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

Question #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?

Response:
People deserve access to equitable health care, free of discrimination, consistent with the law. This work is led by the HHS Office for Civil Rights (OCR) and Section 1557 does not authorize OCR or CMS to require a health plan not otherwise subject to section 1557 to comply with the statute.

The Public Health Service Act (PHS Act) section 2791(d)(8)(C) defines the term "Non-Federal governmental plan" as a governmental plan that is not a Federal governmental plan. Some examples of non-Federal governmental plans are group health plans that are sponsored by states, counties, school districts, and municipalities. Under 45 C.F.R. § 146.145(a), a "group health plan means an employee welfare benefit plan to the extent that the plan provides medical care (including items and services paid for as medical care) to employees (including both current and former employees) or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise." Non-Federal governmental plans can operate as self-funded group health plans, purchase a fully insured group health insurance product, or consist of a mixture of self-funded and fully insured options.

Non-Federal governmental plans are not regulated the same way as insurance companies or private employer health plans. The statutory framework for enforcement of non-Federal governmental plans was established in Part A of title XXVII of the PHS Act with the enactment of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Patient Protection and Affordable Care Act, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010, enacted on March 30, 2010, (collectively known as the Affordable Care Act or ACA) reorganized, amended, and added to the provisions of Part A of title XXVII of the PHS Act. On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which included the No Surprises Act, was signed into law. The No Surprises Act (NSA) provides federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise bills arise most frequently. The CAA added provisions that apply to group health plans and health insurance issuers in the group and individual market in a new Part D of title XXVII of the PHS Act. Accordingly, non-Federal governmental plans are subject to the provisions of Part A of title XXVII of the PHS Act, including any changes made by the ACA and NSA.

The provisions of title XXVII of the PHS Act that apply to group health plans that are non-Federal governmental plans are enforced by the Centers for Medicare & Medicaid Services (CMS), on behalf of HHS, under PHS Act section 2723(b)(1)(B) using the procedures described in 45 C.F.R. §150.301, et seq. Pursuant to this authority, CMS may investigate, work with the plan to implement corrective action, or impose civil monetary penalties for any non-Federal governmental plan that fails to comply with applicable PHS Act requirements.

Question #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?

Question #3

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

Question #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?

Question #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?

Question #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?

Response to Questions 2-6:

More than 21.4 million people selected or were automatically re-enrolled in an Affordable Care Act (ACA) Marketplace health plan nationwide during the 2024 Marketplace Open Enrollment Period (OEP) that ran from November 1, 2023-January 16, 2024 for most Marketplaces. More Americans signed up for high-quality, affordable health insurance during the 2024 Marketplace OEP than ever before, and millions of working families are saving $800 a year on their premium due to the expanded premium tax credits extended in the Inflation Reduction Act. Total plan selections include 5.2 million people who are new to the Marketplaces for 2024, and 16.2 million people who had active 2023 coverage and made a plan selection for 2024 coverage or were automatically re-enrolled. 5.1 million more consumers signed up for coverage during the 2024 OEP compared to the 2023 OEP, a 31% increase. Nationwide, the number of new consumers selecting Marketplace coverage during the 2024 OEP increased by 41%, to 5.2 million from 3.7 million in the 2023 OEP.

This year, individuals benefited from a highly competitive Marketplace. For the third consecutive year,

consumers continue to have more choices of health insurance issuers. For plan year 2024, 96% of HealthCare.gov consumers have access to three or more health insurance issuers, up from 93% in plan year 2023. At the same time CMS created policies aimed to mitigate choice overload and present consumers with meaningful plan choices. New standardized plan options were available beginning in 2023 through HealthCare.gov, which helped consumers compare and select plans. ACA plans are serving a demonstrated need for Americans who may not have the option to enroll in employer-sponsored coverage.

To build on this success, the FY 2025 budget would invest in making private insurance even more affordable. The FY 2025 budget proposes to permanently extend the enhanced premium tax credits that were extended through 2025 in the Inflation Reduction Act. The budget would provide Medicaid-like coverage to low-income individuals living in states that have not expanded Medicaid under the Affordable Care Act, paired with financial incentives to ensure States maintain their existing expansions. The budget would build on the No Surprises Act to extend consumer surprise billing protections to ground ambulances. In addition, the budget would extend the $35 cap per monthly insulin product, already in place for Medicare beneficiaries under the Inflation Reduction Act, to consumers with group and individual market coverage.

With respect to the use of stop-loss insurance by employers with self-insured group health plans, the Department of Labor is the agency primarily tasked with administration of requirements applicable to private employer sponsored self-insured group health plans under Title I of ERISA.

Question #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?

Response:

See response to question 8 and response to Questions 12-13.

Question #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?

Response (7-8):

Patients and their families deserve the security of knowing that the insurance they buy will be there for them when they need it. Short-term, limited-duration insurance (STLDI) is a type of health insurance that is designed to fill temporary gaps in coverage when an individual is transitioning from one source of coverage to another. STLDI is excluded from the definition of individual health insurance coverage under the Public Health Service Act and, therefore, is generally not subject to the applicable federal individual market consumer protections and requirements for comprehensive coverage under the ACA and other federal laws. For example, STLDI is not subject to the prohibition on discrimination based on health status, prohibition of preexisting condition exclusions, and the prohibition on lifetime and annual dollar limits on essential health benefits. Thus, individuals

who enroll in STLDI are not guaranteed these key consumer protections under the ACA. STLDI policies tend to offer limited benefit coverage and have relatively low actuarial values. These plans therefore expose enrollees to the risk of high out-of-pocket health expenses and medical debt.

On April 3, 2024, the Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, the Departments) released final rules regarding STLDI and independent, noncoordinated excepted benefits coverage. These final rules finalize some of the amendments set forth in the July 12, 2023, proposed rules. These regulatory amendments further the goals of the ACA by improving access to affordable and comprehensive coverage, strengthening health insurance markets, and promoting consumer understanding of their coverage options. Because STLDI and fixed indemnity insurance are sold outside of the Exchanges and are generally not subject to the Federal consumer protections and requirements for comprehensive coverage, consumers may have limited information about the limitations, value, and quality of the coverage being sold, and it might be mistakenly viewed as a substitute for comprehensive coverage.

Question #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?

Response:

A group health plan is subject to Section 1557 if it is a recipient (or subrecipient) of Federal financial assistance as set forth under 45 C.F.R. § 92.2(a)(1). See 89 Fed. Reg. 37522, 37620 (May 6, 2024). A health insurance issuer is subject to Section 1557 if it is a recipient (or subrecipient) of Federal financial assistance as set forth under 45 C.F.R. § 92.2(a)(1). Section 1557 applies to all the operations of a recipient principally engaged in the provision or administration of health insurance coverage or other health-related coverage as set forth under the definition of "health program or activity" at 45 C.F.R. § 92.4, including its third-party administrator activities for a self-funded group health plan. See 89 Fed. Reg. 37522, 37541, 37625 (May 6, 2024).

HHS does not regulate TPAs. The Department of Labor has jurisdiction over TPAs if they are acting as fiduciaries for an ERISA group health plan.

The Department of Labor is the agency primarily tasked with administration of requirements applicable to private employee benefit health plans under Title I of ERISA, including certain service providers who provide "brokerage services" or "consulting" to ERISA-covered group health plans.

Question #10

Telehealth

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?

Response:
The Departments of HHS, Labor, and the Treasury recognize that telehealth and other remote care services can be an important tool in the delivery of healthcare. The COVID-19 pandemic posed critical challenges to the delivery of healthcare services as jurisdictions issued stay-at-home orders and providers limited their operations in order to minimize the risk of exposure to and the community spread of COVID-19. The Departments generally encouraged use of these telehealth services during the COVID-19 pandemic to help ensure that plans and issuers were able to provide a robust variety of treatment, including for mental health and substance use disorder services, and to ensure that consumers were able to access the healthcare services they needed.

As noted in the 2022 Mental Health Parity and Addiction Equity Act (MHPAEA) Report to Congress, the Departments continue to recommend that Congress consider ways to permanently expand access to telehealth and remote care services, while ensuring that individuals receiving telehealth or remote care are still covered by important consumer protections that might not otherwise apply to stand-alone telehealth benefits. Telehealth has become a vital means of providing health care, including mental health and substance use disorder care, especially in light of the COVID-19 pandemic. Nonetheless, there are noteworthy barriers to ensuring access to telehealth services, including limited broadband access and interstate licensing requirements. The Departments look forward to working with Congress and stakeholders to identify ways to achieve this goal.

Question #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?

Response:
As hospitals expand ownership of outpatient and physician office settings, consumers are seeing an uptick in fees for more than just the care provided to them. These "facility fees" are increasingly a driver of healthcare costs in America, and are leading to consumers being charged as though they received treatment in a hospital even if they never entered one. This proposal would prohibit hospitals from billing unwarranted facility fees for telehealth services and for certain other outpatient services.

Question #12

Association Health Plans

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?

Question #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?

Response (12-13):
The Department of Labor is the agency primarily tasked with administration of requirements applicable to private employee benefit health plans under Title I of ERISA.

Short-Term Limited-Duration Insurance

Question #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?

Response:
On April 3, 2024, HHS, Labor, and the Treasury (collectively, the Departments) released final rules regarding short-term, limited-duration insurance (STLDI) and independent, noncoordinated excepted benefits coverage. These final rules finalize some of the amendments set forth in the July 12, 2023, proposed rules. These regulatory amendments further the goals of the ACA by improving access to affordable and comprehensive coverage, strengthening health insurance markets, and promoting consumer understanding of their coverage options.

Patients and their families deserve the security of knowing that the insurance they buy will be there for them when they need it. STLDI is a type of health insurance that is designed to fill temporary gaps in coverage when an individual is transitioning from one source of coverage to another. STLDI is excluded from the definition of individual health insurance coverage under the Public Health Service Act and, therefore, is generally not subject to the applicable federal individual market consumer protections and requirements for comprehensive coverage under the ACA. For example, STLDI is not subject to the prohibition on discrimination based on health status, prohibition of preexisting condition exclusions, and the prohibition on lifetime and annual dollar limits on essential health benefits. Thus, individuals who enroll in STLDI are not guaranteed these key consumer protections under the ACA.

The Departments acknowledge that some individuals who purchase STLDI policies may lose coverage and have to wait until the next annual individual market open enrollment period to purchase comprehensive coverage (for example, if an individual with STLDI purchased after September 1, 2024, exhausts their renewal or extension options or is unable to enroll in STLDI offered by a different issuer in a 12-month period) or may choose to become uninsured. Some individuals might also seek coverage in unregulated markets. 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. The Departments find, however, that the overall risk that some individuals may become uninsured or lose coverage because of the above circumstances is outweighed by the fact that a substantial number of individuals will likely benefit as a result of the final rules' STLDI provisions. Overall, the Departments are of the view that STLDI serves better as a bridge between different sources of comprehensive coverage than as an alternative to comprehensive coverage.

Surprise Billing

Question #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?

Question #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?

Question 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?

Response to Questions 15-17:

The Departments are continuing to work to address specific issues critical to improving the Federal IDR process in response to feedback and challenges noted by interested parties. On October 27, 2023, the Departments released proposed rules on new processes and polices related to the operation of the Federal IDR process which we believe would expedite the processing of disputes by certified IDR entities. The "Federal Independent Dispute Resolution (IDR) Operations" proposed rules address specific issues critical to improving the functioning of the Federal IDR process in response to feedback and challenges noted by interested parties. Overall, if finalized, the proposed rules would facilitate improved communications between payers, providers, and certified IDR entities; adjust specific timelines and steps of the Federal IDR process; establish new batching provisions; create more efficiencies; and change the administrative fee structure to improve accessibility of the process. It is the Departments' intention that together, these proposals, if finalized, would result in improved operations of the Federal IDR process and more timely payment determinations.

The comment period for the proposed rules, closed on January 2, 2024 but it was subsequently reopened from January 22, 2024, to February 5, 2024, to provide additional time for interested parties to consider and comment on any implications of the IDR Fees final rules. The Departments are in the process of reviewing the comments received.

In addition, we have made numerous updates to the Federal IDR process since it opened, and we always welcome open dialogue with our stakeholders regarding the functionality of the Federal IDR portal. The Departments understand that there are additional functionalities that would help disputing parties engage more efficiently with the Federal IDR process. We will continue to explore changes to Federal IDR portal functionalities to address feedback from interested parties.

The number of disputes initiated through the Federal IDR portal over the first six-month period of 2023 was 13 times greater than the Departments initially estimated the number of disputes initiated would be over the course of a full calendar year and has grown each quarter. The majority of disputes were initiated by a small number of initiating parties or their representatives. The top ten initiating parties represented approximately 78% of all disputes initiated in the first six months of 2023. Many of the top initiating parties are (or are represented by) large practice management companies, medical practices, or revenue cycle management companies representing hundreds of individual practices, providers, or facilities. The top three initiating parties represent thousands of clinicians across multiple states and accounted for approximately 58% of all disputes submitted in the first six months of 2023. Increased dispute submissions from these top initiating parties in 2023 contributed to the overall increase in dispute volume in the first six months of 2023.

For example, to address the high volume of disputes, the Departments worked to improve and automate how the Federal IDR portal operates, as well as provide technical assistance and guidance to certified IDR entities and disputing parties to make the process run more smoothly. For example, the Departments made major updates to the Federal IDR portal, including updating webforms to capture information to aid in eligibility determinations, expanding data validations to ensure disputing parties are inputting accurate information, updating system functionality to accommodate changing requirements as a result of court rulings (including temporarily suspending the Federal IDR portal functionality to ensure that guidance and IT systems were consistent with court orders), automating email communications to reduce delays between disputing parties and certified IDR entities, and improving how the Departments respond to inquiries from certified IDR entities and disputing parties.

The Departments' work to respond to initial IDR process challenges is yielding substantial results. Certified IDR entities have scaled up their operations to address the high volume of disputes. Certified IDR entities rendered 83,868 payment determinations in the first six months of 2023, more than five times the number of payment determinations made in all of 2022 (16,238). Certified IDR entities have increased their payment determination output each quarter compared to the prior quarters. Certified IDR entities made 26,741 payment determinations in the first quarter of 2023, 64% more than the prior quarter, and made 57,127 payment determinations in the second quarter of 2023, which was more than twice the number from the prior quarter. Certified IDR entities closed 134,036 disputes in the first six months of 2023. Disputes were closed for several reasons, including: a payment determination was made, the dispute was determined ineligible for the Federal IDR process, the dispute was withdrawn, parties reached a settlement, or the dispute was closed for administrative reasons, such as unpaid fees. Despite the increase in the number of payment determinations, due to the high volume of disputes initiated, some disputing parties are still awaiting eligibility and payment determinations. The Departments' objective is to help certified IDR entities and disputing parties obtain resolution on disputes as expeditiously as possible.

For each calendar quarter in 2022 and each calendar quarter in subsequent years, the Departments are required to publish on a public website certain information about the Federal IDR process. This information includes the following:

1. The number of Notices of IDR Initiation submitted during the calendar quarter.
2. In the case of items or services that are not air ambulance services, the size of the provider practices and the size of the facilities submitting Notices of IDR Initiation during the calendar quarter.
3. The number of Notices of IDR initiation for which a final determination was made, including for each final determination:
    a. A description of each item and service or air ambulance service (as applicable);
    b. The geographic area in which the items and services were provided;
    c. The amount of the offer submitted by each party expressed as a percentage of the qualifying payment amount (QPA);
    d. Whether the offer selected by the certified IDR entity was the offer submitted by the plan or issuer (as applicable) or was the offer submitted by the nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable) and the amount of the selected offer expressed as a percentage of the QPA;
    e. In the case of items or services that are not air ambulance services, the category and practice specialty of each provider or facility involved in furnishing such items and services;
    f. In the case of air ambulance services, the air ambulance vehicle type; including the clinical capability level of such vehicle;
    g. The identity of the health plan or health insurance issuer, provider, or facility;

    h. The length of time in making each determination; and
    i. The compensation paid to the certified IDR entity.
4. The number of times the payment amount determined (or agreed to) exceeds the QPA, specified by items and services.
5. The amount of expenditures made by the Departments during the calendar quarter to carry out the Federal IDR process.
6. The total amount of administrative fees paid during the calendar quarter.
7. The total amount of compensation paid to certified IDR entities during the calendar quarter.

The Departments are committed to publishing this required data, bringing transparency to the Federal IDR process, and providing important information to the public, disputing parties, and Congress.

Since first launching the Federal IDR portal, the Departments have made, and will continue to make, adjustments to operations and policy, including through regulations (such as the operations and fees rules described above), as the Departments find more ways to refine and improve the Federal IDR process. As a result of system enhancements that the Departments have implemented over the past year, the Departments have been able to extract all the data necessary to begin publishing the quarterly report required under the NSA. On February 15, 2024, the Departments released the first set of detailed Public Use Files containing all required data elements for quarterly reports, covering the first two calendar quarters of 2023, as well as supplemental data to improve transparency around the Federal IDR process.

Question #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.

Response:

On September 16, 2022, the Centers for Medicare & Medicaid Services (CMS), along with the Departments of Health and Human Services (HHS), Labor, and the Treasury (the Departments) and the Office of Personnel Management (OPM) published a Request for Information (RFI) that sought comments from interested parties on a number of issues related to AEOB and insured Good Faith Estimate (GFE) provisions, including recommendations on exchanging data between providers and facilities to payers, and the economic impacts of implementing these requirements. The Departments and OPM received 285 comments from providers, payers, vendors, consumer and patient advocates, and other stakeholders. The Departments and OPM are carefully considering this feedback as we engage in rulemaking on these provisions.

The Departments and OPM are working to implement the GFE and AEOB requirements in stages. Using this approach, the Departments and OPM can better ensure each stage is informed by thorough research and collaboration with impacted stakeholders and, importantly, supported by appropriate technical standards for data sharing between providers and payers. This deliberate, incremental approach will ensure that patients get meaningful and actionable information about their care. The Departments and OPM are incorporating lessons learned from implementing the uninsured (or self-pay) GFE provisions as well as industry feedback from the

preliminary development of GFE and AEOB data exchange standards as we develop proposed rules on insured GFE and AEOB provisions and technical requirements. The Departments and OPM have been, and continue to be, engaged in a number of efforts that will help inform successful rulemaking and implementation of the insured GFE and AEOB requirements.

Question #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?

Response:
To implement the No Surprises Act, the Departments scaled up expertise and resources for rulemaking, technical builds, enforcement, and staffing. Section 103 of the NSA directed the Departments to establish a Federal IDR process that would be funded by administrative fees that are estimated to account for the estimated costs of carrying out the Federal IDR process. However, the Federal IDR process is only one part of the NSA, which contains a number of other provisions that protect consumers from surprise medical bills and promote transparency in health coverage. While the original appropriation expires at the end of 2024, most of the statutory requirements added by the No Surprises Act and Title II Transparency provisions are permanent and the Departments will have ongoing responsibilities. Some of these responsibilities include enforcement of critical consumer protections against surprise billing and cannot be funded with IDR administrative fees.. Without additional dedicated funding, the Departments may need to phase-down or phase-out certain enforcement efforts, including investigation and resolution of some health plan and provider complaints. For example, HHS may have to significantly adjust its staffing of the No Surprises Help Desk, curtailing consumers' and providers' access to a crucial resource for information about NSA requirements and protections, and leaving them without a central point of contact to submit complaints. HHS further may limit its provider enforcement activities, leaving consumer complaints of illegal balance bills and other violations of the NSA unanswered.
Other impacts include:
Plan enforcement activities, including market conduct exams related to late payments by non-prevailing parties following a payment determination;
Policy development and program implementation related to the NSA's advanced explanations of benefits (AEOBs);
Prescription drug data collection, preventing HHS from collecting, analyzing, and publishing findings about prescription drug pricing and the impact of prescription drug rebates on patient out-of-pocket costs; and
Air ambulance data collection.

Mental Health Parity

Question #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.

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

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

Question #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?

Response 20-21:

Ensuring robust access to mental health care has been a bipartisan priority for almost 16 years, since the 2008 enactment of the Mental Health Parity and Addiction Equity Act (MHPAEA), a landmark law that called for mental health care benefits covered by health plans to be provided in parity with medical/surgical benefits health care benefits, and which was strengthened on a bipartisan basis in 2020 with the enactment of the Consolidated Appropriations Act, 2021 (CAA, 2021). Yet today, too many Americans still struggle to find and afford the mental health care they need. Of the 21% of adults who had any mental illness in 2020, less than half received mental health care; fewer than one in ten with a substance use disorder received treatment. Research shows that people with private health coverage have a hard time finding a mental health provider in their health plan's network. Despite the repeated bipartisan efforts aimed at strengthening mental health parity, insurers too often make it difficult to access mental health treatment, causing millions of consumers to seek care out-of-network at significantly higher costs and pay out of pocket, or defer care altogether.

On July 25, 2023, the Departments of Labor, Health and Human Services, and the Treasury (the Departments) proposed rules to amend regulations implementing MHPAEA. The proposed rules reinforce MHPAEA's fundamental goal of ensuring that individuals have comparable access to mental health and substance use benefits and medical/surgical benefits health benefits. The proposed rules, if finalized, would increase parity in access to in-network mental health and substance use disorder care as compared to medical/surgical care and eliminate greater barriers to access to mental health and substance use disorder care as compared to medical/surgical care that keep people from getting the care they need, when they need it. The Departments recognize that telehealth has become a vital means of providing health care, including mental health and substance use disorder care, especially in rural areas, and in light of the COVID-19 pandemic. In the 2023 MHPAEA proposed rules, the Departments solicited comments on issues related to rural Americans' access to providers of mental health and substance use disorder services and telehealth. For example, the Departments solicited comments on ways that telehealth or other remote care services can be used to enhance access to mental health and substance use disorder treatment under the Departments' existing authority for both routine and crisis care for behavioral health conditions, including through parity requirements with respect to financial requirements and treatment limitations.

In 2020, Congress enacted the CAA, 2021, which made changes to MHPAEA to require group health plans (plans) and health insurance issuers offering group or individual health insurance coverage (issuers) that include both medical/surgical benefits and mental health or substance use disorder benefits and impose nonquantitative treatment limitations (NQTLs) on mental health and substance use disorder benefits to perform and to document comparative analyses of the design and application of NQTLs. The Departments' proposed rules, if finalized, would make clear that plans and issuers need to evaluate the outcomes of their coverage rules to make sure that the NQTLs that plans and issuers apply do not create material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. This would include looking at data such as claims denials, as well as in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers

accepting new patients), and provider reimbursement rates. These NQTL comparative analyses would show plans and issuers where they are failing to meet requirements under MHPAEA. Where they fail to meet the requirements of the law, plans and issuers would be required to improve parity in access to mental health and substance use disorder care – for example, by including more mental health professionals in their networks.

The proposed rules would, if finalized, provide specific examples that make clear that plans and issuers cannot impose more restrictive prior authorization requirements, other medical management techniques, or network participation requirements that make it harder for people to access mental health and substance use disorder benefits than their medical/surgical benefits. Under the proposed rule, health plans would have to use similar factors in setting out-of-network payment rates for mental health and substance use disorder providers as they do for medical providers. The comment period on these proposed rules closed on October 17, 2023.

As stated in the 2022 and 2023 MHPAEA Reports to Congress, the Departments continue to recommend that Congress consider ways to permanently expand access to telehealth and remote care services. As noted above, telehealth has become a vital means of providing health care, including mental health and substance use disorder care, especially in light of the COVID-19 pandemic. Nonetheless, there are noteworthy barriers to ensuring access to telehealth services, including limited broadband access and interstate licensing requirements. The Departments look forward to working with Congress and stakeholders to identify ways to achieve this goal.

Question #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?

Question #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?

Question #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?

Question #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 Mental Health and Substance Use Disorders 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?

Question #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.

Response 22-26:

On July 25, 2023, the Departments of Labor, Health and Human Services, and the Treasury (the Departments) proposed rules to amend regulations implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and proposed new regulations implementing the nonquantitative treatment limitation (NQTL) comparative analyses requirements under MHPAEA, as amended by the Consolidated Appropriations Act, 2021. The proposed rules would amend the existing NQTL standard to prevent group health plans and health insurance issuers offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits from using NQTLs to place greater limits on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. As part of these changes, the proposed rules would require plans and issuers to collect and evaluate relevant data in a manner reasonably designed to assess the impact of NQTLs on access to mental health and substance use disorder benefits and medical/surgical benefits, and propose a special rule for NQTLs related to network composition. The proposed rules also would amend existing examples and add new examples on the application of the rules for NQTLs to clarify and illustrate the protections of MHPAEA. In addition, the proposed rules would set forth the content requirements for NQTL comparative analyses and specify how plans and issuers must make these comparative analyses available to the Departments, as well as to an applicable State authority, and participants, beneficiaries, and enrollees. The Departments also solicited comments on whether there are ways to improve the coverage of mental health and substance use disorder benefits through other provisions of Federal law. The comment period closed on October 17, 2023.

Drug Pricing

Question #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?

Response:

The Inflation Reduction Act limits Medicare beneficiary cost-sharing to $35 per covered insulin product for a month's supply. The President's FY 2025 Budget includes a proposal to extend the cap on patient cost-sharing to insulin products in commercial markets. This would allow more of the over 37 million Americans with diabetes to lock in this lower cost.

Question #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.

Question #28a
Please provide an update on these oversight efforts.

Response:
HRSA places the highest priority on the integrity of the 340B Program and continually works to strengthen oversight of the Program within its current authority. Specifically, the FY 2025 President's Budget proposes to enhance program integrity by requiring covered entities to annually report to HRSA how savings achieved through the 340B Program benefits the communities they serve and provide HRSA with regulatory authority to implement this requirement.

Approximately 14,000 covered entities and over 800 manufacturers participate in the Program. HRSA audits 200 covered entities, including their off-site, outpatient facilities and contract pharmacies, annually using a risk-based selection method, executes targeted audits where potential compliance issues may exist, and employs a number of approaches to oversee covered entity compliance of the 340B Program.

Since 2012, HRSA has completed over 2,200 covered entity audits, including reviews of over 29,000 offsite outpatient facilities, over 58,000 contract pharmacies, and 46 manufacturer audits. The results of these audits are available on the HRSA website.

Question #28b
Should hospitals be able to use the 340B program to pad their bottom lines?

Response:
The 340B Program enables safety net health care providers to generate savings on their purchases of prescription drugs to support a broader array of services for the individuals and communities they serve.

Question #28c
What protections will you put in place to ensure that providers are only using the government-set price drugs for eligible patients?

Response:
HRSA currently assesses covered entities' eligibility when they seek to join the program, reviews compliance with program requirements annually, and conducts program integrity audits of covered entities. These efforts include oversight regarding compliance with the statutory prohibition on covered entities reselling or transferring 340B drugs to ineligible patients. The President's Budget also included a legislative proposal to require covered entities to report on the amount and use of their 340B savings. Additionally, HRSA has engaged in risk-based program integrity efforts focused on hospitals that were at higher risk of compliance issues due to volume of purchases; number of off-site, outpatient sites; or prior audit findings.

Question #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?

Response :
HHS supports continued drug innovation and believes it is vitally important that beneficiaries have access to innovative new therapies. The statute provides that drugs that have been approved by the FDA for at least seven years, or biologicals that have been licensed by the FDA for at least 11 years, are eligible for negotiation. Any drugs or biologicals selected for negotiation will have been on the market for quite some time.

The law requires CMS to exclude certain orphan drugs when identifying qualifying single source drugs, referred to as the orphan drug exclusion. Section 1192(e)(3)(A) of the Act describes a drug that qualifies for the orphan drug exclusion as "a drug that is designated as a drug for only one rare disease or condition under section 526 of the Federal Food, Drug, and Cosmetic Act and for which the only approved indication (or indications) is for such disease or condition." The draft guidance for the second cycle of negotiations can be accessed at: https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

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

HHS remains strongly committed to doing what we can, such as through recommendations in guidance documents for industry and stakeholder engagement activities, to maintain and promote the robustness of the development pipeline for safe and effective drugs, including biological products to treat patients, including those with rare diseases. For example, FDA has published more than 18 guidances since 2018 on topics that are highly relevant to drug, including biological product development for rare diseases. Some recent examples of draft and final guidance documents include:

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

Question #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?

Response:
HHS intends to address, through rulemaking, issues left open by the Court's opinion, including whether financial assistance provided to patients by drug manufacturers qualifies as "cost sharing" under the Affordable Care Act. Pending the issuance of a new final rule, HHS does not intend to take any enforcement action against issuers or plans based on their treatment of such manufacturer assistance.

Question #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.

Response:
Since 2011, the Centers for Medicare & Medicaid Services (CMS) has produced a monthly NADAC file that almost all states use to set payment rates for pharmacies for covered outpatient drugs under the fee-for-service Medicaid program. The NADAC files are drawn from a voluntary, confidential, monthly survey that collects drug ingredient costs from retail community pharmacies based on their invoice prices. Recent NADAC rates from the April and May 2024 files show a decrease in the average costs of some drugs. CMS has confirmed the fluctuation is due to an increased number of, and more diverse set of, retail pharmacies responding to the survey for these two months.

Market Consolidation and Decreased Competition

Question #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*?

Response:
Enforcing the hospital price transparency requirements is a high priority for CMS in order to increase competition and bring down costs. It is imperative that consumers can access cost information to shop for care and save money and for employers to use data to negotiate more competitive rates. The hospital price transparency regulation became effective January 1, 2021, and requires each hospital operating in the United States to make public its standard charges for the items and services it provides. After significant outreach and technical assistance to hospitals, hospitals have made substantial progress since the hospice price transparency regulation went into effect in January 2021.

In CMS' enforcement of the hospital price transparency rules, the agency's goal is to increase access to useful, meaningful information for consumers and ensure hospitals are following through on their obligations to make information available. CMS is working closely with hospitals to bring them into compliance, and the agency in the process of examining further improvements to the program, including ways that CMS enforcement could be used to increase compliance. Between September and November 2022, CMS conducted website assessments of 600 hospitals randomly sampled from Homeland Infrastructure Foundation-Level Data. Of the 600 acute care hospitals sampled for the 2022 analysis, 493 (82 percent) posted a consumer-friendly display that met the consumer-friendly display website assessment criteria, 490 (82 percent) posted a machine-readable file that met the website assessment criteria, and 421 (70 percent) did both. The results of this website assessment suggest that there has been substantial progress in hospitals' implementation efforts since the Hospital Price Transparency regulation first went into effect, although approximately 30 percent of hospitals must still do more

to achieve full compliance. CMS is working closely with hospitals to bring them into compliance, and the agency in the process of examining further improvements to the program, including ways that CMS enforcement could be used to increase compliance.

In the CY 2024 Hospital Outpatient Prospective Payment System (OPPS), CMS finalized policies to strengthen compliance and improve the public's understanding and automated use of hospital information. CMS finalized a requirement for hospitals to display their standard charge information by conforming to a CMS template layout, data specifications, and data dictionary. These changes will increase standardization to help deliver on the promise of hospital price transparency, improve hospitals' ability to comply, enhance the public's ability to aggregate information (for example, for use in consumer-friendly displays), and streamline CMS's ability to enforce the requirements. Additionally, CMS finalized several regulatory additions and modifications to its enforcement provisions to improve CMS enforcement capabilities and increase transparency. These include submission of certification by an authorized hospital official as to the accuracy and completeness of the data in the machine-readable file and submission of additional documentation as needed to determine hospital compliance; submission of an acknowledgement of receipt of the warning notice in the form and manner and by the deadline specified; notification to health system leadership of compliance action; and publication on the CMS website CMS' assessment of a hospital's compliance, any compliance action taken and the status or outcome of such action, and notifications sent to health system leadership.

As of September 2023, CMS had issued approximately 989 warning notices and 631 requests for CAPs since the initial regulation went into effect in January 2021. Approximately 346 hospitals were determined by CMS after a comprehensive compliance review to not require any compliance action and approximately 738 hospitals received a closure notice from CMS after having addressed deficiencies indicated in a prior warning notice or a request for a CAP following an initial comprehensive compliance review. At the time of the publication of the CY 2024 OPPS/ASC proposed rule, we had imposed CMPs on four hospitals and publicized those CMP impositions on our website.

Question #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?

Response:

We understand this is an increasing concern, particularly as consolidation and closures continue to impact cost and access to care. CMS is happy to provide technical assistance on any legislation you have on this issue.

With respect to facility fees, as hospitals expand ownership of outpatient and physician office settings, consumers are seeing an uptick in fees for more than just the care provided to them. These "facility fees" are increasingly a driver of healthcare costs in America, and are leading to consumers being charged as though they received treatment in a hospital even if they never entered one. The FY 2025 Biden-Harris Budget would prohibit hospitals from billing unwarranted facility fees for telehealth services and for certain other outpatient services.

Question #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?

Response:
On August 20, 2021, the Departments of Labor, Health and Human Services (HHS), and the Treasury (the Departments) released FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (FAQs Part 49) announcing the deferral of enforcement regarding certain requirements, including the requirement that plans and issuers publish machine-readable files related to prescription drugs, pending further consideration by the Departments. In deferring enforcement of this requirement, the Departments noted the enactment of the prescription drug requirements under section 204 of division BB of the Consolidated Appropriations Act, 2021 (CAA), and stakeholder concern about potentially duplicative and overlapping reporting requirements for prescription drugs.
On September 27, 2023, the Departments released FAQs About Affordable Care Act Implementation Part 61 (FAQs Part 61) rescinding Q1 of FAQs Part 49, which had expressed the Departments' general policy of deferring enforcement of the TiC Final Rules' prescription drug machine-readable file requirement pending further consideration in a future rulemaking by the Departments. The Departments will address enforcement decisions under the relevant requirements of the TiC Final Rules on a case-by-case basis, as the facts and circumstances warrant.

Question #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.

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

In April 2022, CMS finalized a policy that requires Part D plans to apply all price concessions they receive from network pharmacies to the negotiated price at the point of sale, so that the beneficiary can also share in the savings. Specifically, CMS redefined the negotiated price as the baseline, or lowest possible, payment to a pharmacy, effective January 1, 2024. CMS is applying the finalized policy across all phases of the Part D benefit. This policy reduces beneficiary out-of-pocket costs and improves price transparency and market competition in the Part D program. We additionally published a memo to all Part D plan sponsors via CMS's Health Plan Management System (HPMS) on November 6, 2023, titled "Application of Pharmacy Price Concessions to the Negotiated Price at the Point of Sale Beginning January 1, 2024,"[1] which reiterates and emphasizes several key points related to this policy. In this memo, we strongly encouraged Part D plan sponsors to consider options such as payment plans or alternate payment arrangements in advance of the January 1, 2024, effective date and to provide a straightforward means of requesting such an arrangement. We additionally emphasized that Part D plan sponsors must meet the prompt payment requirements at 42 CFR § 423.520 and

[1] Available at https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-2-november-6-10

pharmacy access standards at 42 CFR § 423.120.

More recently, we reiterated these points in our December 14, 2023, "CMS Letter to Plans and Pharmacy Benefit Managers."[2] In this letter, we identified several concerns about practices by some plans and PBMs that threaten the sustainability of pharmacies and impede access to care. We encouraged plans and PBMs to work with pharmacies to alleviate these issues and safeguard access to care.

Our authority to specifically regulate pharmacy reimbursement from PBMs is limited. Section 1860D-11(i) of the Social Security Act prohibits CMS from interfering with the negotiations between drug manufacturers, pharmacies, and prescription drug plan sponsors and generally prohibits CMS from instituting a price structure for the reimbursement of covered part D drugs. However, CMS will continue to explore opportunities to bring transparency and market reforms that are within our statutory authority.

Religious Freedom, Gender, and Abortion
Gender Identity and Religious Freedom

Question #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?

Response
This rule does not require any foster parents with a religious objection to serving as a Designated Placement to seek a religious accommodation to continue to participate in the program. The rule welcomes faith-based organizations and religious foster parents to continue participation in the program, and the Administration for Children and Families (ACF) anticipates that many will choose to do so. The obligation to provide an environment that supports the child's LGBTQI+ status or identity under this rule applies only to those providers who have chosen to be Designated Placements. We anticipate that numerous faith-based organizations and religious foster parents will choose to be Designated Placements. But this rule does not require any provider to make that choice, and it does not impose any penalty or adverse consequence on providers with religious objections to serve as a Designated Placement. Indeed, the final rule states: "Nothing in this section shall be construed to require or authorize a State or Tribe to penalize a provider in the titles IV–E or IV–B programs because the provider does not seek or is determined not to qualify as a Designated Placement under this section." It makes clear that nothing in the rule requires or authorizes a state or tribe to penalize a provider that—for whatever reason—chooses not to be a Designated Placement. Rather, the rule places the responsibility on states and tribes—rather than on providers—to find Designated Placements for LGBTQI+ identifying children.

Question #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?

[2] https://www.cms.gov/newsroom/fact-sheets/cms-letter-plans-and-pharmacy-benefit-managers

Response
No, there is no contradiction. The final rule requires that title IV-E/IV-B agencies ensure a Designated Placement is available for all LGBTQI+ children in foster care who request or would benefit from such a placement and specifies the Designated Placement requirements for such children. It does not require that any specific provider become a Designated Placement for any child.

In contrast, the rule prohibits the state from discriminating against current or prospective foster or adoptive parents on the basis of their religious beliefs, sexual orientation, gender identity, gender expression, or sex. The financial penalties and mandatory corrective action would apply if the state delays, denies, or otherwise discourages individuals from being considered or serving as foster or adoptive parents based on these categories.

Question #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 gendertreatments?
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?

Response:
a. NIH has funded observational research studies to gather data about the short- and long-term effects of treatments that transgender youth and their parents have chosen in consultation with their medical providers.
b. Evidence from an NIH-funded observational study suggests puberty blockers have important mental health benefits for transgender youth, including reduced symptoms of depression and anxiety and higher rates of mental wellbeing, compared to youth who were not able to access puberty blockers. Puberty blockers are also used to treat cisgender girls with early onset puberty (i.e., entering puberty too early) and adolescent girls with endometriosis. Studies of puberty blockers in these contexts suggests no long-term physical health consequences[3,4] and in endometriosis, can halt disease progression and relieve debilitating pain.[5]
c. NIH has not funded any studies on the impact of puberty blockers on brain development.
d. NIH has not studied the fertility impacts of puberty blockers for transgender youth. However, as mentioned above, puberty blockers are also used to treat cisgender girls with early onset puberty and conditions like endometriosis. Studies of puberty blockers in these contexts suggest that there are no long-term fertility impacts of using puberty blockers.

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8686727/
[4] https://pubmed.ncbi.nlm.nih.gov/24033561/
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5997553/

e. Puberty blockers are reversible and ceasing to take puberty blockers will resume normal puberty[6,7].
f. There is no evidence to suggest that puberty blockers will lead to long-term sterility.
g. NIH is currently funding observational studies to understand the long-term health consequences of the use of puberty blockers. Studying puberty blockers on a range of outcomes is crucial to building our evidence base and improving our understanding of their long-term impacts so that children and their parents can make informed decisions about their use.

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

Response:
Yes. The Department's Office for Civil Rights enforces a range of civil rights, conscience, and religious freedom statutes and takes seriously the responsibility to effectively enforce each one. Within the last year, OCR has strengthened protections for conscience and religious freedom through the publication of three final rules including *Safeguarding the Rights of Conscience as Protected by Federal Statutes* (effective March 11, 2024), *Health and Human Services Grants Regulation* "HHS Grants Rule" (effective June 3, 2024), and Section 1557 of the Affordable Care Act: *Nondiscrimination in Health Program and Activities* (effective July 5, 2024).

The *Safeguarding the Rights of Conscience as Protected by Federal Statues* final rule clarifies the process for enforcing federal conscience laws and strengthens protections against conscience and religious discrimination in health care.

The HHS Grants Rule and Section 1557 of the Affordable Care Act final rules reiterate that a recipient may rely on applicable Federal protections for conscience and religious freedom, and that a particular application of a provision of either rule is not required when such protections apply.

Question #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?

Response:
Yes, the freedom to practice religious faith from discrimination certainly exists in the practice of medicine. That freedom is protected by various laws and regulations, including several conscience and religious freedom statutes that are enforced by the Department's Office for Civil Rights including the Church Amendments; Public Health Service Act, Section 245; The Weldon Amendment; and the Affordable Care Act. If a provider believes their Federally protected conscience or religious freedom rights have been violated, they may file a complaint with the Office for Civil Rights here.

Border Crisis and Child Labor

Question #41

[6] https://pubmed.ncbi.nlm.nih.gov/8198390/
[7] https://pubmed.ncbi.nlm.nih.gov/30112593/

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?

Question #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.

Did DOL warn HHS that these children were at risk for human labor trafficking at any time during this administration?
Do you believe that HHS properly vetted the sponsors of unaccompanied children who were found to be exploited by human labor traffickers?
Did HHS follow all protocols when vetting sponsors for unaccompanied children?

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

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?

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

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?

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?

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

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

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?

Response (41-42):

In fulfilling its sponsor placement responsibilities, HHS employs thorough sponsor screening and vetting processes for each category of sponsors that are based on child-welfare principles. To that end, ORR has implemented and funded seven-day-a-week case management, which seeks to ensure comprehensive staff support and that every child's case is worked on even after normal business hours. Additionally, ORR has made technological improvements to build in safeguards, streamline processes, and make it easier to identify potential

child welfare concerns during sponsor suitability assessments.

ORR identifies potential sponsors for unaccompanied children in different categories of cases: Category 1 includes parents or legal guardians; Category 2 includes brothers, sisters, grandparents, or other immediate relatives; Category 3 includes distant relatives or unrelated individuals; and Category 4 includes unaccompanied children for whom a sponsor has yet to be identified.

ORR's sponsor suitability assessment process includes verifying the sponsor's relationship to the child; speaking with the child's parents when possible; conducting separate interviews with the child and sponsor; collecting supporting documentation to verify the sponsors' information; and administering background and address verification checks—which include public records and sex offender registry checks for all sponsors, as well as FBI fingerprint checks in certain cases.

To verify the identity of a sponsor, all potential sponsors must submit original versions or legible copies of government-issued identification documents. For verification of the relationship claimed with the unaccompanied child, the potential sponsor must also provide at least one form of evidence such as a birth certificate, marriage certificate, death certificate, court records, guardianship records, hospital records, school records, or a written affirmation of relationship from a Consulate. All sponsors are required to comply with each provision of the Sponsor Care Agreement, under which, the potential sponsor agrees to provide for the physical and mental well-being of the child, ensure the child's presence at all future immigration proceedings, notify local law enforcement or local child protective services if the child has been or is at risk of being subjected to abuse, abandonment, neglect, or maltreatment, and notify the National Center for Missing and Exploited Children if the child disappears, has been kidnapped, or runs away.

While ORR's custodial responsibilities end when a child is discharged from ORR care, ORR has policies in place to promote unaccompanied children's well-being after they have been released as they transition into a new community. This includes providing children with multiple ways to connect following their sponsor placement, such as through Safety and Well-being calls, post-release services (PRS), legal services, and the ORR National Call Center (ORRNCC), which connects children and sponsors with community resources and is required to report all safety concerns to ORR and other federal, state, and/or local entities. ORR has now expanded PRS to historic levels. In FY 2021, an average of just over 20 percent of children were offered access to PRS. Today all children are currently being referred for such services. Similarly, ORR has increased the number of unaccompanied children receiving direct, ORR-funded legal representation, which is another protective measure against labor trafficking.

ORR and ACF's Office of Trafficking in Persons (OTIP) work closely with DOL, through the joint Memorandum of Agreement between HHS and DOL, to share information about child labor exploitation under the Fair Labor Standards Act (FLSA), including particular trends or cases within the Department of Labor's jurisdiction.

When ORR receives a report of suspected labor exploitation or trafficking, all formal reports are provided to the Department of Homeland Security (DHS) Homeland Security Investigations Division, the DHS Center for Countering Human Trafficking, and OTIP. DOL does not have enforcement authority under the anti-trafficking laws, but when it encounters possible human trafficking during the course of its investigations, it provides that information to OTIP so that OTIP may connect individuals with appropriate benefits and services. In addition, ORR requires care providers to create a Significant Incident Report within 24 hours of all suspected trafficking or exploitation concerns, which is used to notify stakeholders and OTIP. ORR also requires that ORRNCC notify local law enforcement and child welfare agencies when it receives concerns about unaccompanied

children who have been released from ORR's custody.

While ORR does not have the authority to remove a child from their home and retake federal custody after releasing a child to a vetted sponsor, ORR does everything it can to notify local law enforcement and child welfare agencies of children who may be in need of child protective services or be victims of criminal offenses. Local law enforcement and child welfare agencies are the entities with the authority to determine whether to remove a child that is not in government custody from their current home based on alleged abuse, neglect, or other welfare concerns.

Per the Trafficking Victims Protection Act, any Federal, State, or local official with concerns that a foreign national child may be a victim of human trafficking are required to notify HHS (via OTIP) within 24 hours to facilitate assistance. Per the Trafficking Victims Protection Reauthorization Act of 2022, which added labor trafficking to the definition of child abuse and neglect, mandatory reporters are or will soon be required to report known and suspected instances of child labor trafficking under state law.

Question #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?

Response:

In furtherance of its mission not only to provide for the care and custody of unaccompanied children but also for eligible refugee populations as authorized by Congress, ORR provides services to all eligible populations, regardless of its projected capacity. As such, ORR received supplemental funding to meet the needs of Cuban arrivals during an historic influx in FY 2022. Since base appropriations are inadequate to serve arrivals and referrals, Congress provided $2.4 billion in emergency supplemental funding and a $1.775 billion anomaly in the continuing resolution in FY 2023 to help ORR fulfill its statutory and legal obligations in FY 2023 and FY 2024, which ORR estimates spending down before the end of FY 2024. ORR does not have the discretion to choose how many eligible beneficiaries it serves because ORR is mandated to serve them all. Additionally, carryover funding is necessary every year to support states that have provided services to ORR eligible populations in the months immediately preceding the end of the prior fiscal year. For the ORR Refugee Program Bureau's cash and medical assistance grant, states provide cost estimates and receive quarterly funding allocations during the designated fiscal year. After the close of the fiscal year, any difference between costs incurred by the state and funds provided by ORR are reconciled and states must be fully reimbursed. As a result, ORR must always have a substantial amount of carryover funds to ensure these reimbursements can be made.

Question #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's 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?

Response:

The Interagency Taskforce to Combat Child Labor Exploitation, led by the Department of Labor (DOL), works to improve cross-training, outreach, education, and health outcomes of children that could be subject to child

labor violations under the Fair Labor Standards Act. As part of this effort, DOL and HHS entered into a Memorandum of Agreement (MOA) on March 23, 2023, regarding interagency data sharing to enhance the well-being of children and the enforcement of federal child labor laws. The MOA formalizes how the Departments' work together to help identify communities and employers where children may be at risk of child labor exploitation, aid investigations with information that could help identify circumstances where children are unlawfully employed, and further facilitate coordination to ensure that when DOL detects child labor trafficking victims or potential victims, they have access to critical services through OTIP. As part of this effort, ORR collaborates with DOL to share enforcement information under the laws that DOL's Wage and Hour Division enforces. Further, ORR, DOL, and ACF's Office of Trafficking in Persons (OTIP) collaborate on potential macro-level solutions, such as how to potentially detect patterns and ways that information provided could inform policies and procedures. Through this collaboration, some children who are still minors have received expedited referrals for additional PRS through ORR, and OTIP has assessed the individual's eligibility for services available through their program. Where needed, ORR also places appropriate flags so that individuals of concern cannot sponsor a child in the future.

In April 2023, HHS and DOL also developed and distributed new materials and trainings to provide information to children and sponsors about child labor laws in the United States so that children and vetted sponsors understand the laws on labor rights and restrictions to working in the United States. HHS and DOL have also worked collaboratively to provide training to ORR and OTIP contractors, grantees, and service providers on the child labor protections of the Fair Labor Standards Act. These efforts are ongoing.

In addition to increasing its efforts to better inform children, sponsors, and providers about child labor exploitation, ORR has worked with its ORRNCC to require a follow-up call for unaccompanied children previously released to vetted sponsors who contact the helpline with safety concerns. The ORRNCC has also incorporated language into its materials to ensure that such children who call them understand which authorities their safety concerns will be reported to and will connect the child with local resources as available.

Question #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.

What changes have been made as a result of this audit?
What changes have been made to release unaccompanied children to individuals who have previously sponsored children?

Response:

ORR continuously reviews its vetting policies and procedures for ways to improve its processes to promote the safety and well-being of children and to be more efficient and effective. For instance, on June 2, 2023, HHS released the results of its audit of the vetting process for potential sponsors who have previously sponsored an unaccompanied child, to ensure all necessary safeguards are in place without unnecessarily keeping children in government-funded, congregate care settings. In October 2023, ORR awarded a contract to an outside entity to conduct future in-depth reviews of random samples of case files by sponsor category for all children released from ORR care from January 2021–December 2022. Also, on June 2, 2023, HHS announced additional efforts to protect the safety and well-being of unaccompanied children, including a new ORR program and accountability team, now termed the Integrity and Accountability team, which will further enhance ORR's work to assess and address potential exploitation risks faced by unaccompanied children.

Moreover, on February 13, 2024, ORR published policy and procedure revisions that enhance its sponsor vetting requirements. Among other enhancements, these revisions require parent and legal guardian (Category 1) sponsors to provide proof of address documentation (already a requirement for all other sponsors) and also requires, at minimum, sex offender registry checks for all adult household members and adult caregivers, including in Category 1 cases. Further, the revisions require, at minimum, proof of identity and criminal history public records background checks for all adult household members and adult caregivers, with a narrow exception for certain Category 1 cases such as where there are no safety concerns. These recent revisions strengthen and expand home study policies and guidance to include mandatory home studies for potential sponsors of more than two children, regardless of the potential sponsor's relationship to the children. The February 2024 policy revisions supersede Field Guidance 10, 11, and 15. ORR's robust sponsor vetting requirements are also set forth in the UC Program Foundational Rule 45 CFR Part 410, Subpart C.

Head Start

Question #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."

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

Response to #46a:

In recent years, Head Start programs have experienced significant and persistent underenrollment where the number of children actually served is far less than the number of children they are funded to serve, leaving a large number of slots unfilled due in large part to widespread staffing shortages. As Head Start programs work to improve their actual enrollment levels, many are also requesting reductions in their funded enrollment. Head Start programs are trying to right-size their funded enrollment to match their community needs, staffing realities, and fiscal constraints. The Office of Head Start (OHS) is also concerned about quality in Head Start, including child safety incidents and the ability to recruit and retain staff that meet the teacher qualification requirements in the Head Start Act and can support enriching interactions and early learning experiences.

If the proposed rule becomes final, OHS expects that most of the costs associated with the rule, when fully phased in after seven years, will be covered within the existing funding allocation for Head Start assuming a full cost of living adjustment (COLA) investment is provided each year and programs right size their funded enrollment to match actual enrollment levels. We estimate that many programs can approach full implementation of the policies when phased in by 2031 without additional appropriations (beyond COLA increases to account for inflation) by reducing their funded enrollment levels to align with their actual enrollment. Those programs would then have the ability to reinvest the resources associated with the reduced slots within their existing budgets to increase wages and compensation for staff. Based on the Notice of Proposed Rulemaking (NPRM) estimates, reducing funded enrollment would result in about 1 percent fewer

funded slots than FY 2023 actual enrollment. Thus, if Head Start receives no additional funding from Congress beyond a full COLA each year—as represented by the $543.7 million included in the President's Budget for FY 2025—a one percent reduction in currently filled slots would be needed to reach full implementation of the policies in the proposed rule by 2031. It is also important to note that these projections are based on standard COLA rates; the actual amount of COLA needed per year is subject to change based on updated measures of inflation.

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

Response to #46b:
No children currently enrolled in Head Start will be removed from programs as a result of these proposed policies. If these policies are enacted in a final rule and programs must reduce their funded enrollment levels in response, they will do so by eliminating slots already vacant or by lowering the number of slots available in future years. All children and families who are currently enrolled can remain in the Head Start program in accordance with the existing eligibility and enrollment requirements.

Question #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?

Response:
The existing phrasing of §1302.44(a)(3) implies that mental health consultants provide treatment when, in fact, they provide consultation services to adults (e.g., classroom teachers) and do not require parental consent because the child is not directly receiving the service. Mental health consultation is designed to support teachers and staff in supporting children's mental and behavioral health needs. Programs will continue to be required to apply the advanced authorization regulations for health, mental health, and developmental procedures.

Question #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?

Response:
HHS believes that the proposed rule supports the Continuous Quality Improvement (CQI) efforts of Head Start programs. The proposed rule ensures that the Head Start Program Performance Standards represent all necessary elements for high-quality programming, while retaining the level of local flexibility and discretion to which Head Start programs are accustomed. Several of the new policies proposed in the NPRM will help guide programs in their CQI efforts, including by focusing their community assessments on the most relevant data, reflecting on whether the program's approach to mental health is meeting the specific needs of their community, and allowing for the leadership of each program to guide the creation and implementation of employee engagement practices. The NPRM also proposes to remove the requirement that Head Start programs participate in their State or local quality rating and improvement systems, allowing for a more flexible approach that

recognizes the high standards of Head Start programs and reduces the duplication of efforts. HHS continues to support and value the need for local flexibility in Head Start and will provide tailored training and technical assistance to Head Start programs as they implement strategies for CQI.

Universal Preschool

Question #49

The Biden administration continues to propose universal preschool in FY 2025 with $5 billion in mandatory funding. However, several economic impact studies[8] warn that a 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?

Response:

The President's Budget request would fund states to expand access to high-quality child care to more than 16 million young children and dramatically expand access to and increase the quality of preschool so that all of the approximately four million 4-year-old children in the United States have access to high-quality, voluntary, universal, free preschool, with the flexibility for states to expand preschool to three-year-olds once high-quality preschool is fully available for four-year-old children.

Importantly, high-quality preschool would be offered through a mixed delivery system that builds on and strengthens the current ecosystem of early care and education providers. Preschool would be offered in the setting of the parent's choice—from public schools to child care providers to Head Start. This mixed delivery approach would offer a wide range of quality settings to provide choices for families, build on the expertise and capacity of existing providers—including community-based child care providers, schools, Head Start, and family child care homes—and leverage existing Federal, state and local funding to enhance existing services and expand access to high-quality preschool.

High-quality early care and education from birth to kindergarten entry is one of the most significant and impactful investments we can make as a nation. When children have access to high-quality early learning programs, the benefits extend across their lifespan they are more likely to succeed in school, graduate from high school, and go on to college. Early learning programs also make it easier for parents— especially mothers—to become employed, boosting family earnings and promoting economic stability and well-being.

Unfortunately, early care and education programs, including both child care and preschool, are financially out of reach for many children and families, and current federal investments in child care and early learning fall far short of meeting the true need. Most U.S. children do not have access to public preschool, with less than half of all four-year-old children and just 17 percent of all three-year-old children attending publicly funded preschool. The Head Start program—which provides high-quality early childhood education and comprehensive services to children birth to five to those most in need—is funded to reach just half of income-eligible preschool-aged

[8] 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,

children (i.e., three- and four-year-olds) and less than 10 percent of income-eligible infants and toddlers. Higher-income children are more likely to attend preschool because their families can afford to pay for it, leaving too many children in low-income families and children of color behind.[9]

The early childhood workforce is essential to delivering high-quality early care and education programs, yet child care, Head Start, and preschool programs across the country are facing unprecedented challenges recruiting and retaining qualified educators due to persistently low wages that do not recognize the value and importance of their work, as well as historic racial, ethnic, linguistic, and economic barriers to accessing degree and credentialing programs. Through increased investment in child care, preschool and Head Start, this proposal will help improve compensation for early educators across settings towards a wage that can enable recruitment and retention of staff and increase the supply of high-quality early care and education options for families.

Together, investments in high-quality affordable child care and preschool will advance the President's goal of ensuring that all families can access affordable, high-quality early care and education, helping children learn, giving families breathing room, and growing the economy.

Child Care

Question #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.

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

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?

Response:
The President's FY 2025 Budget would expand access to high-quality child care for lower- and middle-income families, such that families with the lowest incomes pay nothing and most families pay no more than $10 per day for child care, while helping to support the economy and improve outcomes for children in families. This proposal would save the average family over $600 per month, per child, and reduce the family's child care costs by nearly two thirds. Research has documented that reducing the cost of child care for families can increase labor force participation, employment, and earnings among parents.[10]

Our current child care system is untenable. Child care costs are a significant and destabilizing financial strain on low- and middle-income families. Yet, the child care workforce is deeply underpaid for the essential work they do and child care providers struggle to fully staff their programs because of challenges recruiting and retaining staff. Subsidizing child care costs for low- and middle-income families will facilitate a stronger U.S. economy, strengthen family economic stability and security, and support businesses and communities, while allowing parents the freedom to select high-quality child care for their children that meets their families' needs.

[9] See for example https://www.aecf.org/blog/low-preschool-enrollment-rates-threaten-to-worsen-student-achievement

[10] Morrissey T. Child care and parent labor force participation: a review of the research literature. Rev Econ Househ 2016. doi:10.1007/s11150-016-9331-3.

Working families across income levels currently struggle to find and pay for high-quality child care. Difficulty in finding high-quality, affordable early care and education leads some parents to drop out of the labor force entirely, reduce their work hours, or turn down promotion opportunities. In very large counties, the average price of center-based child care for an infant ($17,171) and a toddler ($13,500) would together represent over 15 percent of a family's income at $200,000, and some families at this income level would need to pay for more than two children.[11] For families with incomes at $100,000, the cost burden would be even higher, with care for an infant and a toddler representing more than 30 percent of their family income. Research has documented that reducing the cost of child care for families can increase labor force participation, employment, and earnings among parents. The President's Council of Economic Advisers found that recent federal investments in child care increased labor force participation among mothers of young children by roughly three percentage points, equivalent to over 300,000 more women in the labor force.

Child care that is reliable, high-quality, and affordable allows parents to make ends meet, advance in their careers, and stay in the workforce, while offering children the opportunity to benefit from enriching learning environments that support healthy child development. This investment would help hundreds of thousands of women with young children enter or re-enter the workforce more quickly and reduce child care costs to allow parents the freedom to select a high-quality child care option for their children to provide a strong foundation for learning and health across the child's lifespan.

Question #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."

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

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

Response to #51a:

Under the 2024 Child Care and Development Fund (CCDF) Final Rule, Lead Agencies are still required to establish and periodically revise a sliding fee scale as articulated by the statute. The 2024 Final Rule ensures that the upper end of that sliding fee scale is affordable for families and not a barrier to accessing CCDF.

Response to #51b:

The Biden Administration prioritizes lowering family costs for child care. Despite the Child Care and Development Block Grant (CCDBG) Act requiring that Lead Agency sliding fee scales be affordable for families and not a barrier to families accessing CCDF, the majority of states still allowed for some co-payments above seven percent of a family's income and could allow co-payments that were even as high as 27 percent of a family's income. By prohibiting co-payments above seven percent of household income, the 2024 Final Rule helps minimize cost barriers for families accessing CCDF and supports affordability.

Question #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.

[11] Landivar, C. L., Graf, N.L., and Rayo, A. Childcare Prices in Local Areas: Initial Findings from the National Database of Childcare Prices. Women's Bureau, U.S. Department of Labor and American Community Survey 2014-2018, U.S., Census Bureau (prices represented in 2022 real dollars using the CPI-U for child care). Retrieved at://www.dol.gov/sites/dolgov/files/WB/NDCP/508_WB_IssueBrief-NDCP-20230213.pdf.

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

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?

Response:
The Office of Child Care (OCC) and its technical assistance partners continually offer support to Lead Agencies to implement CCDF regulations. This includes in-person opportunities convenings, peer sharing opportunities, and targeted and tailored technical assistance to provide additional opportunity for Lead Agencies to learn and seek support for full CCDF implementation.

Additionally, while the 2024 Final Rule went into effect on April 30, 2024, HHS recognizes that Lead Agencies may need additional time to plan and thoughtfully implement required changes. Therefore, HHS has used its authority under the CCDBG Act to allow Lead Agencies to apply for temporary waivers from provisions in the 2024 Final Rule in certain circumstances. Capping co-payments at seven percent of family income (§ 98.45(b)(5) and § 98.45(l)(3)) is one of the allowable provisions for this temporary waiver. Guidance for state and territory waivers (ACF-OCC-CCDF-PI 24-03) was released on April 24, 2024, and guidance related to Tribal Nations will be issued separately.

The CCDBG statute is clear that family co-payments cannot be a barrier to child care access for families participating in CCDF. Families with low incomes on average pay between nine and 31 percent of their incomes for child care, while families with higher incomes pay between six and eight percent. Families participating in CCDF should not be required to pay a greater share of their income than higher income families.

As part of the regulatory process, HHS conducted a Regulatory Impact Analysis and calculated that the seven percent cap would result in an annualized transfer of $12.6 million from families who would otherwise pay unaffordable co-pays or forgo care to Lead Agencies. This analysis estimates implementing the seven percent cap requirement may lead to a caseload reduction of up to 1,870 slots annually at the highest point of implementation (e.g., all states implementing the requirement). The individual state impact varies depending on where Lead Agencies are in the implementation process. For example, 15 Lead Agencies had set their co-payments to seven percent or less before the 2024 Final Rule and would presumably not need to make any policy changes to meet this new requirement. In addition, Lead Agencies have significant flexibility in how they allocate CCDF resources, which will affect the impact of the policy changes included in the 2024 Final Rule.

The Biden administration continues to call on Congress to make significant long-term investments so that all families can afford and access the high-quality child care that meets their needs.

Rep. Joe Wilson (R-SC)

Question #53
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.

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?

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?

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?

Response:
CMS proposed the Increasing Organ Transplant Access (IOTA) Model for transplant hospitals in a Notice of Proposed Rulemaking, Alternative Payment Model Updates and the Increasing Organ Transplant Access Model, released on May 8, 2024 with an opportunity for public comment. CMS anticipates receiving robust comment on the proposed rule from stakeholders.

The IOTA Model, as proposed, is complementary to other models tested by the Innovation Center, such as the ESRD Treatment Choices (ETC) and Kidney Care Choices (KCC) Models, and to other CMS and HRSA initiatives, including holding organ procurement organizations accountable for their performance, with the collective goal of achieving improvements in processes among transplant hospitals that would spur an increase in both deceased donor and living donor kidney transplantation and reduce population health disparities. While

the IOTA Model and the OPO rule both are focused on improving the number of transplants and health outcomes, they are distinct in terms of the levers they use to support performance improvement. The IOTA Model proposes performance-based payments that hold transplant hospitals selected as the IOTA participants financially accountable for improvements in access to both deceased and living donor kidney transplantations. CMS will carefully review all of the comments on the proposed rule before issuing a final rule regarding the IOTA model.

Rep. Glenn Grothman (R-WI)

Question #54

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?

Response:
The 340B Program is an integral component of the safety-net system in our country, from health centers, to Ryan White clinics, rural hospitals, and children's hospitals. These clinics and hospitals are foundational to our country's health care system, focusing on our most vulnerable, underserved, and isolated patient populations. The President's Budget Request includes legislative proposals to sustain and strengthen the Program.

Question #55
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 RNs, do not currently exist?

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.

Response:
Staffing in LTC facilities is a persistent concern, especially among low-performing facilities that are at most risk for providing unsafe care. Numerous studies have shown that staffing levels are closely correlated with the quality of care that LTC facility residents receive.[12] CMS believes that national minimum nurse staffing standards in LTC facilities are necessary at this time to protect resident health and safety and ensure residents' needs are met. We intend to promote safe, high-quality care for all residents regardless of geographic location. At the same time, CMS acknowledges the unique challenges that rural LTC facilities face, especially related to

[12] Abt Associates. (2022). Nursing Home Staffing Study Comprehensive report. Report prepared for the Centers for Medicare & Medicaid Services.

staffing, and recognizes the need to strike an appropriate balance that considers the current challenges some LTC facilities are experiencing.

CMS expects that LTC facilities will be able to meet the comprehensive staffing requirements, inclusive of the minimum staffing standards, 24/7 Registered Nurse (RN) requirement, and enhanced facility assessment. Flexibilities included in the rule include a staggered implementation timeline of up to five years based on geographic location. Additionally, eligible facilities that are facing a significant staffing hardship, despite their best efforts to hire and a financial commitment to staffing, will be able to qualify for exemptions to these minimum staffing standards.

CMS will monitor the implementation of the finalized requirements including, but not limited to, the minimum staffing standards, 24/7 RN requirement, exemption process, and definition of rural, as they are implemented over the next several years, and assess the effectiveness of the requirements in improving safety and quality.

Question #56

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?

Question #57

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 access to care u communities across Wisconsin and across the country.

Response to Questions #56 and #57

The Biden-Harris Administration is committed to ensuring that all residents living in Medicare and Medicaid nursing homes receive safe, high-quality care. Specifically, In February 2022, alongside a suite of other reforms, CMS committed to expanding financial penalties and other enforcement sanctions to improve the safety and quality of care in the Nation's nursing homes.

Nursing home oversight is one of CMS's most important tasks, and resident safety is CMS's top priority in nursing homes and all facilities that participate in the Medicare and Medicaid programs. Monitoring patient safety and quality of care in nursing homes requires coordinated efforts between the federal government and the states, and CMS works in partnership with state survey agencies to oversee nursing homes, since these agencies are generally also responsible for state licensure. While it is critical to hold nursing homes accountable for the quality of care they provide, CMS's goal is not to punish nursing homes, but to bring them into compliance and ensure they can continue to provide care to the residents who rely on the facility for their home. Our policies and our work with state survey agencies reflect this goal.

As a part of this effort, in the Fiscal Year 2025 Skilled Nursing Facility Prospective Payment System proposed rule, CMS proposed to expand existing nursing home enforcement authority to enhance the safety and quality of care provided in the nation's nursing homes. These revisions will allow CMS to expand the mix and number of penalties in response to situations that put residents' health and safety at risk and, therefore, encourage facilities

to promptly correct and maintain lasting compliance with CMS's health and safety requirements. CMS believes these revisions will allow for more consistent imposition of Civil Monetary Penalties and better alignment of those penalties with the noncompliance that occurred. This also ensures that CMS retains the authority to impose CMPs related to the nature of the harm that is caused by—or could be caused by—a facility's noncompliance and the length of such noncompliance, rather than the date that a standard survey was conducted or a finding of noncompliance was identified, even if the administration of imposing the CMP occurs after another survey has been conducted.

It is important to note, however, that these CMPs are still subject to statutory daily limits, and CMS can exercise discretion with regard to a nursing home's financial condition in determining the appropriate CMP. CMS remains focused on improving the health and safety of nursing home residents by ensuring quality care and ensuring access to care with these policies.

Question #58
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.

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?

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

Response:
HRSA calculates scores using our online portal, the Shortage Designation Management System. The System contains standard national data sets, and State Primary Care Offices (PCOs) and facilities can provide HRSA with supplemental data. Additionally, we calculate Health Professional Shortage Area (HPSA) scores based on methodology that includes three disciplines: primary care, dental health, and mental health.

Three scoring criteria are common across all HPSA disciplines:

- Population-to-provider ratio
- Percent of population below 100% of the Federal Poverty Level (FPL)
- Travel time to the nearest source of care outside the HPSA designation area

HRSA collaborates closely with State PCOs and stakeholders, providing technical assistance, conducting monthly and quarterly calls, and keeping them updated on HPSA designation and update requirements. State PCOs can leverage this information to secure additional data and request updates or new analyses at any time. HRSA provides the State PCOs with several reminders of HPSA designation update requirements and details what the "proposed for withdrawal" status means in the Shortage Designation Management System. HRSA

informs and supports State PCOs to work with stakeholders in submitting new or updated HPSA data at any time to minimize the impact of lapsing designations. Additionally, HRSA conducts technical assistance calls with the State PCOs to discuss and review potential HPSA designation updates and score changes, and contacts all State PCOs to alert them of potential HPSA withdrawals and deadlines to update designations.

HPSA withdrawals occur when areas no longer meet criteria due to improved population-to-provider ratios, reduced poverty levels, or increased access to nearby health care services, for example. Maintaining outdated designations risks diverting limited resources from areas in greater need. HRSA is statutorily required to publish an annual Federal Register Notice announcing the availability of the list of all designated HPSAs. During the COVID-19 pandemic, HRSA paused these withdrawals to accommodate challenges faced by the health workforce. Recognizing the pandemic's impact, HRSA provided jurisdictions and facilities additional time to adjust to potential HPSA designation changes.

HRSA instituted an additional step in the annually required Federal Register Notice process in 2023. HRSA first published a Federal Register Notice in July 2023 that informed State PCOs of designations at risk of losing their HPSA status, giving State PCOs at least six months to update designations with new data. The second Federal Register Notice published in January 2024 officially withdrew designations if no action was taken.

HRSA urges jurisdictions with withdrawn HPSAs, or HPSAs with non-competitive scores, to contact their State PCO to review their options. HPSA scores can change due to factors like provider availability, population shifts, and poverty rates. Under HRSA's cooperative agreement, State PCOs assess needs, determine eligible areas, and then submit designation applications to HRSA. HRSA reviews these applications and designates HPSAs if they meet eligibility criteria. This process applies to all jurisdictions, including those that lose HPSAs or have HPSAs with low scores.

Although each maintains statutorily directed eligibility criteria, most of HRSA's approximately 70 programs that work to connect health care providers to communities in need do not depend on HPSA scores. More information about HRSA's health workforce programs, including an overview of eligibility criteria, is available on HRSA's health workforce program profile page: https://bhw.hrsa.gov/programs. HRSA remains committed to collaborating with all parties to ensure underserved communities are accurately identified through HPSA designations.

Rep. Rick Allen (R-GA)

Question #59

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?

Response:
On August 20, 2021, the Departments of Labor, Health and Human Services (HHS), and the Treasury (the Departments) released FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (FAQs Part 49) announcing the deferral of enforcement regarding certain requirements, including the requirement that plans and issuers publish machine-readable files related to prescription drugs, pending further consideration by the Departments. In deferring enforcement of this requirement, the Departments noted the enactment of the prescription drug requirements under section 204 of division BB of the Consolidated Appropriations Act, 2021 (CAA), and stakeholder concern about potentially duplicative and overlapping reporting requirements for prescription drugs.

On September 27, 2023, the Departments released FAQs About Affordable Care Act Implementation Part 61 (FAQs Part 61) rescinding Q1 of FAQs Part 49, which had expressed the Departments' general policy of deferring enforcement of the TiC Final Rules' prescription drug machine-readable file requirement pending further consideration in a future rulemaking by the Departments. The Departments will address enforcement decisions under the relevant requirements of the TiC Final Rules on a case-by-case basis, as the facts and circumstances warrant.

Question #60

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?

Response:
The Department of Labor is the agency primarily tasked with administration of requirements applicable to private employee benefit health plans under Title I of ERISA.

Question #61
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?

Response:
The Federal IDR portal first opened for disputing parties on April 15, 2022. After opening, the Departments observed that the volume of disputes was substantially larger than the Departments or certified IDR entities initially expected. Between January 1, 2023, and June 30, 2023, disputing parties initiated 288,810 disputes. The number of disputes initiated through the Federal IDR portal over this six-month period was 13 times greater than the Departments initially estimated the number of disputes initiated would be over the course of a full calendar year and has grown each quarter. In the first quarter of 2023, 136,111 disputes were initiated, which was a 24% increase compared to disputes initiated in the fourth quarter of 2022 (110,034). In the second quarter of 2023, 152,699 disputes were initiated, which was a 12% increase in disputes initiated over the first quarter of 2023.

The backlog and throughput difficulties facing the Federal IDR process can be ascribed to two main issues: higher than expected volume of disputes and the complexity of eligibility determination. When a dispute is submitted through the Federal IDR portal, and before proceeding to a payment determination, certified IDR entities must first make complex determinations about whether the dispute is eligible for the Federal IDR process. Eligibility for the Federal IDR process depends on a number of factors, including federal vs. state jurisdiction, whether the particular items or services are covered by the NSA protections, correct batching or bundling of items and services, compliance with applicable deadlines, and completion of the 30-business-day open negotiation period. In order to make an eligibility determination, certified IDR entities often need to reach out to disputing parties for additional information, lengthening the overall time needed to process a dispute.

Moreover, as a result of opinions and orders issued in several lawsuits that vacated portions of the regulations and guidance on the Federal IDR process, the Departments had to suspend initiation of new disputes multiple times to make changes to the process to align with court orders. While the goal was to keep these suspensions as short as possible, the repeated need to suspend IDR operations due to court orders has been highly disruptive to the process and has contributed to a backlog of IDR cases.

However, to address the high volume of disputes, the Departments worked to improve and automate how the Federal IDR portal operates, as well as provide technical assistance and guidance to certified IDR entities and disputing parties to make the process run more smoothly. For example, the Departments made major updates to the Federal IDR portal, including updating webforms to capture information to aid in eligibility determinations, expanding data validations to ensure disputing parties are inputting accurate information, updating system functionality to accommodate changing requirements as a result of court rulings (including temporarily suspending the Federal IDR portal functionality to ensure that guidance and IT systems were consistent with court orders), automating email communications to reduce delays between disputing parties and certified IDR entities, and improving how the Departments respond to inquiries from certified IDR entities and disputing parties.

The Departments' work to respond to initial IDR process challenges is yielding substantial results. Certified IDR entities have scaled up their operations to address the high volume of disputes. Certified IDR entities rendered 83,868 payment determinations in the first six months of 2023, more than five times the number of payment determinations made in all of 2022 (16,238). Certified IDR entities have increased their payment determination output each quarter compared to the prior quarters. Certified IDR entities made 26,741 payment determinations in the first quarter of 2023, 64% more than the prior quarter, and made 57,127 payment determinations in the second quarter of 2023, which was more than twice the number from the prior quarter. Certified IDR entities closed 134,036 disputes in the first six months of 2023. Disputes were closed for several reasons, including: a payment determination was made, the dispute was determined ineligible for the Federal IDR process, the dispute was withdrawn, parties reached a settlement, or the dispute was closed for administrative reasons, such as unpaid fees. Despite the increase in the number of payment determinations, due to the high volume of disputes initiated,

some disputing parties are still awaiting eligibility and payment determinations. The Departments' objective is to help certified IDR entities and disputing parties obtain resolution on disputes as expeditiously as possible.

The Departments understand that the enforcement of the timeline for non-prevailing parties to make outstanding payments following a certified IDR entity's payment determination is an issue and we have received complaints regarding late payments after a payment determination has been made. We are actively working to review and resolve these complaints and we take the issue of late payments after IDR payment determinations very seriously. Additionally, based on our review of the complaints, we have made operational changes to help mitigate issues we have identified. These changes include developing a new payment determination template for certified IDR entities to use which includes claim line-level details and developing a process for sending these templates through the Federal IDR portal. While we believe these operational enhancements should help mitigate some of the identified issues related to missing information, we continue to investigate complaints as they are received. In 2022, we provided guidance for certified IDR entities and, additionally, in November 2023, the Departments issued the Federal IDR Operations notice of proposed rulemaking which, if finalized, is intended to help ensure a more efficient Federal IDR process. In general, the Departments are seeing progress in payers making timely payments following a payment determination when we reach out to payers in response to complaints. As we continue to work with all parties to improve this process, we encourage parties who use the Federal IDR process and who are not receiving timely payments on closed determinations to submit complaints.

Rep. Aaron Bean (R-FL)

Question #62

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?

Response:

HHS intends to address, through rulemaking, the issues left open by the Court's opinion, including whether financial assistance provided to patients by drug manufacturers qualifies as "cost sharing" under the Affordable Care Act. Pending the issuance of a new final rule, HHS does not intend to take any enforcement action against issuers or plans based on their treatment of such manufacturer assistance.

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

Question #63
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?

Response:
Program partners notified the Office of Community Services (OCS) on February 17, 2023, that funds were not available to local administering agencies. On that same day, Florida's Department of Commerce (Florida Commerce), responded to OCS that they had reached their budget authority spending limit in mid-to late December 2022. Florida Commerce notified OCS that additional spending authority was approved on February 28, 2023. Florida Commerce subsequently indicated they began reimbursing local administering agencies by approximately March 10, 2023.

OCS interviewed four local administering agencies during its August 2023 monitoring review. These agencies included local governments and community action agencies. The agencies interviewed indicated reimbursements from Florida Commerce to the administering agencies were paused for approximately three months in the spring of 2023.

Additionally, Broward County Community Action stated that they laid off 14 temporary workers during the time-period when Florida Department of Commerce sought additional spending authority. For both Community Services Block Grant and Low Income Home Energy Assistance Program grantees, Capital Area and Northeast Florida Community Action Agencies stated they paused applications for at least one-week during this time-period and were not reimbursed for approximately three months on expenditures. Capital Area Community Action Agency stated that they needed to draw on a personal line-of-credit to make ends meet. These agencies did not identify the number of individuals that could not receive benefits; however, these agencies were located in highly populated areas in the State of Florida, including Tallahassee, Jacksonville, Fort Lauderdale, and Miami.

Question #64

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.

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

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

Response:

To implement the No Surprises Act, the Departments scaled up expertise and resources for rulemaking, technical builds, enforcement, and staffing. While the original appropriation expires at the end of 2024, most of the statutory requirements added by the No Surprises Act and Title II Transparency provisions are permanent and the Departments will have ongoing responsibilities. Some of these responsibilities, including enforcement of critical consumer protections against surprise billing, cannot be funded with IDR administrative fees. Without additional dedicated funding, the Departments may need to phase-down or phase-out certain enforcement efforts, including investigation and resolution of some health plan and provider complaints. For example, HHS may have to significantly adjust its staffing of the No Surprises Help Desk, curtailing consumers' and providers' access to a crucial resource for information about NSA requirements and protections, and leaving them without a central point of contact to submit complaints. HHS further may limit its provider enforcement activities, leaving consumer complaints of illegal balance bills and other violations of the NSA unanswered. Other impacts include:

- Plan enforcement activities, including market conduct exams related to late payments by non-prevailing parties following a payment determination;
- Policy development and program implementation related to the NSA's advanced explanations of benefits (AEOBs);
- Prescription drug data collection, preventing HHS from collecting, analyzing, and publishing findings about prescription drug pricing and the impact of prescription drug rebates on patient out-of-pocket costs; and
- Air ambulance data collection.

The impact of the loss of funding to the Departments of Labor and the Treasury should be directed to those agencies.

Rep. Suzanne Bonamici (D-OR)

Question #65

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

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

Response:

HHS works expeditiously to release funding to state agencies on quarterly basis. State agencies under the CSBG are required to comport with specific State Accountability Measures outlined in policy that stipulates funds are to be distributed to local agencies within 30 calendar days of the state agency receiving the funds (ACF-OCS-CSBG-IM-144). When HHS monitors grant recipients in accordance with regulations, we assess the timeliness of funding releases to local agencies.

Question #66

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.

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?

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

Response:

In an effort to reduce the reporting burden of individuals, families, local, and state agencies, HHS examined the CSBG Annual Report (OMB #0970-0492) and identified any data points that were not essential for federal reporting that could be removed. On April 22, 2024, the Administration for Children and Families (ACF) published a notice in the *Federal Register* inviting comments on a version of the annual report that significantly reduces reporting burden and removes 160 data points. This effort considered where there is duplication in the data reported across several federally funded programs. ACF received many comments on the updated version and after ensuring time to consider all comments received, is currently finalizing the streamlined report for submission to the Office of Management and Budget.

HHS has examined where there is duplication in the reporting to eliminate several data points that are collected in multiple federal reports and has removed certain data points that are collected in other federal datasets (including those collected by the Low Income Home Energy Assistance Program).