

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

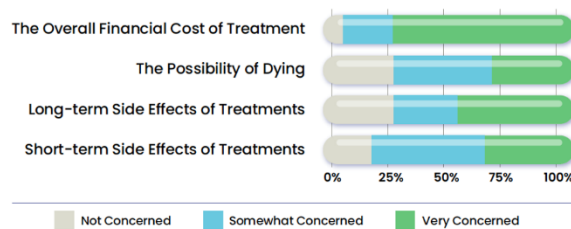
Dear Secretary Becerra and Administrator LaSure:

National Patient Advocate Foundation (NPAF) appreciates the opportunity to provide feedback on the documents related to No Surprises Act (NSA) implementation that includes standard notice and consent, complaints processes, model disclosures and their supporting statements. Surprise medical billing represents one of many factors influencing total costs of care, both financial and emotional costs, that patients contend with every day.

NPAF advocates for inclusive policies and practices that elevate patient and caregiver voices and put their perspectives and essential health equity principles at the heart of healthcare. Our direct services counterpart, Patient Advocate Foundation (PAF), has provided skilled needs navigation supporting patient and caregiver social and financial well-being for thousands of families coping with complex chronic conditions across the country for over 25 years. Most of these individuals are from low-income families living in limited resourced communities. PAF’s navigators work to identify patient’s unmet needs and guide them to available safety net supports and programs to help ease concerning financial burdens. These navigation services are an essential aspect of accounting for numerous social determinants of health and other sources of distress that often cause disparate health outcomes.

Experiencing financial distress is a reality for many patients. Surprise medical bills and other unexpected costs of care confronting patients and families are major contributors to medical debt and financial burden that patients characterize as top concerns. In fact, 63 percent of patients surveyed by PAF ranked financial distress as a bigger worry than dying from their disease.¹

TOP HEALTH CONCERNS IN LIMITED RESOURCED AND UNDERSERVED POPULATIONS



Responses to PAF’s 2019 survey of more than 2,800 patients report financial distress as a top concern, with many stating that their family’s financial viability is a critically important goal of care.

¹ Patient Advocate Foundation. 2019 Cost of Care Survey of more than 2,800 patients.

Understanding information in EOBs and medical bills is challenging for nearly everyone. In 2020, almost one-third (29 percent) of patients contacted PAF because of medical bill issues alone.² Deciphering third-party payment and cost sharing responsibilities for in- or out-of-network charges is even more confusing and frustrating. Likewise, health care system and health insurance plan processes are rarely intuitive for consumers to absorb, and the specialized lexicon used is unfamiliar without years of exposure to the various terms, what they mean, and how they affect ability to access care. These barriers collectively interfere with equitable access and affordability of quality care. As such, skilled needs navigation is a lifeline for patients and families to ease these strains and provide relief that improves their understanding, lived experiences and health outcomes.

NPAF appreciates the Administration's efforts to pull patients out of payment negotiations between health plans and providers. Effective implementation of Part I of the NSA Interim Final Rule has the potential to reduce the occurrence of surprise medical bills. The proposal takes important steps to ensure that providers, health care facilities, and plans provide adequate notice to patients about their responsibilities if they choose to receive out-of-network care, which may help them avoid medical debt and other harmful downstream effects.

Prioritizing skilled conversations for discussing patients' affordability concerns and payment responsibilities for treatment must be a routine part of practice in every care setting. Integrating needs navigation services offers a practical and proven process solution to capture financial and social risk assessments information and identify responsive safety net programs, assistance, and other resources to contain the documented cost concerns. Further, providing this skilled and personalized navigation support helps patients and families make more informed and financially viable decisions for them that can lead to better health outcomes overall.

We appreciate the opportunity to work with the Department of Health and Human Services (HHS) to ensure that all processes and forms are understandable, accessible, and actionable. In these comments, NPAF has included suggested revisions to enhance content in the written notices and forms as well as the notification processes outlined in the NSA's paperwork reduction act (PRA) notices CMS-10780 and CMS-10779. These adjustments are important to improve patient understanding of the proposed disclosure information concerning surprise bills. Please refer to Appendices I and II attached to this letter for specific suggestions to the patient-facing documents that we believe will enhance patient understanding about their balance billing and cost-sharing protections.

Prioritize affordability conversations about costs of care

The proposed notice, consent, and disclosure forms represent a positive step towards achieving HHS' goal of empowering patients to better understand their protections. Yet the forms alone cannot substitute for conversation. Patients already experience consent fatigue from the numerous forms they are required to review and sign in clinic and hospital settings with little to no guidance at medical facilities. HHS has

² Patient Advocate Foundation. 2020 Annual Impact Report. Published June 2021. Available at: <https://www.patientadvocate.org/download-view/2020-annual-impact-report/>

acknowledged similar concerns around consumer understanding of the Notice of Privacy Practices under the Health Insurance Portability and Accountability Act (HIPAA) and proposed modifications to make HIPAA forms more understandable.³

We agree that enhancing existing forms, regardless of the topic, is worthwhile to help clarify an individual's rights and how they may exercise those rights. Even with clear and understandable language, however, written forms still present barriers for the general population and in particular, accessibility barriers for individuals with visual or hearing impairments, low health literacy, limited English proficiency, and other underserved populations.

The IFR outlines standard notice and consent instructions with the requirement that a "representative of the provider or facility must be physically present or available by phone to explain the documents and estimates to the individual." In practice, we know that requiring staff to be available does not necessarily translate to routinely having the desired conversation nor is it easily enforced or evaluated. To improve HHS' proposal, the disclosure process description should reinforce the expectation of affordability conversations to continue between patients and health care team members that assess options and anticipated costs and allow adequate time for patients' questions.

Patients consider costs of care and the impacts on their financial well-being as the basis of every health care decision they make. A meaningful conversation must occur at the time treatment is being discussed to ensure that providers are aware of potential barriers to care, and individuals are aware of their options and costs as well as what the surprise billing protections or waiving protections may mean for them financially. Needs navigation services to assess and address patient financial and social needs should be integrated as an essential aspect of operationalizing the proposed disclosure process.

Shift disclosures upstream to the time when patients make their treatment plans

The health care system has historically operated under one-sided and asymmetric information exchange between patients, providers, and plans that puts the burden on patients to make decisions without complete information far enough in advance. Regarding timing of disclosures, the IFR outlines that the notice and consent documents must be provided to the individual (or representative) at least 72 hours before the date of service for planned care. Given that the notice and consent documents contain critical information that influences a patient's decision about where, when and by whom they will receive care, this information should be provided when the treatment options are being discussed. Providers and health plans should be accountable for working together to provide a reasonably accurate cost estimate for out-of-network care as well as inform patients about any prior authorization requirements.

At a minimum, we recommend requiring that patients receive notice and consent documents at least a week before the date of service. The proposed 72 hours' notice is not sufficient for patients to make necessary transportation, employment, or other arrangements if they must go to a different facility or

³ The Department of Health and Human Services. Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, December 2020.

reschedule their appointment due to a provider's network status and associated cost-sharing. We are also concerned by the three-hour rule pursuant to same-day appointments for urgent situations. Patients need adequate time to review and understand the notice and consent forms followed by enough time to make decisions and necessary arrangements based on this information.

Even with improvements to the notice and disclosure forms and processes, patients will still need personalized navigation providing guidance for avoiding financial distress. Integrating needs navigation services into the standard of care is a promising and practical solution for facilitating cost of care conversations along with referrals to assess patients for their financial and social needs.

Strengthen Model Disclosure Notice instructions for health plans to proactively inform beneficiaries of their rights

The Model Disclosure Notice outlines minimal requirements for group and individual health plans to make their enrollees aware of balance billing protections. In particular, the instructions note that plain language information of balance billing restrictions must be included on each explanation of benefits (EOB) for an item or service. EOB documents are routinely mailed to individuals after they receive care from a provider, and thus, such information would not be useful for a patient planning to pursue care from a particular provider in advance of the service. In general, EOB forms are already confusing for patients, necessitating dedicated educational resources such as what PAF and other organizations produce to help people understand them.⁴ We recommend that HHS clarify the instructions around timing for EOB disclosure and strengthen disclosure processes by requiring that health plans proactively disclose the notice to enrollees each year during their annual open enrollment period and upon changes to a provider's network status.

Conclusion

NPAF appreciates the opportunity to provide comments to the PRA listings of the No Surprises Act. Improving patient health literacy and providing needs navigation services directly to patients and caregivers is a hallmark of PAF's two and a half decades of organizational experience, expertise, and history. We are happy to share lessons learned from our work with limited-resourced populations in providing these services and welcome the opportunity to meet directly with Administration staff to discuss these comments. Please contact Nicole Braccio, Policy Director, at Nicole.Braccio@npaf.org or 202-301-9552 if we can provide further details.

Respectfully submitted,



Rebecca A. Kirch, JD
EVP, Policy and Programs

⁴ Patient Advocate Foundation. If It's Not A Bill, Why Is The EOB Important To Me? Available at: <https://www.patientadvocate.org/wp-content/uploads/PAF-Empowerment-Pathways-Why-EOB-Is-Important.pdf>

Surprise Billing Protection Form

The purpose of this document is to let you know about your protections from unexpected medical bills that you could receive from an out-of-network provider at an in-network facility. It also asks whether you would like to give up those protections and pay more for out-of-network care if an in-network provider is not available.

IMPORTANT: You aren't required to sign this form and should only sign it if you hadn't have a choice of health care provider when you received care. You can choose to get care from a provider or facility in your health insurance plan's network, which may cost you less. If you do sign this form, you can change your mind and revoke consent before receiving care.

If you'd like assistance with this document, ask your provider or a patient advocate. Take a picture and/or keep a copy of this form for your records.

You're getting this notice because this provider or facility isn't in your health insurance plan's network and is considered out-of-network. This means the provider or facility doesn't have an agreement with your plan for payment of services. Therefore, getting care from this provider or facility could cost you more.

Getting care from this provider or facility could cost you more.

If your insurance plan covers the item or service you're getting, federal law protects you from higher bills:

- When you get emergency care from out-of-network providers and facilities, or
- When an out-of-network provider treats you at an in-network hospital or ambulatory surgical center without your knowledge or consent.

Ask your health care provider or patient advocate if you need help knowing if these protections apply to you.

If you sign this form, you may pay more because:

- You are giving up your protections under the law.
- You may owe the full costs billed for items and services received.
- Your health plan might not count any of the amount you pay towards your deductible and out-of-pocket limit. Contact your health plan for more information.

You shouldn't sign this form if you didn't. You should only sign this form if you were given have a choice of providers when receiving care. For example, if a doctor was assigned to you with no opportunity to make a change, you may NOT want to sign this form.

Before deciding whether to sign this form, you can contact your health insurance plan to learn about your out-of-pocket cost obligations for out-of-network care or find an in-network provider or facility and learn about its associated costs. If there isn't one an in-network provider is not available, ask your health insurance plan about your options. might work out an agreement with this provider or facility, or another one.

See the next page for your cost estimate.

Commented [NGB1]: For the average patient, most medical bills are unexpected. It would be helpful to articulate when unexpected medical bills may occur and why a patient would have to pay more. Consider adding additional language here.

Commented [NGB2]: We recommend using the term "health insurance plan" for additional clarity where "health plan" appears throughout the entire document.

Commented [NGB3]: Include a note up front in the "IMPORTANT" box that patients are permitted to revoke their consent before receiving care. This will help ensure patients do not feel unfairly pressured to give up / waive their surprise billing protections.

Commented [NGB4]: "Agreement" language may confuse patients. Consider clarifying that the agreement is regarding payment of services.

Commented [NGB5]: Consider including the list of providers who can never balance bill (emergency medicine, anesthesiology, pathology, radiology, diagnostics) so patients know that they are guaranteed protection in those instances

Commented [NGB6]: Patients may find the double negative language confusing. Consider rewording and see similar language in IMPORTANT box.

Commented [NGB7]: This language may be too presumptive. We wouldn't want patients to decide signing based on the assumption that their plan and provider will work together if in fact they will not come to an agreement.

Estimate of what you could pay for out-of-network care if you sign this form

Patient name: _____

Out-of-network provider(s) or facility name: _____

| | |
|---|--|
| Total cost estimate of what you may be asked to pay: | |
|---|--|

- ▶ **Review your detailed estimate.** See Page 4 for a cost estimate for each item or service you'll get.
- ▶ **Call your health plan.** Your plan may have better information about how much you will be asked to pay. You also can ask about what's covered under your plan and your provider options.
- ▶ **Questions about this notice and estimate?** Call [*Enter contact information for a representative of the provider or facility to explain the documents and estimates to the individual, and answer any questions, as necessary.*]
- ▶ **Questions about your rights?** Contact [*contact information for appropriate federal or state agency*]

Prior authorization or other care management limitations

[*Enter either (1) specific information about prior authorization or other care management limitations that are or may be required by the individual's health plan or coverage, and the implications of those limitations for the individual's ability to receive coverage for those items or services, or (2) include the following general statement:*

Except in an emergency, your health plan may require prior authorization (or other limitations) for certain items and services. This means you may need your plan's approval that it will cover an item or service before you get them. If prior authorization is required, ask your health plan about what information is necessary to get coverage.]

[*In the case where this notice is being provided for post-stabilization services by a nonparticipating provider within a participating emergency facility, include the language immediately below and enter a list of any participating providers at the facility that are able to furnish the items or services described in this notice*]

Understanding your options

You can also get the items or services described in this notice from these providers who are in-network with your health plan:

More information about your rights and protections

Visit [*website*] for more information about your rights under federal law.

By signing, I give up my federal consumer protections and agree to pay more for out-of-network care.

With my signature, I am saying that I agree to get the items or services from (select all that apply):

[doctor's or provider's name] [If consent is for multiple doctors or providers, provide a separate check box for each doctor or provider]

[facility name]

With my signature, I acknowledge that I am consenting of my own free will and am not being coerced or pressured. I also understand that:

- I'm giving up some consumer billing protections under federal law.
- I may get a bill for the full charges for these items and services, or have to pay out-of-network cost-sharing under my health plan.
- I was given a written notice on [enter date of notice] explaining that my provider or facility isn't in my health plan's network, the estimated cost of services, and what I may owe if I agree to be treated by this provider or facility.
- I got the notice either on paper or electronically, consistent with my choice.
- I fully and completely understand that some or all amounts I pay might not count toward my health plan's deductible or out-of-pocket limit.
- I can end this agreement by notifying the provider or facility in writing before getting services.

IMPORTANT: You **don't** have to sign this form. But if you don't sign, this provider or facility might not treat you during your scheduled appointment. You can choose to get care from a provider or facility in your health insurance plan's network. This may mean making a new appointment for a different date, at a different facility, and/or with a different provider.

Patient's signature

or

Guardian/authorized representative's signature

Print name of patient

Print name of guardian/authorized representative

Date and time of signature

Date and time of signature

Take a picture and/or keep a copy of this form.

It contains important information about your rights and protections.

Commented [NGB8]: See comment below about cost-sharing terminology.

Commented [NGB9]: See comment below about out-of-pocket cost terminology.

Commented [NGB10]: It will be helpful for patients to know what practical options they have for getting care if they don't sign this form.

More details about your cost estimate for out-of-network care

Patient name: _____

Out-of-network provider(s) or facility name: _____

The amount below is only an estimate; it isn't an offer or contract for services. This estimate shows the full estimated costs of the items or services listed. It doesn't include any information about what your health plan may cover. It also doesn't include any information about your cost-sharing obligations and associated out-of-pocket costs. These costs vary depending on whether the provider you are seeing is in- or out-of-network. This means that ~~the final cost of services~~ your final out-of-pocket costs may be different than this estimate.

Contact your health plan to find out how much, if any, your plan will pay and how much you may have to pay.

[Enter the good faith estimated cost for the items and services that would be furnished by the listed provider or facility plus the cost of any items or services reasonably expected to be provided in conjunction with such items or services. Assume no coverage would be provided for any of the items and services.]

[Populate the table below with each item and service, date of service, and estimated cost. Add additional rows if necessary. The total amount on page 2 must be equal to the total of each of the cost estimates included in the table.]

| Date of service | Service code | Description | Estimated amount to be billed |
|--|--------------|-------------|-------------------------------|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| Total estimate of what you may owe: | | | |

Commented [NGB11]: The content of this page and chart below reads like an Explanation of Benefits document. These EOB documents are known to be confusing and difficult for patients to decipher due to the verbiage of "billed charges". The billed charges typically indicate what the provider will be billing to both the patient and the insurance plan.

However, the billed charges itemization is not useful for patient decision-making. Patients want to see the total cost-sharing amount that they will be expected to pay. This estimate does not include an adequate description about cost-sharing or out-of-pocket costs obligations that a patient incurs upon receiving care.

Cost-sharing and out-of-pocket costs are important terms that should be laid out in this document, especially since they are briefly mentioned in the bulleted list on page 3 (see highlight). Description of these terms and how it relates to in- and out-of-network care would be helpful to include on this page.

Your Rights and Protections Against Surprise Medical Bills

When you get emergency care or get treated by an out-of-network provider at an in-network hospital or ambulatory surgical center, you are protected from surprise billing or balance billing.

What is “balance billing” (sometimes called “surprise billing”)?

When you see a doctor or other health care provider, you may owe certain out-of-pocket costs, such as a copayment, coinsurance, and/or a deductible. You may have other costs or have to pay the entire bill if you see a provider or visit a health care facility that isn’t in your health [insurance plan’s network](#).

“Out-of-network” describes providers and facilities that haven’t signed a contract with your health plan. Out-of-network providers may be permitted to bill you for the difference between what your plan agreed to pay and the full amount charged for a service. This is called “**balance billing**.” This amount is likely more than in-network costs for the same service and might not count toward your annual out-of-pocket limit.

“Surprise billing” is an unexpected balance bill. This can happen when you can’t control who is involved in your care—like when you have an emergency or when you schedule a visit at an in-network facility but are unexpectedly treated by an out-of-network provider. [Surprise medical bills could amount to thousands of dollars depending on the procedure or service.](#)

You are protected from balance billing for:

Emergency services

If you have an emergency medical condition and get emergency services from an out-of-network provider or facility, the most the provider or facility may bill you is your plan’s in-network cost-sharing amount (such as copayments and coinsurance). You **can’t** be balance billed for these emergency services. This includes services you may get after you’re in stable condition, unless you give written consent and give up your protections not to be balance billed for these post-stabilization services.

[Insert plain language summary of any applicable state balance billing laws or requirements OR state-developed model language as appropriate]

Certain services at an in-network hospital or ambulatory surgical center

When you get services from an in-network hospital or ambulatory surgical center, certain providers there may be out-of-network. In these cases, the most those providers may bill you is your plan’s in-network cost-sharing amount. This applies to emergency medicine, anesthesia, pathology, radiology, laboratory, neonatology, assistant surgeon, hospitalist, or intensivist services. These providers **can’t** balance bill you and may **not** ask you to give up your protections not to be balance billed.

Commented [NGB1]: Recommend changing “health plan” to “health insurance plan” throughout the document.

Commented [NGB2]: Patients will want to know if there is a possibility that they may receive a bill that they cannot afford to pay. It would be helpful to contextualize surprise medical billing and acknowledge that the bill could be up to thousands of dollars.

If you get other services **such as lab work, X-rays, or imaging** at these in-network facilities, out-of-network providers **can't** balance bill you, unless you give written consent and give up your protections.

Commented [NGB3]: Patients will want to know what is included under "other services". Consider adding patient-friendly examples here.

You're never required to give up your protections from balance billing. You also aren't required to get care out-of-network. You can choose a provider or facility in your plan's network.

[Insert plain language summary of any applicable state balance billing laws or requirements OR state-developed model language regarding applicable state law requirements as appropriate]

When balance billing isn't allowed, you also have the following protections:

- You are only responsible for paying your share of the cost (like the copayments, coinsurance, and deductibles that you would pay if the provider or facility was in-network). Your health plan will pay out-of-network providers and facilities directly.
- Your health plan generally must:
 - Cover emergency services without requiring you to get approval for services in advance (**prior authorization**).
 - Cover emergency services by out-of-network providers.
 - Base what you owe the provider or facility (**cost-sharing**) on what it would pay an in-network provider or facility and show that amount in your **explanation of benefits**.
 - Count any amount you pay for emergency services or out-of-network services toward your **deductible** and **out-of-pocket limit**.

Commented [NGB4]: Patients would benefit from additional education around the following highlighted terms. Where this disclosure notice is displayed on a provider or health plan's website, it should link to definitions and more information for the following terms.

If you believe you've been wrongly billed, you may contact *[applicable contact information for entity responsible for enforcing the federal and/or state balance or surprise billing protection laws]*.

Visit *[website]* for more information about your rights under federal law.

[If applicable, insert: Visit [website] for more information about your rights under [state laws].]