privacy Rule do not regulate the decisions of individuals with respect to who an individual chooses to receive a copy of their protected health information.

The Department is carefully reviewing all comments received during the comment period and your expressed concerns to ensure that the final rule implements the statutory requirement and protects privacy in a manner that does not place unreasonable burdens on providers or harm patients. When a final rule is published, OCR will ensure adherence to the final rule through education about the

requirements and enforcement actions.

The Honorable Gus Bilirakis

Question #74

1. Domestic pharmaceutical manufacturing initiatives are a key component of securing American independence from China, among others. It is estimated that Chinese manufacturers make up around 40 percent of all APIs used worldwide, and that China and India are the source of approximately 80 percent of the APIs imported to the United States. As part of the PAHPA reauthorization, are there new authorities needed to further help acquire, construct, or alter non-federally owned facilities to better allow ASPR to support efforts to develop net new domestic manufacturing capacity for medical countermeasures, including their active pharmaceutical ingredients (APIs)? If so, why is such authority needed?

HHS Response: ASPR is investing in securing a strong domestic manufacturing base to produce essential products such as medical equipment, pharmaceuticals, vaccines, and personal protective equipment. Since the beginning of the COVID response, ASPR has supported over 87contracts to build and sustain domestic manufacturing of critical medical supplies and to produce medical countermeasures on U.S. soil. In addition, with ASPR's reorganization in February 2023, ASPR established the Industrial Base management and Supply Chain (IBMSC) Office to ensure we have dedicated, full-time staff devoted to addressing this long-term challenge. We are requesting funds in the 2024 President's Budget to support this office and their important work.

The $400 million requested in the FY24 President's Budget for Pandemic Preparedness and Biodefense, will also ensure we are able to maintain the capabilities built and used extensively during the COVID-19 pandemic to strengthen medical countermeasure development and manufacturing. Funds could also support purchasing domestically made product for inclusion in the SNS, reducing reliance on foreign production. The $400 million Pandemic Preparedness and Biodefense request will ensure BARDA has ready resources to immediately scale up manufacturing of vaccine, diagnostic and therapeutic prototypes at the first indication of an outbreak. The requested funding would also accelerate advanced development and additional manufacturing of medical countermeasures for clinical trials and, when appropriate, patient care as part of an emergency response.

If appropriated by Congress, the Department will develop specific spend plans as funds are allocated to programs across HHS.

During the COVID-19 response, multiple challenges needed to be overcome, including addressing critical deficiencies with personal protective equipment, pharmaceuticals, therapeutics, and vaccine supply chains. The COVID-19 pandemic highlighted the need for these critical public health industrial investments at a scale never seen before in the United States. At the beginning of the pandemic, many products were manufactured outside of the United States. With

significant supplemental investments from Congress, we are building a program to ensure we have personal protective equipment and critical supplies manufactured in the United States moving forward. COVID-19 supplemental legislation also included language that allowed ASPR to support the physical construction of domestic manufacturing facilities. These construction authorities have been used to support the construction of new factories nationwide for COVID-19 related medical supplies. Once the COVID-19 funds are expended, ASPR loses construction authority. It is important to have construction authority to sustain the work we have started and to expand this work to other parts of the public health supply chain.

Question #75

2. How is HHS coordinating with the Department of Defense to leverage its DPA-Title III authority to prioritize grants, loans or other financial incentives to build domestic manufacturing capacity with the goal of mitigating a future public health emergency?

HHS Response: As of the date of this hearing, HHS/ASPR was working to establish an independent DPA Title III capability with the directive of incentivizing domestic capacity for the production of medical countermeasures (MCMs) that support the national defense. Once established and authorized, the HHS DPA Office will offer HHS with its own internal capability to expand, onshore, maintain, create, and sustain domestic MCM production capacities by pursuing projects that focus on scaling emerging technologies, commercializing R&D investments, and sustaining critical production capabilities to strengthen domestic public health supply chains and ensure a more robust response to a future public health emergency.

Question #76

3. The quality-adjusted life year metric, or "QALY," often used in cost effective analyses, is a discriminatory metric, leading to biases against patients with disability, terminal disease, and the elderly. Cost-effective analyses can also assign lower value to the lives of underserved and under-represented patient populations, further exacerbating existing health disparities and treatment gaps. Stakeholders are specifically concerned with how discriminatory metrics such as QALY derivatives may influence CMS' value assessments. Advocates for patients and caregivers from all walks of life have echoed similar concerns, as illustrated across dozens of comments submitted to the Institute for Clinical and Economic Review (ICER), an organization that relies heavily on QALYs and other comparable benchmarks in developing value assessments for new medical technologies. Can you ensure that CMS will not use any discriminatory metric, including a QALY or any QALY-adjacent metric that devalues patients who are elderly, disabled, and underserved/underrepresented, such as rare disease patients, for the purposes of government price setting? Can you commit to ensuring that the QALY or any other discriminatory metric will not be used to ration health care in federal health programs?

HHS Response

It has been a long-standing policy that Medicare does not use QALYs, in accordance with the law.

We are happy to provide technical assistance on any legislation you draft.

Question #77

4. The Biden Administration's open border policies have created a stark increase in unaccompanied minors crossing into our country. Poorly designed and implemented policies dating back to the Obama Administration in 2008 allow children crossing the US Southern border to live with sponsors while they go through immigration proceedings. According to the New York Times, over the course of the last two years HHS has lost contact with 85,000 migrant children. You recently told the Senate Finance committee that you were unfamiliar with that number – Mr. Becerra, have you had an opportunity to look into these stats and can you provide the latest update?

HHS Response: The 85,000 statistic cited by the New York Times misrepresents ORR's work and its follow-up activities. ORR has policies in place to promote the safety and well-being of unaccompanied children by linking them to services after they have been released from ORR care and transition into a new community. These policies include Safety and Well-Being Calls to children and sponsors after a child is released from ORR care. Per ORR policies, ORR care providers are required to make a minimum of three attempts to reach and speak with the child and the sponsor. Although children and sponsors are not required to participate in Safety and Well-Being Calls and may choose not to answer a call for a variety of reasons, in fiscal year FY 2022, ORR care providers made contact with either the child, the sponsor, or both in more than 81 percent of households.

In addition, ORR has been developing and progressing with the implementation of expanded post-release services (PRS), including a pilot project that began in September 2022. Under this pilot, expanded PRS consists of three levels of services, which may be elevated at any time, ranging from Level 1 (consisting of three check-ins) to Level 3 (involving intensive, in-person case management). Safety and Well-Being Calls will be categorized under "Level 1 Services," in which three in-person or virtual comprehensive check-ins are conducted with the unaccompanied child and sponsor at 7-, 14-, and 30-days following release from ORR care. This full rollout is anticipated to start January 1, 2024.

Question #78

5. The President's budget requests funding to ensure these children have adequate support including access to legal resources – If you cannot reach these children how do you plan to implement such a policy? Why does it seem you are doing less with more money?

HHS Response

HHS is required to ensure legal representation for unaccompanied children to the greatest extent practicable (*See* 8 U.S.C. §1232(c)(5)). ORR's Unaccompanied Children (UC) Program Policy Guide Section 3.7 states that when in ORR custody, unaccompanied children should receive "Know Your Rights" presentations on immigration law and the children's rights and responsibilities, and legal screenings within ten business days of admission.

Direct representation services are prioritized for the most vulnerable children, including those who are expected to have a protracted stay in ORR care, such as children in long-term foster care or who do not have an identified sponsor, and children who are seeking voluntary departure or who otherwise have complex legal cases.

ORR has expanded and continues to expand access to legal representation to children. In fiscal year (FY) 2021, 13,579 children received direct representation in their immigration proceedings through ORR's contractor, and in FY 2022 this number increased to 16,299 children. Over the coming year, ORR plans to reach a historic expansion in direct representation by funding an additional 15,000 direct representation cases. ORR will achieve this by bringing on new legal service providers in high release counties, where there has not historically been immigration legal representation. ORR's goal is to ensure that all unaccompanied children served by ORR can access legal representation by the end of calendar year 2027.

Question #79

6. Heart disease is the leading cause of death in the U.S., yet the number of new cardiovascular medicines researched has declined across all stages of development over the last 20 years, representing less than 6% of all new drug launches. This is largely because the cost, complexities, and risks of running large scale cardiovascular clinical trials are greater than ever. It often takes multiple years and tens of thousands of patients worldwide to conduct a pivotal Phase III cardiovascular clinical trial as well as additional years of post-approval real-world evidence studies for new cardiovascular medicines to become established in clinical practice and treatment guidelines. As many of the cardiovascular medicines currently in development are small molecule drugs, what will CMS do to ensure that the Inflation Reduction Act does not exacerbate the ongoing decline in cardiovascular research and development?

HHS Response

CMS supports continued drug innovation and believes it is vitally important that beneficiaries have access to innovative new therapies. The law requires that at least seven years, for drugs, or 11 years, for biologicals, must have elapsed between the selected drug publication date and the FDA approval or licensure, as applicable. We are implementing the Negotiation Program in accordance with the law.

CMS has been regularly engaging with members of the public to get their feedback so that we are implementing the Negotiation Program in a thoughtful way that both improves drug affordability and accessibility for people with Medicare and supports innovation. We plan to get public input throughout the implementation of the Negotiation Program to make sure that we know what is occurring in the market.

Question #80

7. There has been a lot of discussion on the chilling effect that the IRA will have on

innovation and the development of new molecular entities. However, one aspect that is largely under-discussed is the ongoing research and innovation that occurs well past a product's initial approval. Many therapies are approved for a singular initial indication and go on to secure multiple indications over a period of time. This is often the case in oncology drug development, where further research on an approved drug leads to approvals for additional tumor types, stages, and combinations. There is concern that the IRA has the potential to reduce FDA-approved, follow-on oncology indications. Stakeholders are concerned that oncology patients who have exhausted their approved therapeutic options will not be able to find and enroll in post-approval research studies as they would no longer be conducted by industry. How will CMS ensure that there is a robust innovation ecosystem so that manufacturers can continue to do this iterative development on approved products, despite the IRA's disincentives to pursue additional clinical trials, to discover the full breadth of a medicine's potential benefit to patients?

HHS Response

CMS supports continued drug innovation and believes it is vitally important that beneficiaries have access to innovative new therapies. The law requires that at least seven years, for drugs, or 11 years, for biologicals, must have elapsed between the selected drug publication date and the FDA approval or licensure, as applicable. We are implementing the Negotiation Program in accordance with the law.

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Question #81

8. In a 2019 Report, GAO recommended that the Administrator of HRSA should ensure that the information it uses to verify nonprofit status for all nongovernmental hospitals that participate in the 340B Program is reliable. As of January 2023, the status of this GAO recommendation remains open. Neither HRSA nor the agency that collects the data has evaluated the reliability of the data for verifying nonprofit status. HRSA believes that the information it uses to determine nonprofit status is reliable, because hospital administrators attest to its accuracy. By what metric will HRSA utilize to ensure reliable information is used to determine if nongovernmental hospitals participating, or seeking to participate, in the 340B Program meet the statutory eligibility requirements?

HRSA Response

It is difficult for HHS to issue enforceable standards such as those recommended by the GAO. In order to do so, HHS would need regulatory authority to allow HRSA to set legally binding standards for participation in the 340B Program that it could enforce to help ensure compliance with 340B Program requirements. The FY 2024 President's Budget includes a proposal to enhance 340B Program integrity by requiring covered entities to annually report to HHS on how the savings achieved through the 340B Program benefits the communities they serve and provide HHS regulatory authority to implement this requirement.

Question #82

9. In a June 2018 report, GAO recommended the HRSA require covered entities to register contract pharmacies for each site of the entity for which a contract exists. Furthermore, GAO noted that "manufacturers lack important information to help ensure that 340B discounted drugs are only provided to pharmacies with a valid 340B contract with the covered entity site for which the drug is being dispensed." According to GAO, HHS did not concur with this recommendation and, as of March 2021, indicated that it did not plan to take any actions to implement the recommendation. However, in January 2023, HRSA noted that the agency had requested regulatory authority for all aspects of the 340B Program in the FY 2023 President's Budget. However, GAO noted, "HRSA already requires covered entities to register contract pharmacies, just not for each site of the entity for which a contract exists. Thus, it is unclear why regulatory authority would be needed to implement this recommendation." HRSA already requires covered entities to register contract pharmacies, given the number of contract pharmacies have increased by 4000% in the past 10 years, when will HRSA extend this guidance to include all contract pharmacies for each site of the entity for which a contract exists?

HHS Response

In the FY 2024 President's budget request, HRSA proposed explicit regulatory authority to strengthen compliance and transparency specifically related to the utilization of contract pharmacies. HHS would welcome the opportunity to provide technical assistance on this proposal.

Question #83

10. PBMs receive significant rebates in connection with drug formulary placement. In some cases, PBMs have not passed portions of these rebates down to patients or health plans, which leads to higher out of pocket costs and more expensive premiums for patients. What can the Administration do to ensure that patients directly benefit from the growing prescription drug rebates and discounts from being pocketed by PBMs?

HHS Response

The Departments of HHS, Labor, and the Treasury will be releasing a report which will include information on the impact of prescription drug rebates, fees, and other remuneration on premiums and out-of-pocket costs. The department looks forward to continuing to work with you on reforms to ensure that there are no unnecessary costs in our health care system.

In April 2022 CMS finalized a policy that requires Part D plans to apply all price concessions they receive from network pharmacies to the negotiated price at the point of sale, so that the beneficiary can also share in the savings. Specifically, CMS is redefining the negotiated price as the baseline, or lowest possible, payment to a pharmacy, effective January 1, 2024. CMS is applying the

finalized policy across all phases of the Part D benefit. This policy reduces beneficiary out-of-pocket costs and improves price transparency and market competition in the Part D program.

Question #84

11. I am concerned about the recent action your Department took to raise the IDR administrative fee to $350 – a hike of 600%. As I hope you know, this amount is significantly higher than the charges submitted by many providers, especially those who routinely perform low-cost services. As a result, insurers are now free to significantly reduce provider reimbursement, safe in the knowledge that all providers whose charges fall below $350 can no longer afford to access IDR. Under your policy, after all, such providers would lose money, even if they prevail in IDR. What detailed analysis did the Department perform that led it to conclude raising the fee 600% to $350 would be sustainable for providers and not reduce Medicare beneficiaries' access to providers and the services they deliver? Please provide analysis.

Question #85

12. In light of the sharp disconnect between the high fee your Department is now imposing and the low-dollar charges submitted for many essential services, why did HHS choose to raise the administrative fee instead of taking action to promote reasonable reimbursement by insurers? And why did HHS announce this surprise change on December 23, 2022 – just four business days before it was put into effect?

Question #86

13. I am concerned about the impacts of the way that the three agencies have chosen to implement the No Surprises Act. The massive backlog of claims that are not being paid, the current halt to all dispute resolution, and the 600% increase in dispute filing fees all seem to have negative impact on the doctors and nurses providing care in our emergency departments. According to HHS, of the over 90,000 claims that were disputed through September last year, only about 25% have been closed, and of those, only 15% had any payment determination made – just 3,576 out of more than 90,000 disputes, or about 4%. What is the reason for the lack of resolution here? What do small physician practices do while waiting to be paid for services rendered last year?

HHS Response 84-86

The No Surprises Act requires the Departments to establish the IDR administrative fee at a rate where the total amount of fees paid is estimated to be equal to the amount of expenditures estimated to be incurred by the Departments in administering the Federal IDR process. There is a very high volume of disputes being submitted for resolution, which led to increased Federal administrative costs. Through December 5, 2022, there were over 160,000 disputes submitted for resolution through the IDR portal, nearly 10

times greater than the Departments initially estimated. During that time, non-initiating parties challenged the eligibility of over 68,000 disputes for the Federal IDR process. As detailed in the Departments initial report on the first two calendar quarters of the IDR process, many claims are ultimately determined ineligible. That report details the reasons claims were determined ineligible. IDR entities have had to perform a substantial amount of outreach and analysis to determine whether a submitted dispute is eligible for the Federal IDR process. Assessing the information received and making an eligibility determination can be a time-consuming process for IDR entities, but an eligibility determination must be made before a dispute can proceed to IDR. Cases can be ineligible for a number of reasons. Some common reasons include: incomplete documentation, lack of compliance with applicable timelines, non-completion of open negotiation, incorrect batching and incorrect jurisdiction (federal vs State). These issues are detailed in our first report on the IDR process and the amended 2023 fee guidance. In order to address these issues, the Departments have engaged a contractor and government staff to conduct pre-eligibility reviews, which have also led to increased Federal costs. The Departments are also considering additional policy and operational improvements, including through rulemaking, to improve the process for determining the eligibility of disputes and ultimately increase the speed with which certified IDR entities render payment determinations. We plan to adjust the administrative fee as operational requirements change over time.

Question #87

14. CMS includes a measure every year in the MA Rate Announcement called the effective growth rate, which is meant to account for inflation and the cost drivers of care. CMS' math said the effective growth rate this year is expected to be 3.32%. The Medicare Trustees report projects an annual growth rate of 5.4%. CPI (Consumer Price Index) is up 6%, food costs are up 9%, and health care inflation is expected to rise to 9% this year. How does the 3% growth rate you all have proposed in any way help bridge the cost of caring for vulnerable seniors given this level of inflation?

Question #88

15. Medicare Advantage is a critical choice for seniors' health care in Florida, today 54% of seniors in my state choose Medicare Advantage including more than 2.6 million seniors. Beneficiaries consistently report high satisfaction with the quality of care under the program and cost savings – MA beneficiaries spend approximately 40% less than Medicare Fee-for-Service beneficiaries nationwide which is critical for the 53% of beneficiaries that live on annual incomes of less than $24,500. MA's holistic clinical care model is supported by a value-based payment system that helps manage total costs of care, lower beneficiary costs, and improve health outcomes. In the 2024 Rate Announcement for Medicare Advantage, CMS proposed changes that could result in patients experiencing higher costs. Will the Administration provide analyses to ensure that the policy changes will not lead to increased beneficiary costs or disruption for Medicare Advantage seniors in 2024? How will you ultimately ensure that this Final Rule

will not negatively affect MA beneficiaries, particularly vulnerable populations such as those on Special Needs Plans?

HHS Response 87 and 88

Core Medicare benefits, such as hospital care and physician visits, are guaranteed in Medicare Advantage like they are in Medicare fee-for-service. Regardless of the payment update, Medicare Advantage plans must cover those core Medicare benefits. We expect Medicare beneficiaries to continue to have a broad array of choices of MA plans with supplemental benefits. CMS anticipates stable premiums and benefits for beneficiaries in 2024, as seen previously in years with comparable updates. Historical experience shows plans compete in this highly competitive market to keep premiums down and maintain supplemental benefit levels, with beneficiary choice remaining strong.

As required by law, CMS adjusts payments to health plans offering MA to reflect the expected health care costs of enrollees based on health status and demographic characteristics through a process known as "risk adjustment." This ensures CMS pays more for enrollees with greater health care needs and reduces incentives for plans to favor healthier beneficiaries. Additionally, there are protective features built into the MA risk adjustment system to ensure plans who care for dually eligible individuals are paid adequately, and nothing in this proposal changes those features. CMS routinely makes updates to the MA risk adjustment model to reflect more recent utilization and cost patterns and to ensure MA payments accurately reflect the costs of care for MA enrollees. In February, CMS proposed technical, data-driven, and clinically-based updates to improve the accuracy of MA payments in the 2024 Advance Notice. CMS received public feedback on these proposals, and will take this feedback into account when finalizing the 2024 Rate Announcement.

Question #89

16. I appreciate that you have proposed that Medicare cover seat elevation systems on power wheelchairs for people with disabilities. This is an issue where many of us, regardless of political party, agree that something needs to be done. I encourage you to finalize this important coverage decision as quickly as possible. What next steps will you be taking to issue a coverage proposal for medically necessary standing systems which help people with disabilities perform important activities of daily living and avoid clinical complications that result from sitting in a wheelchair?

HHS Response

In February 2023 CMS published a proposed National Coverage Determination (NCD) to expand Medicare coverage for power seat elevation equipment for individuals with a Group 3 power wheelchair. The public comment period closed on this NCD last month. CMS plans to consider standing equipment in a separate future national coverage analysis. I'm happy to stay in touch with you as CMS undertakes this process.

Question #90

17. In the Consolidated Appropriations Act for FY 2023, Congress granted the FDA more

authority to enforce sponsors to complete post-market studies for accelerated approval treatments. Did CMS take this new policy into account when formulating the CMMI Accelerating Clinical Evidence Model? If not, does this provide grounds for them to reconsider the demonstration?

CMS Response
The Accelerating Clinical Evidence Model will not change the way CMS covers new drugs, and it does not change the FDA accelerated approval process. The model is intended to test whether changes to Medicare payment might encourage evidence development via timely completion of confirmatory trials.

Question #91

18. The FDA has been established as the "gold standard" for judging safety and efficacy of a drug. Does allowing CMS to make Medicare coverage decisions based on the pathway for approval undermine the role of the FDA?

HHS Response
The FDA performs a vital and an important role. CMS recognizes the important and related – but different – roles of the respective agencies. The FDA determines whether to approve a new drug or biological based on a careful evaluation of the available data and a determination that the drug or biological is safe and effective for its intended use. In general, CMS makes national coverage decisions based on whether something is reasonable and necessary for the diagnosis or treatment of an illness or injury for the Medicare population. In determining the generalizability of the results of the body of evidence to the Medicare population, CMS considers, at minimum, the age, race and gender of the study participants. CMS conducts its own independent review to determine whether an item or service is reasonable and necessary for use in the Medicare population and should be covered nationally by Medicare.

Question #92

19. This year, 2023, is the 40-year anniversary of the Orphan Drug Act, which has increased the number of FDA-approved orphan drugs by 1,576% – from just 38 to more than 600 treatments for more than 1,000 rare diseases. The FDA recently announced Accelerating Rare disease Cures (ARC) Program and Operation Warp Speed - how will the agency work holistically across centers to streamline the rare disease development process?

HHS Response
The Accelerating Rare disease Cures (ARC) Program is managed by the Center for Drug Evaluation and Research's (CDER) Rare Diseases Team (RDT). "Operation Warp Speed for Rare Diseases," also referred to as the "Communications Pilot Program," is a Center for Biologics Evaluation and Research (CBER) initiative, for which planning is still underway by CBER leadership and the Office of Therapeutic Products in CBER as a CBER Rare Disease Program (RDP) activity. CDER's RDT and CBER's RDP staff work closely together and are jointly committed through PDUFA V, VI, and VII to continuing to advance and facilitate the development and timely approval of drugs and biologics for rare diseases. Through this synergistic relationship,

the centers collaborate on knowledge sharing, rare disease programming, and policy generation (including guidances) to advance our approach to the development of safe and effective rare disease drug development. In addition, RDT and RDP also work closely with the Office of Orphan Products Development on important FDA activities, such as FDA Rare Disease Day and the review of grants under the Orphan Products Grants Program and the Rare Neurodegenerative Disease Grant Program. FDA remains strongly committed to doing what we can via guidance for industry and stakeholder engagement activities to maintain and promote the robustness of the development pipeline for safe and effective drugs and biological products to treat patients with rare diseases, including rare cancers. FDA has published more than 18 guidances since 2018 on topics that are highly relevant to drug and biological product development for rare diseases, including rare cancers. Some recent examples include:

- 2023 Draft Guidance for Industry*: Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics*[31]
- 2023 Draft Guidance for Industry: *Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products*[32]
- 2022 Guidance for Industry: *Human Gene Therapy for Neurodegenerative Diseases*[33]
- 2022 Draft Guidance for Industry: *Tissue Agnostic Drug Development in Oncology*[34]

Question #93

20. Do you support Medicaid coverage and reimbursement for genetic testing (e.g., single gene testing, gene panels, whole exome sequencing, whole genome sequencing, etc.) to provide earlier accurate diagnoses for individuals with rare diseases?

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[31] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-trial-considerations-support-accelerated-approval-oncology-therapeutics. This draft guidance, when finalized, will represent the current thinking of FDA on this topic. FDA updates guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[32] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-design-and-conduct-externally-controlled-trials-drug-and-biological-products. This draft guidance, when finalized, will represent the current thinking of FDA on this topic. FDA updates guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[33] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/human-gene-therapy-neurodegenerative-diseases. FDA updates guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[34] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tissue-agnostic-drug-development-oncology. This draft guidance, when finalized, will represent the current thinking of FDA on this topic. FDA updates guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

HHS Response

Cell and gene therapies (CGTs) are a rapidly growing class of treatments that have the potential to treat or even cure previously intractable diseases, such as sickle cell disease, beta thalassemia, or cancer. In general, CGTs and other genetic/genomic testing diagnostic services may be covered by states in their Medicaid programs under several mandatory and optional benefit categories. Specifically, genetic and genomic testing diagnostic services should be furnished to children enrolled in Medicaid and who are under age 21 and eligible for the Early Periodic Diagnostic, Screening, and Treatment (EPSDT) benefit when determined medically necessary for the individual child, and the genomic sequencing/genetic testing is not considered experimental (the state's determination of whether a service is experimental must be reasonable and should be based on the latest scientific information available). States develop medical necessity criteria consistent with federal regulations and application of the criteria are under state purview; CMS does not review or approve state medical necessity criteria.

Question #94

21. I want to reiterate my strong desire to work to ensure CMS proposes a robust and meaningful separate expedited pathway for transitional coverage of innovative FDA-approved devices. While I am discouraged this Administration withdrew the Medicare Coverage of Innovative Technologies (or "MCIT") rule I have remained hopeful the important goals can still be accomplished through the rebranded "Transitional Coverage for Emerging Technologies" rule. However, after nearly two years, numerous congressional inquiries and letters, and several delays, we have not seen a proposed rule or confirmation of its timing. Furthermore, I am concerned that CMS is moving in the wrong direction with this proposed rule --- toward just expanding or refining the Coverage with Evidence Development (CED) process for those with inadequate evidence as the only pathway under TCET. This would be a significant departure from creating a separate pathway for accelerated coverage for those many truly innovative products that may not need to develop additional data for coverage due to existing sound clinical data, and for whom existing protracted (i.e. NCD and LCD) coverage processes have led to significant delays in coverage. What will HHS do to dedicate the right resources to ensure the Agency puts forward a proposed rule that is a meaningful, separate pathway for new devices with existing sound data that does not require additional evidence generation, that Congress, patients, and those developing innovative technology have urged the Administration to pursue?

Question #95

22. The Fall 2022 HHS Unified Agenda regulatory calendar currently lists April 2023 as the target date for CMS to release the TCET proposed rule (CMS-3421), which would provide transitional Medicare coverage for new medical technologies. Can you assure us that CMS will issue the TCET proposed rule by April 2023, particularly given that this rule was initially scheduled for release in 2022, and originally discussed over two years ago when the MCIT rule was repealed? Assuming that CMS publishes the TCET proposed rule in April 2023, when does the agency expect to release and implement the

final rule?

Question #96

23. Does CMS anticipate that provisions in the TCET rule will extend beyond refining the existing CED study criteria and process or does CMS envision TCET as limited to those new devices that CMS deems as requiring additional data collection to secure Medicare coverage through a revised CED process with updated study criteria?

Question #97

24. Without a specific option in TCET that guarantees seamless and timely coverage without the need for additional data collection, please explain how CMS is achieving its policy goals of providing "transitional coverage" and "promoting access to emerging medical technologies" for new and innovative devices that do not require additional evidence collection.

Question #98

25. Does TCET as envisioned address how patients seeking to access new devices with sound clinical evidence and safety data will not continue to face significant delays in coverage and access due to existing the LCD and NCD approval backlogs?

HHS Response 94-98

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

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

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

forward to working with you and hearing your feedback as we move forward with these efforts.

Question #99

26. Please describe the process that CMS envisions for establishing permanent Medicare coverage for those new medical items and services that undergo CED studies, which successfully demonstrate they are reasonable and necessary for Medicare beneficiaries. How will CMS ensure a seamless transition to permanent coverage in these cases? What metrics will CMS use to evaluate and assess whether CMS has appropriately and seamlessly transitioned items and services in CED studies to permanent Medicare coverage?

Question #100

27. Please describe the process that CMS envisions for establishing permanent Medicare coverage for those new medical items and services that do not have to undergo CED studies as part of TCET, but rather receive expedited coverage under the TCET pathway without additional data collection. How will CMS ensure a seamless transition to permanent coverage in these cases? What metrics will CMS use to evaluate and assess whether CMS has appropriately and seamlessly transitioned items and services that received coverage under TCET without CED studies to permanent Medicare coverage?

HHS Responses to 99 and 100

Medicare's Coverage with Evidence Development (CED) is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. In making coverage decisions involving CED, CMS decides after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary. Coverage in the context of ongoing clinical research protocols or with additional data collection can expedite earlier beneficiary access to innovative technology while ensuring that systematic patient safeguards, including assurance that the technology is provided to clinically appropriate patients, are in place to reduce the risks inherent to new technologies, or to new applications of older technologies.

The Honorable Greg Pence

Question #101

Under the direction of the White House, CMS announced their intention to propose minimum staffing ratio requirements for nursing homes in the coming months. On March 10th, I sent a

letter to CMS with several of my colleagues on both sides of the aisle to oppose this policy. Nursing homes are already struggling to maintain current staff levels and fill vacancies. Data from the Bureau of Labor Statistics confirms that skilled nursing care facilities are facing some of the worst job losses compared to any other health care sector, with more than 200,000 fewer workers since the start of the pandemic. Mandating additional staff ratio requirements on top of ongoing workforce shortages could inherently reduce the number of patients served in these facilities. For those in rural communities, there could be few alternatives. Your agency's budget, however, does not explain how the agency intends to support this staffing requirement.

A. Is this policy still a priority for your agency?

B. If this rule is implemented, how would penalties for non-compliance impact providers, patients, and rural communities in my district?

HHS Response

CMS initially published a Request for Information (RFI) soliciting public comments on minimum nursing home staffing requirements in April 2022, within the Fiscal Year (FY) 2023 Skilled Nursing Facility Prospective Payment System Proposed Rule. CMS received many comments on the RFI from members of the public who identified themselves as family members or caretakers of residents living in nursing homes. The vast majority of those comments voiced concerns related to residents not receiving adequate care because of chronic understaffing in facilities. Multiple commenters stated that residents can go entire shifts without receiving toileting assistance, leading to falls or increased presence of pressure ulcers. One commenter, whose parents live in a nursing home, noted that they visit their parents on a daily basis to ensure the provision of quality care and reported that staff in the facility have stated that they are overworked and understaffed. The feedback received has and will be used to inform the research study design and proposals for minimum direct care staffing requirements in nursing homes we expect to propose in 2023 rulemaking.

The Social Security Act requires nursing homes to provide "24-hour licensed nursing service which is sufficient to meet nursing needs of its residents," and must use the services of a registered professional nurse at least eight consecutive hours a day, seven days a week. Current regulations specify that nursing homes are required to conduct an annual facility assessment, which considers resident needs and staff ability to provide care. In determining what 24-hour services provide "sufficient" staff—meaning registered nurses (RNs), licensed practical and vocational nurses (LPNs and LVNs), and certified nurse aides (CNAs)—facilities must account for individual resident assessments and plans of care, in addition to the facility assessment. Despite these existing requirements, understaffing continues to be a concern. For that reason, CMS believes it essential to patient safety that it conduct new rulemaking to propose more specific, detailed, and quantitative minimum staffing requirements to ensure that all CMS-regulated facilities have sufficient staff. CMS is conducting a mixed methods study with qualitative and quantitative elements to help to inform the minimum staffing proposed requirements.

The information obtained through these and other efforts will inform future proposed notice and

comment rulemaking on minimum staffing requirements, which CMS expects to issue this Fall. It is CMS's goal to consider all perspectives, as well as findings from RFI responses and the staffing study, as CMS develops future proposed minimum staffing requirements to advance the public's interest in safe, quality care for residents. CMS is aware of ongoing challenges to health care staffing providers across the country are facing, particularly rural providers. CMS intends to seek workable, implementable solutions that ensure safe, quality care for residents while also considering the current reality that many providers are facing. CMS appreciates the interest shown by so many stakeholders to date and looks forward to robust response from stakeholders when the proposed rule is issued.

The Honorable Anna Eshoo

Question #102

1. Medicare is currently covering at-home Covid tests. You have said that you will end that important benefit on May 11th. You aren't required to do that and you shouldn't. About 250 Americans are dying of Covid each day, most of whom are Medicare beneficiaries. At-home tests are a smart and cheap way to keep beneficiaries healthy. Will you commit to continuing the coverage? If not, why?

HHS Response

CMS prioritizes supporting beneficiary access to the care they need and after the end of the public health emergency (PHE), Medicare beneficiaries can continue to access medically necessary COVID-19 polymerase chain reaction (PCR) tests and antigen tests performed by a laboratory at no cost to them when the test is ordered by a physician or non-physician practitioner. Medicare Advantage plans must cover the same types of laboratory tests as Fee-For-Service Medicare Part B covers, but may have different cost sharing or limit coverage to use of in-network laboratories and providers. Some Medicare Advantage plans may also provide coverage for over-the-counter (OTC) tests as a supplemental benefit.

By law, Medicare does not generally cover OTC services and tests. Current access to free OTC COVID-19 tests will conclude at the end of the PHE. When the demonstration was implemented, it was announced that the demonstration would end at the end of the PHE.

Group health plans and health insurance issuers offering group or individual health insurance coverage are required to provide benefits for certain items and services related to testing for the detection COVID-19 when those items or services are furnished on or after March 18, 2020, and during the applicable emergency period. Plans and issuers must provide this coverage without imposing any cost-sharing requirements (including deductibles, copayments, and coinsurance), prior authorization, or other medical management requirements. The requirement for group health plans and health insurance issuers offering group or individual health insurance coverage to cover COVID-19 tests without cost sharing, both for OTC and laboratory tests, will end at the end of the PHE. However, coverage may continue if plans choose to continue to include it. We are encouraging private insurers to continue to provide such coverage going forward.

Question #103

2. The ACA says that private plans should cover CDC-recommended vaccines at no cost, but the implementing regulations don't match the law and some CDC-recommended vaccines still have a co-pay. In the next CMS private insurance regulation, will you include a policy clarifying that that ALL CDC-recommended vaccines are covered at no cost for the patient?

HHS Response

Under the Affordable Care Act, as implemented in regulations, most group health plans and health insurance issuers offering group or individual health insurance coverage must provide coverage and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or deductible) for vaccines for children, adolescents, and adults that have in effect a recommendation for routine use from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) with respect to the individual involved.

CMS, together with our colleagues at the Departments of Labor and the Treasury, share authority for administering the Affordable Care Act's preventive services requirements for group health plans and group and individual health insurance issuers. The department's implementing regulations provide coverage for ACIP recommended vaccines as described above.

The Honorable Yvette Clarke

In the Summer of 2021, I joined 40 members of the Congressional Black Caucus in sending a letter to you, encouraging a multi-stakeholder dialogue regarding access to potentially curative sickle cell disease (SCD) treatments. I want to applaud you and Administrator Brooks-LaSure for following through on our request. I'm thrilled you are prioritizing sickle disease warriors and recently launched the CMMI Cell and Gene Access Model to ensure Medicaid beneficiaries have access to potentially curative medicines. With several gene therapies for SCD launching in the next few years, I would like to ensure that Medicaid programs do not wait to provide access to these therapies, once approved.

Question #104

1. Can you please share with the Committee what steps CMS is taking to ensure there is no delay in access, and any other information about this promising demonstration project?

In response to feedback from CMS and other stakeholders, the Restore Act has been revised to further clarify the legislation's intent to close the loophole in the Medicare Secondary Payer Act (MSPA) created by the June 2022 Supreme Court ruling. The Supreme Court ruling undoes the longstanding MSPA provisions that prohibit private insurers from discriminating against individuals with end stage renal disease (ESRD).
Absent a transplant, patients with end stage renal disease (ESRD) must receive regular dialysis treatments to sustain their lives. In addition, patients with ESRD often have one or more

hospitalizations each year. They suffer from multiple comorbidities, including diabetes, depression, and heart disease, requiring specialty care and multiple medications. The illness has a disproportionate impact on communities of colors and is one of the starkest examples of health inequities in our country.

Congress recognized ESRD patients' vulnerability, and that the availability of Medicare coverage creates strong incentives for private insurers to discourage their enrollment. To protect ESRD patients and their right to elect the coverage that best meets their needs and that of their families, Congress created the MSPA. It also limited the time period for which private insurers are the primary payer for care delivered to ESRD patients to up to 30 months. Unfortunately, in a June 2022 ruling, the Supreme Court narrowly interpreted the law, creating a loophole that allows private insurers to evade the MSPA protections for ESRD patients, and we have been told that employers and insurers are starting to take advantage of it.

Last year, I joined my colleagues in introducing the Restore Protections for Dialysis Patients Act to close the loophole, and we have since revised the legislation to further clarify the bill's intent. We appreciate CMS' work to offer Congressional offices feedback and technical assistance on legislative drafts.

HHS Response

The *Cell and Gene Therapy Access Model* would allow for collaboration among CMS, manufacturers, and state Medicaid agencies, and would test a new approach for administering outcomes-based payment arrangements that may help Medicaid beneficiaries gain access to potential life-changing, high-cost specialty drugs. The model would seek to expand access and reduce the cost of cell and gene therapies, while also reducing the administrative and financial burden on states to administer the outcomes-based payment arrangements on their own. Participation in this model would be voluntary for states.

Medicaid beneficiaries, including those in underserved communities, could benefit from potential cures early in life or early in the course of the disease. This Model could expand access to cell and gene treatments for difficult-to-treat diseases and potentially reduce the amount patients would pay out-of-pocket for the treatments.

Question #105

1. Can you please assure me that CMS will provide that assistance as soon as possible on the Restore Act to avoid any delay in reintroducing this important legislation?

Additionally, I've been pleased to see this Administration take Health Equity seriously and begin to look at policies that ensure all Americans, no matter their racial and ethnic background, have the same access to health care. Unfortunately, last June, the Supreme Court upended decades old law that allowed patients with End Stage Renal Disease (ESRD) to elect health

coverage options that best meets their needs, whether private health plan or Medicare. Given that African Americans are 3 times more likely to have ESRD than White Americans, I am concerned that this ruling will limit their coverage choice and prevent their ability to access a transplant, health coverage for their family, or coverage for things such as Vision, Dental or Drugs for their other comorbidities.

HHS Response

HHS agrees that it is critical to preserve and increase access to high quality, affordable health care, including services to treat ESRD. As always, HHS appreciates the opportunity to provide technical assistance to Congress on important health care issues.

Question #106

2. How do you plan to ensure that health plans do not discriminate against this patient population and ensure they can continue to choose the coverage that fits them and their families best?

HHS Response

Thank you for your leadership on behalf of people with End Stage Renal Disease (ESRD). HHS shares your commitment to health equity and access to care for Medicare beneficiaries with ESRD.

On the issue of Medicare Secondary Payer coverage for beneficiaries with ESRD, under the statute, Medicare is the secondary payer to group health plans (GHPs) for individuals entitled to or eligible for Medicare based on ESRD for a coordination period of 30 months regardless of the number of employees and whether the coverage is based on current employment status. As required by law, during this coordination period, the GHP may not take into account an individual's Medicare entitlement or eligibility. The statute further requires that a GHP may not differentiate in the benefits it provides between individuals who have ESRD and others enrolled in the plan, on the basis of the existence of ESRD, the need for renal dialysis, or in any other manner. For example, GHPs are prohibited from terminating coverage, imposing benefit limitations, or charging higher premiums on the basis of the existence of the individual's ESRD.

Additionally, CMS is happy to provide technical assistance on any legislation you draft related to coverage for people with ESRD.

The Honorable Tony Cárdenas

Question #107

1. This past winter we saw a perfect storm in pediatric care – with Flu, Covid-19, and RSV – overwhelming our hospitals, especially those that specialize in pediatric care. This surge made it clear that we need to invest in our health care infrastructure- particularly when it comes to children. What can Congress do to support access to pediatric health resources, not

just in terms of beds but also workforce dedicated to youth and child populations?

HHS Response

HHS, through HRSA, supports important training at children's hospitals which expands their capacity to provide care. In FY 2022, the Children's Hospitals Graduate Medical Education (CHGME) Program funded 59 freestanding children's teaching hospitals across 29 states, including DC and Puerto Rico. Through this annual funding, the program trains more than half of all general pediatrics pediatric sub-specialty residents and fellows. The President's FY 2024 budget request proposes to continue these vital investments in training the pediatric health care workforce.

The President's Budget for FY 2024 also seeks to strengthen community-based graduate medical education by requesting a three-year extension of mandatory funding for the Teaching Health Center Graduate Medical Education (THCGME) Program, which expires at the end of the current fiscal year. The program supports training physician and dental residents in primary care residency programs, which include pediatrics and pediatric dentistry, to meet the health care needs of rural and underserved communities.

HHS, through HRSA, will also launch a new Pediatric Specialty Loan Repayment Program in FY 2023 to support and enhance communities' access to pediatric care by offering a student loan repayment opportunity to pediatric medical subspecialty, pediatric surgical specialty, and child and adolescent mental or behavioral health care clinicians in exchange for providing health care in a Health Professional Shortage Area or Medically Underserved Area or serving a Medically Underserved Population.

Question #108

2. I am concerned about last year's rollout of a Medicare fee for service prior authorization policy—the Repetitive Scheduled Non-Emergent Ambulance Transport (RSNAT) initiative. The policy requires prior approval for a Medicare beneficiary to use ambulance non-emergency medical transportation to dialysis, wound care, and other services. This policy is tough on low-income, dual eligible patients that qualify for Medicaid and Medicare that need transportation for critical care. Since CMS implemented the RSNAT program nationwide during the COVID emergency, my colleagues and I – including Reps. Buddy Carter and Sanford Bishop – co-led legislation that we plan to reintroduce to address this problem of non-emergency transport access for dual eligible beneficiaries. Will you commit to working with us to address this gap?

HHS Response

CMS has provided technical assistance to your staff related to legislation that would assist certain dually eligible beneficiaries in accessing NEMT under Medicaid. CMS would be happy to continue to provide technical assistance to your staff regarding that legislation.

Question #109

3. HHS' Test to Treat program is designed to ensure that COVID-19-positive patients receive real-time access to life-saving treatments. It's also my understanding that the Test to Treat program has specifically targeted communities that may have more challenges accessing medical care, so this program is particularly helpful to socially vulnerable communities. Given the seriousness of COVID-19 for people at high risk, regardless of whether the country is still under a PHE or not, will you plan to extend the Test to Treat program?

HHS Response

The Test to Treat Program is a program run by pharmacies who provide both tests and treatment to those with COVID-19 in a one-stop setting. With the end of the PHE, pharmacies can continue to provide both services to those that are seeking it. The government will continue to cover the cost of the treatments until they are moved to the commercial market sometime in the future. Once the treatments are moved to the commercial market, costs will vary depending on the person's insurance coverage. The cost of the test will vary with the end of the PHE depending on the person's insurance coverage.

ASPR has invested significantly to ensure that tests remain available. ASPR has invested over $8 billion in domestic test manufacturers to accelerate production of rapid tests, expand manufacturing capacity, and support a skilled manufacturing workforce here in the United States. HHS facilitated the execution of two primary programs to ensure access of over-the-counter antigen tests through the At Home Delivery Program, also referred to as COVIDTests.gov. The second program is ASPR's Testing and Diagnostics Work Group (TDWG) Delivery. Both programs ensure broad access to COVID-19 tests for vulnerable populations. In January 2022, President Biden announced a plan to make one billion free at-home tests available to the American people that included mailing them directly to homes via the At Home Delivery Program in direct partnership with the U.S. Postal Service (USPS). Since this effort began in January 2022, ASPR, in partnership with USPS, has delivered more than 755 million tests to homes across the country.

The Equitable Distribution Index was leveraged to prioritize distribution from the onset of both programs. Of those, 308 million (41%) were delivered to households in High Equitable Distribution Index (EDI) ZIP codes through the At Home Delivery Programs. We also continue to supply more accessible tests to blind and low vision people through the At Home Delivery program.

COVIDtests.gov relied on users to order tests. Tests were not distributed without a user-initiated order. Everyone living in the United States and U.S. territories, as well as U.S. government and military employees with a valid APO or FPO address, were eligible to order tests. People were able to order tests through the online COVIDTests.gov website or through a 1-800 toll-free call center. Households were only allowed to place one order during each of the four ordering rounds.

The Honorable Debbie Dingell

Question #110

1. Seniors, individuals with disabilities, and those with chronic diseases rely on Medicaid to access important long-term services and supports (LTSS) like bathing, eating, managing medication, personal care services, and other activities of daily living. Medicaid covers LTSS through a range of programs, including home and community-based services (HCBS). HCBS not only allows individuals to age with dignity, but also helps improve health outcomes and a better quality of life. How does the President's Budget address the wellbeing of seniors, specifically when it comes to Medicaid home and community-based services?

Question #111

2. In stark contrast to the President's proposal that strengthens these services, Republicans are attempting to cut trillions of dollars from Medicaid and severely curtail services. How will the proposed Medicaid cuts impact important long-term care services and affect vulnerable Americans' health?

Question #112

3. And how would these cuts affect the Department's ability to serve the needs of children with special
health care needs?

HHS Response to 110-112

Medicaid provides critical health coverage to millions of Americans, including eligible low-income adults, children, including children with special health care needs, pregnant people, elderly adults, and people with disabilities, with an estimated enrollment of 93.7 million people in FY 2023. The Administration's vision is to protect and strengthen Medicaid and the Affordable Care Act by expanding access to coverage, improving health equity, and making our health care system less complex to navigate.

The Administration is committed to reducing inequities in Medicaid and the Children's Health Insurance Program (CHIP) and ensuring every eligible child can access the coverage and care for which they are eligible, furthering the Administration's initiative to advance health equity and reduce disparities. Acting through CMS, the Administration has undertaken several initiatives to strengthen children's access to critical Medicaid and CHIP services, especially for those with special health care needs. These initiatives include, but are not limited to:

- Issuing an informational bulletin in August 2022 to remind State Medicaid Agencies of the federal requirements for the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit. The mandatory EPSDT benefit is a hallmark of the Medicaid program and requires states to provide comprehensive services and furnish nearly all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions, based on certain federal guidelines. The EPSDT benefit is key to ensuring that eligible children and adolescents enrolled in Medicaid receive appropriate preventative, dental, and behavioral health services, as well as developmental and specialty services. This

informational bulletin is available on Medicaid.gov here: https://www.medicaid.gov/federal-policy-guidance/downloads/bhccib08182022.pdf;

- Issuing a separate informational bulletin in August 2022 to states on how to pay for, document, and expand access to Medicaid school-based services (SBS). This guidance complies with requirements of the Bipartisan Safer Communities Act and is one of several steps CMS is taking to support access to Medicaid SBS. The Medicaid SBS informational bulletin is available on Medicaid.gov here: https://www.medicaid.gov/federal-policy-guidance/downloads/sbscib081820222.pdf; Other steps include issuing, in consultation with the U.S. Department of Education, a comprehensive guide for Medicaid SBS to make it easier for schools to deliver and receive payment for health care services to millions of eligible students and establishing a technical assistance center to assist and expand the capacity of State Medicaid agencies, local education agencies (LEAs), and school-based entities to provide greater assistance under Medicaid. The guide and more information about the technical assistance center are available on Medicaid.gov here: https://www.medicaid.gov/resources-for-states/medicaid-state-technical-assistance/medicaid-and-school-based-services/index.html; and
- Issuing a letter to State Medicaid Directors in August 2022 on a new Medicaid health home benefit for children with medically complex conditions. This new optional benefit helps state Medicaid programs provide Medicaid-eligible children who have medically complex conditions with person-centered care management, patient and family support, and care coordination, including coordination of care from out-of-state providers. This optional benefit was enacted as part of the Medicaid Services Investment and Accountability Act. The letter to State Medicaid Directors is available on Medicaid.gov here: https://www.medicaid.gov/federal-policy-guidance/downloads/smd22004.pdf.

Additionally, the Biden Administration and Congress prioritized promoting access to care and continuity of coverage through the passage of the Consolidated Appropriations Act, 2023 (CAA, 2023). The CAA, 2023 provides 12 months of continuous eligibility for all children under the age of 19 enrolled in CHIP starting on January 1, 2024, and requires health screenings, referrals, and case management services for eligible juveniles in public institutions during the period within 30 days prior to scheduled release and removes certain long-standing federal funding limitations for this group to promote continuity of care as these youth transition back to the community.

Lastly, the President's FY 2024 Budget includes several proposals that would also strengthen children's access to critical Medicaid and CHIP services, especially for those with special health care needs and for seniors and individuals with disabilities. For example, the FY 2024 Budget proposes $150 billion over 10 years to invest in Medicaid home- and community-based services, enabling seniors and people with disabilities to remain in their homes and stay active in their communities. At the same time, the proposal would promote better quality jobs for home care workers and enhance supports for family caregivers, many of whom are too often forced out of the workforce due to the demands of caring for a loved one. This investment builds on the $12.7 billion short-term HCBS funding that passed as part of the American Rescue Plan Act of 2021.

Question #113

4. I continue to hear from health centers across my district about difficulties attracting and

retaining a talented primary care workforce. We know workforce shortages limit patients' ability to access care and threaten to destabilize the health care safety net, which is why I was intrigued by the Budget's proposal to create a new Workforce Innovation Fund within HRSA. Can you discuss how the Workforce Innovation Fund will support ongoing innovative efforts to improve pre-apprenticeships, apprenticeships, and career laddering programs to bolster the health workforce and encourage more people to start a rewarding career in health care?

HHS Response

Innovative, community-driven approaches to health professions education are needed today more than ever. The National Center for Health Workforce Analysis has identified current projected shortages through 2035 in a wide range of health care occupations. In response, the President's Budget requests an investment of $28 million for a new initiative, the Health Care Workforce Innovation Program which seeks to seed innovative approaches and jumpstart new strategies to grow the health care workforce at a time of significant concern about workforce shortages across physicians, nursing, and behavioral health providers. Addressing urgent workforce challenges – and delivering on the promise of the Administration's significant policy steps in support of behavioral health, health care coverage, and care in home and community settings – will require innovative new approaches to accelerate the transformation of health care workforce training into a more modern, robust, and diverse workforce pipeline. Examples of innovative models could include approaches such as:

- Revamping health professions pre-admission readiness programs to better serve students from rural, underserved, or disadvantaged backgrounds;
- Building training and employment models that better integrate clinical practitioners into faculty development programs;
- Building a training-to-practice model for behavioral health professionals; and
- Expanding career pathways by creating career ladders for paraprofessionals.

Question #114

5. Earlier this month, assisted living and memory caregivers from Michigan came to DC to discuss the workforce shortages within their communities. Today, there is a shortage of over 400,000 caregivers across all of long-term care, and with estimates citing 70% of adults will need long-term care, workforce shortages are projected to exceed 20 million jobs by 2040. Report language in the FY23 Omnibus urged HHS to prioritize this crisis by re-targeting existing workforce programs. Secretary Becerra, how does HHS plan to re-focus these workforce development programs to address historic long-term caregiving shortages?

HHS Response: Within HHS the Administration for Community Living (ACL) is funding a Direct Care Workforce Center where state, private, and federal entities that recruit, train and retain direct care workers can access model policies and practices, training materials, technical assistance, and learning collaboratives. FY 2024 Center funding will establish demonstration grants for partnerships across state aging, disability, Medicaid, and labor/workforce agencies and stakeholder groups to strengthen the direct care workforce at state and local levels. The Center will also catalyze change at systems levels to address the insufficient supply of trained direct care workers, promote promising practices at all service system levels and improve data collection. Anticipated

outcomes include:
1. Increasing the availability and visibility of resources to attract, train and retain the direct care workforce in quality jobs, earning livable wages, with a voice in their working environment and access to benefits and advancement opportunities; and
2. Increasing the number of states that develop and sustain collaborations to improve the recruitment, retention, and advancement of high-quality direct care workforce jobs.

Over 53 million people are family caregivers and many rely on direct care workers to augment their caregiving efforts. To better support them, ACL, in collaboration with the Family Caregiving Advisory Council, delivered the first National Strategy to Support Family Caregivers (the Strategy) to Congress and the nation in September, 2022. (https://www.hhs.gov/about/news/2022/09/21/hhs-delivers-first-national-strategy-support-family-caregivers.html). Of the Strategy's five critical priorities areas, one, Outcome 3.9, addresses the need for "an agile, flexible, and well-trained direct care workforce to partner with and support family caregivers." The Strategy also put forth a series of action ideas that multiple sectors can use to increase the availability and viability of the direct care work force. Funding in FY 2024 will allow ACL to provide training and technical assistance to a range of caregiver support networks and to establish demonstration grants to enable states and local communities to test solutions and strategies identified in the Strategy.

HHS Response The FY 2024 President's Budget seeks to enhance our nursing programs. Specifically, HHS is seeking an increase of $32.5 million for the Nurse Education, Practice, Quality and Retention Programs. The additional funding will be used to expand, enhance, and modernize nursing education programs by increasing the number of faculty and students at schools of nursing.

The FY 2024 President's Budget also requests $47.2 million to fund approximately 43 new Geriatrics Workforce Enhancement Program awards and 26 continuing Geriatrics Academic Career Awards. These programs provide training focusing on interprofessional and team-based care across the educational continuum (students, faculty, providers, direct service workers, patients, families, and lay and family caregivers).

The Honorable Ann Kuster

Data modernization

Question #115

1. Could you please provide additional details on how investments in the data modernization initiative will put the nation on a more solid foundation in terms of establishing modern, interoperable, real-time and seamless immunization data? How does the CDC's data modernization initiative align with HHS Protect, and will immunizations be a part of this effort moving forward?

Question #116

2. Secretary Becerra, the President's FY24 budget includes long overdue investments in data modernization at the Centers for Disease Control and Prevention. The COVID-19 pandemic tested data systems and exposed the shortcomings of our fragmented and outdated health data network. Many were frustrated by the lack of timely, accurate and consistent immunization data during the height of the pandemic. Could you please provide additional details on how investments in the data modernization initiative will put the nation on a more solid foundation in terms of establishing modern, interoperable, real-time and seamless immunization data? How does the CDC's data modernization initiative align with HHS Protect, and will immunizations be a part of this effort moving forward?

HHS Response to #115 and #116

CDC's data modernization investments are enhancing data infrastructure at all levels to improve the real-time, interoperable sharing of data seamlessly across the public health and healthcare systems, including immunization data. These efforts include improvements to how immunization data is shared, managed, accessed, and analyzed across public health and healthcare; DMI investments ensure that faster, more reliable data is available in a more useful and standardized format to better benefit all Americans and communities.

Data modernization is creating smarter ways to share data. CDC has expanded the immunization gateway that routes immunization data from health departments through a central hub in an automated fashion, while maintaining the privacy and security of the data. As of May 16, 2023, 28 of funded jurisdictions have been onboarded to share data with another jurisdiction, and 42 have been onboarded to share data with a multi-jurisdictional provider, such as a federal agency. We are working now to enable the gateway as a tool to help jurisdictions automate their routine immunization data reporting to CDC.

At CDC, data modernization is helping drive the implementation of more modern, efficient technologies. CDC has moved data and processing for immunization data to the NCIRD Data Lakehouse Platform (NDLP), a cloud-based platform leveraging CDC's Enterprise Data, Analytics, and Visualization tools, to save time and eliminate manual processes. NDLP offers real-time processing in the cloud, and an analytical layer sits on top, allowing CDC's experts to perform analysis without having to move the data to a different system.

CDC is also working with public health and healthcare partners to develop a common approach to access immunization histories in immunization information systems (IIS). The use of the FHIR standard helps to make the experience more consistent across IIS sites, reducing burden for the requesters and the immunization program and helping to close gaps in healthcare delivery.

HHS Protect is a complementary platform to CDC's overall modernization effort. HHS Protect (now known as Response Ready Enterprise Data Integration platform (RREDI) since its transition to CDC) aligns with CDC's Data Modernization Initiative by bringing together outbreak data, including immunization data, and making it available as needed for decision making. RREDI provides a single, secure place where data can be managed, analyzed, and accessed, so that public

health and policy leaders at all levels are able to make data-driven decisions to protect individuals and communities. Public health data brought together in RREDI are shared across all public health partners, including health departments, CDC, and other federal agencies to facilitate the rapid deployment and use of advanced data analytics. Public health data in RREI are also made available to the public through data.cdc.gov and public facing websites with data visualization products. RREDI enhances capabilities to generate actionable insights that support data-driven decision-making.

The platform provides speed and efficiency to translate public health data into actionable information, creating interactive, geolocation-based data visualizations and informing resource allocation and medical supply chain decisions. Continued support for HHS Protect will allow CDC to develop scalable and adaptable tools that enable a core public health data management and integration platform that can be used during the steady-state time periods between emergency responses and rapidly tailored in an emergency or multiple, simultaneous outbreak responses.

Behavioral Health Workforce

Question #117

1. The U.S. spends about $16 billion a year on developing the health care workforce. Of that amount, only 1% is devoted to behavioral health workforce development. And of that 1%, only a fraction of that amount is allocated for the pediatric behavioral health workforce. How does the President's proposed budget rebalance our federal workforce spending so we invest more in pediatric behavioral health professionals to help our children and youth?

HHS Response

The FY 2024 President's Budget invests $387.4 million, $190.3 million above the FY 2023 enacted level for HRSA's Behavioral Health Workforce Development Programs, to support training for 18,000 providers. The increased resources will support the Behavioral Health Workforce Education and Training Programs for Professionals and Paraprofessionals, which include a focus on children, adolescents, and youth transitioning to adult care who are at risk for behavioral health conditions.

The FY 2024 President's Budget includes $13 million for the Pediatric Mental Health Care Access Program to support statewide or regional pediatric mental health care programs that train pediatricians in mental health and provide tele-consultation support to pediatricians from mental health experts.

HRSA's Pediatric Mental Health Care Access Program integrates behavioral health into pediatric primary care through state or regional networks of pediatric mental health care teams. These teams provide tele-consultation, training, technical assistance and care coordination. With this support, pediatric primary care providers can diagnose, treat and refer children to the

care they need for behavioral health concerns. The telehealth technologies promote long-distance clinical health care, clinical consultation, and patient and provider education, helping to address challenges in accessing psychiatrists, developmental-behavioral pediatricians, and other behavioral health clinicians who treat behavioral concerns in children and adolescents.

The FY 2024 President's Budget also includes $40 million to integrate behavioral health support in non-traditional community settings. Grants will support communities that are traditionally underserved or are part of a Mental Health Professional Shortage Area to engage and train community-based organizations to identify and address the mental health and substance use disorder care needs of mothers and children.

Th FY 2024 President's Budget also request resources to more than double the current Health Center Program investments in behavioral health services through a new $700 million behavioral health service expansion funding opportunity and includes a legislative proposal to require all health centers provide mental health and substance use disorder services under Section 330 of the Public Health Service Act.

Certified Community Behavioral Health Clinics

Question #118

1. Can you share how the president's FY24 budget supports CCBHCs and their use by children and their families?

HHS Response Increased investments in CCBHCs will continue to transform community behavioral health systems and provide comprehensive, coordinated behavioral health care, including for children and their families. The President's FY24 budget requests $552.5 million in funding for SAMHSA's CCBHC Expansion (CCBHC-E) grant program, a $167.5 million increase from the FY23 enacted levels. This funding would support 360 CCBHC-E continuation grants, a new cohort of 158 CCBHC-E grants, and a technical training assistance center to continue improvement of mental disorder treatment, services, and interventions for children and adults. With the increased FY24 funding, SAMHSA expects to serve approximately 400,000 children and adults in FY24. The Federal CCBHC Criteria requires CCBHCs to provide evidence-based services that are developmentally appropriate, youth-guided, and family/caregiver driven. Services encompass a wide array of child and adolescent care that addresses behavioral health crises and family/caregiver, school, mental health, substance use, psychosocial, and environmental issues. The President's budget also proposes to establish an accreditation process for CCBHCs which would ensure consistent adherence to the CCBHC model and create capacity to confirm that all CCBHCs are adhering to the criteria and the model of best practices.

Question #119

2. What efforts are made by SAMHSA and HHS to ensure outreach and education are done directed to children and their families to make them aware of the available mental health resources at CCBHCs?

HHS Response: In March 2023, SAMHSA released the updated criteria for certifying CCBHCs, which strengthened the criteria requiring CCBHCs to provide outreach and engagement within their communities. CCBHCs are now required to establish partnerships with schools, child welfare agencies, juvenile and criminal justice agencies and facilities, Indian Health Service, youth regional treatment centers, state licensed and nationally accredited child placing agencies for therapeutic foster care services, and other social and human services. SAMHSA requires all CCBHC-E grantees attest to meeting CCBHC criteria.

Question #120

3. Please share data that SAMHSA and HHS collect on the portion of clients receiving services at CCBHCs who are children, and the settings in which children are reached, including schools.

HHS Response: Children receive services at CCBHCs, a CCBHC's designated collaborating organization, or in a school setting serviced by the CCBHC. Since the CCBHC Expansion (CCBHC-E) grant program was initiated in FY 2018, CCBHC-E grantees have served nearly 120,000 children, teens, and young adults ages 0-25, including 2,066 children ages 0-4, 15,092 children ages 5 to 9 years, 15,167 children ages to 10 to 12 years, 21,210 teens ages 13 to 15 years, and 65,383 teens and young adults ages 16 to 25. In FY 2022, 5% of clients served by CCBHC-E grantees were children and teens ages 0-15 years and 18.61% were teens and young adults ages 16 to 25 years.

Caregiving Workforce

Question #121

1. Senior caregivers working across assisted living and memory care have been instrumental in the frontline fight against the pandemic. Now, even as 10,000 Americans turn age 65 each day, burnout among these frontline senior caregivers is leading to 96% of assisted living communities experiencing workforce shortages. America's rapidly aging population will only exacerbate the current workforce crisis as the U.S. Census Bureau estimates over 20 million additional long-term caregivers will be needed by 2040. Secretary Becerra, how is HHS preparing to grow the caregiving workforce and prioritizing long-term care settings such as assisted living?

HHS Response: Within HHS the Administration for Community Living (ACL) is funding a Direct Care Workforce Center where state, private, and federal entities that recruit, train and retain direct

care workers can access model policies and practices, training materials, technical assistance, and learning collaboratives. FY 2024 Center funding will establish demonstration grants for partnerships across state aging, disability, Medicaid, and labor/workforce agencies and stakeholder groups to strengthen the direct care workforce at state and local levels. The Center will also catalyze change at systems levels to address the insufficient supply of trained direct care workers, promote promising practices at all service system levels and improve data collection. Anticipated outcomes include:
1. Increasing the availability and visibility of resources to attract, train and retain the direct care workforce in quality jobs, earning livable wages, with a voice in their working environment and access to benefits and advancement opportunities; and
2. Increasing the number of states that develop and sustain collaborations to improve the recruitment, retention, and advancement of high-quality direct care workforce jobs.

Over 53 million people are family caregivers and many rely on direct care workers to augment their caregiving efforts. To better support them, ACL, in collaboration with the Family Caregiving Advisory Council, delivered the first National Strategy to Support Family Caregivers (the Strategy) to Congress and the nation in September, 2022. (https://www.hhs.gov/about/news/2022/09/21/hhs-delivers-first-national-strategy-support-family-caregivers.html). Of the Strategy's five critical priorities areas, one, Outcome 3.9, addresses the need for "an agile, flexible, and well-trained direct care workforce to partner with and support family caregivers." The Strategy also put forth a series of action ideas that multiple sectors can use to increase the availability and viability of the direct care work force. Funding in FY 2024 will allow ACL to provide training and technical assistance to a range of caregiver support networks and to establish demonstration grants to enable states and local communities to test solutions and strategies identified in the Strategy.

Question #122

2. Earlier this month, assisted living and memory caregivers from New Hampshire came to DC to discuss the workforce shortages within their communities. Today, there is a shortage of over 400,000 caregivers across all of long-term care, and with estimates citing 70% of adults will need long-term care, workforce shortages are projected to exceed 20 million jobs by 2040. Report language in the FY23 Omnibus urged HHS to prioritize this crisis by re-targeting existing workforce programs. Secretary Becerra, how does HHS plan to re-focus these workforce development programs to address historic long-term caregiving shortages?

HHS Response: Within HHS the Administration for Community Living (ACL) is funding a Direct Care Workforce Center where state, private, and federal entities that recruit, train and retain direct care workers can access model policies and practices, training materials, technical assistance, and learning collaboratives. FY 2024 Center funding will establish demonstration grants for partnerships across state aging, disability, Medicaid, and labor/workforce agencies and stakeholder groups to strengthen the direct care workforce at state and local levels. The Center will also catalyze change at systems levels to address the insufficient supply of trained direct care workers, promote promising practices at all service system levels and improve data collection. Anticipated outcomes include:

1. Increasing the availability and visibility of resources to attract, train and retain the direct care workforce in quality jobs, earning livable wages, with a voice in their working environment and access to benefits and advancement opportunities; and
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HHS Response: The FY 2024 President's Budget seeks to enhance our nursing programs. Specifically, HHS is seeking an increase of $32.5 million for the Nurse Education, Practice, Quality and Retention Programs. The additional funding will be used to expand, enhance, and modernize nursing education programs by increasing the number of faculty and students at schools of nursing.

The FY 2024 President's Budget also requests $47.2 million to fund approximately 43 new Geriatrics Workforce Enhancement Program awards and 26 continuing Geriatrics Academic Career Awards. These programs provide training focusing on interprofessional and team-based care across the educational continuum (students, faculty, providers, direct service workers, patients, families, and lay and family caregivers).

Question #123

3. Secretary Becerra, by 2034 there will be more seniors than children for the first time in our nation's history. The assisted living caregivers in my state of New Hampshire already experience persistent workforce shortages and will need to fill at least 64,800 jobs by 2040 to care for America's rapidly aging population. What is HHS doing to address the shortage of direct caregivers in assisted living communities?

HHS Response: Within HHS the Administration for Community Living (ACL) is funding a Direct Care Workforce Center where state, private, and federal entities that recruit, train and retain direct care workers can access model policies and practices, training materials, technical assistance, and learning collaboratives. FY 2024 Center funding will establish demonstration grants for partnerships across state aging, disability, Medicaid, and labor/workforce agencies and stakeholder

groups to strengthen the direct care workforce at state and local levels. The Center will also catalyze change at systems levels to address the insufficient supply of trained direct care workers, promote promising practices at all service system levels and improve data collection. Anticipated outcomes include:
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Question #124

4. The Department of Veterans Affairs (VA) recently raised concerns about the cost of long-term care in a report to the Senate VA Committee. The VA found that assisted living is less than half the cost of a skilled nursing facility per veteran per year, at $51,600 vs $120,701. As you know, assisted living is a private-pay option providing a cost-saving opportunity for taxpayers that skilled nursing facilities, which primarily rely on Medicaid payments, do not. What is HHS doing to ensure that non-veteran seniors have adequate access to important cost-saving assisted living care?

HHS Response
Medicaid is the single largest payer of long-term care services and supports (LTSS) and over the past several decades, states have used several federal authorities and grant programs to develop a broad range of home and community-based services (HCBS) to provide alternatives to institutionalization and support beneficiaries' preferences of where they would like to receive their care. Most Medicaid HCBS services are optional Medicaid services and can be implemented through state plan or waiver options. CMS ensures that states operate their Medicaid HCBS programs according to federal guidelines, provides technical assistance on policy and operational issues as requested, and takes compliance action where needed.

The budget invests $150 billion over 10 years in Medicaid HCBS, as well as support for the workers and caregivers who provide these services, to keep more people in their homes and communities.

Addiction and access to treatment

Question #125

1. Do you believe the federal government has a responsibility to educate providers and patients about non-opioids and make FDA-approved non-opioids as easily accessible as possible now to prevent the 200 deaths a day from opioid addiction? What else can CMS do right now to increase access to non-opioids for Medicare beneficiaries?

HHS Response:

Addressing the opioid overdose crisis continues to be one of FDA's top public health priorities, and we agree that there is still much work to do as deaths from opioid overdoses remain at historically high levels. One of FDA's four Overdose Prevention Priorities under our Overdose Prevention Framework[35] is supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing. As part of the effort, the FDA's Opioid Analgesic Risk Evaluation and Mitigation Strategy[36] requires opioid analgesic manufacturers to make education be available to all health care providers who are involved in the management of patients with pain, including nurses and pharmacists. The education component includes educating health care providers about the range of therapeutic options for managing pain, including nonpharmacologic approaches and pharmacologic (non-opioid and opioid analgesics) therapies.

In addition, a key activity under the prevention priority is supporting the development of novel, non-opioid pain therapies, which we believe will ultimately help reduce the risk of opioid overdose and associated deaths. We are committed to doing our part to help spur this development. To support such developments, the Agency recently published draft guidances titled "Development of Non-Opioid Analgesics for Acute Pain"[37] (February 2022) and "Development of Local Anesthetic Drug Products With Prolonged Duration of Effect"[38] (March 2023). These draft guidances are intended to assist sponsors in the development of alternatives to opioids for the management of pain. Additionally, we are developing a guidance for industry on the development of non-addictive medical products for the management of chronic pain, as stated on our 2023 CDER guidance agenda.

Question #126

2. How can we work together to ensure that registered and licensed practitioners are able to still provide clinically appropriate medication to patients via telemedicine across state lines?

[35] https://www.fda.gov/drugs/drug-safety-and-availability/food-and-drug-administration-overdose-prevention-framework

[36] https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems

[37] Development of Non-Opioid Analgesics for Acute Pain

[38] Development of Local Anesthetic Drug Products With Prolonged Duration of Effect

HHS Response:
In response to the COVID-19 public health emergency, which is set to expire in May 2023, flexibilities for Medicare telehealth services were issued through legislative and regulatory authorities to increase access to care for patients and providers. The Consolidated Appropriations Act of 2023 recently extended many of these flexibilities through December 31, 2024. Extended telehealth flexibilities include waiving geographic and site of service originating site restrictions so that Medicare patients can continue to use telehealth services from their home and allowing audio-only telehealth services under certain circumstances. Additionally, the expanded list of providers eligible to deliver telehealth services is also extended so Medicare beneficiaries can continue to receive telehealth services furnished by physical therapists, occupational therapists, speech language pathologists, and audiologists, as well as receive telehealth services from Rural Health Clinics and Federally Qualified Health Centers through December 31, 2024. If you are interested in drafting legislation to make these waivers permanent, CMS would be happy to provide technical assistance.

Additionally, recent legislative and regulatory changes made several Medicare telehealth flexibilities permanent. Federally Qualified Health Centers and Rural Health Clinics can furnish certain behavioral and mental health services via telecommunications technology. Health center patients with Medicare coverage can continue to receive these telehealth services in their home as geographic restrictions on the originating site are eliminated for these telehealth services. Certain behavioral and mental telehealth services can be delivered using audio-only communication platforms, and rural emergency hospitals can serve as an originating site for Medicare telehealth services.

For Medicaid and CHIP, telehealth flexibilities are not tied to the end of the COVID-19 PHE and have been offered by many state Medicaid programs long before the pandemic. Medicaid and CHIP telehealth policies will ultimately vary by state. CMS encourages states to continue to cover Medicaid and CHIP services when they are delivered via telehealth.

Health care providers can furnish telehealth and other services using communications technology wherever the patient is located, including at home, even across state lines. However, practicing across state lines is subject to requirements set by the states involved.

HHS Response: HRSA's Licensure Portability Grant Program is a key resource for increasing delivery of health care to rural and underserved areas across state lines via telehealth. This program provides support for state professional licensing boards to work together to reduce the burden on clinicians who provide telehealth services in multiple states. The FY 2024 President's Budget request supports new awards in FY 2024 to ensure we can continue to increase participation in this program. The President's Budget request would also fund the continuation of the HHS Telehealth Hub, which allows for the rapid dissemination of critical telehealth resources for patients, providers, states, researchers, and other stakeholders through Telehealth.HHS.gov.

Question #127

3. How can we work together in the face of a growing mental health and addiction crisis to find the right balance between practitioners registering with the DEA in multiple states and the need to address the current mental health provider shortages?

HHS Response: The COVID-19 pandemic has illustrated that telemedicine can be effectively delivered to address mental and substance use disorders. Through the SAMHSA-funded Technology Transfer Centers' and strategic partnerships with Single State Authorities, treatment provider associations, state, tribal, local community organizations, and with input from people with lived experience, SAMHSA has promoted an integrated approach to address patients' both mental and physical health conditions that contribute to the addiction crisis across the nation. HHS has also supported the Interstate Medical Licensure Compact, which was created in 2017 by the Federation of State Medical Boards' and expanded during the COVID-19 public health emergency, which allows providers to more easily obtain licenses to treat patients in multiple states. Another example, is the collaboration between SAMHSA and the DEA to implement the repeal of the X-Waiver required in the Consolidated Appropriations Act, 2023. By repealing this waiver, any clinician with a DEA registration that includes Schedule III authority is able to prescribe buprenorphine for opioid use disorder within their state's scope of practice. Removal of the X-Waiver increases the number of potential prescribers from 130,000 to 1.8 million, which increases access to treatment and reduces barriers for people living in areas that lack specialized care such as those found in rural and remote communities. These regulatory, programmatic, and educational efforts seek to expand services for patients in areas of mental health provider shortages, ensuring better outcomes and overall improvements to systems of care.

Despite these efforts, state law variations can be a significant impediment to allowing providers to deliver services across state lines without being licensed in that state. Providing telemedicine services across state lines may require statutory changes to facilitate true interstate license reciprocity.

Organ donation

Question #128

1. As HHS moves forward with organ donation reform, how specifically will it make sure that the best innovators in the country are showing up to compete and serve some of our most vulnerable patients?

HHS Response: HRSA's Organ Procurement and Transplantation Network Modernization Initiative is intended to strengthen accountability, equity, and performance in the organ donation and transplantation system. HRSA is committed to transparency in a modernized OPTN.

The Initiative is focused on five key areas with the following goals:

- Technology – ensure that the system is reliable, secure, patient-centered, user-friendly, and reflective of modern technology functionality. There is a continuous focus on improved IT system functionality and security, while ensuring continuity of services, protecting patient safety, and accelerating innovation in line with industry-leading standards.

- Data Transparency and Analytics – ensure data is accessible, user-friendly, and patient-oriented. The modernization process provides easily accessible, high-quality, and timely data to make informed patient, donor, and clinical decisions; measure and evaluate program performance; inform oversight and compliance activities; and support the advancement of scientific research
- Governance – The OPTN Board of Directors is high-functioning and has greater independence; represents the diversity of communities; and delivers effective policy development.
- Operations – The OPTN is effective and accountable in its implementation of organ policy, patient safety and compliance monitoring, organ transport, OPTN member support, and education of patients, families, and the public.
- Quality Improvement and Innovation – The OPTN promotes a culture of quality improvement and innovation across the network by leveraging timely data and performance feedback, collaborative learning, and strategic partnerships

HRSA is committed to robust stakeholder and industry engagement to help bring forward the best ideas and innovators to support modernization. For updates see: https://www.hrsa.gov/organ-procurement-transplantation-modernization.

COVID-19 Therapeutics

Question #129

1. Secretary Becerra, the Administration has provided free access to COVID therapeutics that have saved the lives of countless Americans who were at high-risk for life-threatening complications caused by COVID-19. Medicare Advantage Part D plans are able to realize the savings associated with these treatments in the near term, as patients have avoided costly hospitalizations and other health care resources. However, as access to free COVID therapeutics ends and we transition to traditional insurance coverage, I'm concerned that stand-alone Part D plans, who do not directly benefit from savings on the medical side, will begin restricting access to such therapeutics and subject beneficiaries to prohibitive out-of-pocket expenses. Needless to say, the resulting costs would be borne by Parts A and B. I was proud to support Part D copay smoothing, but that does not begin until 2025. What will HHS do in the meantime to ensure that beneficiaries continue to have unrestricted access to COVID therapeutics for affordable co-pays?

HHS Response

CMS is always committed to providing beneficiaries access to the therapeutics they need. There is no change in Medicare coverage of treatments for those exposed to COVID-19 once the PHE ends, and in cases where cost sharing and deductibles apply now, they will continue to apply. Generally, the end of the COVID-19 PHE does not change access to oral antivirals, such as Paxlovid and Lagevrio. For individuals enrolled in a Medicare Advantage (MA) plan, the plans must cover treatments that Traditional Medicare covers, but they may require the individual to see a provider who is in the MA plan's network and may have different cost sharing than Traditional Medicare.

CMS has also permitted Part D sponsors to pay pharmacy claims for dispensing fees U.S.

government-procured Emergency Use Authorization (EUA) oral antiviral drugs for treatment of COVID-19 without enrollee cost- sharing. Additionally, the agency has strongly encouraged Part D sponsors to pay dispensing fees for these drugs that may be higher than a sponsor's usual negotiated dispensing fees, given the unique circumstances during the COVID-19 PHE. This flexibility will continue following the end of the COVID-19 PHE while U.S. government-procured product remains available.

On December 29, 2022, the Consolidated Appropriations Act, 2023 was enacted (Pub. L. 117-328) and revised the definition of a covered Part D drug to temporarily (upon enactment and through December 31, 2024) include oral antiviral drugs approved under an EUA from the FDA, on the basis of the COVID-related Emergency Use Authorization declaration published in 2020. Oral antiviral drugs for COVID that meet the statutory definition of a covered Part D drug and are not procured by the US government must be covered by Part D plans as a formulary product or through the formulary exception process.

Question #130

2. Secretary Becerra, your Department's Test to Treat program has ensured that COVID-19-positive patients receive real-time access to life-saving treatments. This effort ensures that high-risk patients avoid needless delays where the coronavirus might have otherwise escalated and caused significant and costly health care interventions and hospitalizations. It's also my understanding that the Test to Treat program has specifically targeted communities that may have more challenges accessing medical care, so this program is particularly helpful to socially vulnerable communities. Given the seriousness of COVID-19 as it relates to people at high risk for progression to severe disease, regardless of whether the country is still under of PHE or not, will you commit today to extending the Test to Treat program to ensure that at-risk patients have timely and affordable access to COVID-19 tests and treatments?

HHS Response: The Test to Treat Program is a program run by pharmacies who provide both tests and treatment to those with COVID-19 in a one-stop setting. With the end of the PHE, pharmacies can continue to provide both services to those that are seeking it. The government will continue to cover the cost of the treatments until they are moved to the commercial market sometime in the future. Once the treatments are moved to the commercial market, costs will vary depending on the person's insurance coverage. The cost of the test will vary with the end of the PHE depending on the person's insurance coverage.

ASPR has invested significantly to ensure that tests remain available. ASPR has invested over $8 billion in domestic test manufacturers to accelerate production of rapid tests, expand manufacturing capacity, and support a skilled manufacturing workforce here in the United States. HHS facilitated the execution of two primary programs to ensure access of over-the-counter antigen tests through the At Home Delivery Program, also referred to as COVIDTests.gov. The second program is ASPR's Testing and Diagnostics Work Group (TDWG) Delivery. Both programs ensure broad access to COVID-19 tests for vulnerable populations. In January 2022, President Biden announced a plan to make one billion free at-home tests available to the American people that included mailing them directly to homes via the At Home Delivery Program in direct partnership with the U.S.

Postal Service (USPS). Since this effort began in January 2022, ASPR, in partnership with USPS, has delivered more than 755 million tests to homes across the country.

The Equitable Distribution Index was leveraged to prioritize distribution from the onset of both programs. Of those, 308 million (41%) were delivered to households in High Equitable Distribution Index (EDI) ZIP codes through the At Home Delivery Programs. We also continue to supply more accessible tests to blind and low vision people through the At Home Delivery program.

COVIDtests.gov relied on users to order tests. Tests were not distributed without a user-initiated order. Everyone living in the United States and U.S. territories, as well as U.S. government and military employees with a valid APO or FPO address, were eligible to order tests. People were able to order tests through the online COVIDTests.gov website or through a 1-800 toll-free call center. Households were only allowed to place one order during each of the four ordering rounds.

ARPA- H

Question #131

1. In the context of pandemics and other global health threats, neither NIH nor BARDA are expected or funded to lead projects of that nature or scale. Do you foresee ARPA-H considering projects in the global health security and pandemic preparedness realms if promising ones come through the door? Are you establishing a cross-agency referral system to ensure that solid research projects in the global and domestic arenas receive consideration even if they "show up" at the wrong agency initially? When can we see that?

HHS Response:

ARPA-H's mission is to accelerate better health outcomes for everyone by working on health breakthroughs that cannot readily be accomplished through traditional research or commercial activity. As such, ARPA-H may develop and fund programs in pandemic preparedness. ARPA-H's Resilient Systems focus area will advance technologies that enhance the robustness and reliability of health systems in the face of unexpected disruptions, and these innovations may directly address disruptions caused by pandemics. In addition, ARPA-H's Health Science futures and Proactive Health focus areas will pursue breakthrough research on platform technologies and preventative medicine. It can be anticipated that novel, ambitious efforts that address global health security and pandemic response would be incorporated into these thrust areas.

An essential component of any ARPA-H concept development includes robust engagement with stakeholders to ensure only the most transformative projects in health are pursued. ARPA-H is already actively engaging our partners across government, including NIH institutes, BARDA, CDC, FDA, CMS, and DARPA, discussing technical concepts early in development and ensure there is not a duplication of effort. ARPA-H is also establishing processes to prevent duplication of effort and foster inter-agency collaborations that enhance return on investment. ARPA-H is committed to working closely across all HHS operating divisions, NIH ICs, BARDA, and other federal agencies that fund R&D to share ideas, ensure scientific collaboration and productivity, and avoid unnecessary and/or unintentional duplication of scientific and administrative efforts.

ARPA-H announced a Request for Information (RFI) seeking ideas on how to best collaborate with FDA to encourage and incentivize public-private partnerships in the health ecosystem. Finally, ARPA-H is also standing up an Interagency Advisory Committee that is tasked with coordinating efforts and providing advice and assistance on specific program or project tasks with other federal agencies. ARPA-H is currently in the process of standing up the committee and will provide notice and information once the committee is stood up.

The Honorable Robin Kelly

Question #132

1. Are there ways we in Congress can support the work of the IMPROVE initiative to help expedite dissemination of research findings that help to change the United States' present maternal mortality and morbidity narrative?

HHS Response

Maternal morbidity and mortality are a priority for the National Institutes of Health. In 2019, to address this crisis, NIH developed the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) Initiative[39] to reduce preventable causes of maternal deaths and improve health for women before, during, and after delivery. This NIH-wide initiative, led by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, the Office of Research on Women's Health (ORWH), and the National Institute of Nursing Research (NINR), includes a special emphasis on health disparities and populations that are disproportionately affected by maternal mortality, such as racial and ethnic minorities, women of advanced maternal age, and people with disabilities. The IMPROVE initiative builds upon NIH's investments in community building and partnerships. The dissemination of research findings through these networks by trusted partners in the community is essential and will help expedite the adoption of evidence-based recommendations in the clinical practice setting.

Initiatives under IMPROVE include: (1) Maternal Health Research Centers of Excellence, a national network to develop, implement, and evaluate community-tailored interventions to address health disparities in maternal morbidity and mortality; (2) the Rapid Acceleration of Diagnostics (RADx®) Tech for Maternal Health Challenge, to accelerate the development of advanced technologies that can be used to improve maternal health (e.g., wearable devices, sensors, smartphone-enabled tools) for use in geographic areas where maternity care is more difficult to access; (3) Connecting the Community for Maternal Health Challenge, a prize competition to help community and advocacy organizations build research infrastructure; (4) Community Implementation Program, in which researchers and community organizations will work together to integrate interventions of known effectiveness into community settings; (5) research to study dissemination and implementation of maternal health efforts, and (6) a "Connectathon" to work towards electronic health record standards with the HHS Office of the National Coordinator to enable real world maternal health research before and after pregnancy, connecting maternal health during pregnancy to child outcomes.

[39] https://www.nichd.nih.gov/research/supported/IMPROVE/NIH-resources

Starting in FY2023, the cornerstone of the IMPROVE program will be the Maternal Health Research Centers of Excellence (COEs). Strong community partnerships will be a priority for each COE and they will build upon these community partnerships and implement evidence-based interventions in communities of need, as well as create technology solutions to help improve health outcomes in maternity care deserts, where prenatal or labor and delivery care may not be easily accessible.

Part of this community engagement could include working with trusted community partners, such as Members of Congress. NIH would be happy to work with you to identify ways we can work together to help disseminate information and ensure we are meeting the needs of the community.

We appreciate your interest in this topic and look forward to working with you to address our shared goal of reducing maternal morbidity and mortality and its associated health disparities.

Question #133

2. Are there specific initiatives at HRSA to help understand and address the needs of mothers with disabilities? If so, please explain. If not, please discuss any efforts to better address the needs of mothers with disabilities.

HHS Response: HRSA's maternal health programs are designed to improve the health of all mothers in the U.S., including mothers with disabilities. For example, HRSA's Healthy Start Program supports grants to advance a community-based approach for improving maternal health outcomes before, during, and after pregnancy and reducing racial and ethnic disparities in rates of infant death and other adverse perinatal outcomes. Additionally, HRSA's Maternal, Infant, and Early Childhood Home Visiting Program supports voluntary, evidence-based home visiting services for pregnant people and parents with young children living in communities that face barriers to positive health outcomes. These programs meet pregnant women and mothers where they are and assess their needs, including needs related to disabilities, and connect them to community resources. Altogether, this work supports healthy pregnancies and parenting practices to advance maternal health.

The Honorable Nanette Barragan

Question #134

1. Can you elaborate upon the health care sector's contribution to U.S. GHG emissions, including disaggregating the emissions under scopes 1, 2 and 3. For example, following from this recent Washington Post article, Health care itself is worsening climate change. One small switch can help, what is HHS doing to help hospitals reduce their anaesthetic gas emissions, a potent GHG?

HHS Response:

Evidence suggests the health sector's contribution to greenhouse gas emissions has been growing, with one paper finding that US health care greenhouse gas emissions overall rose 6 percent from 2010 to 2018, totaling approximately 8.5 percent of domestic US greenhouse gas emissions. Many

health care organizations, including the Veterans Affairs health system, already measure scopes 1 and 2, but accounting of emissions from scope 3 is still evolving. More published product-level carbon-footprint data from manufacturers would facilitate more detailed accounting.

HHS does offer a number of resources to support emissions reduction across all scopes, including the Agency for Healthcare Research and Quality's *Primer on Measures and Actions for Healthcare Organizations to Mitigate Climate Change,* an action guide for healthcare organizations to begin the journey to reduce greenhouse gas emissions. The Primer recommends tracking total greenhouse gas emissions from inhaled anesthetics in order to measure and reduce emissions. The Office of Climate Change and Health Equity (OCCHE) *Compendium of Federal Resources for Health Sector Emissions Reduction and Resilience* features additional tools and supports that can assist the health sector in emissions reduction including the Department of Agriculture's *BioPreferred Program Catalog*, Environmental Protection Agency Center for Corporate Climate Leadership's *Scope 3 Inventory Guidance,* and General Services Administration's *Sustainable Facilities Tool*. OCCHE and the Environmental Protection Agency also recently published guidance on how health stakeholders can use the free benchmarking tool ENERGY STAR® Portfolio Manager® to track their building-related energy use and greenhouse gas emissions.

HHS and OCCHE also support efforts to convene experts and share best practices. The National Academy of Medicine's Action Collaborative on Decarbonizing the U.S. Health Sector, which Assistant Secretary for Health Admiral Rachel L. Levine cochairs, is playing a crucial role in convening industry actors to jointly address health care's contribution to overall U.S. carbon emissions.

Question #135

2. A 2019 study of these hospital ventilation requirements found that 73.5% of the standards have no proven evidence of any patient safety benefit. Further research is needed to determine evidence and outcome based standards for hospital ventilation, which will increase patient safety while removing a large barrier to improved hospital energy efficiency. What is HHS doing to address this discrepancy and need for further research?

HHS Response: The Agency for Healthcare Research and Quality (AHRQ) supports investigator-initiated research on prevention of healthcare-associated infections (HAIs) through its HAI Prevention Notices program announcements. AHRQ welcomes applications focused on prevention of NV-HAP, though we have not received meritorious applications in this area in recent years.

As part of the AHRQ Safety Program for MRSA Prevention, one of the educational webinars focuses on prevention of both ventilator-associated pneumonia (VAP), and NV-HAP. The webinar includes recommendations for routine oral care, as recommended by the Association for Professionals in Infection Control and Epidemiology (APIC) and the Society for Healthcare Epidemiology of America (SHEA).

Question #136

3. I applaud the HHS Centers for Medicare & Medicaid Services (CMS) for issuing a new waiver that will allow U.S. health care facilities to transition to safer, cheaper, and more reliable clean energy infrastructure in the form of renewable-powered microgrids or independent electric grids. This was necessary because a condition of participating in Medicare and Medicaid programs (CMS) through its adoption of the Life Safety Code (LSC), requires that certain health care facilities adhere to National Electric Code (NEC, NFPA 70) guidance from 2011. The 2011 NEC guidance in turn requires the use of fossil-fuel-based generators (or, in limited circumstances, a battery) as the emergency power source for health care buildings. Electrical experts have since updated the 2011 NEC guidance—most recently in the 2023 NEC—to permit the use of microgrids and other clean energy systems for emergency power generation at health care facilities.
    a. What steps, if any, has HHS or CMS taken to update the Conditions of Participation to adopt the most up-to-date National Electrical Code?
    b. What other CMS Conditions of Participation reference standards that are out of date?
    c. What effect do outdated codes have on patient health and safety?
    d. What effect do outdated codes have on hospital resiliency?
    e. What barriers, if any, exist to adopting and maintaining up-to-date codes in the CMS Conditions of Participation?

HHS Response

Updates to the Conditions of Participation are federal rules, which require notice and comment rulemaking. With respect to the NFPA, CMS reviews new editions of the codes to evaluate the changes and their potential impact on regulated health care facilities. To provide regulatory stability, CMS carefully evaluates the totality of changes in a new code edition in order to determine its suitability for new regulatory action. As such, the time between regulatory updates varies to assure that regulations are changed only when the need and advantages of such changes outweigh the burden that the regulatory changes may create for health care facilities. CMS last issued fire safety regulations in 2016 to incorporate the 2012 edition of the Life Safety Code. The categorical waiver referenced was issued in March 2023 to allow certain health care facilities to use alternate sources of power other than a generator set or battery system, if in accordance with the 2021 edition of the NFPA 99, 2023 edition of the National Electric Code (NFPA 70) and associated references.

Question #137

4. Among federal agencies, what is the unique value-add of HHS action and/or leadership to reduce carbon emissions, move toward clean energy, and address the impact of climate change?

HHS Response:

Climate change is the most significant threat to human health in the 21st century according to more than 200 medical journals. Given the Department's mission to improve the health and well-being of all Americans, HHS operating divisions must take action to make certain that their constituents are protected from these impacts, that health care facilities are capable of

providing sustained operations during climate catastrophes and that they do not contribute to harm through emissions.

OCCHE is the only federal office specifically focused on supporting the health sector in meeting the clinical and operational challenges presented by climate change while also offering unique guidance on how the sector can decarbonize the delivery of care. Since the health sector accounts for 8.5% of U.S. carbon emissions, it is key to both lowering our country's contribution to climate change and caring for people adversely affected by extreme heat, wildfires, drought, hurricanes, and other climate hazards. Climate change multiplies inequities in access and quality of care for the most vulnerable communities, meaning that health equity solutions and climate change responses are inextricably linked. OCCHE's expertise in public health, quality improvement, and climate adaptation and mitigation allows it to bridge the gap between the best practices developed by climate experts and the needs and strengths of the health sector.

OCCHE also functions as a convener within HHS, enabling the Office to address a single issue through multiple mechanisms. For example, consider an area frequently impacted by hurricanes. The local government may apply for Hospital Preparedness Program (Administration for Strategic Preparedness and Response) funds to invest in healthcare system readiness. Many providers are also required to adhere to federal emergency preparedness requirements (e.g., Centers for Medicare & Medicaid Services emergency preparedness regulations). The Centers for Disease Control and Prevention (CDC) helps prepare clinicians and health departments for potential disasters. After a disaster, Medicare will pay for the care of older and disabled community members and help them get replacement medical equipment. Part of OCCHE's role is helping these elements work together seamlessly to advance climate resilience, and ultimately support HHS' core mission of protecting the health of the American people.

Question #138

5. What support do health care providers need to build resilient and adaptable systems that are prepared for climate threats?

HHS Response:

Despite a growing recognition of the health problems associated with climate change and the need for action, many organizations – and particularly those serving the most at-risk communities – struggle to make investments in sustainability and resilience because of insufficient funding. In addition to direct funding, providers have cited a need for training a sufficient workforce to lead health sector climate resilience work; geospatial hazard forecasts integrated with population health information; and technical assistance for benchmarking high performers and identifying best practices for resilience planning. The HHS Office of Climate Change and Health Equity (OCCHE) is working to address these important issues, but more direct facility-level assistance could be offered with broader funding to OCCHE or among HHS divisions. For FY24, the President's

Budget requested $5 million for OCCHE.

One important resource OCCHE has developed is the Quickfinder for Leveraging the Inflation Reduction Act (IRA) for the Health Sector. The Quickfinder zeros in on the most relevant IRA provisions for the sector. It also explores valuable investments and actions potentially facilitated by the IRA. Many of these investments have the potential to improve care, deepen resilience, and reduce costs. For example, investments in renewable energy allow facilities to save money that would previously have gone to their local utility, opening the possibility for increased investments in patient-centered activities. If that renewable energy is stored onsite in a microgrid, it can also help the provider stay open in emergencies when the grid loses power.

Another key resource is the Sustainable and Climate-Resilient Health Care Facilities Toolkit, which includes a framework describing affordable measures that can help make health care facilities more resilient, and resources for responding to challenges associated with climate change impacts.

Question #139

6. Where does the US health care system stand in comparison to other US industries and health care systems in other countries in tracking, transparently reporting, and addressing its contributions to the climate crisis? Are there strong models or adaptable tools, either from other countries or U.S. industries, that the U.S. healthcare system can utilize in tackling their role in the climate crisis?

HHS Response

The United States has the opportunity to be a global leader in health sector emissions reduction. Federal facilities like the Weed Army Community Hospital at Fort Irwin and private health systems are among the vanguard of carbon-neutral providers. A group of 116 private sector organizations representing 872 hospitals have signed the White House-HHS Health Sector Climate Pledge, a voluntary commitment to climate resilience and emissions reduction that includes cutting greenhouse gas emissions by 50 percent by 2030 and achieving net zero emissions by 2050. Federal systems like the Indian Health Service (IHS), Veterans Health Administration (VHA), and Military Health System (MHS) are working together to meet goals similar to those the private sector organizations have embraced. Combined, this means that over 1,080 federal and private sector hospitals have made such commitments, together representing over 15% of U.S. hospitals.

One important support for Pledge signees and federal health systems is the Environmental Protection Agency's (EPA's) free benchmarking tool ENERGY STAR® Portfolio Manager®, which thousands of providers already use to track their building-related energy use and greenhouse gas (GHG) emissions. The HHS Office of Climate Change and Health Equity worked closely with the EPA to develop Guidance for the Health Sector on using ENERGY STAR® Portfolio Manager®, including a crosswalk of health provider and supplier types to the property types available in Portfolio Manager.

The Office of Climate Change and Health Equity is also partnering with other countries committed to this work such as the United Kingdom (U.K.). The U.K. has made significant progress; for example, the National Health Services of Scotland and England are phasing out desflurane, a potent greenhouse gas used as an anesthetic.

Question #140

7. What are the potential health and economic benefits to the US health system and to the public of decarbonization?

HHS Response:

Climate change creates both acute and chronic risks, particularly to vulnerable populations, and already costs the American economy billions of dollars a year due to the harm it creates, significantly burdening the nation's healthcare system.

Health effects related to climate change range from heat stroke to asthma exacerbation to vector-borne diseases. In general, historically underserved groups and regions tend to be the hardest hit by climate events. For instance, lack of health insurance has been associated with greater risk of hospital admission after exposure to certain weather events. As climate change accelerates, so do these inequities. If the world warms by 2 degrees Celsius, Black and African American individuals are 34% more likely to live in areas with the highest projected increases in childhood asthma. In addition, climate change presents acute threats and disruptions to facility operations, with the majority of hospital evacuations coming as a result of climate-sensitive events.

Decarbonization efforts have the potential to both limit harm to vulnerable people living in the United States and help avoid dangerous disruptions to facility operations, ultimately saving money through avoided health care costs. Recent articles in *The Lancet*, for example, have suggested that lowering greenhouse gas emissions can lead to substantial health benefits, especially through reductions in harmful air pollutants, as well as associated economic co-benefits (i.e., costs avoided) that can help pay for decarbonization investments.

Climate action by healthcare facilities can also lead to direct savings. America's Essential Hospitals reports that some hospitals have cited a cost savings of about $1 million a year thanks to efficiency projects and, more broadly, the Commonwealth Fund suggests that U.S. hospitals could save roughly $15 billion over 10 years by adopting basic energy efficiency, waste-reduction and smart purchasing measures.

The Honorable Angie Craig

Beginning on January 1, 2024, practitioners who provide telehealth services from their homes will be required to enroll their home addresses in Medicare. The enrollment requirement will make their home addresses publicly available, which raises real safety and privacy concerns for our telehealth providers, many of whom provide mental health and substance use disorder

(SUD) care via telehealth. I have heard fears that practitioners will leave health care or stop providing care to Medicare patients, adding to the provider shortage and patient access challenges.

Connecting more Americans to mental health care is a key objective of President Biden's Mental Health Strategy, which seeks to address the forty percent of American adults who report symptoms of anxiety and depression, and the thirty percent rise in the percent of children and adolescents with anxiety and depression.

Question #141

1. Secretary Becerra, is the Department of Health and Human Services (HHS) willing to revisit the requirement to report practitioner home addresses in Medicare to prevent the unintended consequence of practitioners no longer providing telehealth mental health and SUD services and the potential significant impact on patient access to care?

Question #142

2. Secretary Becerra, absent a revisitation of this requirement, would you be willing to encourage the Centers for Medicare and Medicaid Services (CMS) to provide more details on the provider enrollment requirement to Medicare Administrative Contractors (MACs) to ensure that they are in compliance come January?

HHS Response to 141 and 142

During the Public Health Emergency (PHE) for COVID-19, CMS allowed practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location. This waiver will continue through December 31, 2023.

The Honorable Lori Trahan

Question #143

The Department of Labor is in the process of finalizing a rule related to Independent Contractors that has mainly been associated with gig economy workers. Seniorlink is concerned about the potential impact to Medicaid beneficiaries and their family caregivers, who receive a small stipend through Medicaid Home and Community Based Services. Since CMS/Medicaid provides the stipend, they wanted to make sure that CMS and DOL are communicating about this issue.

1. The millions of older adults and people with disabilities who are covered by Medicaid and live at home receive the majority of their care from family caregivers. Most of that care is "informal" and unpaid, but many family caregivers are paid through various Home and Community Based Services (HCBS) administered by providers contracted with State Medicaid agencies. The Administration has consistently encouraged the growth of HCBS and expanded support to family caregivers.

The DOL issued a proposed rule in October 2022, the "Employee or Independent Contractor Classification Under the Fair Labor Standards Act". There is concern that the rule, as proposed, will have unintended consequences for family caregivers paid through Medicaid HCBS when those family caregivers are delivering services through HCBS that currently appropriately allow them to be classified as independent contractors (e.g. Shared Living, Adult Foster Care).
Has CMS engaged with DOL on this proposed rule to ensure federal policies are aligned to protect this potential HCBS capacity and continue support to the thousands of family caregivers who are currently delivering such care?

HHS Response

Supporting family caregivers is an urgent public health issue, exacerbated by the long-term effects of the COVID-19 pandemic. CMS works to build bridges with caregiver organizations, both federal and non-federal, to better serve Americans in need with national and local resources to assist in their caregiving efforts. Under Medicaid 1915(c) Home and Community-Based Services (HCBS) waivers, States may choose to pay relatives, legal guardians, and/or legally responsible individuals (LRIs) for providing HCBS so long as the individual meets established provider qualifications and the state provides adequate monitoring. If an LRI is rendering personal care services (PCS) or similar services under the waiver, then the service can only be paid if it is considered "extraordinary care," meaning that the care exceeds what an LRI would ordinarily provide, and the service is necessary to assure the beneficiary's health and welfare and to avoid institutionalization lt. We are happy to continue to work with you to support to family caregivers.

Question #144

2. It has come to our attention that multiple vendors nationwide, including several not-for-profit hospitals have not been paid for stepping up to the plate and providing COVID related services to uninsured individuals due to the rushed closure of the HRSA portal. It appears the government has not paid debts owed for services rendered as a result. How do you know how much money to ask for when these vendors haven't even been able to fully submit claims since the portal closure was rushed with only a 7 day notice?

With the public health emergency ending in May and the waivers that eased access to respiratory care under Medicare winding down, there is concern that CMS and its contractors are going to go back to the inefficient and inconsistent ways of determining medical necessity.

HHS Response: In February 2022, the cost of Uninsured Program claims was up to $2 billion a month. Continuing to pay claims at this rate was not sustainable with the funds allotted for the program at that time.

Therefore, on March 15, 2022, the White House announced that the COVID-19 Uninsured Program would have to stop accepting claims for testing and treatment on March 22, 2022, and stop accepting claims for vaccination administration on April 5, 2022, due to a lack of sufficient funding. HHS followed up on this public announcement with additional notices to providers and Congress, alerting them of the deadlines to submit claims. Unfortunately, some providers were unable to complete the claims submission process for all potential claims by the submission deadlines.

In the three weeks after the announcement that the COVID-19 Uninsured Program would need to wind down, nearly 35 million claims were submitted to the Program's portal. The claims submitted after the announcement represents over 12.3 percent of all claims submitted to the Uninsured Program – nearly 1 in 8 claims received. HHS has now processed and paid all eligible claims submitted to the program by the deadlines with the exception of a small number of claims requiring technical, administrative adjustments or program integrity review of which impacted providers have been notified.

Question #145

3. I am interested in the documentation requirements to qualify for home respiratory therapy. I understand that CMS contractors rely on physician medical record notes as the only source for determining medical necessity. We know from CMS' own data that when these subjective documents are used, contractors deny the vast majority of claims despite knowing that the patient actually does qualify for the equipment. CMS has created a standardized template form that includes a set of clinical data elements that physicians prescribing supplemental oxygen could use to make sure they are providing the consistent information that Medicare contractors need to review claims. However, CMS has not yet required its contractors to adopt this commonsense approach, putting patient access to these essential services at risk. Will the agency act quickly to require the

contractors to use this type of objective documentation once the public health emergency ends?

HHS Response

CMS recognizes that it is important for stakeholders to understand how CMS anticipates performing medical review after the Public Health Emergency (PHE) has ended. During the PHE, flexibilities were applied to medical reviews across claim types. For certain DME items, this included the non-enforcement of clinical indications for coverage. Since clinical indications for coverage were not enforced for certain DME items provided during the PHE, once the PHE ends CMS plans to primarily focus reviews on claims with dates of service outside of the PHE, for which clinical indications of coverage are applicable. CMS may still review these DME items, as well as other items or services rendered during the PHE, if needed to address aberrant billing behaviors or potential fraud. The HHS-Office of the Inspector General may perform reviews as well. All claims will be reviewed using the applicable rules in place at the time for the claim dates of service. As the PHE comes to an end, CMS will continue to work with stakeholders to ensure beneficiary access.

CMS has designed printable clinical templates and suggested clinical data elements (CDEs) to assist providers and IT professionals with data collection and medical record documentation to support coverage of selected items and services. These templates and suggested CDEs are intended to help reduce the risk of claim denials and ensure that medical record documentation is more complete. Specifically, CMS released a clinical template and suggested CDEs for ordering home oxygen therapy. The template is designed to assist a clinician when completing an order for home oxygen therapy to meet requirements for Medicare eligibility and coverage. The template meets the requirements for both the Detailed Written Order and Written Order Prior to Delivery, and is available to the clinician and can be kept on file with the patient's medical record or can be used to develop an order template for use with the system containing the patient's electronic medical record. While completing the "Home Oxygen Therapy Order Template" does not guarantee eligibility and coverage, it does provide guidance in support of home oxygen therapy equipment and services ordered and billed to Medicare. CMS has also released clinical templates and suggested CDEs for documenting the face-to-face encounter for Medicare home oxygen therapy eligibility and coverage and for documenting information regarding home oxygen therapy laboratory test results to meet requirements for Medicare coverage for home oxygen therapy. The home oxygen therapy templates and suggested CDEs are available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Electronic-Clinical-Templates/template-and-CDE-downloads.

At this time, use of these templates and suggested CDEs is voluntary; however, we welcome provider and stakeholder feedback and suggestions on how to improve all our templates and CDEs.

Question #146

4. For more than forty years, the American Portable Diagnostic Association (APDA) has been a national, non-profit organization representing members across the country who provide portable diagnostic services, including x-ray, ultrasound, echocardiography, EKG, blood testing, bone densitometry, pulmonary function testing, telemedicine and

other emerging portable modalities. All of which are delivered at the patient's bedside when deemed medically appropriate by a patient's physician. I am interested in receiving more information on what is being done to hold Medicare Administrative Contractors (MACs) accountable for following guidelines from CMS to ensure transparency and reasonableness when setting reimbursement rates for portable x-ray services.

Question #147

5. The Medicare Claims Processing Manual (MCPM) states, "The MACs are required to update the rate on an annual basis using independently determined measures of the cost of providing the service. A number of readily available measures (e.g., ambulance inflation factor, the Medicare economic index) that are used by the Medicare program to adjust payment rates for other types of services may be appropriate to use to update the rate for years that the MAC does not recalibrate the payment." NGS has not complied with the MCPM provisions of using an annual update index that reflects the changes in costs to provide PXR transportation services. 2018 was the last year NGS provided any update to the PXR transportation rate. What steps can CMS take to intervene and hold MACs accountable to ensure PXR providers receive annual rate adjustments as required to allow them to continue serving vulnerable patients at their bedside?

Question #148

6. The Medicare Claims Processing Manual further requires that "MACs should periodically review (at least every five years, or more frequently if local conditions warrant) their locally determined payment amount to determine whether the payment amounts reflect the relative resources (e.g., staff, equipment, supplies and general expenses) required to perform MAC-priced services." Additionally, "if portable x-ray transportation suppliers request such a review, MACs should work with the local suppliers to review the payment amounts for R0070, taking into account local factors and any data available regarding the resources required to provide these services." Given additional new costs stemming from the pandemic compounded by the lack of annual rate adjustments, PXR suppliers operating in the NGS jurisdiction formally requested a rate review in November of 2021 that was rejected by the MAC. What steps can CMS take to intervene to ensure MACs reassess cost inputs for periodic reviews as quickly as practicable in accordance with current rules, in order to allow PXR to serve vulnerable patients at their bedside?

Question #149

7. MACs are not required to disclose methods or provide the rationale behind the final rates in relation to cost data submitted by PXR suppliers. This has resulted in significant variances in transportation rates by state that remain unexplained. Compounding matters further is that some rates are never increased, despite multiple economic indexes highlighting the significant increase in costs. How can CMS intervene to ensure

transparency and reasonableness when MACs set reimbursement rates, both during the required annual process and when conducting periodic comprehensive rate reviews?

HHS Responses 146-149

CMS works with Medicare Administrative Contractors (MAC) to ensure payments for contractor-priced services are developed using a collaborative process that allows for transparency and consistency. CMS established contractor pricing for services related to transportation of portable x-ray equipment (HCPCS codes R0070 and R0075). This means that CMS did not establish a national payment rate for these services, and the Part B MACs can establish payment rates for the fee schedule areas under their jurisdiction. CMS establishes contractor pricing for various reasons, such as when we do not have sufficient information to establish national pricing or when services have low Medicare utilization. Additional information on pricing of the transportation component for portable x-ray services is available in the Medicare Claims Processing Manual, Chapter 13, Section 90.3.[40]

The Medicare Access and CHIP Reauthorization Act of 2015 requires contractor performance transparency to the extent possible without compromising the process for entering into and renewing contracts with MACs. Under the law, the Secretary must make available to the public the performance of each MAC with respect to such performance requirements and measurement standards.

CMS measures overall MAC performance by the Quality Assurance Surveillance Plan (QASP) and Award Fee Plan (AF). The QASP ensures that systematic quality assurance methods are used in administration of the contract and provides Government Surveillance oversight on the quality, quantity, and timeliness of contractor performance. The Award Fee Plan is provided to motivate exceptional performance above what is outlined in the Statement of Work. In FY 2019, FY 2020 and FY 2021 MACs were evaluated on approximately 80 performance metrics/requirements for Part A/B and 50 performance metrics/requirements for DME.

[40] Medicare Claims Processing Manual, Chapter 13 – Radiology Services and Other Diagnostic Procedures: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c13.pdf