



COLLEGE of AMERICAN PATHOLOGISTS

September 7, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services (HHS)
Attention: CMS-9909-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

Subject: Requirements Related to Surprise Billing; Part I

Dear Administrator Brooks-LaSure:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the interim final rules (IFR) 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 ([available online here](#)), which we believe will safeguard patients from surprise bills while appropriately balancing disputes between our members and insurers. Here, we reiterate these recommendations, while responding specifically to the requirements outlined in the IFR and our priority concerns. 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. 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 an independent dispute resolution (IDR) process that is accessible to all.

Specified State Law

As is detailed in the *No Surprises Act* and the IFR, a "specified state law" is "a state law that provides a method for determining the total amount payable under a group health plan or group or individual health insurance coverage to the extent the state law applies." According to the IFR, HHS interprets this broadly, and believes Congress intended that "where state law provides a method for determining the total amount payable under a plan or coverage, the state law regarding balance billing would govern, rather than the alternative method for determining the out-of-network rate under the *No Surprises Act*." This could mean the state law includes a mathematical formula, a set predetermined amount, and/or negotiation/arbitration. Accordingly, we understand that most, if not all, state laws would govern and federal protections against surprise billing will fill in the gaps as needed. As we stated in our June letter, the CAP generally supports allowing state laws to continue to operate and improve their patient protections. However, we still feel that additional clarity would be helpful around where and explicitly how state law applies. We encourage the agency to provide ongoing education and resources in this area, beyond the initial examples already provided in the IFR. Providers, state regulators/legislators, health plans, and other stakeholders will need to



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understand this information and its consequences for patient protection and payment dispute resolution, as well as any complaint process and enforcement.

Additionally, the agency seeks comments on whether health insurers should be able to opt in to a program established under state law. While the agency is appropriately concerned about increasing health care prices, we emphasize that the regulations must also ensure an equitable and balanced system for resolving payment disputes, not one that allows only insurers to pick and choose their own beneficial system. As such, we oppose any ability to allow insurers to opt-into state laws on an episodic basis and cherry-pick the system that benefits them most at the expense of a balanced system.

Methodology for Calculating the Qualifying Payment Amount (QPA)

As is explained in the IDR, the “qualifying payment amount,” or QPA, is used in certain circumstances to calculate cost-sharing requirements, and is also a factor that must be considered by IDR entities when selecting between the offer submitted by a plan or issuer and the offer submitted by a facility or provider. The QPA generally is the median of the contracted rates recognized by the plan or issuer, for similar services in that geographic region as of 2019, updated annually by the percentage increase in the consumer price index for all urban consumers. It is critical that regulations around the QPA ensure an accurate and transparent calculation.

1. Insurance markets – by statute, the QPA must be differentiated by individual market, large group market, and small group market. We appreciate the agency’s clarification that for purposes of this IFR, “insurance market” does not include Medicare Advantage or Medicaid managed care organization plans. As is explained in the IFR, this approach is consistent with the statutory requirement that the median contracted rate is determined with respect to all “group health plans” of the sponsor or all “group or individual health insurance coverage” offered by a health insurance issuer in the same insurance market.
2. Same or similar items/services – to accurately determine the QPA for items or services, it is important that the in-network rates used are as specific as possible. For pathology services, using Current Procedural Terminology (CPT) “family” (aggregating data from CPT codes in a given family) is not practical, as there is significant variance in payment. For example, the surgical pathology 88300 – 88309 “family” of Medicare rates ranges from \$15.70 to \$441.75 as a result of the correspondingly large differences in physician work and practice expense. The amount of physician work varies in the time, intensity, and complexity of the services. The practice expense varies in the time and resources required for the clinical labor, the amount and types of medical supplies, and equipment usage.

Therefore, we appreciate the agency’s definition that for purposes of the IFR, the term “same or similar item or service” means a health care item or service billed under the same service code, or a comparable code under a different procedural code system. Service code means the code that describes an item or service, including a Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) code.

We also appreciate the IFR requirements to account for modifiers and agree it is important that the QPA methodology account for modifiers that affect payment rates



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under contracts with participating providers and facilities. We would urge the agency to require insurers to provide upfront any information regarding the use of modifiers in calculating the QPA so the providers can appropriately understand the calculation.

3. Provider in the same or similar specialty – the QPA is calculated separately for each provider specialty, as applicable, and the IFR defines “provider in the same or similar specialty” as the practice specialty of a provider, as identified by the plan or issuer consistent with the plan’s or issuer’s usual business practice. We understand this was done to provide appropriate flexibility and decrease burden, but would encourage mechanisms that allow for transparency around this determination.
4. Facility of the same or similar facility type – the QPA is calculated separately for each facility type where a plan or issuer has contracted rates for services that vary based on the type of facility (the IFR emphasizes a hospital emergency department v. independent freestanding emergency department and the agency specifically noted the “appreciable differences in the case-mix and level of patient acuity between these types of facilities”). On the other hand, the IFR specifies that the rules do not allow plans or issuers to separately calculate a median contracted rate based on “other characteristics of facilities that might cause contracted rates to vary, such as whether a hospital is an academic medical center or teaching hospital.” We understand and agree with this determination, but we continue to have questions about what can be accounted for in making payment adjustments based on quality or facility type, especially for nonemergency services. Further, we continue to urge consideration of the range of activities within pathology services and the variation of associated costs and resources across different provider settings, especially as it relates to the differences between hospital laboratories and freestanding laboratories, as a typical case-mix even within the same CPT code can vary significantly between these two kinds of settings.
5. Geographic regions – under the IFR, a geographic region is generally defined as one region for each metropolitan statistical area (MSA) in a state and one region consisting of all other portions of the state. We appreciate the agency’s commitment to monitor the effect of these geographic regions and periodically update such regions, as appropriate.
6. Information to be shared about the QPA – as is explained in the IFR, the *No Surprises Act* directs the Departments to specify the information that a plan or issuer must share with a nonparticipating provider or nonparticipating emergency facility, as applicable, when making a determination of a QPA. The agency also notes that they recognize providers subject to the rules need transparency around how the QPA was determined. Additionally, to borrow from the IFR, “to decide whether to initiate the IDR process and what offer to submit, a provider, emergency facility, or provider of air ambulance services must know not only the value of the QPA, but also certain information on how it was calculated.”

We agree that the QPA should be shared with providers for each item or service involved and information should be shared immediately on how to initiate the open negotiation period, including contact information. We also appreciate that additional information must be provided upon request of the provider/facility, but 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



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regarding the same or similar item or service, the geographic area, the market that was used in the determination, etc.) must be shared upfront without having to first request that information.

7. Audits – agencies are required to establish a process under which group health plans and health insurance issuers are audited by the Secretary or applicable state authority to ensure compliance around the QPA. This process will be critical in preventing abuse or manipulation and we reiterate that it should determine the accuracy of QPAs using independent data with the results of the audit publicly available. Further, the audit process should include clear non-compliance penalties and enforcement mechanisms for violations of QPA calculation requirements.

Initial payment or providing a notice of denial

The initial payment or notice of denial of payment starts the process for determining the out-of-network rates to be paid, and specifically, starts the clock for the 30-day open negotiation period. The IFR clarifies that plans and issuers are required to send the initial payment or notice of denial of payment not later than 30 days after a nonparticipating provider/facility submits a bill related to the items and services that fall within the scope of the new surprise billing protections. As we have communicated previously, it is clear that health plans are already finding ways to circumvent the protections provided in the *No Surprises Act* and shift medically necessary health care costs onto their enrollees. We appreciate the IFR emphasizing that additional standards may be needed if the agencies become aware of instances of abuse and gaming. We continue to request clarity around the notice of denial of payment, as well as details on the “clean claim” requirements, and believe any additional standards that can prevent abusive claims payment practices will be extremely beneficial.

The IFR notes that no specific amount of minimum initial payment is required and seeks comment on whether to set a minimum payment rate or methodology for a minimum initial payment in future rulemaking. The CAP has continually opposed a set payment rate/standard, and instead, we have argued that “commercially reasonable” rates should be paid for physician services. Relying on an initial/benchmark rate for out-of-network services, especially those based on median or mean in-network contract rates, is contrary to the legislative intent of the *No Surprises Act* and would create imbalance and threaten patient access in the U.S. health care system. An initial payment rate/standard can distort and skew both the arbitration process and contracted rates negotiated between providers and health plan payers in the commercial market, and it is also inconsistent with the approach taken by many states that have successfully operationalized their out-of-network laws without payment formulas.

Instead, we support the IFR clarification that the initial payment is meant to reflect the amount the plan reasonably expects to pay for the services (we believe this kind of “commercially reasonable” clarification should inform health plans who may not have good faith intentions with the initial payment and who may endeavor to encumber providers with reliance upon negotiation and/or arbitration to resolve payment disputes). In addition, we believe it could be helpful in reducing the amount of arbitration/IDR if the initial payment rate provided by the insurer is required to also be the insurer’s offer in the IDR process for instances where there is a dispute not resolved during the open negotiation period.



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Surprise Billing Complaints

The *No Surprises Act* requires the Secretary to establish a process to receive complaints about violations of the requirements around the QPA. We applaud the agencies for broadening this process to include all the consumer protection and balance billing requirements, and we support the decision in the IFR for the complaints process to be extended. We also appreciate the efforts to “minimize the burden of filing a complaint” and only requiring the information necessary to process the complaint and conduct an investigation if deemed necessary. Finally, we also agree that “every complaint should be processed and investigated as appropriate to ensure that any necessary enforcement action can be taken,” so it may make sense to not include a time period upon which a complaint must be filed, but still require HHS to respond to complaints (upon receiving the information necessary to file a complaint) within 60 days of receipt.

Notice and Consent

Included in the *No Surprises Act* is an exception to the ban on balance billing for certain non-emergency services if providers give prior written notice at least 72 hours in advance and obtain the patient’s written consent. The notice must indicate the provider does not participate in-network, provide a good faith estimate of out-of-network charges, and include a list of other participating providers in the facility whom the patient could select. By statute, this exception does not apply for “ancillary services” (including pathology) or diagnostic services (including laboratory services). Therefore, we understand this to mean that the majority of pathologists will not be able to balance bill under any circumstances. However, as outlined in the IFR, the statute “authorizes HHS to specify a list of advanced diagnostic laboratory tests that would not be considered ancillary services under this definition.” Any such advanced diagnostic laboratory tests would still be subject to the surprise billing protections described in the IFR, but the notice and consent exemption process would also be available for these tests.

When establishing a list of ADLTs for purposes of this section, we urge the agency to proceed with caution, and limit the exception only to those situations where there would be serious harm to the patient to not receive such a service. The agency should also require that the entity performing or responsibly supervising the service directly bill for their services. Allowing a non-performing ordering facility or treating physician to bill for such services increases costs for the patient (as a treating physician may mark up the laboratory services) and creates an economic incentive to order other than necessary tests (as each service ordered results in an incremental increase in profit). The CAP has long believed that payment for pathology services should be made only to the person or facility that personally performed or supervised the service, which is consistent with American Medical Association (AMA) ethics policies and is in the best interest of both good patient care and cost control.

Summary

The CAP appreciates the hard 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. Please contact Elizabeth Fassbender, CAP Assistant Director, Economic and Regulatory Affairs at efassbe@cap.org if you have any questions on these comments.