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Dec. 6, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

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

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

**Re: Requirements Related to Surprise Billing; Part II (RIN 1210–AB00)**

Dear Secretaries Becerra, Walsh, and Yellen:

On behalf of the nation's children's hospitals and the patients and families we serve, we thank you for the opportunity to comment on the **Interim Final Rule (IFR), Requirements Related to Surprise Billing; Part II (RIN 1210–AB00)**. We look forward to working with you to ensure that implementation of the No Surprises Act has the best result for children and the providers that care for them.

We support the intent of the act and this IFR to protect patients, including children and their families, from surprise medical bills for out-of-network care during an emergency or when they receive care from an out-of-network provider at an in-network facility. However, we are very concerned about the potential implications for children's access to care because of the rule's approach to the independent dispute resolution (IDR) process and its implementation of the act's requirement that providers give patients a good faith estimate of their expected charges.

The more than 220 children's hospitals that comprise the Children's Hospital Association (CHA) are dedicated to the health and well-being of our nation's children. Children's hospitals advance child health through innovations in the quality, cost and delivery of care—regardless of payer—and serve as a vital safety net for uninsured, underinsured and publicly insured children. We are regional centers for children's health, providing highly specialized pediatric care across large geographic areas.

Fortunately, surprise billing is a rare occurrence amongst children's hospitals. However, we believe that the rule's IDR and good faith estimate provisions could have an inadvertent negative impact on children's and families' access to timely, appropriate and high-quality pediatric specialty care, including tertiary and quaternary care. In particular:

- **We urge you to revise the rule's IDR provisions to reflect congressional intent that arbiters consider a variety of factors equally with the qualifying payment amount (QPA) when making final payment decisions.** We believe that the rule's requirement that arbiters give the QPA precedence when determining the final payment will unfairly tilt the arbitration process to the payer's advantage and effectively create a de facto benchmark rate. The emphasis on the QPA could disincentivize insurers from contracting with

specialty providers, such as children's hospitals, or lead to artificially low rates and impede children's access to needed care.

- **We are appreciative of the enforcement discretion accorded under the rule related to certain aspects of the act's good faith estimate requirements and urge you to delay enforcement of all aspects of the good faith estimate requirements and to simplify the requirements to allow for the development of realistic workflows and related administrative technologies.** While we agree that consumers should have access to accurate information regarding their potential costs of care, we are very concerned about the complexity and scope of the rule's good faith estimate requirements and the resulting administrative burden on providers.

- **We urge HHS to revise the rule's $400 threshold that triggers the option for patients to seek a dispute resolution process with a provider so the dispute resolution process is triggered under valid circumstances.** Allowing patients to seek dispute resolution when their actual charges are just $400 more than the good faith estimate does not appropriately reflect the unpredictable nature of health care, particularly hospital inpatient and surgical care.

We also want to emphasize that the best way to protect patients from surprise medical bills is to ensure that all plans, including ERISA plans, are subject to strong network adequacy standards. Issuers should not be permitted to use this rule as a way to avoid negotiating and contracting with providers and facilities. Federal and state standards must address the unique needs of children, particularly those with specialized health care needs. We urge the departments to work with the states and Congress to strengthen and enforce network adequacy rules where they exist and to establish them where they do not (i.e., ERISA) so all children have timely access to appropriate, high-quality care.

Our detailed comments on the above issues and other aspects of this rule are below.

**Independent Dispute Resolution (IDR) Process. Submission of Offers**
The departments seek comment on whether additional guidance is needed on how hospitals or practices that do not employ their medical staff should report their number of employees when submitting an offer to the IDR entity. We believe that additional guidance is needed for these situations as many children's hospitals do employ their medical staff, and in some instances dental and advanced practice practitioners.

**IDR Process. Selection of Offer**
We urge the departments to revise the IFR provisions that require the IDR entity to presume that the QPA is an appropriate payment amount and only to consider additional information submitted by the payer or provider if the entity determines that information to be credible. Not only do we believe that this approach will unfairly tilt the final payment decision to the payer's advantage, effectively creating a de facto benchmark rate, but it also conflicts with congressional intent. When Congress enacted the No Surprises Act, it recognized that the establishment of a benchmark payment rate to resolve payment disputes would incentivize payers to set artificially low rates or exclude certain providers from their networks altogether. Therefore, Congress purposefully created a balanced IDR process that requires arbiters to give equal consideration—in all IDR situations—to the plan's median contracted rate for similar items and providers and to other factors that include facility type, prior payment history, patient acuity, case mix, quality measurements and provider training.

This rule's requirement that the IDR entity base their final payment decision on the QPA, without considering other factors except in extremely limited circumstances, could have major negative consequences for pediatric health care, as plans will use that QPA as the basis for their future network negotiation strategies. Based on the QPA calculation methodology that is delineated in the *IFR: CMS–9909–IFC, Requirements Related to Surprise Billing; Part I*, we know that it is unlikely that the QPA will be representative of children's hospitals' median rates, making the undue weighting of the QPA in the final payment decision especially problematic. As we highlight in our Sept.

7, 2021, comment letter[1] on the rule, the current QPA methodology does not adequately distinguish between adult and pediatric providers and services. For example, as our letter notes, a child neurology patient requires more "child-sized" staffing and specialized equipment to correspond to that child's age and weight than an adult patient. However, the IFR as proposed does not require payers to take into account these differences in care delivery methods and the related costs between the care of children and adolescents and that of adults when calculating the QPA.

This IFR's unbalanced approach to the IDR, which relies on a QPA that we know will be unrepresentatively low, could incentivize insurance companies to set artificially low payment rates or to simply exclude specialty providers, such as children's hospitals, from their network because they could pay a lower rate by doing so. Either of these scenarios could lead to an inadequate network and leave vulnerable and very sick children and families without access to the high-quality, timely pediatric-appropriate services they need, putting children's health and their family's financial well-being at risk, and threatening children's long-term quality of life and future productivity.

We urge you to return to the original intent of the No Surprises Act and delineate an IDR process that includes full consideration of all allowed factors. We also urge you to revisit and revise the QPA methodology so it reflects the case mix and other considerations that differentiate pediatric specialty care from adult care as we articulated in our Sept. 7 comment letter.[2] An IDR process that is based on a sound QPA calculation and consideration of all allowed factors, will lead to a fair and final payment rate for both providers and payers involved in the payment dispute. It will also protect against disincentives for insurers to negotiate with providers to establish appropriate networks for all services covered by the plan.

In addition, we urge the departments to clearly state in the final regulations on the IDR that arbiters should not overly weight the QPA during arbitration and that plans/issuers may not use the QPA as the initial payment rate unless providers agree to that rate through negotiation. We also reiterate the need for strong network adequacy standards and oversight and urge the departments to work with states on the development and enforcement of strong network adequacy standards for the fully insured market and the Department of Labor to develop more robust standards and oversight. Payers should not be allowed to rely on the IDR process and outcome as a means to strengthen their negotiating position and must be able to fully demonstrate that their networks include the full range of providers. Nor should payers be permitted to use this rule as a way to push down rates during contract negotiations or to avoid negotiating and contracting with providers and facilities at all. The rule should require evidence of good faith negotiations by both parties and be able to demonstrate that any gaps in network access that necessitate out-of-network services that are payable under the act is not a standard business practice.

Furthermore, issuers should be required to negotiate single case agreements in good faith for those circumstances where patients must travel outside of the issuer's service area for medically necessary specialty care for which an appropriate provider is not available in the network. This is particularly important for children with a serious, chronic or complex condition given the regionalization of specialty care.

**Good Faith Estimates for Uninsured (or Self-Pay) Individuals**

We agree with the intent of the act and IFR to ensure that patients are fully aware of the potential costs of their care and are committed to helping families understand their out-of-pocket obligations, so they have the information they need to make appropriate care decisions, particularly when deciding whether to use an out-of-network provider. However, we are very concerned about the feasibility of developing appropriate workflows and administrative structures that will be needed to provide the detailed and binding good faith cost estimates required under this IFR—even in its limited scope targeting uninsured and self-pay patients only. We are appreciative of the department's decision to use enforcement discretion to delay the requirement that estimates include all outside

[1] See CHA letter to Secretaries Becerra, Walsh, and Yellen on CMS–9909–IFC—Requirements Related to Surprise Billing; Part I; Interim Final Rules with Request for Comments, Sept. 7, 2021.

[2] See CHA letter to Secretaries Becerra, Walsh, and Yellen, Sept. 7, 2021.

providers' costs, and urge you to extend the same enforcement discretion to the remainder of the IFR's good faith estimate provisions to give providers sufficient time to make the necessary system, process and staffing revisions.

Children's hospitals provide financial counselling to patient families, and many try to provide cost estimates upon request for certain services. However, the amount of information required under this rule that must be included in each estimate combined with the extremely short timelines to share that information with the uninsured and self-pay patients will require hospitals to significantly increase their staffing and related resources. In fact, children's hospitals will likely need to create or radically expand existing teams of full-time employees who are dedicated to this effort to coordinate among facilities and providers. The sheer number of estimates that will need to be provided under this rule will be particularly challenging and will further stretch hospital resources that have already been strained by the COVID-19 pandemic. Even those hospitals with relatively sophisticated financial counselling programs will experience a large increase in the volume of required estimates. For example, one children's hospital that currently provides estimates upon request anticipates a 12- to 15-fold increase in their volume of estimates under the rule.

Furthermore, it will be very difficult to meet these requirements within the rule's timeline of one to three business days, even with a significant ramping up of staff and administrative resources. We strongly encourage the department to modify that timeline to allow for more time for the provider to develop accurate estimates. Gathering and coordinating information from internal sources, as well as multiple outside providers, will require more time than allowed. In addition, this short timeline does not allow sufficient time for more in-depth financial counselling with the family to determine possible eligibility for Medicaid, Marketplace coverage or charity care.

We also note several areas where further guidance is needed. First, we seek further clarification on how the definition of uninsured/self-pay applies in circumstances where individuals have coverage for certain services only, coverage that does not include the needed item or service. The rule appears to require the provider to identify plan exclusions for patients who have coverage and deem them uninsured/self-pay if the plan does not cover the specific item or service. In some instances, however, it is not clear from the limited information that a family or a plan may provide as to whether a particular service is covered nor are all plan exclusions clearly articulated. In addition, some plans may deny a service upfront because it is "non-covered" due to a coding discrepancy when it is, in fact, covered. More parameters for what constitutes "uninsured" could help ease the administration burden associated with the provision of potentially unnecessary estimates.

In addition, the rule requires the estimate to be added to the patient's medical record. We encourage the departments to provide further guidance on how to operationalize this requirement given that the child for whom the estimate is being prepared may not have an established electronic medical record because they may not have had prior contact with the provider. In particular, clarification is needed on whether providers are required to establish a record for every uninsured/self-pay patient for whom an estimate is created, regardless of whether they are scheduling care or simply shopping for services.

We also seek clarification of the term "reasonably expected," which is used throughout the rule (e.g., "including for items and services that are reasonably expected to be provided in conjunction with care"). Further specificity regarding the parameters of the term and how it is to be interpreted will be extremely helpful to providers as they construct their estimates. In the absence of more specificity, one person's interpretation of "reasonably expected" could be completely divergent from another's. One approach might be to limit "reasonably expected" to scheduled services and charges that are inherently included in the specific episode of care, such as contrast when scheduling an MRI.

In addition, clarification is needed regarding the rule's applicability to newborns and infants who do not yet have coverage. Under some plans it can take up to 75 days for an infant to be added to their guardian's coverage and, in some instances, they are eligible for Medicaid but are not yet enrolled. We seek guidance on whether these

newborns and infants would be considered uninsured for the purposes of the good faith estimate requirements in the event they need scheduled care.

**Good Faith Estimates for Uninsured (or Self-Pay) Individuals. Requirements for Convening Providers and Facilities**

While we appreciate the intent of the IFR's "convening provider" provisions to give consumers an aggregated estimate of charges from any provider that might be involved in the period of care, we are very concerned that operationalizing these requirements will be extremely difficult. We are pleased that the department has delayed enforcement of this requirement in recognition of its complexity and respectfully urge you to revise these provisions, in consultation with the provider community, to better reflect the realities of workflows and information exchange capabilities amongst providers.

At a minimum, the rule should establish a safe harbor for the convening provider in the event an outside provider is unwilling to provide an estimate, does not transmit the estimate within the established timeframe, or gives an inaccurate estimate. In addition, the establishment by HHS of a standard electronic technology or transaction to share this information could help alleviate workflow and communication challenges that the convening provider will face in collecting estimates from co-providers. Coordinating estimates from all co-providers will be challenging under existing workflows and systems as there is currently no established process for the sharing of information on expected charges between providers. The development of systems that allow for that timely information exchange will require substantial resources and coordination, as well as cooperation amongst the providers.

Furthermore, not only will it be extremely difficult to gather this information within the rule's timeframe of one to three business days, but there is no guarantee that outside providers will be willing to share the required information with the convening provider, and there are no enforcement mechanisms in the rule to require those outside providers to do so. In addition, the convening provider does not have a mechanism to verify the accuracy of co-providers' estimates or charges, but is liable for inaccurate estimates through the patient-provider dispute resolution process. Standard transaction formats, established by HHS, combined with a safe harbor to protect the convening provider when the co-providers' information is inaccurate or not shared, could help address some of these challenges.

**Good Faith Estimates for Uninsured (or Self-Pay) Individuals. Content of Estimate**

Again, we appreciate the department's interest in providing consumers with estimates of their potential costs to inform their health care decision-making. However, the required content of the good faith estimate will be extremely difficult, if not impossible, to gather and provide within the one to three business day timeframe. A delay in enforcement of the estimate requirements will give providers more time to develop the resources and administrative and data structures to collect this information, but a more reasonable timeframe for the development of the estimates is also needed. We also encourage the departments to consider both streamlining the content requirements to those elements most relevant to the consumer and allowing providers to use existing online cost estimator tools with patients who are shopping for care rather than requiring them to create a complete good faith estimate.

Though children's hospitals work closely with families to determine their financial needs, the extensive information in the good faith estimate may do more harm than good. A streamlined estimate that focuses on the information that is most relevant to, and understandable by, the patient and their family can help prevent patient confusion, while reserving hospital staff time and resources. The level of complexity of the required itemized list of services in the estimate is likely to be overwhelming to patient families, and may confuse them rather than provide them with relevant information they can understand. While we agree that the estimate may help some patient families make care decisions, we anticipate that many of our families will need additional assistance from our financial services teams to review it and answer questions and will simply find the process overwhelming, rather than helpful.

Furthermore, the creation of an itemized list of additional services, grouped by provider or facility, that are reasonably expected to be provided in conjunction with the primary services, with the charges associated with each applicable diagnosis and service code, as well as the list of services that the convening provider anticipates will require separate scheduling and resources that most hospitals currently do not have. Hospital administrative, data and electronic information systems and workflows are not currently organized in such a way as to allow for the regular collection of this information. For example, the department that provides estimates does not have the information/insight about what will require separate scheduling. Those are clinical decisions and require provider input, which may change throughout the course of treatment.

In addition, the provision of the detailed estimates required under this rule to a patient who is shopping for care is not necessary when those individuals can find needed cost information using automated online cost estimator tools, when available. Working with these individuals to enable their access to these tools will steer them to the appropriate degree of specificity and will help alleviate workflow demands on the provider.

We also believe further clarification is needed in several areas. First, we seek guidance regarding the information that must be provided to a new patient for whom there is no diagnosis (e.g., the patient who is shopping for services). As written, the rule requires that diagnosis codes be included in the estimate. However, this information cannot be provided in the case of a new patient who has not yet been diagnosed, but is requesting an estimate for services. We also ask that rule clarify that the provider will not be at fault if unable to transmit the good faith estimate to the consumer due to their lack of internet access or a functioning mailing address. Finally, we ask the department to clarify whether the required NPI/TIN is for the group practice or for the individual provider.

Finally, we urge the department to strongly consider the concerns that we have articulated in this letter as it develops its framework for the implementation of the act's broader good faith estimate and advanced explanation of benefit (EOB) provisions. Developing an estimate prior to a procedure for inclusion in the advanced EOB will require double the billing office work effort. The sheer volume of information for every scheduled case that will need to be created, transmitted to the plan, and then generated into an EOB will require additional staff (including clinical staff who can address the likelihood of complications or additional services) for both the provider and the plan.

**Good Faith Estimates for Uninsured/Self-pay Patients. Patient-Provider Dispute Resolution**

We urge the department to reconsider its approach to the patient-provider dispute resolution process, particularly the requirement that actual charges be within $400 of the good faith estimate of charges, which we believe is excessively low in relation to the variability of hospital-based care and would likely result in an inordinate number of disputes over legitimate, medically necessary issues. One approach might be the setting of a trigger for dispute resolution that is based on the percentage of the total bill rather than a flat dollar amount. This would more accurately reflect the unpredictability in costs of care, particularly related to more complex treatments.

Accuracy is very difficult to achieve when estimating potential health care costs, particularly those related to surgeries and inpatient admissions. For example, if a patient family comes to a children's hospital to get an estimate for a myringtomy (ear tube placement), the hospital can provide information on the cost of the procedure, materials and medications during that procedure. However, there are numerous unpredictable factors connected to that care, such as exactly how long the surgeon will need once the surgery commences, how much pain/nausea medication a patient may need, how long a patient takes to recover from anesthesia, or what kind of (and how much) follow-up is needed. In regards to anesthesia alone, the costs for a patient who is under anesthesia for an unanticipated additional period of additional time, would quickly surpass the rule's threshold. In fact, almost any redirection or change in the care plan will lead to a cost differential that exceeds the rule's $400 threshold, rendering the estimate immediately inaccurate and triggering dispute resolution, according to this rule. Those inaccuracies are likely to be greater for more complex services, such as fetal medicine and other highly specialized services.

Since estimates will likely exceed the $400 threshold, the only recourse providers may have under this rule will be to inflate charges to account for every potential negative outcome and protect themselves from multiple disputes. Such an outcome does not align with the spirit of transparency, nor does it provide families with a useful estimate. Instead, we strongly encourage the department to work with the hospital community to identify a more appropriate trigger for a patient-provider dispute resolution process, such as a percentage of the total bill. We also recommend that the department track dispute resolution cases during the first year of implementation and modify the threshold if it appears that there are an excessive number of proceedings.

Thank you for your efforts to implement the No Surprises Act and protect patients from surprise bills. We look forward to working with you to ensure that children and families have access to appropriate and timely care when they need it and are not subjected to unexpected financial trauma. If you have any questions or would like additional information, please contact Jan Kaplan at 202-753-5384 or jan.kaplan@childrenshospitals.org.

Sincerely,

Aimee C. Ossman
Vice President, Policy Analysis
Children's Hospital Association