



# COLLEGE of AMERICAN PATHOLOGISTS

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December 6, 2021

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

Attention CMS–9908–IFC

Subject: Requirements Related to Surprise Billing; Part II

Dear Secretary Becerra:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the interim final rules (IFR), issued by the Department of Health and Human Services (HHS), the Department of Labor (DOL), and the Department of the Treasury (collectively, the Departments), implementing certain provisions of the *No Surprises Act*. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

The CAP provided initial recommendations to HHS in June 2021<sup>1</sup> and submitted comments on the Part I IFR in September 2021. Our position on implementation of surprise billing requirements seeks to safeguard patients from surprise bills while appropriately balancing disputes between our members and insurers. Here, we comment further on those requirements related to a federal independent dispute resolution (IDR) process to determine the out-of-network rate for certain items and services, as well as those requirements that address good faith estimates of health care items and services for uninsured or self-pay individuals and the associated patient-provider dispute resolution process. As you know, the CAP worked closely with Congress and other stakeholders in the development of the *No Surprises Act*, and we have repeatedly called for protections that keep patients out of the middle of billing disputes. Importantly, we continue to believe that regulations must support an equitable and balanced system for resolving payment disputes, so as to ensure fair reimbursement for out-of-network services and IDR process that is accessible to all.

To that end, our comments here respond to the areas of (1) initial payment, (2) open negotiation, (3) initiation of the federal IDR process, (4) IDR entities and fees, and (5) treatment of batched items and services. Additionally, regarding the payment determination, **we strongly urge the Departments to revise the decision to require the certified IDR entity to select the offer closest to the qualifying payment amount (QPA) and instead allow the certified IDR entity to fully consider all relevant information.** There are no statutory elements, text or guidance, that support the interpretation in these rules, and the policy considerations support a balanced IDR system – not one that favors insurers. Finally, we also outline below a number of concerns related to the good faith estimate requirements and the patient-provider

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<sup>1</sup> <https://documents.cap.org/documents/CAP-Recommendations-No-Surprises-Act-Regulations.pdf>



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dispute resolution process. The CAP supports patient protections and access to price information in these areas, but there are serious risks for patient harm and substantial difficulty in determining the cost of pathology services in advance of services conducted by the pathologist. We thank you for your consideration of these important issues.

### Initial Payment

The Part I IFR clarified that the initial payment from a plan or issuer to a provider or facility for out-of-network items/services “should be an amount that the plan or issuer reasonably intends to be payment in full based on the relevant facts and circumstances.” As we stated in our comments responding to the Part I IFR, we support this clarification and urge HHS to ensure plans comply with this requirement. **We continue to believe it would be helpful in minimizing insurer manipulation/underpayment and in reducing utilization of the IDR process if the initial payment rate provided by the insurer is required to also be the insurer’s offer in IDR for instances where the dispute is not resolved during the open negotiation period.**

### Open Negotiation

Once an initial payment or notice of denial of payment is received, providers and health plans can enter a 30-day “open negotiation period” to try to agree on a payment amount. As the IFR overviews, the open negotiation period can be initiated by any party by providing written notice to the other party of its intent to negotiate. This written notice is referred to in the IFR as an “open negotiation notice,” which must include information sufficient to identify the items or services subject to negotiation, “including the date the item or service was furnished, the service code, the initial payment amount or notice of denial of payment, as applicable, an offer for the out-of-network rate, and contact information of the party sending the open negotiation notice.” Specifically, the parties must use a standard notice issued by the Departments,<sup>2</sup> which can be sent electronically (by email) if certain conditions are satisfied. **We appreciate the added clarity around “business-day” and the ease of providing notice, as we agree these requirements must ensure both parties are afforded the full open negotiation period.**

### Initiation of the Federal IDR Process

As is explained in these interim final rules, if the parties have not reached an agreed-upon amount for the out-of-network rate by the last day of the open negotiation period, either party may initiate the federal IDR process during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period. To initiate the federal IDR process, the initiating party must submit a notice to the other party as well as to the Departments (Notice of IDR Initiation). It is our understanding that the notice submitted to the other party will be accomplished with the use of the standard form developed by the Departments,<sup>3</sup> while notice to the Departments will be accomplished through the federal IDR portal, available at <https://www.nsa-idr.cms.gov>.

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<sup>2</sup> <https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/surprise-billing-part-ii-information-collection-documents-attachment-2.pdf>

<sup>3</sup> <https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/surprise-billing-part-ii-information-collection-documents-attachment-3.pdf>



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The IFR specifies information that must be included in the Notice of IDR Initiation by the initiating party, such as dates and location of the items or services, the names and contact information of the parties involved, and the initiating party's preferred certified IDR entity. While we support and urge the sharing of as much information as possible by both parties at the outset of the IDR process, we stress that some of the information outlined in the IFR may not be readily available to a provider/facility at the time they would be initiating IDR (i.e., additional information about the QPA, amount of cost sharing allowed). Additionally, some of the information (i.e., the QPA) is contingent on the plans and issuers making the required disclosures with each initial payment or notice of denial of payment and highlights the importance of this early communication. **Thus, we urge the Departments to consider how to fully ensure providers/facilities can successfully initiate IDR when needed (for example, addressing cases of extenuating circumstances, incomplete information, etc.). Further, we strongly believe any relevant information around how the QPA was determined (what types of providers or specialties are included, contracts, how the service was grouped regarding the same or similar item or service, the geographic area, the market that was used in the determination, etc.) must be shared upfront at the initial payment or notice of denial of payment, without having to first request that information, in order to ensure the provider/facility has the necessary insurer-held information to make a decision about negotiation and to successfully initiate IDR if required.**

### IDR Entities and Fees

The CAP appreciates the requirements related to the selection of a certified IDR entity and believes few challenges exist today with the electronic-only approach. Our primary concerns in this area remain that the IDR entity have sufficient medical, legal, and other expertise (including medical coding and billing), while also being free of conflicts of interest, such as a direct or indirect affiliation with a group health plan/payer, provider, facility, or payer/provider organization. Additionally, given the determination provided in the IFR regarding whether the federal IDR process applies, the IDR entity must have the expertise to make such a determination. Further, the process for certifying and selecting IDR entities should be transparent to ensure no bias, and there should be ongoing processes for complaints/audits regarding IDR entities and any bias in their decisions.

Specifically, we urge the agency to make additional information public about the IDR entities, including as much information as possible about the professional background of the IDR entity (including beyond the 1-year prohibition) and conflict of interest attestations. Especially given the short timeframe for making a selection, having additional information included along with the websites and service areas will ensure the parties can select, agree with, or object to the certified IDR entity in a timely manner.

Regarding costs of the federal IDR process and payment, the IFR specify that each party must pay to the certified IDR entity (1) the administrative fee due to the Departments and (2) the entire certified IDR entity fee (estimated to generally be around \$400). These fees will be viewable in the federal IDR portal during the IDR entity selection process. Then, within 30 business days of making the determination, the certified IDR entity will refund to the prevailing party the amount the party submitted for the certified IDR entity fee, thus accomplishing the requirement that the non-prevailing party pays the certified IDR entity fee. We appreciate this approach as a way to reduce administrative hurdles and complexity, which will ensure ease of access and an equitable system. **As we have previously argued, insurers – not small/rural**



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**providers/practices – will generally benefit from any added costs or complexity (which could contribute to increased gaming/underpayment), and especially with the provision of advance payment, it is vital that these requirements provide an even and fair playing field for all IDR parties.**

### Treatment of Batched Items and Services

As we have previously stated, the ability for providers to batch together claims (allowing “multiple qualified IDR dispute items and services” to be “considered jointly as part of a single determination by an entity”) was an important provision included in the *No Surprises Act*. Batching ensures an equitable and accessible IDR system, while also encouraging efficiency and minimizing costs, and therefore, we urge the agency to reject additional criteria that would limit the ability to batch claims. **Especially for pathology services, which often have lower reimbursement rates, any flexibility that facilitates broader batching of qualified IDR items and services will ease access to the IDR process and further the statute’s goals of encouraging “procedural efficiency” and minimizing administrative costs.**

In particular, we appreciate the specification that items and services are billed by the same “provider or group of providers or facility” if the item or services are billed with the same National Provider Identification (NPI) or Taxpayer Identification Number (TIN). Again, not only does this ensure efficiency and minimize administrative costs, but it is necessary to ensure the IDR process is accessible to providers no matter their individual situation. We also appreciate the consistent definition of a same or similar item or service and the recognition that certain batched items and services may have different QPAs. **We continue to urge the agency to evaluate how providers can batch together all claims/codes with the same modifier, such as modifier 26 used to report professional component interpretation services. These claims involve similar services and would make efficient and practical sense for all parties to consider together in a single batch.**

### Payment Determination

After the parties to the federal IDR process have submitted their offers, the certified IDR entity “must select one of the offers submitted by the plan or issuer and the provider or facility to be the out-of-network rate for the qualified IDR item or service.” The IFR, surprisingly, dictates that in selecting the offer, the certified IDR entity “must select the offer closest to the QPA, unless the credible information submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate.” The Departments are of the view that this is the “best interpretation” of the statute. **However, we strongly disagree and urge you to revise this decision immediately.**

To start, the Departments argue that because the statutory text lists the QPA as the first factor the certified IDR entity must consider in determining which offer to select, that this signifies the importance of the QPA. However, without explicit language that signifies the list is one of priorities, each specific paragraph should be given weight as separate factors that must all be considered by the IDR entity. Per the plain language of the statute, the certified IDR entity “*shall* [emphasis added] consider” the QPA; the level of training, experience, and quality and outcomes measurements of the provider or facility that furnished such an item or service; the market share held by the nonparticipating provider or facility or that of the plan or issuer; the acuity of the individual or the



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complexity of furnishing such item or service to such individual; the teaching status, case mix, and scope of services of the nonparticipating facility; and demonstrations of good faith efforts (or lack of good faith efforts) made by the nonparticipating provider or nonparticipating facility or the plan or issuer to enter into network agreements and, if applicable, contracted rates between the provider/facility and the plan. The current regulations clearly derogate consideration of all listed items except the initial one.

The administration also points to limited guidance on how to consider or define these additional circumstances, while the statute sets out detailed rules for calculating the QPA. Using this as evidence of the importance of the QPA is also flawed, as the additional circumstances require less guidance than the calculation of a novel and statutorily-created item, which clearly necessitates additional specification. For example, the “level of training” of the provider should be a relatively straightforward factor for consideration. There are simply no “statutory elements” that show that the “statute contemplates that typically the QPA will be a reasonable out-of-network rate.” In fact, legislative proposals considered and discarded by Congress specifically set out an initial payment rate that was the equivalent of the QPA.<sup>4</sup> The fact that these proposals were not ultimately adopted is counter to the Departments’ insistence that the QPA is a reasonable out-of-network rate.

Further, the existence of an IDR process at all indicates that there is no established presumptive/default rate. If Congress wanted to default to the QPA as the out-of-network rate, they certainly could have provided for that in the statute. Instead, they outlined a process that includes an open negotiation period, consideration in IDR of a number of factors, a neutral arbitrator, and a balanced method for resolution. A process that essentially predetermines the outcome places a thumb on the scale in favor of health insurers and is not a “process” at all.

Finally, the Departments also point to policy considerations they believe support the approach taken under these interim final rules. However, the considerations they believe support their position are flawed, and at the same time, the Departments overlooked other critical policy considerations that directly impact patient care. To start, “standard market rates arrived at through typical contract negotiations” represent an in-network rate, which is not representative of a reasonable out-of-network rate as the Departments argue. In addition, by defaulting to an insurer-controlled benchmark rate, this approach will further contribute to ongoing health plan manipulation, leading to an environment where insurers are disincentivized from offering fair contracts to providers. As we have stated already, “in implementing the IDR process in a way that essentially predetermines the outcome to be at the 50<sup>th</sup> percentile of contract rates,” the Departments have removed an “important check on negotiation incentives established by Congress.”<sup>5</sup> Especially in today’s environment, where “the majority of health insurance markets in the United States are highly concentrated,”<sup>6</sup> this is hugely problematic. Finally, while it may take time to understand the full extent of resulting narrower networks, physician practice closures, and increased consolidation, these changes have the potential to decrease

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<sup>4</sup> See <https://newsroom.cap.org/news-by-topic/cap-opposes-payment-scheme-in-no-surprises-act/s/46195acf-d0ae-41c3-9ea5-a2bed0944fd4> and <https://newsroom.cap.org/news-by-topic/cap-objects-to-latest-surprise-billing-agreement/s/ce2f642f-d60b-4f4d-af5c-c54526a70098>

<sup>5</sup> [https://searchlf.ama-](https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-11-17-sign-on-letter-NSA-IFR-2.pdf)

[assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-11-17-sign-on-letter-NSA-IFR-2.pdf](https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-11-17-sign-on-letter-NSA-IFR-2.pdf)

<sup>6</sup> <https://www.ama-assn.org/system/files/competition-health-insurance-us-markets.pdf>





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access to care for the most vulnerable, particularly in rural and underserved communities. And the financial strain placed on physicians to benefit insurers should not be considered in isolation – without congressional action, pathologists are facing a nearly 10 percent cut in Medicare payments as they continue to respond on the frontline to the COVID-19 public health emergency. Now more than ever, pathologists must be able to continue to focus on the essential task of testing and ensuring proper treatment of patients, not going up against insurers for fair reimbursement for their services.

**For these reasons, we strongly urge the Departments to revise the decision to require the certified IDR entity to select the offer closest to the QPA and to rescind other limitations on factors that may be relevant; instead, rulemaking must allow the certified IDR entity to fully consider all relevant information in determining fair reimbursement for out-of-network services.**

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

Included in the *No Surprises Act* are requirements that health care providers and facilities, upon scheduling an item/service to be furnished to an individual or upon request of an individual, inquire about such individual's health coverage status and provide a notification of the good faith estimate of the expected charges for furnishing that item or service and any item or service reasonably expected to be provided in conjunction or provided by another provider or facility. **The CAP agrees that patients must be able to make informed decisions about their health care, and we understand how access to price information prior to services may be useful for patients, but we remain concerned about the risk for patient harm from any delays and the difficulty in determining the cost of pathology services in advance of services being performed by the pathologist.**

As HHS itself acknowledges, the accuracy of the good faith estimate is relevant because “if the actual billed charges substantially exceed the amounts reported in the good faith estimate, an uninsured (or self-pay) individual could seek a determination under the patient-provider dispute resolution process.” However, there is significant – and particular – difficulty in determining the cost of pathology services in advance of services conducted by the pathologist. For instance, a surgical or invasive diagnostic procedure performed by a dermatologist, surgeon, gastroenterologist, urologist, or other clinician may result in no specimens obtained or it may result in multiple specimens requiring anatomic evaluation. Additionally, anatomic pathology services typically involve a pathologist performing microscopic analysis of tissue or body fluids to determine whether cancer or other disease is present and, if so, its characteristics. The type of specimen or complexity of the analysis is often not known in advance of the initial microscopic analysis conducted by the pathologist, making it impossible to provide a reliable estimate of costs. In fact, this reality is reflected by CMS in Medicare's Benefit Policy Manual with a surgical/cytopathology exception that notes there are additional tests a pathologist may need to perform after an examination or interpretation, “even though they have not been specifically requested by the treating physician/practitioner.”<sup>7</sup>

We acknowledge that these IFR “do not require the good faith estimate to include charges for unanticipated items or services that are not reasonably expected and that could occur due to unforeseen events.” Still, even where the number/frequency and the

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<sup>7</sup> <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>



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extent of or exact items/services are known in advance, requiring a co-provider or co-facility to provide good faith estimate information no later than 1 business day after the request is received extremely burdensome. Additionally, there are no requirements for what information the convening provider or convening facility must share to ensure the co-provider or co-facility can provide a timely and accurate good faith estimate (patient information, clinical history, etc.). Ensuring co-providers and co-facilities have timely access to the required information will be necessary to provide an accurate cost estimate. The IFR specification that a provider or facility (including co-provider and co-facility) will not fail to comply with the requirements because it relied in good faith on the information from the other entity is also important in this regard.

Additionally, HHS acknowledges that some states “have existing state laws related to the furnishing of good faith estimates,” but establishes that providers or facilities that issue good faith estimates under state processes that “do not meet the minimum requirements” in the IFR fail to comply with the requirements of the federal law. **HHS should provide additional guidance regarding the interaction of state and federal requirements related to good faith estimates and should continually update publicly available information/education in this area to avoid confusion or unintended non-compliance with the myriad of related requirements.**

Further, HHS recognizes the “potential disincentive” some of these requirements could have on a provider’s or facility’s willingness to provide an item or service in certain circumstances. The CAP believes in the importance “consumer protections” and has continually called for protecting the patient, but we do not feel this should come at the cost of medically necessary care. **We appreciate the enforcement discretion provided through December 31, 2022 and urge the agency to continue revising the good faith estimate requirements during this time.**

Relatedly, we have previously expressed concerns about encouraging consumers to shop for lower-cost health care, where it could jeopardize patient health and/or coordination/quality of patient care. Specifically, the CAP agrees that patients should be empowered to make cost-effective health care choices, but we believe any program, provision, or protocol that impinges on the practice of medicine and could improperly encumber and curtail medically necessary clinical laboratory and pathology services in serving the financial interest of the payer is problematic. Further, in selecting an immediate lower-cost service that presents coordination/quality issues, there could be additional utilization and/or costs downstream. Unless patients have a full understanding of all pricing information and consequences of shopping for care, there is a risk of patients making care decisions that disrupt coordination, add burdens, or lead to lower quality. This is a particular concern for the most vulnerable patient populations, including those with low income and/or chronic conditions.

### Patient-Provider Dispute Resolution

The *No Surprises Act* establishes a process for uninsured (or self-pay) individuals to seek a determination from a selected dispute resolution (SDR) entity for the amount to be paid by the uninsured (or self-pay) individual to the provider or facility for certain items/services. As these IFR explain, an uninsured (or self-pay) individual is eligible for the patient-provider dispute resolution process after being furnished an item or service for which they received a good faith estimate if the individual is billed charges that are substantially in excess of the good faith estimate.



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The IFR define “substantially in excess” to mean an amount that is at least \$400 more than the total amount of expected charges for the provider or facility listed on the good faith estimate. We appreciate the balance HHS hoped to achieve, between an amount sufficiently large to justify the dispute resolution process, minimizing burdens on providers and facilities, and ensuring all uninsured (or self-pay) individuals are able to access to dispute resolution process to resolve unexpected billed amounts. We also agree that applying a percentage to items/services where the associated dollar amounts are small would lead to an overuse of the dispute resolution process and higher burden/cost to providers. **Thus, at this time, we support the more “straightforward” \$400 amount but urge regular evaluation of this approach.**

Importantly, we understand that where the SDR entity determines that the provider or facility has provided credible information that the difference between the billed charge (including new items/services) and the expected charge “reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided,” the uninsured (or self-pay) individual must pay the lesser of (1) the billed charge or (2) the median payment amount for the same or similar service in the geographic area. However, for new items or services that do not meet this standard, as determined by a single SDR entity, a payment amount of \$0 is overly punitive and we urge the agency to find a different approach to protect the uninsured (or self-pay) patient from surprise charges that are not reflected in the good faith estimate. **Without changes to this provision, it is imperative that, similar to the certified IDR entity, the SDR entity have sufficient medical expertise to make a determination of whether items/services are medically necessary and/or unforeseeable.**

### Summary

The CAP appreciates the work put forward to address these important issues, as well as the opportunities to provide comments on this IFR while continuing efforts to find an equitable and balanced solution to protecting patients from surprise medical bills. Again, we strongly urge the Departments to revise the decision to require the certified IDR entity to select the offer closest to the QPA, and instead the Departments must allow the certified IDR entity to fully consider all relevant information. We also urge consideration of our concerns related to the good faith estimate requirements and the patient-provider dispute resolution process, as there are serious risks for patient harm from any delays and substantial difficulty in determining the cost of pathology services in advance of services being performed by the pathologist.

Please contact Elizabeth Fassbender, CAP Assistant Director, Economic and Regulatory Affairs at [efassbe@cap.org](mailto:efassbe@cap.org) if you have any questions on these comments.