



Via electronic submission

September 7, 2021

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

The Honorable Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, DC 20220

The Honorable Martin Walsh
Secretary
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Re: CMS-9909-IFC – Requirements Related to Surprise Billing; Part I
[85 Fed. Reg. 7088 (July 13, 2021)]

Dear Secretaries Becerra, Yellen, and Walsh:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on Part I of the Requirements Related to Surprise Billing Interim Final Rule. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is critical to the fight for a world without cancer.

In the United States, almost 1.9 million Americans will be diagnosed with cancer this year.¹ An additional 16.9 million Americans are living with a history of cancer.² Being able to afford care is essential to preventing cancer, early diagnosing, and treating it successfully. In 2018 cancer patients in the U.S. paid \$5.6 billion out-of-pocket for cancer treatments.³ Because of high costs, many cancer patients and survivors experience financial hardship, including problems paying bills, depletion of savings, delaying or skipping needed medical care, and potential bankruptcy.⁴

Because cancer patients often see different physicians at multiple facilities throughout the course of their treatment, they are vulnerable to surprise medical bills. When ACS CAN surveyed cancer patients and survivors in October 2019 – before the passage of the No Surprises Act – 24% of survey respondents said they had received a surprise medical bill.⁵ Sixty-one percent of the surprise bills were over \$500, and 21% were \$3,000 or more.⁶ Surprise bills negatively affected respondents' behavior, making them less likely to follow up with a recommended specialist who may be out-of-network, and less likely to call an ambulance or visit the emergency room when experiencing a serious health issue related to their



cancer. The impact is more severe among lower income cancer patients and survivors. Compared to higher income individuals, respondents with annual household income below \$30,000 reported a higher incidence of each of these negative behavioral impacts⁷ – showing how surprise billing furthers health inequities.

ACS CAN strongly supports Congress' and the Administration's efforts to protect patients from surprise medical bills and we are encouraged by the important steps this interim final rule takes. Specifically, we applaud the Departments' proposed policies related to:

- Prohibiting surprise billing for emergency services, including post-stabilization services unless the patient is reasonably able to choose and travel to an in-network provider
- Protecting patients from surprise bills who receive care from a facility via a single case agreement, which is a common method of securing necessary specialized care for cancer patients
- Establishing strong enforcement mechanisms and a consumer-friendly complaints process to ensure these patient protections

We also encourage the Departments to go further in protecting patients by taking measures including:

- Prohibiting all providers from balance billing patients at an in-network facility
- Closing loopholes in the notice and consent provisions that allow certain providers to gain permission to send patients a balance bill in situations where the patient has not been given enough time or information to choose a different provider
- Ensuring patients are not asked to waive their protections in a coercive manner, including after they have arrived at the facility to receive their scheduled service

ACS CAN believes the goal of the Departments should be to prevent as many surprise bills as possible from reaching patients or impacting their treatment, and the Departments should assume that the vast majority of individuals who understand their rights under the No Surprises Act will not want to waive them and be charged more for out-of-network care. Accordingly, we ask the Departments to consider the following detailed comments:

III. OVERVIEW OF THE INTERIM FINAL RULES – DEPARTMENTS OF HHS, LABOR, AND THE TREASURY

B. Preventing Surprise Medical Bills

1. *Scope of the New Surprise Billing Protections*
 - i. Emergency Services

The Departments define “emergency medical condition” and clarify that it is not permissible for plans and issuers to determine whether an episode of care involved an emergency medical condition (and therefore what billing and cost-sharing rules apply) based solely on the final diagnosis.

ACS CAN strongly supports these provisions and appreciates the clarification from the Departments. Many cancer patients receive emergency services. One study found that 35.9% of cancer patients visited the emergency department (ED) an average of 1.79 times during the year-long study period.⁸ This study also found that 77% of cancer patients did not make the decision alone to go to the ED: health care

providers (40%, most commonly oncologists) and caregivers (36%) were the other reported decision-makers in these cases.⁹ Patients should not be financially penalized for seeking care at an ED. The Departments are right to clarify this definition, so patients have thorough protection from surprise medical bills when needing emergent care.

Furthermore, we urge the Departments to carefully monitor consumer appeals and complaints and track whether any issuers or providers have a higher rate of complaints regarding this policy. This information will be helpful in determining whether there are denial or billing patterns that warrant enforcement action.

ii. Post-Stabilization Services

The Departments consider “post-stabilization services” to be emergency services subject to surprise billing protections unless certain conditions are met and defines those conditions.

The Departments are right to recognize that services provided to a patient who was admitted through the ED but is then stabilized are a significant potential loophole for No Surprises Act protections. This is an important concern for cancer patients, according to one study 59.7% of cancer-related ED visits resulted in an inpatient admission.¹⁰

ACS CAN supports the definition of post-stabilization services as it is written, as it protects patients from surprise bills who began their care in an emergency when they had no choice of provider or facility.

The Departments ask if specific standards are needed regarding what constitutes an unreasonable travel burden for patients in a post-stabilization scenario. ACS CAN believes that clear standards, with examples, are necessary because a patient’s ability to travel can be very subjective based on an individual’s unique situation. Standards should account for transportation challenges posed by a patient’s socioeconomic status and the proximity to an in-network facility (which may be particularly challenging in a rural environment). Standards preventing ‘unreasonable travel burden’ should include the patient’s ability to travel by multiple means of non-medical transportation, allowing for patients who do not drive or are uncomfortable driving in their current condition. A patient’s ability to travel may also be impacted by their condition. For example, a cancer patient’s only transportation option may be public transportation, but because they are immunocompromised using public transit is not advisable. Because the patient is not able to travel to an in-network facility they should not be penalized.

iv. Health Care Facilities

With respect to in- or out-of-network non-emergency services, a participating health care facility is defined as having a contractual relationship directly or indirectly with a group health plan or health insurance issuer, including where there is a single case agreement between a facility and the plan or issuer to address unique situations in which an enrollee requires services that are typically out-of-network services.

ACS CAN supports the inclusion of the facilities already designated in this section. We applaud the Departments for including facilities having a single case agreement with the plan/issuer. This type of single case agreement is common among patients with rarer or advanced stage cancers – such agreements allow patients to receive care from large cancer centers when their cancer type or condition warrant it, and this necessary coverage should be treated as in-network. We also support the addition of

urgent care facilities to this definition, as many insurers are now heavily encouraging their use as preferable to the ED, but patients may not know that an urgent care facility is out-of-network. Adding urgent care facilities to this definition is also important because – particularly for cancer patients who live in remote or rural areas – an urgent care facility might be significantly closer to the patient, or easier to travel to, than a hospital ED. If the Departments do not immediately add these facilities to this definition, we encourage the Departments to track how many balance bills are generated from such facilities in order to inform future rulemaking.

2. *Determination of the Cost-Sharing Amount and Payment Amount to Providers and Facilities*

ii. Cost-Sharing Amount

The cost-sharing amounts for protected items or services must be calculated as if the total amount that would have been charged for the services is equal to the “recognized amount.” The recognized amount is defined as: (1) an amount determined by an applicable All-Payer Model Agreement; (2) if there is no applicable All-Payer Model Agreement, an amount determined by a specified state law; or (3) if there is no applicable All-Payer Model Agreement or specified state law, the lesser of the amount billed by the provider or facility or the qualified payment amount (QPA).

ACS CAN is concerned that this order of operations does not guarantee that the patient’s cost sharing will be based on the lowest amount of these options. Under this provision, if there is an amount available under the All-Payer Model Agreement or state law, those amounts are to be used in calculating cost sharing, regardless of which amount is higher. It is possible that in some cases, the patient’s cost sharing would be a smaller amount if they are charged based on the QPA. One of the fundamental purposes of the No Surprises Act is to prohibit patients from being financially penalized for situations out of their control. **Therefore, we urge the Departments to revise this provision to ensure the recognized amount is the lowest amount of the three options as applicable.**

4. *Surprise Billing Complaints Regarding Group Health Plans and Health Insurance Issuers*

ACS CAN supports giving patients ample time to submit complaints. Cancer treatment often lasts several months, and patients receive many bills from providers and explanation of benefits forms from insurers. Patients may not realize that they have been incorrectly billed long after the bill was received. Despite the Departments’ efforts to notify patients of their rights under the No Surprises Act, some patients will not become aware of their rights until after their treatment and/or receiving a bill. For all these reasons, consumers and patients must be given enough time after receiving a surprise bill to submit a complaint.

ACS CAN also supports the creation of a single intake system for complaints. This single-intake system will make it easier for patients and family members to file a complaint. The Departments must recognize that patients will initially be unfamiliar with these new standards and the protections they are entitled to. Significant patient/consumer education will be required. It is also worth noting that patients will always be at a disadvantage compared to providers and insurance plans, both of which have more experience navigating these rules. Therefore, the complaint process and resolution of such complaints must be as consumer friendly as possible. **ACS CAN asks the Departments to carefully consider the following recommendations regarding the complaints process:**

- Shorten the required response time from the agency receiving the complaint from 60 to 30 days. Some providers send unpaid bills to collections in as few as 30 days.
- Establish a process for accepting complaints in multiple formats, including via letter, phone, email, website submission, etc.
- Specify the complainant's preferred response format (mail, phone call, email, etc.) and incorporate the preference into the complaint intake process.
- Require the investigating agency to notify the provider to withhold sending a bill (or additional bills, as applicable) or sending debt to collections while the complaint is pending.
- Provide the complainant with official acknowledgement that can be used as evidence that they have filed a complaint if their provider sends a bill.
- If a complaint is referred to another state or federal resolution process or regulatory authority with jurisdiction, the Departments should ensure a "warm handoff." The respondent/investigator should ensure that the entity the complaint has been referred to is actively investigating the complaint. The complainant should be given direct contact information for the new entity investigating the complaint. When transferring the complaint from one entity to another, the information provided by the complainant should be transferred as well, thus preventing the complainant from having to re-submit information already provided.
- Create a standard complaint submission form so that complainants will only have to submit their complaint once.
- Require states to share their complaint data with federal regulators, including states that have responsibility for enforcement of the provisions that apply to providers to provide a more complete picture of implementation and enforcement essential to informing any needed revisions to the regulations.
- Undertake a broad, well-funded education campaign to notify consumers of their new rights and how to submit complaints and appeals if they believe their rights have been violated. Such education campaign must be designed to reach all types of patients, with an emphasis on patients who are most likely to need help, including populations who have historically been disadvantaged in healthcare and health coverage.

IV. OVERVIEW OF INTERIM FINAL RULES – DEPARTMENT OF HEALTH AND HUMAN SERVICES

A. Preventing Surprise Medical Bills

1. In General

In implementing rules and penalties to enforce the No Surprises Act, we encourage the Departments to err on the side of protecting patients and preventing as many errant balance bills as possible. Receiving a surprise balance bill can negatively impact patient experience and outcomes – even if that bill is withdrawn later. Patients may make important treatment decisions based on bills they receive. Even if the bill is later withdrawn, the patient may have already made medical decisions based on the bill and it may be too late to change those decisions. For example, a patient with an advanced stage of cancer receives a surprise bill for \$10,000 – which is an amount they have no hope of paying off. The patient is afraid they will leave their family with medical debt, and decides it is not worth pursuing any further curative treatment. By the time this patient discovers they were billed in error, their opportunity to join

a clinical trial may have passed, or their cancer may have metastasized to a new area of their body, or they will have already lost their life to the cancer.

In future regulations, the Departments should set a firm timeline under which providers are expected to have processes in place to avoid mistakenly billing patients directly. Additionally, the Departments' enforcement mechanism(s) must include an ability to track patterns in violations and act on these patterns. Providers who repeatedly violate the No Surprises Act by billing multiple patients, or billing the same patient multiple times, should incur penalties related to each violation.

2. *Notice and Consent Exception to Prohibition on Balance Billing*

i. Standards for Notice

The Departments have provided a standard notice and consent document that contains the elements required by statute. ACS CAN refers the Departments to August 12, 2021 comments we and several partner groups submitted regarding these documents.

Timing of Notice. The Departments specify the required timing of providing notice and consent, which allows certain providers to balance bill under certain conditions.

ACS CAN is concerned about the practical implications of the proposed timelines. As previously stated in an August 12, 2021 group letter, we suggest the Departments restrict the use of notice and consent (for balance billing) to 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. Limiting the use of these documents to an out-of-network facility 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 the notice and consent inappropriately to create a loophole to No Surprises Act protections.

We are concerned about the amount of time required for a patient to arrange for in-network care in the event they do not want to waive their rights under the No Surprises Act. As the Departments allude to in the proposal, patients wishing to arrange alternative in-network care may have to resolve prior authorization or other care management limitations. Cancer treatment often requires coordination between multiple health care providers, specific sequencing of tests occurring before treatments, and in the case of surgery, many hours of preparation. These complications require extra time to coordinate if a patient must change health care facilities or providers to maintain their protections and/or not be balance billed. Allowing notice and consent to be provided 3 hours in advance of a service scheduled on the same day could result in a patient being asked to waive their protections while undergoing preparation for a service, like surgery, when it is near impossible logistically to change plans.

We strongly encourage the Departments to restrict the use of notice and consent to services scheduled at least 72 hours in advance and, at minimum, urge the Departments to disallow out-of-network providers from seeking consent to waive protections once a patient arrives at a facility for their scheduled procedure or service.

Additionally, in the case of services that are scheduled more than 72 hours in advance, **we urge the Departments to require the provider to offer notice and consent within 72 hours of scheduling the service.** If any information changes after the initial notice and consent form is signed, the provider

should be required to provide an amended notice and consent form at least 72 hours before the service occurs.

Content of Notice. Many requirements regarding the content of the notice are contained in the standard notice and consent document, and we refer HHS to our comments regarding that document submitted on August 12, 2021.¹¹ We have some additional concerns regarding the content of the notice.

Providers are required to include in the notice and consent form information indicating whether prior authorization or other medical management limitations may apply. The proposed standard notice and consent document allows for providers to include general language related to these requirements if the provider does not have specific information.

ACS CAN agrees with the Departments that including specific information on these matters would greatly improve the form's utility to patients. Providing the patient with general information puts the onus on the patient – the entity least likely to be familiar with prior authorization standards or other utilization management tools – and is contrary to the statutory intent of the No Surprises Act. **We encourage the Departments to require this specific information to be included in the notice.** We note that if the Department adopts the timeline requirements, we suggest above it will be more feasible for a provider to contact the patient's insurer to determine the specifics of these requirements and include them on the form.

ii. Exceptions to the Availability of Notice and Consent

Under certain circumstances, notice and consent exceptions to the No Surprises Act requirements are not available – meaning that the provider or facility in these circumstances are never able to send a balance bill to a patient.

ACS CAN strongly supports the exceptions detailed in this rule as written, and believes they are crucial to preventing many cancer patients from receiving surprise bills. An ACS CAN survey showed that the services that most commonly led to surprise bills for cancer patients and survivors were outpatient radiology, pathology, outpatient hospital services, surgery, and anesthesiology¹² – meaning most of these surprise bills would have been prevented had these patients already been protected by the No Surprises Act and this rule.

The statute permits the Department of Health and Human Services (HHS) to expand the definition of ancillary services and seeks comment on whether additional services should be made ineligible for the notice and consent exception (and therefore balance billing would be prohibited).

ACS CAN strongly encourages HHS to use its authority given by the statute to make all services delivered at an in-network facility ineligible for the notice and consent exception. 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. Creating such a standard will not only protect all patients who have followed the correct procedure to receive in-network care, but it will also simplify implementation of the statute for providers, facilities, and enforcement agencies. ACS CAN is concerned about any exceptions being left open for balance billing at an in-network facility, as some providers will likely find loopholes in the policies to circumvent the law. If HHS does not implement this change immediately, we ask that the

Department collect data on the number and type of balance bills that occur when patients receive care at in-network facilities and re-evaluate this policy in 2023.

Additionally, we strongly encourage the Departments to collect and publish data on the types of providers that generate balance bills in 2022, trigger the independent dispute resolution process, and/or result in consumer complaints. We encourage the Departments to use this information when considering whether to add to these exceptions in future rulemaking.

Conclusion

On behalf of the American Cancer Society Cancer Action Network, we thank you for the opportunity to comment on Part I of the Requirements Related to Surprise Billing Interim Final Rule. We strongly support this rule, while also encouraging the Departments to carefully consider our and other stakeholder comments on how to further improve patient protections. If you have any questions, please feel free to contact Jennifer Hoque, Associate Policy Principal at Jennifer.Hoque@cancer.org or 202-585-3233.

Sincerely,



Lisa A. Lacasse, MBA

President

American Cancer Society Cancer Action Network

¹ American Cancer Society. Cancer Facts & Figures: 2021. Atlanta: American Cancer Society, 2021.

² American Cancer Society. Cancer Treatment & Survivorship: Facts & Figures 2019-2021. Atlanta: American Cancer Society, 2019.

³ Data retrieved from the Agency for Healthcare Research and Quality. Medical Expenditure Panel Survey, 2018. <https://meps.ahrq.gov/mepsweb/>.

⁴ Yabroff KR, Bradley C, Shih YCT. Understanding Financial Hardship Among Cancer Survivors in the United States: Strategies for Prevention and Mitigation. *Journal of Clinical Oncology* 2020 38:4, 292-301.

⁵ ACS CAN. Survivor Views: Surprise Billing and Prescription Cost and Coverage Survey Findings Summary. October 2019.

https://www.fightcancer.org/sites/default/files/National%20Documents/Survivor%20Views.Surprise%20Billing_Prescription%20Drugs%20Polling%20Memo%20FINAL.pdf.

⁶ Ibid.

⁷ Ibid.

⁸ Panattoni L, Fedorenko CR, Kreizenbeck KL, et al. Costs of potentially preventable emergency department use during cancer treatment: A regional study. *JCO*. 2017;35(8_suppl):2-2. doi:10.1200/JCO.2017.35.8_suppl.2.

⁹ Lash RS, Bell JF, Reed SC, et al. A Systematic Review of Emergency Department Use Among Cancer Patients. *Cancer Nurs*. 2017;40(2):135-144. doi:10.1097/NCC.0000000000000360.

¹⁰ Rivera DR, Gallicchio L, Brown J, Liu B, Kyriacou DN, Shelburne N. Trends in Adult Cancer-Related Emergency Department Utilization: An Analysis of Data From the Nationwide Emergency Department Sample. *JAMA Oncol*. 2017;3(10):e172450. doi:10.1001/jamaoncol.2017.2450.

¹¹ Ibid.

¹² ACS CAN. Survivor Views: Surprise Billing and Prescription Cost and Coverage Survey Findings Summary. October 2019.

https://www.fightcancer.org/sites/default/files/National%20Documents/Survivor%20Views.Surprise%20Billing_Prescription%20Drugs%20Polling%20Memo%20FINAL.pdf.