NATIONAL ASSOCIATION OF Community Health Centers

Healthy Future Task Force Affordability Subcommittee RFI
NACHC Response

III. Increasing Transparency and Marketplace Innovation

Less than ten percent of existing price transparency tools provide price estimates based on patient insurance status or specific health plan. At the end of 2019, Congress passed a law to ensure both service and plan specific advanced, true and honest estimates for patients. Implementation of that provision is delated because told the Administration they don't have the technology to do it, despite the use of technology to conduct prior authorizations and after-the-fact explanation of benefits.

Q. What standards must the Administration issue to ensure this critical patient benefit can be implemented as soon as possible?

On behalf of the National Association of Community Health Centers (NACHC), thank you for the Subcommittee's interest in the policy topics included in this RFI. NACHC is pleased to provide feedback on specific questions that directly impact our members.

NACHC is the national membership organization for federally qualified health centers (also known as FQHCs or health centers). Health centers are federally funded or federally supported nonprofit, community-directed provider clinics serving as the health home for nearly 29 million people, including 1 in 5 Medicaid beneficiaries and 1 in 3 people living in poverty. It is the collective mission and mandate of the 1,400 health center organizations around the country to provide access to high-quality, cost-effective primary and preventative medical care, as well as dental, behavioral health, pharmacy, and other support services that facilitate access to care to people located in medically underserved areas. Nearly half of all health centers across the country are in rural communities, and 1 in 5 rural residents are served via the health center program.

As you know, this and the following question relate to the requirement in the No Surprises Act and subsequent rulemaking that providers give patients a "good-faith estimate" (GFE) of expected costs for the care they are scheduled to receive. This GFE must be provided to all patients, though as noted in the RFI questionnaire, this provision for patients with insurance is currently delayed. However, the requirement that uninsured or self-pay patients receive a GFE went into effect on January 1, 2022. As such, NACHC's comments on this and the following question pertain to the GFE requirement as a whole.

By way of background, health centers are entities that either receive a grant under Section 330 of the Public Health Service Act (PHSA) or, despite not receiving a grant, are recognized by the U.S. Health Resources and Services Administration (HRSA) as meeting the conditions for such a grant ("look-alikes"). While NACHC strongly supports the goals behind the No Surprises Act to improve consumers' access to accurate information about the costs of health care services, health centers already operate under a comprehensive set of federal laws and regulations that essentially provide the same protections. We strongly encourage the Subcommittee to consider these dynamics as it prepares to influence this new federal law.

Unlike other types of providers, health centers have extensive obligations to their patients. They must meet a host of federal program requirements aimed at ensuring they make comprehensive primary care services available to underserved populations in underserved areas, regardless of the patient's ability to pay or insurance coverage. These include the following:

- Health centers must prepare and maintain a schedule of fees for their services, consistent with locally prevailing rates and designed to cover their reasonable costs of operation.

- Health centers must establish and maintain a schedule of discounts, known as the Sliding Fee Discount Program (SFDP), to be applied to the payment of such fees. Discounts must be available for all patients with income at or below 200% of the Federal Poverty Guidelines (FPG), with discounts structured in tiers based on the patient's income level. Patients with income under 100% FPG are provided with services free of charge, or at most, at a nominal charge.

- The health center must screen and register each new patient, which includes determining their insurance status, income level, and eligibility for the SFDP, and must re-evaluate the patient's discount eligibility periodically.

- When health center services are furnished via contract or formal referral arrangement with another provider, the health center must ensure that the contracted or referral provider also provides discounts to low-income patients. If the health center provides supplies or equipment that are related to but not included in the service itself, the health center must inform patients of the charges of such items before the time of service.

Since health centers serve all consumers – not just low-income patients – it is reasonable to think that this GFE requirement would provide protection against unexpected bills received by patients with income in excess of 200% FPL. However, health centers' functionality as providers for the purposes of billing for the insured is vastly different from any other provider. Health centers' charge-setting methodologies differ from providers more reliant on commercial third-party payers. In practice, providers who customarily rely on commercial third-party payment set rates higher to increase their individual charge profiles, which then serve as the basis for establishing the allowed amount a third party agrees to pay for services. This is not the case for health centers. Section 330 and its implementing regulations require the health center to charge patients and payors based on the schedule of charges. Because of these constraints and their federally-mandated role as safety net providers, health centers have no incentive to inflate their charges.

In most cases, a dispute resolution process would be unnecessary where a patient has a concern about potential charges for a health center appointment because health centers have a federal obligation as a part of the Section 330 health center requirements to work through such issues with patients.

Finally, given the strict federal requirements placed on health centers to use their Section 330 grant funds to support the costs of providing services to low-income patients, NACHC is deeply concerned about the burden that the duplicative nature of this GFE requirement places on health

centers. Health centers are now incurring significant costs – structural changes such as reconfiguring staff responsibilities so that "back-office" clinical and coding personnel can provide "front-office" administrative staff with information about potential diagnoses, service codes, and applicable discounts – at a time when health centers are already facing staffing shortages and new service demands due to the COVID-19 pandemic. Health centers' payor revenues in most instances do not even cover their costs of providing services.

Related to the original question as well as the following question, NACHC provided a series of comments and recommendations in response to the Interim Final Rules with Request for Comments; Requirements Related to Surprise Billing; Part II (CMS-9908-IFC) issued by the Administration last year. NACHC's recommendations included the following:

- The Administration recognize that as a matter of both law and policy, health centers should be excluded from the obligation under the regulations to furnish a good-faith estimate due to the duplicative nature of the requirement.

- If that course is not ultimately pursued, the Administration should confer with HRSA to make adjustments to the requirements in the regulations that more closely align already existing federal requirements placed on health centers related to the SFDP with the spirit of the GFE requirement in the No Surprises Act.

- The Administration delay implementation of and/or compliance with the good faith estimate requirement until the latest of the following: 1) the date as of which *all of the requirements* in Section 112 of the No Surprises Act have been implemented via regulation, specifically the item referred to in this Question, 2) a minimum of six months after the expiration of the federal public health emergency (PHE) and/or 3) specific to health centers, such time that the Administration has conducted collaboration with HRSA on ways to reduce redundancy and potential conflict.

- The Administration consider application of flexibilities surrounding civil monetary penalties and related hardship exemptions included in the Proposed Rule (NPRM) related to "Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement" to protect health centers and reduce redundancy and potential conflict.

Q. How can Congress build on this landmark provision in future legislation to further improve patients' access to pricing information in advance of receiving health care services

NACHC strongly supports the core tenets of the *No Surprises Act* to improve consumers' access to accurate information about the costs of health care services and to reduce the occurrence of surprise medical bills. We are hopeful that any further Congressional action to build on or otherwise revisit this legislation would strengthen the role of health centers in this effort by more closely aligning already existing federal requirements related to the Sliding Fee Discount Program with the good-faith estimate. Specific recommendations on how to achieve this were included in more detail in NACHC's comment letter sent to the Administration in early December in response

to the Interim Final Rules with Request for Comments; Requirements Related to Surprise Billing; Part II (CMS-9908-IFC) and are outlined in the response to the previous question.

Before the Affordable Care Act passed, states set the rules for what private health insurance needed to cover in that state, controlled who could and couldn't offer health insurance, reviewed and set rules for rates, and handled consumer complaints. Now, the federal government is involved in all these activities.

Q. Are there ways to return some of this power to states that would increase affordability while protecting those with pre-existing conditions?

Q. How can 1332 waiver authority be improved to help address affordability?

Q. Would remove the firewall between 1332 and 1115 waivers allow for state innovation to improve affordability.

The following response pertains to all three sub-questions in Part III, Question 3.

Approximately 90% of health center patients are at or below 200% of the federal poverty line, and nearly 60% receive public health coverage. As such, federal laws and regulations governing Medicaid, Medicare, and the marketplace have a sizable impact on health centers' ability to deliver cost-effective care.

Given the unique role of the federal government in the function of FQHCs, NACHC is strongly supportive of an approach that keeps in place federal protections that ensure patients can access high-quality, affordable coverage and protects sufficient payment for health centers. Given the sizable role state policymakers play in regulating both Medicaid and private insurance markets and the vast differences in vulnerable populations and health needs across states, NACHC also supports protecting the role of states to design their health care systems as they see fit.

As you know, 1332 waivers have been utilized in a variety of ways since their initial creation under the Affordable Care Act. NACHC is strongly supportive of a number of these initiatives, including efforts to create state-based insurance exchanges as well as establish and fund reinsurance programs to improve the affordability of marketplace coverage. These efforts – many of which enjoyed broad, bipartisan support in states from across the political spectrum – were highly instrumental in maintaining affordability of marketplace coverage. NACHC supports approaches that seek to continue these successes, provided that any effort to expand the use of 1332 waivers strictly adheres to the statutory guardrails requiring that any coverage provided via a 1332 waiver be as comprehensive as coverage without it.

Similarly, 1115 waivers have long been a critical tool for state Medicaid programs to foster innovation, maintain cost growth, and expand access. With nearly half of all health center patients on Medicaid, their use immensely impacts health centers and their patients. It is imperative that any activity surrounding 1115 waivers take into consideration the unique nature of federal Medicaid law and regulations' interplay with FQHCs and the patients we serve.

IV. Increasing Competition and Identifying Anti-Competitive Consolidation

Hospital consolidation leads to higher prices with no measurable improvement in quality. In 2016, 90% of Metropolitan Statistical Areas (MSAs) were highly concentrated for hospitals, 65% for specialist physicians, 39% for primary care physicians, and 57% for insurers.[1] As of 2020, the top 10 health systems controlled 24% of market share and their revenue grew at twice the rate of the rest of the market.[2] Prices for services provided by acquired physicians increase by an average of 14%.[3] Vertical consolidation is a financial arrangement that occurs when a hospital acquires a physician practice and/or hires physicians to work as salaried employees. According to a 2015 Government Accountability Office (GAO) study, the number of vertically consolidated hospitals increased from 1,400 to 1 ,700, while the number of vertically consolidated physicians nearly doubled from 96,000 to 182,000. The consolidation occurred across all regions and hospitals sizes, leading to higher Medicare charges.[4]

Q. What role should the Federal Trade Commission (FTC) play in preventing and addressing consolidation in the hospital sector?

We appreciate the Subcommittee's attention to what is perhaps the single most important economic trend in the health care industry and one that will have a sizable impact on health centers in the years ahead. Health centers pride themselves providing high-quality, whole-person primary and preventive care. As is required by federal law, at least half of FQHC board members must be health center patients, and non-patient members must be representative of the health center's service area and reflect the demographics of the health center's patients. These requirements mean that health centers are by their very nature driven by the needs of the community. In contrast, health care consolidation often sacrifices direct connection to communities.

While NACHC defers to the Subcommittee on the most effective role the Federal Trade Commission (FTC) can play to address this issue, NACHC is strongly supportive of policies that maintain the role of local providers to improve affordability and lead to better quality of care. Notably, health centers reduce costly negative outcomes such as avoidable hospitalizations for the very patients who tend to be the most expensive to treat.[5] Health centers also have a track record of serving Medicare beneficiaries at 10%-30% lower costs compared to beneficiaries who sought care with other providers. In competitive environments with higher concentrations of health centers, low-income Medicare beneficiaries have 10% lower average medical spending as compared to regions with less competition from health centers.[6]

Since its establishment in 1992, the 340B program's mission has been to help stretch scare federal resources. But as the number of providers increased substantially to roughly 2,500 active hospitals and over 26,000 contract pharmacy sites in 2020, allowing for increased profiting from the program while prices of drugs for patients actually purchasing these drugs increase, we must consider areas that merit reform and modernization in order to deliver on

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[1]https://www.healthaffairs.org/doi/full/ l 0.1377/hlthaff.20 17.0556
[2]https://www2.deloitte.com/us/en/insights/industry/health-care!hospital-mergers-acguisition-trends.html
[3]https://pubmed.ncbi.nlm.nih.gov/29727744/
[4]https://www.gao.gov/products/gao-16-189
[5]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4887267/
[6] https://www.nachc.org/focus-areas/policy-matters/medicare/

targeted drug and services affordability. The 2019 Government Accountability Office (GAO) report and a 2018 House Energy & Commerce Committee report found issues within the program, including high rates of fraud and abuse in the program like duplicate discounts and diversion, and raised the need for reforms. As Congress considers next steps for the program, please provide responses to the following areas of interest: (a) Program Eligibility, (b) Transparency, and (c) Program Integrity.

3(a)(i). Price Eligibility: Are there other recommended measures for program eligibility, other than Disproportionate Share Hospital?

3(a)(ii). Price Eligibility: Should there be separate eligibility standards for child sites?

3(a)(iii). Price Eligibility: How should eligibility for child sites be considered, if the child site becomes a child site after being acquired by a covered entity?

(3)(b)(i). Transparency: In order to shed light on utilization and true cost savings, while also balancing overburdensome reporting, what are appropriate types of information that should be submitted by covered entities to give both patients and taxpayers a better understanding and confidence that the program's mission is being met?

3(c)(i). Program Integrity: If an independent audit was required for some covered entities, what should the audit assess and evaluate, aside from the Health Resources and Service Administration's authorities?

3(c)(ii). Program Integrity: What data and measures should be included in a contract pharmacy audits?

3(c)(iii). Program Integrity: Are there other audit and reform policies that could be taken to reduce rates of duplicate discounts and reforms among eligible entities?

d. Are there any unique issues that have developed since the start of the COVID-19 pandemic that would merit additional considerations?

The following response pertains to the entirety of the 340B topic in Part IV, Question 3.

Since the creation of the 340B program in 1992, health centers have been model stewards of the program. Importantly, health centers are required by law and regulation to reinvest all 340B savings into activities that further their mission of expanding access to care for the medically underserved.

Health centers' reliance on 340B is critical to their financial viability and ability to provide high-quality, comprehensive low-cost health services, including affordable medications, to their patients. When the COVID-19 pandemic started, health centers across the country developed innovative solutions to continue serving their patients as safely and efficiently as possible. Health centers staff from the C-suite to the front desk have been doing their part every step of the way to

educate their patients on the risks of COVID-19, provide preventive safety measures and facilitate testing and vaccination support for vulnerable communities.

Unfortunately, as health centers and other 340B covered entities responded to the pandemic, pharmaceutical manufacturers took aggressive actions to limit patients' access to affordable medications at contract pharmacies. Since June 2021, at least 12 manufacturers have restricted access to contract pharmacies, jeopardizing health centers' ability to provide COVID-19 related care. Health centers rely on contract pharmacies to expand accessibility for patients, ensuring they can access affordable medications in their own neighborhood without creating additional barriers. Without the use of contract pharmacies, many health centers would not be able to participate in the 340B program due to the significant costs associated with opening an in-house pharmacy. When health centers should solely focus on serving and protecting patients, they are constantly worrying about the viability of the 340B program and the ability to retain critical savings to remain on the front lines. It is also important to note that health centers are uniquely required to submit detailed compliance data to HRSA about their use of 340B savings, which is valuable in providing oversight to ensure the program is not abused and is used consistent with its intent to serve vulnerable people.

NACHC appreciated the actions by the Trump administration to finalize the long-awaited Alternative Dispute Resolution Rule in December 2020. This rule established the only legal mechanism for covered entities to hold manufacturers accountable for violating the 340B statute. NACHC filed a petition against Eli Lilly, Sanofi, and AstraZeneca on behalf of 225 health centers for their failure to ship 340B price drugs to contract pharmacies. Even though the ADR rule was upheld in Court, manufacturers refuse to comply with the ADR process, making it virtually impossible for health centers to receive 340B drugs and provide patients affordable medication and the comprehensive care they deserve. Under the law, 340B covered entities cannot intervene in the government's litigation against manufacturers and have no other options to protect the integrity of the 340B program. Every day that passes, health centers are losing vital 340B savings that are reinvested into patient care that is critical during a pandemic. While 340B-supported services vary by FQHC, they often include substance use disorder (SUD) services, adult dental care, behavioral health counseling, and patient outreach and education services. Health centers also cite recent smaller-scale, pandemic-related services such as food pantries for patients with food insecurity, nutritional classes, and travel vouchers for patients in extremely rural areas. Reduced access to 340B discounts threatens these services.

The Health Resources and Services Administration (HRSA) has dedicated countless resources to defend the true intent of the 340B program, which includes the use of contract pharmacies for safety net providers to stretch scarce resources. However, it is clear from the litigation and the manufacturers' continued violation of the 340B statute that Congressional action may be the only solution to the ongoing instability in the 340B program. Specifically, Congress should consider expanding HRSA's regulatory authority to issue comprehensive policies to govern the 340B program. This authority would allow HRSA to develop regulations to address issues in ongoing litigation, like the use of contract pharmacies, data collection, and unilateral pricing restrictions.