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FRANK PALLONE, JR., NEW JERSEY,
RANKING MEMBER

ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE

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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

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

    - How long has Dr. Tabak held this title?
    - What was Dr. Tabak's previous title?
    - How long does Dr. Tabak anticipate remaining in this current position, with the current title?
    - 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.
    - 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."

2. Recent reporting[2] 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.

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

3. A recent JAMA analysis[3] 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 finished trials were registered within 12 months of completion and almost half of trials did not have results published four years after

[1] The Federal Vacancies Reform Act of 1998, Pub. L. 105-277.

[2] CBS News, U.S. government agencies may have been double billed for projects in Wuhan, China, records indicate; probe launched, March 17, 2023.

[3] JAMA Analysis, Dissemination of the Results of Pediatric Clinical Trials Funded by the US National Institutes of Health, Feb. 21, 2023.

completion of NIH funding. A recent HHS OIG[4] 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.

- 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.

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."[5] 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.

   - 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?
   - Please describe any actions HHS is taking to remedy these issues.

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.

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

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

[4] HHS OIG, The National Institutes of Health Did Not Ensure That All Clinical Trial Results Were Reported in Accordance with Federal Requirements, August 2022.

[5] 85 FR 25644, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, May 1, 2010.

validated all diagnostic HIV tests and the critical algorithms used to ensure accurate HIV diagnosis and disease monitoring in PEPFAR.

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

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.

    - 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.
    - Please explain the planned structure and organization of "Project NextGen," including anticipated leadership and subagency within HHS that will be leading the initiative.
    - 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."

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[6] Washington Post, White House launching $5 billion program to speed coronavirus vaccines, April 10, 2023, https://www.washingtonpost.com/health/2023/04/10/operation-warp-speed-successor-project-nextgen/.
[7] Washington Post, White House launching $5 billion program to speed coronavirus vaccines, April 10, 2023, https://www.washingtonpost.com/health/2023/04/10/operation-warp-speed-successor-project-nextgen/.
[8] USA Today, White House to invest $5 billion in next-generation COVID vaccines. Here's why we need new ones., April 10, 2023, https://www.usatoday.com/story/news/health/2023/04/10/project-next-generation-coronavirus-vaccines-biden-administration/11636925002/?emci=5287bf99-02d8-ed11-8e8b-00224832eb73&emdi=a872aaf2-6cd8-ed11-8e8b-00224832eb73&ceid=7758438.

- 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.
- 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.
- Please explain if and how the creation of this new initiative will impact the Administration's FY 2024 budget request.

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.

   - 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?

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."

   - Do you stand by this analysis from the CMS Office of the Actuary?
   - 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)?

- 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?
- 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?
- If not, please explain your analysis.
- 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?

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.

- 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?
- If not on schedule, when do you anticipate the rule coming out?
- When do you expect to release and implement the final rule?

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

- How many of these FDA-approved breakthrough devices have received CMS coding, coverage, and payment?
- How long is the average expected time between an FDA-approved breakthrough device approval and Medicare coverage?

- How long is the average span of "Coverage with Evidence Development" (CED) for FDA breakthrough devices that are covered under CED?

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.

- 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?
- How many current items are on the NCD wait list at this moment?
- Does CMS believe it has discretion to review requests on a different timeline than as prescribed by the statute?

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.

- How many health care workers have left their job because of the mandate?
- 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?

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.

- 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?
- 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?
- 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?
- Should health plans be allowed to incentivize seniors to choose preferred generics?
- 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?

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.

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

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.

- 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?
- 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?

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.

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

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 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.

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

The Honorable Brett Guthrie

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.

- 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"?

- 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?

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.

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

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?

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:

    - Which particular federal policies do you believe lead to greater hospital and provider consolidation?
    - What will your Budget and other Department actions propose to do to throttle consolidation based off of government policy arbitrage?
    - 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.

- 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?
- And what legislative changes have you identified which will address hospital consolidation?

The Honorable Morgan Griffith

1. 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?

2. 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."

    - 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?

    - 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?

    - 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?

3. 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.

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

The Honorable Robert E. Latta

1) 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?

2) 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?

3) 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.

4) 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?

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

6) 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?

7) 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?

8) 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?

The Honorable Dan Crenshaw

1. 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?

2. 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?

3. 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?

4. 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?

5. 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?

5. 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?

The Honorable Mariannette Miller-Meeks

1. 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?

2. 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?

3. 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.

The Honorable Troy Balderson

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?

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?

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 drugs for rare diseases without current treatment options?

The Honorable John Joyce

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

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?

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?

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?

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?

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?

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?

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?

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?

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?

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?
- What is the administration doing to advance therapeutics that could address COVID-19 and its variants?
- What is the administration doing to ensure that the development and approval of therapeutics is equal to vaccines?

The Honorable Michael Burgess

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?

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?

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.

- 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 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?

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

Rare Disease Drugs

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?

NSA/Price Transparency

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?

    - 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?

APIs/Manufacturing

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."

    - 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?

    - 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?

    - 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 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?

    - 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?

    - 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?

- 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?

DEA/Mental Health

7. 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.

   - 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?
   - 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?
   - 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?
   - 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?

Heart Transplant Selection Criteria Oversight

8. 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.

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

    - 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?

    - What role is HRSA playing in oversight of these changes?

    - 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?

The Honorable Larry Bucshon

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?

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):

- 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?

- 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?

- 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.

- 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?

- 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?

- 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?

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?

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?

The Honorable Earl L. "Buddy" Carter

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.

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?"

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?

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?

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?

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?

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?

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?

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.

The Honorable Richard Hudson

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?

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.

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?

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.

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.

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.

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:

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.

- 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?
- 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?
- 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?

- 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?

- 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?

- 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?

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.

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

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, <u>but can you also speak to</u>:
    - The harm this commercialization is doing to the providers in our healthcare system?
    - What is the cost of commercialization to our providers?
    - What is the cost of preventing against such commercialization?

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

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

- 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?

The Honorable Gus Bilirakis

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?

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?

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?

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?

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?

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?

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?

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?

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?

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?

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.

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?

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?

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?

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?

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?

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?

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?

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?

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?

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?

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?

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?

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.

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?

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?

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?

The Honorable Greg Pence

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.

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

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

The Honorable Anna Eshoo

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?

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?

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.

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.

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.

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?

The Honorable Tony Cárdenas

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?

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?

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?

The Honorable Debbie Dingell

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?

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?

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

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?

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?

The Honorable Ann Kuster

Data modernization

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?
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?

Behavioral Health Workforce

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?

Certified Community Behavioral Health Clinics

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

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?
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.

Caregiving Workforce

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?
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?
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?
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?

Addiction and access to treatment

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?
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?
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?

Organ donation

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?

COVID-19 Therapeutics

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?

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?

ARPA- H

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?

The Honorable Robin Kelly

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?

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.

The Honorable Nanette Barragan

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?

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?

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?

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?

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

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?

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

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.

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?

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?

The Honorable Lori Trahan

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?

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.

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?

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.

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?
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?

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?