December 6, 2021

VIA ELECTRONIC SUBMISSION: https://www.regulations.gov

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
Attention: RIN 1210-AB00

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-9908-IFC
Attention: RIN 0938-AU62

RE: Comments on RIN 1210–AC00
Department of Health and Human Services, Department of Labor, Interim Final Rule on Requirements Related to Surprise Billing; Part II

Dear Sir/Madam:

The National Health Law Program (NHeLP) is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and underserved people. NHeLP provides technical support to direct legal services programs, community-based organizations, the private bar, providers and individuals who work to preserve a health care safety net for the millions of low-income people, including those who are uninsured or underinsured. Medical debt is the largest source of debt owed to collections agencies in the U.S.[1] Enactment of the No Surprises Act (NSA) is a timely and critical opportunity to protect consumers from surprise medical bills and provide them with the transparency they deserve to make informed decisions about their health care. Accordingly, NHeLP is pleased to offer our comments on the Department of Health and Human Services (HHS), the Department of Labor (DOL), and the Department of the Treasury's (DOT)

(collectively, the Departments) second interim final rule for requirements related to surprise billing.

Medical debt is an enormous health equity issue. Despite advancements to increase access to health care, millions of people struggle with medical bills. However, the rates of medical debt are drastically lower in states that have Medicaid expansion than those without it. Medical debt continues to grow during the COVID-19 pandemic. Even federal and state efforts to curb health and economic related impacts did not stop hospitals from suing people during 2020 amidst the ongoing health crisis.[2] It is estimated that 43% of families with legal debt also have medical debt.[3] One third of households with medical debt are also paying off student loan debt. Medical debt is also highest in the South and in lower income neighborhoods.

In the discussion below, we offer comments related to: good faith estimate requirements, the patient-provider dispute resolution process (SDR), and language access requirements.

Requirements for the Good Faith Estimate Process

We support the development of the good faith estimate process for the uninsured and self-pay individuals (collectively, uninsured). We believe the requirements outlined in the IFR for providers or facilities (collectively, providers) will help minimize surprise billing and help prevent high medical debt for those without health insurance and who cannot afford to pay for the health care items and services they need. The language under the IFR promotes transparency and advance notice for uninsured consumers. Health care, including insurance coverage and medical billing are notoriously confusing for consumers. Therefore, good faith estimates must be comprehensive, detailed, and understandable to consumers. Requiring providers to deliver good faith estimates of items and services is an important component of the IFR to minimize surprise bills to unsuspecting consumers and will equip them with the necessary information to make fully informed health care decisions.

While we support this piece of the IFR, additional detail on the requirements outlined under 45 C.F.R. § 149.610 are necessary in order for good faith estimate protections to work in practice. We offer the following recommendations to ensure the spirit of these protections is fully realized.

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[1] Kluender R, Mahoney N, Wong F, Yin W., JAMA, Medical Debt in the US, 2009-2020 (July 20, 2021), available at https://jamanetwork.com/journals/jama/article-abstract/2782187.
[2] Owens C, Axios, America's Biggest Hospitals vs. Their Patients (June 14, 2021), available at https://www.axios.com/hospitals-patients-lawsuits-billing-4bfa93b2-3bbf-48a5-b8e2-2f8a68c533a9.html.
[3] Abbi S, Wedderburn R, Aspen Institute Financial Security Program, Medical Debt and Its Impact on Health and Wealth: What Philanthropy Can Do to Help (2020), available at https://assetfunders.org/medical-debt/?mc_cid=a0ce16df10&mc_eid=c56de667d0.

1. **Inquiry about coverage status and delivery of good faith estimates**

We support the requirement that providers must inquire verbally *and* in writing about a consumer's health coverage status. 45 C.F.R. § 149.610(b)(1)(iii). We strongly recommend that the written notice is provided to the consumer in the manner they prefer either by U.S. mail, hand delivery (if produced while the consumer is on site), or electronically. However, we are concerned that the notice requirements will not be sufficient to inform consumers about the good faith estimate and that the amount of information and the way it is presented will be confusing and overwhelming.

For many people, the good faith estimate will arise while they are navigating their personal health issues. Often, medical billing paperwork is challenging to understand and burdensome, especially while dealing with health issues. While we appreciate the IFR seeks to address these concerns through the detailed standards under 45 C.F.R. § 149.610(b), it remains unclear how HHS will monitor compliance with these requirements. We strongly recommend that HHS issue guidance that details uniform protocols and best practices that providers must adopt to help streamline the process between parties and keep a record documenting that providers met the requirements under 45 C.F.R. § 149.610(b)(1)(iii) to both inquire about coverage status and inform *all* uninsured individuals of their right to the good faith estimate. Without uniform protocols and documentation, it will be difficult to determine compliance and potentially undermine the goal of transparency that the good faith estimate process rule seeks to provide.

While we appreciate that the current language under this section considers "any discussion or inquiry regarding the potential costs" of items or services a request for a good faith estimate, it is unclear what the process will be in practice. HHS needs to issue guidance at the very least, in the course of the NSA's implementation that spells out the standards providers must follow so that consumers are provided a good faith estimate when there is, in fact, any discussion or inquiry about potential costs for services. HHS must also exercise oversight and monitoring to ensure providers do provide the required good faith estimates to patients. We also suggest that in the event of noncompliance that HHS enforce these standards by protecting patients from paying anything beyond the amount listed in the good faith estimate.

2. **HHS model notice for accessible good faith estimates**

We support the efforts of HHS to require that good faith estimates be available in accessible formats to all individuals and that information about them are provided verbally, displayed on provider websites, in provider offices, and on-site where scheduling for services may occur. 45 C.F.R. § 149.610(b)(1)(iii). Although the internet is accessible to many, it is not accessible to all, especially populations with lower incomes, uninsured individuals, rural communities, immigrant populations, and houseless individuals, among others. While the IFR contains

standards for accessible formats and language access, HHS must establish additional guidance on best practices to providers to make sure information is consistently available and understandable to consumers.

We also appreciate the opportunity to comment on HHS' anticipated model notice for provider good faith estimates. We support the specific content requirements under 45 C.F.R. § 149.610(c) and the general outline demonstrated in "Chart 1" of the IFR. As explained above, the notice should be clear and understandable, and expected charges should be itemized and grouped with the respective provider or facility to enable readability and organization. We anticipate that good faith estimates will be lengthy for some individuals seeking more intensive treatment, so clear and organized information will be critical for it to be understandable.

We recommend that notices and instructions to consumers are simple. Specifically, we recommend that good faith estimate documents:

- Include white space;
- Use clear headings;
- Be written from a consumer's perspective, not the providers' perspective;
    - This includes assuming no prior knowledge of a billing process or medical industry practices;
    - Use of the "you" pronoun rather than "we" or "I";
    - Provide only the information that is most relevant to a consumer;
    - Anticipate likely questions or concerns that a consumer would have and address those concerns;
- Use a Q&A format for example, rather than long paragraphs;
- Avoid use of jargon or acronyms;
- Use plain English that is at or below a 6th grade reading level;
- Draw attention to key dates and deadlines;
- Use active rather than passive language;
- Provide succinct explanations; and
  Provide contact information to someone who can answer a consumer's likely questions about the notice. This may include a link to an FAQ.

We also agree with HHS' requirement that the expected charges reflect "any available discounts or other relevant adjustments" that providers expect to apply to the billed charges for uninsured consumers. However, it is unclear how providers will screen consumers for financial assistance and calculate the applicable discounts and adjustments within the time constraints outlined under 45 C.F.R. § 149.610(b)(1)(vi). The example in "Chart 1" does not include information about discounts or adjustments. We recommend that HHS include an additional column for discounts and adjustments.

Often, consumers apply for financial assistance after they receive items and services. Consumers may be eligible for a complete or partial write off of the bill which is determined based on several criteria, including income. Therefore, determinations for financial assistance are individualized to the consumer. The IFR does not describe how discounts and adjustments will be calculated, whether set by a pre-determined amount or tailored to the specific circumstances of the consumer. Additional clarity is necessary as to how this financial assistance will be integrated into the good faith estimate calculation so consumers receive the most accurate information to make fully informed decisions about their health care, protect them from surprise bills, and also enable providers to be able to timely deliver the good faith estimates.

We note that this could be an opportunity to streamline the financial assistance process by integrating financial assistance determinations into the good faith estimate process, if that is HHS' intent. Financial assistance can be a lifeline for uninsured patients but it is notoriously underutilized.[4]

3. Clarifying the scope of uninsured and self-pay consumers

We note the broad definitions of uninsured and self-pay patients under the IFR. We have concerns about the broad definitions of "uninsured (or self-pay)" consumers who fall under 45 C.F.R. § 149.610(a)(2)(xiii)(B), because they may have "benefits for such item or service," but do not seek to submit a claim to their insurance. We anticipate that consumers under this category will be a rare occurrence. However, in the event consumers opt for self-pay while they have health benefits, it is critical that clear disclaimers are included in notices, websites, displays, on-site locations, and written and verbal communications to consumers. Providers should be obligated to verify the consumer's insurance status and that they do not want to submit a claim to their insurance when delivering good faith estimates or bills in the event a patient is billed for services who did not inform the provider of this so they can correct and dispute it with the provider. If a consumer is incorrectly billed for services because they were erroneously categorized as self-pay, they must have adequate notice to dispute incorrect charges. We suggest that HHS require these verification safeguards through regulations and in the model notice.

[4] 72% of private nonprofit hospitals had a fair share deficit (spent less on charity care and community investment than they received in tax breaks). Public hospitals are well-represented among the top 10 in the U.S. and 10 hospitals with the largest FSD accounted for 10% of the nation's total ($1.8B). Lown Institute Hospitals Index, 2021 Community Benefit Report (July 2021), available at https://lownhospitalsindex.org/2021-winning-hospitals-community-benefit/.

4. Good faith estimate timing deadlines

We appreciate the requirements in the IFR to ensure timely and expeditious delivery of good faith estimates so that consumers have advance notice of the expected charges for their care. However, additional clarification is needed, particularly around the timelines between urgent and non-urgent services. Realistically, timing for emergency services will require a different level of urgency than non-emergency services. Also, the rule should clarify that "business" days are different for emergency facilities or 24-hour health care settings than for other facilities or providers that do not engage in business every day. Since emergency rooms, hospitals and some urgent care centers are open 24 hours a day, a business day is different than business days for other health care facilities or providers.

We also recommend adding a requirement that providers must issue a good faith estimate in a more expedited timeframe if the date of service is within a period where the provider cannot meet the prior notice requirements under 45 C.F.R. 149.610(b)(1)(vi)(A)-(C). We suggest requiring an expedited timeframe for such necessary services when not expediting delivery of the good faith estimate would seriously jeopardize the life or health of the consumer or would jeopardize the consumer's ability to regain maximum function. As such, we suggest that the good faith estimate be delivered no less than 12 hours or 24 hours before the item or service is rendered.

5. HHS enforcement discretion during the first year of implementation

We realize that implementation of the NSA will take time and that HHS is exercising discretion in enforcing the IFR requirements against convening providers and co-providers in the first year the NSA goes into effect. However, we are concerned that consumers will be erroneously billed. The language under 45 C.F.R. § 149.610(b)(2) requiring good faith estimates from both the convening providers *and* co-providers for an item or service is critical to the goals of the Act. Most major medical procedures require a team of providers to fully administer the item or service, including convening providers and co-providers. The surprise bills that consumers receive often come from out-of-network providers at an in-network provider or facility. We are concerned that enforcement of the core protection of the NSA will get lost during this initial period.

Consumers need a full list of the expected charges for items and services so they can make fully informed decisions about their health care and avoid erroneous bills. This is especially timely as COVID continues to spread across the U.S. which, as cited in the IFR, has

exacerbated already-existing disparities and mistrust among communities of color and other populations who may be underserved by our health care system. We strongly urge that HHS issue, at a minimum, interim guidance to convening providers and co-providers to ensure that consumers are aware of who is providing their care for a given item or service. This could be accomplished by providing the names of all providers involved with the item or service so consumers avoid surprise bills during the first year of implementing the NSA. It is crucial that consumers are informed about *all* co-providers involved in their care, including those who are out-of-network, before the scheduled item or services takes place, otherwise people across the country seeking care are not going to understand that NSA protections are available to them during a health crisis.

Patient-Provider Dispute Resolution Process (SDR)

We support the SDR process for uninsured consumers to assert their rights and dispute erroneous or surprise billing. We also appreciate the minimal criteria set to qualify for SDR. However, we strongly recommend that HHS change the dollar threshold of $400 or more in order for consumers to qualify for the SDR process. An alternative standard could be that bills are "substantially in excess" of the good faith estimate when the bill is either $400 or more than the expected charges, or when the bill is 10% higher than the expected charges for bills that are under the $400 threshold.

1. SDR filing deadline

We appreciate that the IFR seeks to provide consumers with enough time to submit the initiation notice for the SDR process, but we believe 180 days is more aligned with the timeframes under managed care appeals processes. For example, in California managed care appeals, internally reviews allow for 180 days and external reviews allow for six months, in addition to allowing longer for good cause if a consumer had extenuating circumstances.[5] California also extended the suspension period for hospital providers sending outstanding bills to collections agencies from 150 days to 180 days.[6] The reality for many consumers is that medical care takes time and when multiple providers are involved, the arrival of bills staggers over time. Consumers need ample time to collect the necessary bills and documents they need for SDR while also juggling their health care needs.

[5] 28 CCR § 1300.68(b)(9), 28 CCR § 1300.74.30(f)(1)
[6] Cal. Health & Safety Code § 127425(f), (effective January, 2022), available at https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202120220AB1020.

2. SDR administrative fee

We strongly oppose HHS' imposition of a $25 administrative fee for the SDR process. The individual right to a hearing before being deprived of property is fundamental to due process. The purpose of the NSA is to protect uninsured consumers from medical debt, which is only growing in the U.S. Many people are living without health insurance because it is unaffordable or inaccessible. We are concerned that the fee is per billing dispute, as the "substantially in excess" threshold to qualify for SDR is *per provider or facility*. While the $25 fee may not seem exorbitant at a glance, it will pose a barrier to consumers who are already being faced with potential medical debt, especially if consumers receive multiple surprise bills in which case the fee will add up. This is particularly true during the pandemic as many people have lost employment or are struggling financially to make ends meet. The burden of affording a fee to access the SDR process is a barrier and will be the difference between some consumers forgoing their rights and incurring medical debt or potentially avoiding it through successful dispute resolution. We strongly urge HHS to either remove the fee or allow for a fee waiver or hardship exemption for low-income individuals. This is in alignment with many public and government programs that recognize fees are cost prohibitive for low-income individuals.

3. Notice Requirements of the SDR Process

We appreciate the opportunity to comment on the initiation notice and the insufficiency notice under the SDR process. Adequate notices are key to protect due process by informing consumers about the action being taken with respect to their medical care and their legal rights to dispute surprise bills. Additional clarification on the initiation notice and insufficiency notice is necessary to advance due process protections.

A. Initiation Notice:

Consumers must be clearly informed how to exercise their right to the SDR process under 45 C.F.R. § 149.620(c)(2). The initiation notice should be clear, in plain language, and accessible in alternative formats as well as in a culturally and linguistically appropriate manner. It should include language that explicitly mentions that the consumer is getting billed because the consumer either:

(1) indicated that they do not have health insurance benefits,
(2) their health insurance benefits do not cover the item or service provided, or
(3) they have elected to self-pay.

Language should also encourage consumers to contact the billing provider if they believe either of the above reasons are incorrect and that they received the bill in error. We base our recommendation on the hopefully unlikely occasion that consumers will elect to self-pay if they have health insurance benefits. Nevertheless, there is often confusion around what health insurance does and does not cover and providers may also be misinformed or misinform patients about what is covered.

B. Insufficiency Notice:

While we support the insufficiency notice as an opportunity for consumers to have extended time to submit additional or missing documents, we are concerned that the IFR only provides a twenty-one (21) calendar day window to do so. This seems like an arbitrary time period and is too short considering that providers and health plans require advance notice in the event consumers request copies of their records and it puts consumers without internet access who must go through SDR via U.S. mail at a disadvantage. We strongly suggest that this timeframe be extended to a minimum of thirty (30) days or up to a maximum of sixty (60) days. We appreciate that the IFR includes the option to request extensions for extenuating circumstances, however, it is unclear how extension requests will be made, how they will be evaluated or what criteria will be considered in granting them.

We also appreciate that the IFR provides the consumer with a fourteen (14) calendar day extension for an SDR entity's failure to provide the notice in accessible formats for persons with disabilities and LEP within fourteen (14) calendar days. However, it does not go far enough. Persons without disabilities and English-speakers get twenty-one (21) calendar days to provide additional documents. However, individuals without the ability to understand the contents of the notice are deprived of the full twenty-one (21) calendar day timeframe. A core principle of due process is that individuals receive notice before they are deprived of property and they are afforded equal protection of the laws. Inaccessible notices for individuals with disabilities or LEP are not sufficient until they actually receive a notice they can understand. Under the IFR, consumers with disabilities or LEP could potentially get only fourteen (14) calendar days to respond to the insufficiency notice. We strongly recommend that the twenty-one (21) calendar day timeframe start upon receipt of an equivalent insufficiency notice. Once a consumer has received the notice in their requested format or language, then the twenty-one (21) calendar days should begin to preserve and equally administer due process rights for everybody. Or, alternatively, we recommend that the insufficient notice response timeline is tolled for the extra time it takes the consumer to receive the equivalent notice.

Language Access

NHeLP appreciates HHS and the other Departments for recognizing the importance of language access by requiring providers and facilities to provide culturally and linguistically appropriate notices to consumers during the good faith estimate and SDR processes, as well as the internal and external review processes for surprise billing disputes. We strongly support the requirement that providers supply notice and consent documents in the top fifteen (15) languages in a state or geographic region where the provider is located as outlined under the IFR, Part I released in July 2021. While we support that, there should also be at least some safeguards to consumers who do not read one of the top languages so they do not consent to waive their rights when they do not understand. If a consumer does not speak one of the top 15 languages, the provider should obtain a competent interpreter to explain the notice and consent document and obtain oral consent, and document this process. This is crucial to advance health equity for all individuals as language barriers and inaccessible formats are a major barrier for individuals with disabilities and LEP to understand information about their health care and exercise their due process rights.

We support the IFR provisions that specifically require information about the availability of a good faith estimate is supplied "in accessible formats, and in the language(s) spoken by individual(s) considering or scheduling items or services…". 45 C.F.R. § 149.610(b)(iii)(C). We also support that the insufficiency notice will be made available in accessible formats and have specific recommendations, as discussed above.

However, we believe that the IFR does not go far enough to align these protections for the external appeals process. The 2011 federal appeals regulations severely weakened the 2010 appeals regulations regarding language access standards for health plan EOBs and denial notices. Currently, group plans only must provide translated EOBs and other claims notices to consumers if at least 10% of the county population in which the claimant resides is literate only in the same non-English language. Currently, a low number of counties in the U.S. meet this threshold, and an exponentially smaller number of counties meet the threshold in a language that is not Spanish.[7]

In addition, plans and issuers are not required to automatically send all subsequent plan documents in the consumer's requested language, as previously required under the 2010 regulations. Consumers must request translation for each and every EOB they receive. We urge the Departments to return to the prior regulations of 2010 to provide more robust protections for persons with LEP as the current thresholds are too narrow for counties to meet.

[7] Centers for Medicare & Medicaid Services, Culturally and Linguistically Appropriate Services (CLAS) County Data (January 27, 2016), available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CLAS-County-Data_Jan-2016-update-FINAL.pdf.

Given the number of plan documents that consumers receive, it is especially burdensome to require that consumers request that such documents are translated in every instance.

Thank you for your consideration. If you have any questions or need further information, please contact me at (310) 736-1651 or rosellini@healthlaw.org.

Yours truly,

Skyler M. Rosellini
Senior Attorney