



August 12, 2021

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

The Honorable Chiquita Brooks-LaSure
 Administrator
 Center for Medicare and Medicaid Services
 7500 Security Boulevard
 Baltimore, MD 21244

RE: PRA Listings for the Implementation of the No Surprises Act (CMS-10780 & CMS-10779)

Dear Secretary Becerra and Administrator LaSure:

Thank you for the opportunity to submit comments on the documents related to the implementation of the No Surprises Act (NSA) including standard notice and consent, complaints processes, model disclosures and their supporting statements.

The 21 undersigned organizations represent millions of patients and consumers facing serious, acute, and chronic health conditions across the country. We believe that access to affordable, accessible, and adequate health insurance is key to improving the health and wellbeing of all people living in the United States.¹ Together, we worked alongside Congress to develop the bi-partisan, bi-cameral legislation that was enacted at the end of last year to protect patients from receiving unexpected medical bills. Our

¹ Consensus Healthcare Reform Principles: <https://www.heart.org/-/media/files/get-involved/advocacy/access-to-care/050819-healthcare-principles44logos.pdf?la=en&hash=413C07330CE837C8AEDF059454378C45B655594A>

organizations are pleased that the individuals and families we represent have been furnished new rights and protections under the NSA and look forward to working with the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) to further strengthen these safeguards through the regulatory process.

Surprise billing has impacted millions of Americans, with one in six people having received a surprise bill.² A recent study published in JAMA exploring medical debt and its drivers found that Americans owed more than \$140 billion dollars and that unpaid medical bills are its largest source.³ We believe the NSA, if implemented properly, will help reduce the physical and financial burdens of illness on patients and help contribute to longer, healthier lives. We therefore appreciate HHS' consideration of [our previous comments](#)⁴ and can clearly see the interests of the patient and consumer community reflected in both the consumer-facing documents we offer comment on here, and the interim final rule (IFR). While the documents provided by HHS are a strong first step towards improving protections for patients who may be surprise billed, we believe these consumer-facing resources would benefit from further clarification to ensure patients understand their rights and receive full protections under the NSA.

We respectfully offer the following comments and recommendations addressing specific provisions of the documents included in the NSA's paperwork reduction act (PRA) notices CMS-10780 and CMS-10779.

Notice & Consent

The requirements related to the notice and consent exception are set forth in section 2799B-2 of the Public Health Service (PHS) Act, as added by the NSA, and, among other things, outlines the requirements related to the content, method, and timing of the notice and consent communications, the requirements related to language access, and the exceptions to the applicability of the notice and consent process. Notice and consent documentation is amongst the most critical pieces of information patients must understand and assess during their care. Consumers must therefore have complete, accessible information in hand when asked to provide their consent to receive out-of-network care.

Utilization of Notice & Consent

Protecting patients and consumers from the practice of surprise billing lies at the heart of the NSA. As such, our organizations have repeatedly articulated our firm belief that patients and consumers who fully understand their protections under the NSA will not want to waive them. The NSA details the scenarios under which a patient may or may not receive notice and consent documents waiving their protections, as well as a list of providers who may never surprise bill. However, the statute also recognizes the Secretary's authority to extend these protections to additional providers when a patient receives care at an in-network-facility. We ask that you take a comprehensive approach to defining the facilities and providers to which the surprise billing protections apply for both emergency and non-emergency care.

² Lopes, L., Kearny, A., Hamel, L., & Brodie, M. (2020, February 28). Data Note: Public Worries About And Experience With Surprise Medical Bills. Kaiser Family Foundation. <https://www.kff.org/health-costs/poll-finding/data-note-public-worries-about-and-experience-with-surprise-medical-bills/>

³ Kluender R, Mahoney N, Wong F, Yin W. [Medical Debt in the US](#), 2009-2020. JAMA. 2021;326(3):250–256. doi:10.1001/jama.2021.8694

⁴ Partnership to Protect Coverage No Surprises Act Implementation Recommendations: <https://www.heart.org/-/media/partnership-to-protect-coverage-recommendations-for-no-surprises-act.pdf?la=en>

If patients are to be adequately protected by the NSA, it is critically important that notice and consent waivers not be allowed to circumvent patient safeguards. To this end, we believe notice and consent waivers should not be used routinely or used in so perfunctory a manner that they constitute a *de facto* exemption for facilities and providers to avoid adhering to these protections. Use of notice and consent documentation should be infrequent and used only in circumstances where the patient has *knowingly* sought out-of-network care.

To maximize these protections for patients, we suggest the department restrict the use of notice and consent to those services that were scheduled at least 72 hours in advance of the service being performed *and* where the patient knowingly sought out-of-network care. Patients should not be asked to waive protections for out-of-network services at an in-network facility after they enter the facility, even if consultations or services are provided by out-of-network providers during the course of their care. Limiting the use of these documents to out-of-network care that is scheduled at least 72 hours in advance offers patients the most robust protections by drastically reducing the likelihood that providers or facilities would use notice and consent inappropriately.

Post-stabilization Notice & Consent

Our organizations appreciate the steps HHS has taken to safeguard patients from balance billing in emergency and post-emergency situations and look forward to providing additional comments in response to the IFR. However, we recognize that the notice and consent documents modeled by HHS will have a significant impact on how patients, including those who need post-stabilization care, understand their rights and make decisions about their care. There are a significant number of variables that factor in to how a patient is or is not protected during post-stabilization under the NSA. The preamble to the IFR includes a thoughtful discussion of the many ways in which patients may be compromised and vulnerable at this point in their care and therefore unable to provide consent that is truly voluntary and informed. In addition, the presumption that post-stabilization care is emergency care unless and until three criteria are met, as articulated in the rule, we believe adds critical safeguards and recognizes that seeking consent in these circumstances warrants additional considerations. We therefore urge HHS to develop a standalone version of the notice and consent document for use in the event a patient receives a request to waive their rights after receiving emergency care (i.e. post-stabilization).

In addition to including information on the three criteria that must be met (or more, if there are additional requirements or prohibitions under state law), this document should include information about the physician seeking the notice and consent waiver, the patient's ability to travel, any relevant barriers that may prevent the patient from being transferred into an in-network provider or facility (such as access to transportation services, including services for individuals with disabilities), or other extenuating circumstances that may offer patients and consumers continued protection under the NSA. If the patient agrees to be transferred to an in-network provider or facility, documentation about the name, address and contact information of the in-network provider or facility should be included as well as confirmation regarding the availability and arrangement of transportation services and confirmation that the in-network provider or facility has agreed to accept the patient.

Standardized Notice & Consent Documentation

Our organizations welcome HHS' approach to providing standardized documents as part of the notice and consent process. Minimizing paperwork variations and standardizing key information across states, facilities, and providers can help decrease consumer confusion and provide clear expectations about what patients can anticipate should they choose to waive their rights.

As part of the intake process, many patients may receive additional information about their financial obligations stemming from care. While we recognize that providers and facilities may have need to communicate information about payment, billing, or other financial responsibilities related to care, it is critical that patients do not receive competing or contradictory information to that contained in the notice and consent documents. Facilities and providers should not require patients to sign additional documentation waiving (in part or in full) their NSA protections or any other financial protections they may have under separate federal or state laws. The Departments should consider adding additional language to this effect to the standard model and in guidance to providers, issuers, and facilities.

Patients also know that receiving care can come with mountains of overwhelming, confusing paperwork. We strongly support the Department's requirements that notice and consent documentation be provided separately from other paperwork provided by the facility or provider and that a representative must be available to answer questions in-person or via phone.

Language Access Requirements

The requirements that notice and consent documents be provided in plain, easy to understand language helps ensure that patients understand their rights and protections, as well as their responsibilities, under the law. We encourage HHS to apply these standards to all documents, including but not limited to notice and consent. Additionally, our organizations recommend that HHS require all communications with a patient, including their rights under the NSA, be provided to them in the manner and language that they request. This would ensure that patients have the fullest ability to make informed choices about their care and rights as they navigate their treatment.

We thank the Department for reminding covered entities of their obligations under civil rights law to provide meaningful access to individuals with limited English proficiency (LEP) and effective communication with individuals with disabilities. Individuals with LEP and/or disabilities should only be required to request accessible materials once when interacting with a provider, and should subsequently be provided the materials they need in a form and manner accessible to them. Language assistance services should be provided by professionals trained in medical interpretation and who have cultural competency training. Language assistance services including translation services, written translations, and interpretation services should include not only resources for individuals with limited English proficiency (LEP), but also resources for disabled individuals who may require auxiliary aids or other information and communication technologies. To the greatest extent possible, these services should be provided by professionals trained in medical interpretation and who have cultural competency training.

The Department suggests that each individual entity should be responsible for providing documents translated into the 15 most common languages within the applicable geographic area. While we support this policy, we urge the Department to provide an array of standardized documents that have been translated and vetted by the department in language that are commonly spoken across the United States such as Spanish, Chinese (including Mandarin, Cantonese and other dialects), French, Arabic, and Korean. Providing these documents will help ensure that the language, including language specific to medical information, is correctly and appropriately translated.

Notification Timelines

While our organizations strongly support HHS' actions to make information accessible to patients and consumers, it is also important that a patient's ability to access information in a timely manner be considered. Patients who request information in another language or through another mode (such as

braille or via translation services) should not be penalized if the provider or facility fails to provide resources in a timely manner. The requirement that notice and consent be provided at least 72 hours in advance of a scheduled procedure cannot be met until all documentation and information is available to the patient in their preferred language and in an accessible manner.

Our organizations are concerned about the application of the 3-hour notice and consent process as currently drafted in the IFR and feel that it has an unreasonably high risk of abuse. For example, patients may be asked to sign notice and consent documents after they have entered the in-network facility if an out-of-network physician *may* provide them care. Other circumstances, such as shift rotations or schedule changes, could result in out-of-network care being provided. Patients should not be subject to notice and consent in these or other potentially coercive circumstances that may create unreasonable delays in care. While we look forward to providing more robust comments on the 3-hour rule in response to the IFR, we feel that it is important to contextualize this within the documents provided here. It is critical that patients do not feel coerced into signing a waiver of their rights, especially under medically urgent situations.

Model Notice & Consent Form

In addition to the general comments above related to the use, presentation, and accessibility of the notice and consent form, we also offer the following specific feedback on the model document. We have reflected these comments on the document itself, along with suggested changes in **Attachment 1**.

- The current title of the document “Surprise Billing Protection Form” is a misnomer and may create consumer confusion. Instead of offering protections, the documents allow patients to waive them. It is critical that HHS correct this issue. We suggest changing the title to “Waiver of Surprise Billing Protections” or similar. The form currently used in the state of Texas has additional direct and clear language that could be helpful in this instance and asks: “do you agree to pay more for out of network care and give up important legal protections?”⁵ (pg. 1 of model form).
- The model document’s black box section states that patients are not required to sign this document if they didn’t have a choice of doctor when they *received* care. We recommend this be changed to *scheduled* care, to ensure that patients have advance understanding that the services they are seeking are out-of-network and can benefit from the full protections offered under the NSA. Changes to reflect *scheduled* should be made throughout the document. (pg. 1 of model form).
- The black box also directs patients to “take a picture and/or keep a copy of this form for your records”. We suggest that additional language be added to reflect that it is mandatory for your provider/facility to provide you with a copy of this document either in-person or electronically. (pg. 1 of model form).
- On page 2, the model form details a number of bullet points including one titled “questions about your rights.” These sections should always have the federal complaint line and website listed in addition to the state CAP (if applicable) and state agency. It should also include anti-coercion language such that patients know they should not be pressured to sign this paperwork. We suggest the following:
“It is against the law for anyone to force you to sign away your rights. If you have questions or need help understanding your rights, please contact [CAP, Federal Line, State Regulator – list their contact information]”.

⁵ <https://www.tdi.texas.gov/forms/lhlifehealth/ah025.pdf>

- The notice and consent waiver does not currently provide any information about a patient’s right to revoke notice and consent, how they would do so, and what procedural requirements they must adhere to in order to revoke notice and consent. Our organizations strongly urge HHS to include this information prominently on the form. (pg. 3 of model form).
- As drafted, the model notice and consent document does not have information about what constitutes a “substantially different” estimate, what rights a patient may have to challenge the estimate if it is substantially different, or how to challenge it. We feel these rights are important to reflect on the document and encourage HHS to make changes that reflect them. (pg. 2 and pg. 4 of model form).
- Our organizations believe that a separate document should be developed for use in post-stabilization scenarios as there are many criteria that could determine if care should be provided in or out-of-network (see comments under [utilization of notice and consent](#) above). (pg. 2 of model form).
- The bottom of page 2 lists a “more information about your rights” section. This should include the national complaints line, consumer assistance programs (CAPs), and other resources for consumers. Additionally, patients should have access to the 2-page disclosure notice when reviewing these forms. We urge HHS to consider making it mandatory to provide this information at the time of scheduling. (pg. 2 of model form).
- If multiple providers seek a waiver through one notice and consent form, the charges section on page 4 should reflect each individual provider responsible for each charge. Providers should also be required to list their specialty and affirm they are not among those providers barred from seeking consent to waive patient protections. In addition, additional details should be provided on the final bill or bills such that patients can easily make comparisons and track charges. Bills should not be sent in iterations or with long delays. (pg. 3 of model form).
- Since the document represents an agreement that a patient will waive their rights with a specific provider or set of providers/facilities and allow them to balance bill, said providers and/or a representative of the facility should also be asked to sign this document (pg. 3 of model form).
- The language at the bottom of page 3 directing patients to “take a picture and/or keep a copy of this form for your records” should be edited to be consistent with our recommendations from page 1: additional language should be added to reflect that it is mandatory for your provider/facility to provide you with a copy of this document either in-person or electronically.
- Information about “good faith” estimates and patients’ rights when the final bill triggers the “substantially different” threshold should be included. (pg. 4 of model form).

Model Disclosure Notice

Section 2799B-3 of the PHS Act, added by the NSA, requires providers and facilities to provide disclosures regarding patient protections against balance billing. Among other things, the statute requires health care providers, facilities, and issuers to make publicly available, post on a public website, and provide to participants, beneficiaries, and enrollees, a one-page notice about the balance billing requirements and applicable prohibitions. Our organizations are pleased to see that the model disclosure implements many of the key patient protections that we have advocated for.

Display Requirements

While we believe the Department takes positive steps toward ensuring patients and consumers have the opportunity to understand their rights, we remain concerned that providers and issuers may bury the required disclosure information on their public websites. In accordance with the interim final rule, to satisfy the requirement to post the disclosure on a public website, the disclosure or a link to such disclosure must be searchable on the provider's or facility's public website. HHS states that it is of the

view that the required disclosure information would not be publicly available unless displayed in a manner that is easily accessible, without barriers, and that ensures that the information is accessible to the general public, including that it is findable through public search engines. However, as evidenced by the hospital price transparency experience so far, some hospitals bury the data deep on their websites or have not included all the categories of prices required. Additionally, a sizable minority of hospitals have not disclosed the required information at all.⁶ As such we recommend that either a link to or posting of the disclosure be accessible on the homepage or be easily located through a search function on the provider, facility, or issuer website.

In addition to the public display requirements, we encourage HHS to require that this disclosure form be shared with patients more frequently. Specifically, we recommend that the disclosure information be given to patients when they schedule an appointment, when they receive a bill, when they are asked to waive their rights via notice and consent, and when they receive an EOB. This ensures that patients have the basic information they need to navigate their rights under the NSA.

Language Access Requirements

We commend the agency's action to ensure that the required disclosure language is clear and understandable, especially as it applies to the utilization of plain language in the disclosure statements, the provision of meaningful access for individuals with limited English proficiency, and the provision of effective communication with individuals with disabilities. However, we have concerns related to the potential translation services employed by the specific entities covered by this rule. As noted above, to ensure that those patients with limited English proficiency fully understand their protections against balance billing, we recommend that HHS develop additional model disclosures for common languages in the US as well as develop quality standards for translation services that can be used in compliance determinations.

Model Disclosure Notice

In addition to the general comments offered above, we also offer the following specific feedback on the model document. We have reflected these comments on the document itself, along with suggested changes in **Attachment 2**.

- Our organizations strongly support the public disclosure of patient rights under the NSA. However, we feel that providing disclosure frequently will help ensure continuity of understanding for patients. In addition to requiring public display, we urge HHS to provide disclosure for each bill, each EOB, with all requests to waive NSA rights via notice and consent, and any other communication that may be subject to NSA protections. (pg.1 of model disclosure).
- Similar language to the above has been inserted in the "Instructions for Group Health Plans and Health Insurance Issuers" section (pg.4 of model disclosure).
- Our organizations suggest edits to the language at the top of page 7 that reflects that requests to waive NSA protections via notice and consent should be rare and limited to services that were *knowingly scheduled* by the patient more than 72 hours in advance of the service. (pg.7 of model disclosure). With regard to the "your health plan generally must", we recommend amending the second bullet to include "including services provided by air ambulances". (pg. 7 of model disclosure).

⁶ Appleby, Julie, Hospital Prices Must Now Be Transparent. For Many Consumers, They're Still Anyone's Guess, Kaiser Health News, July 2, 2021, <https://khn.org/news/article/hospital-prices-must-now-be-transparent-for-many-consumers-theyre-still-anyones-guess/>.

Complaints Submission Process

We applaud the Departments for beginning its work to establish the consumer complaint process to receive complaints regarding violations by health care providers, facilities, and providers of air ambulance services regarding balance billing requirements under the NSA.

We want to reiterate that the federal complaint system should operate with a “no wrong door” policy that will receive complaints from any source, including but not limited to CAPs, and route complaints to the appropriate state or federal agency for further action. One potential example of a consumer-friendly complaint system is the one operated by the Consumer Financial Protection Bureau (CFPB), found here: <https://www.consumerfinance.gov/complaint/process/>. The CFPB complaint system is clearly accessible from the homepage and allows consumers to track and understand the status of their complaint; be notified if their complaint was routed to another government agency; and get clear information on the likely timeframe for getting a response. CFPB also publishes de-identified complaints through a publicly available database.

Complaint Estimates

While we are pleased to see the Department taking action to set up a complaints process, we write to express concerns with how HHS has calculated the anticipated number of annual complaints, the time it will take for consumers to file a complaint, and the 60-business day timeline for HHS to respond to consumer complaints.

According to the burden estimate provided on page four of *Supporting Statement Part A – Complaints Submission Process under the No Surprises Act*, HHS estimates that there will be, on average, 3,600 balance billing complaints against providers, facilities, providers of air ambulance services, plans, and issuers submitted annually. In our view, this is a significant underestimation of expected annual complaints, and we urge HHS to reevaluate this estimate. In our view, the only scenarios under which the number of received complaints could realistically be this low is if the complaints system is unknown to consumers or incredibly difficult for them to access, or because there is near perfect compliance with the balance billing requirements under the NSA. Given the more than 135 million consumers expected to be covered by the NSA ⁷, an estimate of only 3,600 complaints annually seems entirely inadequate. In contrast, the complaint system run by the CFPB which collects complaints when consumers have problems with a financial product or service, receives hundreds of thousands of complaints annually, including more than 500,000 in 2020. ⁸

Engagement Estimates

Additionally, HHS estimates that it will take complainants (consumers) 30 minutes to collect all relevant documentation related to an alleged violation and to access and complete the complaint form. With our patients’ lived experiences in mind, this estimate does not accurately represent the time it will take to gather documents and file a complaint, and we urge HHS to reevaluate this estimate. Many of our patients, even those who are among the savviest health care consumers can spend considerable time and energy tracking down relevant documentation from plans and providers when billing disputes and other issues arise. Depending on the patient and the provider, there are scenarios where it may take days if not weeks for patients to gather all the information necessary to file a complaint. It may also require patients to obtain information from their health plan or insurer. Further, patients will likely be

⁷The Commonwealth Fund, [“Surprise Billing Protections: Help Finally Arrives for Millions of Americans”](#) Dec. 17, 2020.

⁸ Consumer Financial Protection Bureau, [CFPB Annual Complaint Report Highlights More Than a Half-Million Complaints Received in 2020](#)” Mar. 24, 2021

taking the step to file a complaint following the stress of a hospital-based procedure or emergency care, and for even the most prepared and well-resourced patients this can be a difficult time.

Response Timelines

We also have concerns with the proposed 60 business day timeframe for HHS to respond to consumer complaints regarding violations of the balance billing requirements under the NSA. A shorter timeframe would be preferable for the patients we represent. While all health care providers have their own billing practices, some providers may wait 90 or 180 days before turning medical debt over to collections, while others may only wait 60 days.⁹ Given the varying times for when an unpaid medical bill may be sent to collections, the proposed 60-business day timeline could prove to be problematic for the patients we represent.

Conclusion

Our organizations thank you for the opportunity to provide comments on the PRA Listings for the Implementation of the No Surprises Act (CMS-10780 & CMS-10779) and for the strong steps HHS has taken to implement robust patient and consumer protections. If you have any questions or would like to discuss our comments further, please contact Katie Berge, Director of Federal Government Affairs at the Leukemia & Lymphoma Society at katie.berge@lls.org and Tyler Hoblitzell, Regulatory Affairs Manager at the American Heart Association at tyler.hoblitzell@heart.org.

Sincerely,

American Cancer Society Cancer Action Network
American Heart Association
American Kidney Fund
Arthritis Foundation
Asthma and Allergy Foundation of America
Cancer Support Community
CancerCare
Cystic Fibrosis Foundation
Epilepsy Foundation
Hemophilia Federation of America
National Alliance on Mental Illness
National Eczema Association
National Health Council
National Hemophilia Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Patient Advocate Foundation
Pulmonary Hypertension Association
The AIDS Institute
The Leukemia & Lymphoma Society
WomenHeart: The National Coalition for Women with Heart Disease

⁹Experian, "[How Does Medical Debt Affect Your Credit Score?](#)" Nov. 20, 2020.