COMMITTEE ON
EDUCATION AND THE WORKFORCE
U.S. HOUSE OF REPRESENTATIVES
2176 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6100

June 14, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Secretary Becerra:

Thank you again for testifying at the May 15 Committee on Education and the Workforce hearing on "Examining the Policies and Priorities of the Department of Health and Human Services."

Enclosed are additional questions submitted by Committee Members following the hearing. Please provide a written response no later than July 15, 2024, for inclusion in the hearing record. Responses should be sent to Alexander Knorr of the Committee staff; he can be contacted at Alexander.Knorr@mail.house.gov or (202) 225-7101.

Sincerely,

Virginia Foxx

Virginia Foxx
Chairwoman

Enclosure

Questions for the Record for Xavier Becerra

Committee on Education and the Workforce Hearing
"Examining the Policies and Priorities of the Department of Health and Human Services"
May 15, 2024

Chairwoman Virginia Foxx (R-NC)

Health Coverage

1. During the hearing, I expressed concerns about the Department of Health and Human Services' (HHS) regulatory overreach with respect to self-insured health plans. As I noted, the recent Notice of Benefit and Payment Parameters final rule and the Section 1557 Nondiscrimination in Health Programs and Activities final rule saddle self-insured health plans with new Obamacare regulations. Under current law, self-funded plans are not subject to Section 1557 and are regulated by the Department of Labor (DOL). I asked you the following question during the hearing, but you did not provide an answer. Will you confirm it is HHS policy that self-insured health plans are not subject to HHS regulation, and will you commit to abandoning any unlawful HHS efforts to regulate self-insured health plans?

2. The *Inflation Reduction Act* (IRA) included $33 billion to expand subsidies for Obamacare plans for an additional three years. The President's budget calls for a permanent expansion of enhanced subsidies, which the Congressional Budget Office (CBO) estimates would cost $383 billion over the next decade. Why is HHS instead working to strengthen employer-sponsored health insurance, which is consistently more affordable and of higher quality than Obamacare plans?

3. Three out of four individuals in the *Affordable Care Act* (ACA) exchanges receive subsidies. Does this not demonstrate that these plans are unaffordable?

4. Premiums on the ACA exchanges are skyrocketing. Does the administration have a plan to lower the cost of ACA premiums that does not simply continue to pump money into the system through tax hikes?

5. According to CBO estimates, ACA plans per enrollee are three times more expensive for taxpayers than employer-sponsored health insurance. Do you believe that shifting enrollment from ACA plans to the employer-sponsored market would be beneficial for the federal budget? If so, what steps will HHS take to encourage migration to employer-sponsored health plans?

6. Small businesses rely on stop-loss insurance to provide more affordable, higher quality health care coverage to their employees by self-insuring. Do you agree that stop-loss coverage is a necessary tool for many businesses to self-insure? Why or why not?

7. The administration likes to call any form of health coverage it does not like "junk insurance," as shown by recent regulations to erode the association health plan and short-term, limited-duration insurance markets. Should the government dictate what is and is not beneficial insurance, or should individuals be able to make those decisions for themselves?

8. President Biden once said, "if you like your health care plan ... you can keep it. If in fact you have private insurance, you can keep it." President Obama made a similar promise, saying, "if you like your health care plan, you can keep it," which some outlets considered to be the "lie of the year" in 2013. Will President Biden keep his promise? Does the President want every American on an Obamacare individual market plan? How can the President keep his promise while his administration actively erodes the association health plan and short-term, limited-duration insurance markets and saddles employer-sponsored plans with costly regulations?

9. The Committee has taken steps to help employers ensure that the third-party administrators (TPA) they contract with operate transparently.

    a. What actions is the administration taking to require TPAs to share rates and settled claims amounts with those self-funded employers who have the fiduciary responsibility for their health care spend?

    b. When brokers offer "no-shop" commissions, how does this protect employers and ensure they are getting the best plan for their employees? What actions will the administration put in place to restrict no-shop commissions?

    c. Brokers are being asked to sign non-disclosure agreements with carriers stating they will not disclose their rates to anyone (including the employer they represent). What steps is the administration putting in place to make these practices illegal?

    d. How does the Section 1557 nondiscrimination protections impact self-funded plans, their carriers, and TPAs?

Telehealth

10. Telehealth, in many ways, was a silver lining of the COVID-19 pandemic. Many new patients gained access to these important services because HHS allowed employers to offer stand-alone telehealth coverage. However, telehealth-excepted benefits expired at the end of this past plan year, as the declared Public Health Emergency came to an end on May 11, 2023.

    a. Do you believe this flexibility helped workers gain access to care?

    b. Will you support this Committee's efforts to extend this flexibility going forward?

11. Your budget proposes a ban on telehealth facility fees.

    a. How does HHS justify such a ban?

    b. How would banning facility fees help reduce costs for employers?

    c. Can you provide additional details on the estimated $2.3 billion in savings such a ban would provide the federal government?

    d. Could you elaborate on the meaning of "other outpatient services" to which the proposed ban refers?

Association Health Plans

12. Congressional Republicans have a longstanding interest in allowing associations and businesses to band together to purchase affordable health insurance coverage through association health plans (AHPs). In 2018, HHS issued a final rule to expand access to AHPs. Before a court invalidated the rule, 35 new AHPs were formed, which saw average savings of 29 percent. On April 30, DOL issued a final rule which rescinds the 2018 rule, robbing Americans of an innovative way to access high-quality, low-cost health care.

    a. To what extent do you anticipate that DOL's final rule reversing the expansion of AHPs will raise costs?

    b. Does HHS have any estimates of how many people will be prevented from accessing affordable health coverage due to the new rule?

13. AHPs are an effective way to expand health care coverage options to small businesses and to reduce premiums. Unfortunately, the Biden administration recently released a rule to erode the AHP marketplace.

    a. In your opinion, are Obamacare plans the only acceptable form of insurance?

    b. Why is the Biden administration so intent on taking away innovative coverage models from employers and individuals?

Short-Term Limited-Duration Insurance

14. On April 3, HHS, DOL, and the Department of the Treasury (the Tri-Agencies) jointly published final rules severely reducing access to short-term, limited duration insurance. The final rules stated: "These final rules might also lead to an increase in the number of individuals without some form of health insurance coverage…. Those individuals who become uninsured or obtain coverage in unregulated markets could face an increased risk of higher out-of-pocket expenses and medical debt, reduced access to health care, and

potentially worse health outcomes." How many Americans will become uninsured because of these regulations?

Surprise Billing

15. This Committee's efforts helped lead to the passage of the historic *No Surprises Act* (NSA). However, the law's Independent Dispute Resolution (IDR) process has been mired in litigation, delays, and faulty implementation. Data shows that 77 percent of disputes are ruled in favor of providers, and the Brookings Institution now anticipates that the IDR process will raise costs and premiums, contrary to the law's goals. I asked you the following question during the hearing, but you did not provide a responsive answer. What is HHS doing to improve the operations of the IDR process under the NSA, and are you concerned that the law's current implementation will raise health care costs for employers and employees?

16. I am concerned that, due to current implementation, some companies are using the NSA's IDR process as a moneymaking scheme. The IDR process has been flooded by disputes from just a few large billing consultants and physician-staffing firms. The top 10 dispute-initiating parties submitted 73 percent of the out-of-network payment disputes.

    a. Are you worried that some players are abusing the IDR system?

    b. How are smaller providers disadvantaged if the IDR system is overwhelmed by disputes from large billing consultants and staffing firms?

    c. Do you share my concerns that current implementation of the IDR process may further fuel health care consolidation?

17. There is a lot of frustration from providers, employers, and insurers about the administration's implementation of the NSA's IDR process.

    a. Why has implementation been such a challenge?

    b. Why did HHS so severely underestimate how many disputes would enter the IDR process?

    c. Did the Tri-Agencies' November 2023 proposed rule address these implementation challenges, and can you provide an update on HHS' work to improve IDR operations?

    d. How is the administration ensuring that IDR entities are appropriately and clearly communicating with payers and providers regarding the outcomes of claim disputes?

    e. How is the administration conducting oversight of IDR entities' decision-making?

f. How is the administration handling medical necessity denials for claims which would otherwise be eligible for IDR, particularly for air ambulance services?

18. In addition to protecting against surprise medical bills, the NSA included other important patient protections. The law requires health plans and issuers to provide an advanced explanation of benefits (AEOB) detailing the estimated costs for a scheduled service. However, the Centers for Medicare and Medicaid Services (CMS) has not yet implemented this requirement. Please provide an update on CMS's timeline to implement the AEOB requirement via rulemaking.

19. The NSA's IDR program was intended to be funded through administrative fees from disputing parties. Why does the President's budget request an additional $500 million for NSA implementation when the program is supposed to be self-funded?

Mental Health Parity

20. I have serious concerns about HHS' 2023 proposed rules regarding mental health parity. The proposed rules do little to expand access to quality mental health care while burdening employers with more paperwork requirements.

    a. Do you share my concerns that conditioning mental health parity compliance on reimbursement rates will raise premiums and health care costs, while doing little to alleviate provider shortages?

    b. Should health plans serving areas with mental health provider shortages be given a safe harbor from parity compliance?

    c. Do you support efforts to expand telehealth to help alleviate mental health provider shortages, particularly in rural areas?

21. There is bipartisan consensus on the need to boost mental health care in this country. However, I worry that the administration's recent rule on the *Mental Health Parity and Addiction Equity Act* (MHPAEA) will layer plans with more burdensome regulations, which will raise costs and reduce access to mental health care. What is the administration's timeline for releasing the mental health parity final rule?

22. Under parity requirements, mental health and substance use disorders must be treated the same as physical health. Why does the proposed mental health parity rule include a test for non-quantitative treatment limits (NQTLS), which will allow health plans to perform utilization review on inpatient medical care half the time—but none of the time for mental health and substance use disorder care?

23. The current mental health parity proposal will likely eliminate the ability for health plans to employ utilization management techniques in mental health and substance use disorder care, especially in outpatient settings. These techniques can help ensure people get the

right care at the right time. Was HHS' intent to eliminate the ability of health plans to perform utilization management in mental health and substance use disorder care?

24. I have read some of the health plans and employer comments on the proposed mental health parity rule, and they asked for a sample NQTL analysis that they can use as a guide when doing their analyses. Will HHS commit to working with DOL to make these samples publicly available before the compliance date of the pending final rule?

25. A fundamental proposed change in the proposed rule is adding the Substantially All/ Predominant test to NQTLs. This means that in order for health plans and issuers to apply management techniques such as prior authorization and concurrent review to MH and SUD benefits, these techniques must be applied to 2/3rd or more of the medical/surgical (M/S) benefits in the same classification. This reinterprets the parity statute to subject NQTLs to the quantitative tests currently applied to quantitative treatment limits. It will be impossible to operationalize these tests and will remove nearly all insurer tools to ensure patients receive safe and appropriate care. Please explain why the Tri-Agencies proposed 2/3rds—as opposed to 50 percent or 20 percent for an NQTL test. For example, if value-based purchasing is only used with 61 percent of M/S providers in a classification, is it foreclosed for all behavioral health providers in that same classification?

26. The proposed mental health parity rule shifts the focus from comparing methodologies to comparing outcome measures like denial rates and actual amounts paid to providers. This approach goes well beyond the intent of the MHPAEA and suggests that any disparate outcome equals noncompliance. Please explain why the Tri-Agencies proposed to change from their position that disparate outcomes could be indicative of a parity violation to the proposal's position that says that disparate outcomes are per se violations for certain NQTLs.

Drug Pricing

27. The President's budget request proposes to extend Medicare's $35 out-of-pocket cap for insulin to the commercial market. If enacted, this proposal would cost taxpayers an estimated $1.3 billion over 10 years. Will extending this cap to the commercial market raise premiums for individuals in small- and large-group plans?

28. The 340B drug-pricing program is intended to pass on savings and improve health outcomes for low-income patients. However, there are reports that hospitals and pharmacies are selling these drugs to commercially insured patients to pad their bottom lines, using employer-sponsored plans to subsidize the 340B program at the expense of workers' premiums. The President's budget includes funding for oversight and auditing of covered entities.

    a. Please provide an update on these oversight efforts.

    b. Should hospitals be able to use the 340B program to pad their bottom lines?

c. What protections will you put in place to ensure that providers are only using the government-set price drugs for eligible patients?

29. According to a study from the University of Chicago, government price controls in the *Inflation Reduction Act* will result in 342 fewer cures reaching the market, which will take 330 million years off Americans' lives. What is the Biden administration's plan to ensure that patients will not lose out on access to lifesaving cures and that America will continue to be the world leader in medical innovation?

30. In *HIV and Hepatitis Policy Institute v. HHS*, a federal district court struck down a rule allowing health insurers not to count drug manufacturer copay assistance towards a beneficiary's out-of-pocket costs. In light of this ruling, what is HHS' policy and enforcement stance regarding use of copay accumulator and maximizer programs within self-funded health plans?

31. Pharmacies are experiencing significant reimbursement cuts due to modifications in the methodology that Medicaid uses to establish the national average drug acquisition cost (NADAC). It has been reported that since being implemented in April, pharmacies have seen a 16 percent decrease in generic NADACs with an additional decrease seen in May. NADAC must ensure stable and predictable reimbursements. Please provide clarification on the rationale behind these changes and the lack of public notice and stakeholder input.

Market Consolidation and Decreased Competition

32. As of May 2024, only 11 hospitals have been fined for violating the final hospital price transparency rule. Additionally, it appears that overall compliance with this rule is lacking.

    a. Why has HHS not done more to enforce the hospital price transparency rule?

    b. Does the Biden administration support congressional efforts to codify this rule in the *Lower Costs, More Transparency Act*?

33. Premiums for employer-sponsored health plans increased 7 percent this year. The RAND Corporation, CBO, and other economists have identified provider consolidation as a main driver of health care cost increases. Perverse economic incentives have driven hospitals to acquire provider offices and incorrectly bill for services.

    a. Do you believe that this is a problem for employers and workers?

    b. Would you agree that hospitals should not be allowed to charge facility fees to commercial payers for outpatient services?

c. Does the Biden administration endorse congressional efforts to ensure that health services are charged on a site-neutral basis?

34. Price transparency is vital for employers to make better decisions in choosing and administering employee health plans. HHS is indefinitely deferring enforcement of a rule requiring plans to make drug prices public and to submit them to HHS. Should Congress codify this rule to ensure transparency for drug prices?

35. Prescription drug middlemen like pharmacy benefit managers (PBMs) are raking in profits while evading congressional scrutiny. This Committee has taken a leading role in improving the transparency of PBMs, including through the *Lower Costs, More Transparency Act*. Please provide an update on HHS oversight of PBMs.

Religious Freedom, Gender, and Abortion

Gender Identity and Religious Freedom

36. The recent Title IV-B and IV-E rule requires "Designated Placements," a new category of foster care providers deemed by HHS to be safe and appropriate for LGBTQ+ children. Under the rule, foster care providers who may have religious freedom or conscience concerns regarding your LGBTQ+ policy are permitted to request an accommodation, but ultimately that request must be reviewed by the HHS Office of General Counsel. What conditions would allow foster parents with certain religious beliefs to bypass HHS' "Designated Placements" category requirement?

37. HHS' FY 2025 budget document states, "the proposal includes financial penalties and mandatory corrective action for any state or contract that delays, denies, or otherwise discourages individuals from being considered or serving as foster or adoptive parents based on the above categories." Is that policy in direct contradiction to the finalized rule requiring "Designated Placements" to be the default provider group to LGBTQ+ children?

38. On April 9, Dr. Hilary Cass published the Cass Review, an independent review of gender identity services for children and young people commissioned by England's National Health Service. The review found that thousands of vulnerable young people were given life-altering treatments with "no good evidence on the long-term outcomes of interventions to manage gender-related distress." Another study published on March 23, 2024, by physicians and researchers at the Mayo Clinic reported mild-to-severe sex gland atrophy in puberty blocker-treated children.

    a. What longitudinal studies or systematic reviews of scientific studies has HHS overseen or funded on the effects of puberty blocker usage on youth gender treatments?

    b. Is HHS aware of the long-term effects of puberty blockers for this particular population?

c. What effects do puberty blockers have on the brain development of children?

d. What effects do puberty blockers have on fertility?

e. Are puberty blockers reversible?

f. Can puberty blockers cause permanent sterility in a healthy girl or boy?

g. Why would our federal medical institutions support use of puberty blockers if they have not done the public the service of understanding their long-term effects?

39. Should Americans be able to practice their religious faith free from discrimination?

40. Does the freedom to practice religious faith free from discrimination also exist in the practice of medicine? If so, why does the Biden administration continue its efforts to violate American's religious beliefs through abortion, contraceptive, and gender-reassignment mandates?

Border Crisis and Child Labor

41. According to U.S. Customs and Border Protection data, the CBP encountered more than 137,000 unaccompanied minors at the southern border in FY 2023, a substantial increase compared to just five years ago. As has been reported in the New York Times and other publications, this increase in unaccompanied minors led to the rise in employment of these minors in dangerous jobs in violation of the *Fair Labor Standards Act*. President Biden has implemented an open border policy and even recently admitted the border is not secure. Why has the Task Force to Combat Child Labor (Interagency Task Force)—on which HHS is a member with DOL and the Department of Homeland Security (DHS)—failed to protect so many unaccompanied minors?

42. I am frankly shocked at the lack of coordination between DOL, HHS, and DHS when it comes to protecting the health and safety of unaccompanied migrant children after they have entered the United States. It is the responsibility of HHS to ensure that these children are placed with responsible caregivers after they leave HHS. Yet, it appears as though many of these children were placed with human traffickers and were forced to work in dangerous jobs. This was so prevalent that HHS stopped placing children with sponsors in certain zip codes.

    a. Did DOL warn HHS that these children were at risk for human labor trafficking at any time during this administration?

    b. Do you believe that HHS properly vetted the sponsors of unaccompanied children who were found to be exploited by human labor traffickers?

    c. Did HHS follow all protocols when vetting sponsors for unaccompanied children?

d. Did HHS' failure to vet sponsors contribute to the increase in child labor trafficking?

e. If a child who was under the care of HHS' Unaccompanied Children Program is found to be a victim of human labor trafficking, is the sponsorship immediately terminated, and does the federal government reclaim custody of the child?

f. Are there circumstances under which the child will be returned to the original sponsor?

g. Are there circumstances under which the child will be returned to an immediate relative of the original sponsor? And, if so, what is the vetting process for these individuals?

h. Do some human traffickers promise young children that they can go to school or work in the United States to lure them into being trafficked?

i. Is HHS placing children with members of gangs and cartels, including MS-13?

j. Is it true that HHS has released multiple unaccompanied children to the same address or building?

k. What action is HHS taking to ensure that individuals are not sponsoring multiple children and that multiple children are not being released to the same address?

43. HHS' FY 2025 budget shows a carryover in unaccompanied children program funding of $1.6 billion from FY 2023 to FY 2024. Considering the alarming rate at which unaccompanied children have entered the United States over the last year, can you explain why HHS had so much unused funding?

44. In February 2023, HHS and DOL announced the formation of an Interagency Taskforce to combat child labor exploitation—a move to save face after the neglect of both agencies resulted in illegal child labor scenarios with sad consequences. Part of HHS' responsibility was to expand post-release services to unaccompanied children.

    a. What services have been expanded, and what were the costs of those services?

    b. Are unaccompanied children given materials to explain child labor laws and a way to contact HHS to report any safety concerns?

45. HHS completed an audit of the failed vetting process for potential sponsors—a process that previously resulted in HHS releasing unaccompanied children into the custody of child labor law violators.

    a. What changes have been made as a result of this audit?

b. What changes have been made to release unaccompanied children to individuals who have previously sponsored children?

Head Start

46. HHS' Head Start Workforce proposed rule seeks to make wage and benefit changes to Head Start performance standards in a purported effort to retain the program's workforce. Part of HHS' solution is to implement pay parity for Head Start education staff with public school teachers and set a minimum pay floor of $15 per hour. HHS acknowledges that, "there will be a substantial cost associated with enacting the proposed [wage] standards at current Head Start funded enrollment levels." But the proposal argues the policy changes are "necessary" while admitting, "one potential impact could be a reduction in Head Start slots."

    a. Is it the policy of this administration that Head Start should serve fewer low-income children in order to pay workers more?

    b. What is HHS' plan for children and families who lose access to Head Start due to your reduction in slots?

47. The Head Start statute goes out of its way to describe parent and family engagement in Head Start services. In HHS' recent Head Start Workforce proposed rule, there is even language that claims to ensure "programs are consulting and engaging with current parents and families to be involved in the methods the program uses." However, the proposed rule strikes §1302.44(a)(3) from current regulations, which requires that parent consent be obtained for mental health consultation. Does HHS intend to complete mental health consultations on children without parental consent?

48. Continuous quality improvement (CQI) is a staple of the Head Start program, yet HHS' "Head Start Workforce" proposed rule includes several highly prescriptive and onerous requirements that walk away from the focus on CQI and empowering local communities to do what is best for their children and families. How will the Biden administration ensure the new rule will maintain or strengthen local autonomy and CQI?

Universal Preschool

49. The Biden administration continues to propose universal preschool in FY 2025 with $5 billion in mandatory funding. However, several economic impact studies[1] warn that a

[1] [1] Brown, Jessica, "Does Public Pre-K Have Unintended Consequences on the Child Care Market for Infants and Toddlers?" (Dec. 8, 2018). Princeton University Industrial Relations Section Working Paper 626 finds "a back-of-the-envelope calculation indicates that for every seven 4-year-olds who shifted from day care centers to public pre-K, there was a reduction of one day care center seat for children under the age of 2." Malik, Rasheed, "The Effects of Universal Preschool in Washington, D.C." (Sept. 2018) American Progress Report. "[universal preschool] has the potential to affect the supply and cost of child care for infants and toddlers…private child care providers have traditionally cross-subsidized their smaller infant and toddler rooms by serving one or two full classrooms of preschoolers. Without that revenue, some providers may need to increase prices or enroll fewer children." Costa,

universal preschool program—which aims to pull a majority of 3- and 4-year-olds into a new federal government education system—will have disastrous effects on already strained child care providers. Since HHS also houses federal child care programs through the Child Care Development Fund (CCDF) and Child Care Development Block Grant (CCDBG), has the HHS completed any economic impact studies on the proposed universal preschool program?

Child Care

50. It is no secret that our nation's child care industry is strained at best and broken at worst. The HHS budget requests $10 billion in FY 2025 to expand the federal child care program to include families with annual incomes up to $200,000.

    a. Why is it appropriate to subsidize child care for the wealthy?

    b. A family of four with an annual income of $200,000 is living 641 percent above the federal poverty guidelines. CCDBG eligibility rules require family income at or below 85 percent of state median income. How is a $200,000 income limit appropriate for participation in federally subsidized child care?

51. On March 1, 2024, HHS finalized a rule that makes significant changes to CCDF copayments. Statute clearly articulates that "the State will establish and periodically revise…a sliding fee scale that provides for cost sharing by the families that receive child care services."

    a. How does a copay cap at 7 percent of household income adhere to the "sliding scale" requirement in statute?

    b. HHS has historically recommended - not required - a 7 percent income threshold. Why the abrupt change?

52. This cap at 7 percent of household income will burden lead agencies with the tuition differential, further straining an already fraught child care system.

    a. What supports will HHS put in place to help states manage the new requirement?

Daniela Viana, et. al. "Economic Effects from Preschool and Childcare Programs" (August 2021) Penn Wharton Budget Model. "We find that a combined universal childcare and preschool program produces GDP which is 0.2 percent lower than the current baseline in 2051 while increasing government debt by 5.9 percent." In "Economic Effects of Expanding Subsidized Child Care and Providing Universal Preschool" (November 23, 2021) the Congressional Budget Office estimated that expansion of federal subsidies for child care and providing universal preschool at no cost for eligible children (as presented and passed by the House of Representatives in H.R. 5376) "would increase federal deficits by $381.5 billion from 2022 to 2031." Additionally, for those parents with incomes above an eligibility threshold, even modestly so, the study states "the higher costs of unsubsidized [child] care would discourage work."

b. Will the potential reduction of the number of available slots open to children be an acceptable solution for states that cannot carry this financial burden?

c. With the increased child care costs to states, has HHS estimated how many child care slots might be lost? Is there a reduced case load estimate?

Rep. Joe Wilson (R-SC)

1. The Increasing Organ Transplant Access Model (the IOTA Model) is a proposed mandatory initiative aimed at enhancing access to kidney transplants for patients with kidney disease while also reducing Medicare expenditures. Key objectives of this model include encouraging transplant hospitals to utilize more available kidneys for transplantation, facilitating transplants from living donors, and promoting equitable access to kidney transplants.

   Under this model, participating transplant hospitals are held accountable for their performance. They could receive upside risk payments from CMS, fall into a neutral zone (where neither upside nor downside risk payments apply), or owe downside risk payments to CMS based on their final performance score. This score would be calculated out of 100 points across three domains:1. Achievement: Reflecting the number of kidney transplants performed; 2. Efficiency: Based on the organ offer acceptance rate ratio; and 3. Quality: Assessed using metrics such as the CollaboRATE Shared Decision-Making Score, Colorectal Cancer Screening, Three-Item Care Transition Measure, and post-transplant composite graft survival rate.

   The model aims to improve care delivery capabilities, enhance efficiency, and ultimately enhance the quality of care provided by kidney transplant hospitals selected for participation. It is set to begin on January 1, 2025. Given the criteria used in the IOTA Model please answer the following questions in regard to the metrics used to measure OPOs under CMS-3380-F.

   a. In the proposed Increasing Organ Transplant Access Model (IOTA Model), CMS creates financial incentives for transplant centers with above average performance, a 'neutral zone' median performance and downside financial risk for below average performance. In stark contrast, CMS provides OPOs with no incentive for neutral zone and high performance and creates a penalty for median performance with automatic decertification for below average performance. Why has CMS taken such a drastically different policy approach for two components within the same system? Will CMS reconsider its approach to OPO performance metrics?

   b. In the proposed IOTA Model, CMS sets up 3 domains (achievement, efficiency and quality) with multiple measurable factors to assess transplant center performance. Moreover, CMS intends to risk adjust these measurements to ensure actual program performance rather than the underlying patient population. Does CMS plan to reconsider the current OPO metrics which establishes a single

domain (achievement) and does not risk adjust for underlying patient population? If not, why?

c. In the proposed IOTA Model, CMS explicitly recognizes that transplant program behavior drives whether or not kidneys are accepted and used for transplant. If so, why are OPOs held accountable and subject to automatic decertification based on a transplant rate that is actually measuring transplant center behavior outside of OPOs responsibility and control? Will CMS commit to changing the OPO performance metric to be consistent with its policy approach in IOTA?

Rep. Glenn Grothman (R-WI)

1. For more than 30 years, the 340B Drug Pricing Program has helped eligible providers stretch limited federal resources to reduce the price of outpatient pharmaceuticals for patients and expand health services to the patients and communities they serve. Hospitals use 340B savings to provide, for example, free care for uninsured patients, offer free vaccines, provide services in mental health clinics, and implement medication management and community health programs. Despite significant oversight from HRSA and the program's proven record of decreasing government spending and expanding access to patient care, some want to scale it back or drastically reduce the benefits that eligible providers and their patients receive from the program. Secretary Becerra, what steps is HHS taking to protect the 340B program from these attacks and ensure the program continues to help providers stretch limited resources and provide more comprehensive services to more patients?

2. As of today, more than 60% of Wisconsin's nursing homes would not meet one, two or all three of the minimum staffing standards. What is HHS's plan for assisting nursing homes to meet these standards when the people, especially RN's, do not currently exist?

    a. How does HHS expect facilities to pay for the standard? It is an unfunded mandate. Many facilities operate on thin margins or at a loss because they must rely on Medicaid as their chief payment source.

3. Providers have found the survey process (aka the yearly facility inspection of regulatory compliance and quality assurance) has gotten more and more punitive in nature, where it seems like the goal is to punish a facility rather than advancing quality care. Being overly punitive is counterproductive to what should be the mutual goal of all parties – to advance quality care. Is the purpose of CMS's nursing home survey/enforcement process primarily meant to be punitive, or is it meant to identify and correct areas of concern/noncompliance in an effort to advance quality of care?

4. The CMS FY 25 Prospective Payment System (PPS) Proposed Rule for nursing homes includes an important 4.1% PPS rate increase, but it also includes new opportunities for CMS to pile on financial penalties that could financially cripple many providers. Do you believe CMS's new proposal to create more opportunities to financially devastate nursing homes via high Civil Money Penalties (CMPs – aka fines) will make it harder for

providers to ensure quality care and access to care in communities across Wisconsin and across the country?

5. HRSA began a shortage designation modernization project more than 10 years ago. It had projected to start removing HPSAs under this new methodology during COVID but delayed the implementation until the end of last year when it decided to proceed. As a result, a number of hospitals and other health care facilities lost their HPSA designation in 2024, at a time when healthcare workforce shortages seem to be stabilizing but remain critical for many provider types. We expect more areas will lose their HPSA designation under this next cycle as it progresses this year. HRSA also recently announced it would be increasing loan repayment amounts for those eligible under the National Health Service Corps Loan Repayment Program, which is beneficial for those who retain their HPSAs but does nothing for those who lose access to it. Nearly all sectors are experiencing workforce shortages, and the HPSA tools help health care compete, given the additional challenges the sector faces, such as requirements to staff hospitals and emergency departments 24/7.

    a. Certainly there's value in attempting to modernize data collection. However, did HRSA consider recalibrating how it calculates HPSA scores when it found out the number of areas losing access to HPSA benefits given the new way data is reported and collected by HRSA? Has HRSA considered what impact this continued policy of withdrawing HPSAs will have on the health care workforce?

    b. What can HHS do to help areas that lose their HPSA but still have workforce needs?

Rep. Rick Allen (R-GA)

1. Back in February, the National Association of Attorneys General sent a letter to Congressional leaders on behalf of a bipartisan group of 39 attorneys general, including Georgia AG Chris Carr, urging action on pharmacy benefit manager (PBM) practices. Their letter outlined several PBM business practices, such as spread pricing and tying their own compensation to the list price of medicine, that are increasing costs for millions of patients, employers, and community pharmacies not only in my state but across the country.

    a. Secretary Becerra, since you've mentioned on record that HHS is currently enforcing the Drug Price Transparency rule, I am assuming you also agree something needs to be done to protect patients and stakeholders from such practices. YES, or NO?

    b. Even though you've previously stated that HHS is actively enforcing the Drug Price Transparency rules, we have been waiting years for any enforcement. What is your department doing to directly help community pharmacists and patients, especially those who are in rural and underserved communities, who are being squeezed by PBMs and their bad practices?

2. I recently sent a letter to the Department of Labor regarding so-called alternative funding programs, or AFPs. AFPs intentionally steer beneficiaries toward manufacturer or independent charitable patient assistance programs intended for the uninsured or underinsured. Third-party vendors are increasingly advising employers to turn to AFPs as a solution for high specialty drug costs, while advising plan sponsors to exclude coverage for many of these specialty drugs, forcing enrollees to navigate patient assistance programs to maintain access to their medication. In short, I am concerned that AFPs may mislead employers, make it more challenging for patients to access lifesaving specialty medications, and wrongfully utilize patient assistance funds for their gains. Has HHS taken any actions to address AFPs?

3. Congress passed the No Surprises Act to create transparency in medical billing. However, according to the GAO, the Department's implementation of the No Surprises Act has led to "over 61 percent of the 490,000 filed claims remaining unresolved as of June of 2023." And thanks to this Administration's failed fiscal policies, clinicians are facing increased costs, and the thousands of claims that are held up in the Federal Independent Dispute Resolution (IDR) Process are further exacerbating their financial problems. What will your department do to ensure payment is processed in a timely manner once a resolution is reached in the IDR process so that they can avoid the added burden of reaching out to HHS?

Rep. Aaron Bean (R-FL)

1. Mr. Secretary, I am a co-sponsor of the bipartisan HELP Copays Act (H.R. 830), which would ban copay accumulator adjustment programs and mitigate copay maximizer programs. You recently testified before our colleagues on the House Energy & Commerce Subcommittee on Health on April 17, and in response to a question about the 2023 District Court ruling over copay accumulators from Rep. Buddy Carter, you said, "We will comply with the law; that's our obligation," and "We are going to follow the court ruling wherever we can." However, I was troubled to learn that you went on to confuse the issue, saying that this was an issue in the Medicare program, where you should know that copay coupons are prohibited.

    a. Will your department issue guidance stating that the 2020 Notice of Benefit and Payment Parameters regulation regarding copay accumulators is in effect and that CMS will enforce a ban on copay accumulator adjustment programs except in cases where a generic is available?

    b. If you plan to issue guidance, when can we expect this guidance?

Ranking Member Robert C. "Bobby" Scott (D-VA)

1. On Tuesday, May 21, 2024, the Office of Community Services and the Administration for Children and Families within the Department of Health and Human Services (HHS)

issued a final report related to the state of Florida's administration of the Low Income Home Energy Assistance Program (LIHEAP), the Low Income Household Water Assistance Program (LIHWAP), and the Community Services Block Grant (CSBG) following reports of significant service disruptions in spring of 2023.[2] These programs collectively serve some of our most vulnerable individuals and families. Now that HHS has issued its final report, it is important that the Committee understand the full scope of what occurred in Florida and what will be done to ensure that program participants do not face further disruption.

a. Can you tell the Committee how long LIHEAP and LIHWAP service disruptions in the state lasted? What is the estimated amount of energy and water assistance benefits that were not distributed during that time period? How many people in the state were impacted by Florida's shutdown of LIHEAP and LIHWAP, including those who were unable to apply for or receive LIHEAP and LIHWAP assistance?

b. Media reports and accounts from stakeholders indicate that Community Action Agencies (CAAs) in Florida, which administer the CSBG program as well as other safety net programs, faced a lapse in funding for several weeks, causing service disruptions and staff furloughs. How many CAAs had to shutter their operations due to the state of Florida's funding lapses? How many CAA staff were furloughed? For how long were CAAs shut down? How many CAAs took out credit to cover expenses?

2. The *No Surprises Act* greatly expanded the responsibilities of both the Department of Health and Human Services and the Department of Labor to protect consumers from surprise medical billing. In addition, the law includes several consumer protections on issues, such as health care price transparency, health plans' obligation to maintain accurate provider directories, and continuity of care requirements.

a. How would this year's proposed budget support on-going implementation and enforcement of the *No Surprises Act*?

b. What would the impact be if Congress does not extend the implementation funding provided by the *Consolidated Appropriations Act, 2021*?

Rep. Suzanne Bonamici (D-OR)

1. Community Action Agencies (CAAs) provide essential services and programs that meet the unique needs of their local communities and empower low-income individuals and

[2] Margie Menzel, *Budget snafu leaves agencies serving Florida's poor without a safety net*, WFSU News (Apr. 18, 2023), https://wusfnews.wusf.usf.edu/politics-issues/2023-04-18/budget-snafu-leaves-agencies-serving-floridas-poor-without-a-safety-net. *See* also Alex Harris, *Florida froze program to help with power bills. Advocates worry it could happen again*, Miami Herald (Aug. 23, 2023), https://www.miamiherald.com/news/local/environment/article277473348.html. *See* also Low Income Assistance Programs Temporarily Suspended, Citrus County Board of County Commissioners, https://www.citrusbocc.com/news_detail_T12_R2013.php (last visited May 21, 2024).

families to achieve economic stability. Unfortunately, the slow distribution of federal Community Service Block Grant (CSBG) allotments from state agencies limits CAAs' reach. In 2015, the Department of Health and Human Services (HHS) adopted guidance for state and federal accountability measures, which includes a measure on timely payments of grant and subgrant funding. This metric evaluates payments from HHS to the states and from states to the CAAs. Despite these actions by HHS to address this issue, local agencies remain frustrated by the slow distribution of funds from their state.

a) How can HHS improve delivery of federal CSBG funds to local CAAs in a timely manner?

2. HHS recently requested comments on a proposed revision of the CSBG annual report in an effort to reduce the administrative burden of reporting; however, the annual report is a component and not the entirety of federal CSBG reporting requirements.

   a) How is HHS working to reduce excess paperwork across the board, especially for smaller CAAs, and streamline reporting systems for local agencies that administer multiple programs, such as Head Start and Low-Income Home Energy Assistance, in addition to CSBG?

   b) Many local CAAs work with state agencies that administer CSBG and related programs, how will HHS prevent duplicative state reporting requirements on CAAs?