COLLEGE of AMERICAN PATHOLOGISTS

June 21, 2021

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

Dear Secretary Becerra:

The College of American Pathologists (CAP) understands that the Department of Health and Human Services (HHS), together with other agencies of jurisdiction, has begun the process for implementing the recently enacted *No Surprises Act*. While waiting for rulemaking, we write to provide our initial recommendations, which we believe will further safeguard patients from surprise expenses while appropriately balancing disputes between our members and insurers. 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 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. While sometimes described as “ancillary,” pathologists provide a full range of services critical to patient care. For example, pathologists direct clinical and anatomic pathology laboratory services and serve as expert laboratory consultants to other physicians and to hospital leadership; this is in addition to triaging and interpreting biopsies, and diagnosing surgical, cytology, and autopsy specimens. Clinical pathology services include development, approval, and evaluation of appropriate test methods, pre- and post-analytical oversight, interpretation of clinical laboratory tests and consultation to other physicians, and direct involvement with both technologists and clinical colleagues to ensure prioritization and proper response to test results. During the COVID-19 crisis, pathologists in hospitals and laboratories around the country have been responsible for developing and selecting new test methodologies, validating and approving testing for patient use, and expanding the testing capabilities of the communities they serve to meet emergent needs. The impact of all these pathology services on clinical decision-making is pervasive and constitutes a critical infrastructure and foundation for appropriate care.

Beyond argument, the COVID-19 pandemic has shaken and challenged every health care system and organization. What has remained the same for health care providers is their unwavering commitment to care for their patients and communities. Today more than ever, patients should not be financially penalized for the failure of health insurance plans to establish adequate in-network access to hospital-based physician specialties. Yet, health insurance plans are increasingly relying on narrow and often inadequate networks of contracted physicians, hospitals, and other providers in order to shift medically necessary health care costs onto their enrollees. Even now, health plans are finding ways to circumvent the protections provided in the *No Surprises Act*; for example, by proposing to subject patients to full liability for services received at facilities

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listed as being in-network, but not additionally "designated"[1] as eligible for coverage. We need strong regulations to prevent such health plan manipulation and gaming that harms patients, while ensuring robust oversight and audit/complaint processes.

Additionally, to realize the intent of the *No Surprises Act*, 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.

Qualifying Payment Amount (QPA)

As defined by the statute, the "qualifying payment amount," or 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. As an important part of the IDR process, the Secretary is required by July 1, 2021 to establish the methodology that will be used to determine the QPA, and the information that will be shared with providers when making the determinations, as well as other details. We urge the Secretary to consider the following recommendations related to this area:

1. Insurance markets – by statute, the QPA must be differentiated by individual market, large group market, and small group market. In establishing the QPA methodology, it should also be made clear that Medicare, Medicare Advantage, and Medicaid rates are not included in the calculations of the QPA, as these non-commercial rates will skew the data sets and are expressly excluded under the *No Surprises Act* from IDR consideration. Further, regulations need to provide transparency around these determinations to ensure appropriate data is used, payment is predictable, and enforcement is possible.

2. Geographic regions – the Secretary is required to establish the geographic regions applied for purposes of the QPA, consulting with the National Association of Insurance Commissioners (NAIC). While we do not necessarily oppose the use of Market Geographic Rating Areas as recommended by NAIC, we support instead the use of "geozip" regions (a geographic area defined by the first three digits of a zip code), as this would more accurately account for differences in provider cost.

3. Contracted rates – as outlined above, the QPA is the median of the contracted rates recognized by the plan/issuer as the total maximum payment (including the cost-sharing amount imposed (paid by the patient) for such item/service and the amount paid by the plan/issuer). This should be determined based on the contracted rate for each individual provider rather than as aggregated into group contracts.

4. Same or similar specialty – in determining providers in the same or similar specialty, the QPA methodology must also differentiate by provider type as well as by specialty. These considerations, which reflect education, level of training, and expertise, are critical factors in the contracting and in-network payment processes.

[1] https://documents.cap.org/documents/CAP-Letter-re-UHC-DDP.pdf. See also https://www.nytimes.com/2021/06/10/health/united-health-insurance-emergency-care.html.

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5. 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.

6. Sharing information with providers – the recognized amount or QPA should be shared with providers upon the initial response (payment or denial) from the insurer. When sharing the QPA, additional information should be shared around how the QPA/recognized amount was determined, such as what types of providers/specialties are included, how the service was grouped regarding the same or similar item or service, the geographic area, and the market that was used in the determination.

7. Opportunity for complaints – the No Surprises Act also requires the Secretary to establish a process to receive complaints about violations of the requirements around the QPA. To ensure this complaint process is easily accessible, clarification should be provided regarding how and where providers can issue complaints for federally versus state-regulated plans in each state.

Additionally, the statute specifies that the methodology "may account for relevant payment adjustments that take into account quality or facility type (including higher acuity settings and the case-mix of various facility types) that are otherwise taken into account for purposes of determining payment amounts with respect to participating facilities." We urge the Secretary to take into consideration the range of activities within pathology services and the variation of associated costs and resources across different provider settings. QPA calculations should be differentiated by facility type based on scope of service and case mix to account for each of their unique components of care delivery and costs. In particular, we would suggest that the QPA calculations for hospital facilities (hospital, hospital outpatient department, critical access hospital, etc.) include only hospital-contracted rates, which would appropriately avoid skewing the calculation for those facilities. Given the continuing COVID-19 crisis and the needed focus on addressing health equity, it is more important than ever to ensure access to quality care at a variety of settings and locations.

Finally, agencies are also required to establish a process under which group health plans and health insurance issuers are audited by the Secretary or the State to ensure compliance around the QPA. Such a process should determine the accuracy of QPAs using independent data and the results of the audit should be publicly available. Further, the audit process should include clear compliance penalties and enforcement mechanisms for violations of QPA calculation requirements.

IDR Process

As you know, the process of determining out-of-network rates to be paid by health plans begins with the health plan sending an initial payment or notice of denial of payment

within 30 days of the bill for services. Once that is received, providers and health plans can enter a 30-day "open negotiation period" to try to agree on a payment amount. If at the end of the 30 days, there is no agreement, parties will have four days to decide to bring the claim(s) through the IDR process. Then, within 30 days of IDR notification, an IDR entity must take into account specified factors and select one of the offers submitted by IDR parties to be the amount of payment.

While this is an incredibly simplified overview of the IDR process, we urge the Secretary to consider the following recommendations related to this area:

1. Initial payment or notice of denial of payment – 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. Importantly, the *No Surprises Act* applies only to items or services "for which any benefits are provided or covered by a group health plan or health insurance issuer." Thus, we interpret the legislation, and resulting regulations, to apply only to covered services, and would stress that if an item or service is denied for coverage reasons, such a denial removes the claim from the requirements of the statute. Additionally, an important clarification is that a claim denied for reasons of medical necessity is deemed non-covered and similarly removed from the requirements of the *No Surprises Act* and its regulations. However, if the claim subsequently receives a positive coverage determination, the provider must be afforded opportunity to resolve any payment disputes via the *No Surprises Act*.

   As we mentioned above, 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. Regulations and clarifications in this area must ensure denials by health plans are not used to further this kind of behavior.

   We also stress that regulations should clarify what happens in the situation where there is no response from the health plan to start the open negotiation period, either initial payment or notice of denial of payment. For example, we support clarification that a health plan's failure to respond within 30 days after the bill has been submitted should be deemed a notice of denial for purposes of the IDR process, and the provider can then initiate the open negotiation period

2. Batching claims – 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*, which ensures an equitable and accessible IDR system, while also encouraging efficiency and minimizing costs. Items and services may be batched if (1) furnished by the same provider or facility; (2) involving the same group health plan or insurance issuer; (3) such items/services are related to the treatment of a similar condition; and (4) such items and services were furnished during the same 30-day period. An alternative period of time may be determined by the Secretary, for use in limited situations, such as by the consent of the parties or in the case of low-volume items and services.

   First, we strongly encourage the formulation of longer, alternative periods of time in the cases of low-volume services or by consent of the parties. Especially for pathology services, which often have lower reimbursement rates, any flexibility that

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allows for additional batching ability will ease access to the IDR process and further the statute's goals of encouraging "procedural efficiency" and minimizing administrative costs.

Importantly, providers in the same practice/group (TIN) must be permitted to batch their claims for IDR and bring a single claim together. 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.

Finally, to determine items/services related to the treatment of a similar condition, providers should be able to batch claims at the CPT code or CPT family level. Unlike the specificity needed for the QPA calculation, the CPT family level for batching purposes would allow a broad but still cohesive set of claims to be brought together for consideration. Use of the CPT family is predicated, however, on the ability of the process to adjudicate multiple services with similar circumstances but different payment amounts. As we articulated above, there is significant variance in payment within a given pathology CPT "family," but if the process can accomplish it, batching in this manner will further the goals of efficiency and minimal cost. Further, we 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 to consider together in a single batch.

3. Information submitted to IDR entity – in addition to the information on circumstances articulated in the statute (level of training, experience, and quality of the provider; the market share held by provider/plan; acuity of the individual, etc.), the IDR entity must consider any additional information submitted by either party relating to the offer submitted. While we understand the IDR entity must not consider usual and customary charges or the amount that would have been billed by the provider/facility, we urge the agency to allow flexibility in the contracted rates/history and other data that can be submitted.

4. Weighing factors during IDR consideration – in "determining which offer is the payment to be applied," the certified IDR entity shall consider several factors, including the QPA, the level of training/experience, and quality and outcomes measurements of the provider or facility, the market share held by the provider/facility or of the plan/issuer, the acuity of the individual and complexity of services, the teaching status and case mix and scope of services of the facility, and demonstrations of good faith efforts – or lack thereof – to join the insurer's network and any prior contracted rates over the previous four years.

   To ensure an equitable and balanced system for resolving payment disputes, no single factor should be given preference over the others. In particular, default emphasis should not be given to the QPA as this will further contribute to ongoing health plan manipulation, leading to an environment where insurers are disincentivized from offering fair contracts to providers.[2]

[2] See also https://documents.cap.org/documents/bucshon-ruiz-smb-letter-final-5-5-21.pdf and https://www.cassidy.senate.gov/imo/media/doc/SMB%20Letter%20Final_4_29_21.pdf.

5. IDR entities – the Secretary is required to establish a process to certify the IDR entities that will make determinations regarding the payment to be applied. As is outlined in the statute, the IDR entity must have sufficient medical, legal, and other expertise (including, we believe, specialty-specific medical coding and billing knowledge), 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. Certainly for pathology, there are distinctive characteristics that must be understood to appropriately and equitably determine the amount of payment. The process for certifying and selecting IDR entities should also be transparent to ensure no bias, and there should be ongoing processes for complaints/audits regarding IDR entities.

6. IDR process, generally – in order to ensure ease of access and an equitable system, the agency should make every effort to reduce administrative hurdles and costs. For example, providing an entirely online/virtual process will allow providers, no matter their schedule or resources, to participate more fully. The agency should also create and provide educational resources to explain the process simply. Insurers – not small/rural providers/practices – will generally benefit from any added costs or complexity (which could contribute to increased gaming/underpayment), so it will be important to provide an even and fair playing field for all IDR parties.

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, the statute stipulates that the Secretary may, through rulemaking, establish a list of advanced diagnostic laboratory tests (ADLTs), which shall not be considered as ancillary services, thus allowing balance billing for those tests following notice and consent.

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 make a profit by charging the patient full price for a laboratory service that the physician purchased at a discount) 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.

Specified State Law

As is detailed in the *No Surprises Act*, a "specified state law" is one that provides a method for determining the total amount payable under a plan, coverage, or issuer for certain out-of-network services. Regulations will need to provide clear details on what state laws are included in this definition, and what state laws will be preempted by the federal law. We generally support allowing state laws to continue to operate and improve their patient protections, while understanding that simple bans on surprise billing with no mechanism or accessible process for addressing payment disputes between physicians and health plans should not meet the statutory threshold. In addition to clear details in the regulations, providers, state regulators/legislators, and others will need to understand this information and its consequences for patient protection and payment dispute resolution, as well as any complaint process and enforcement.

Additionally, the ability of physicians to understand which out-of-network rules and patient protections apply greatly depends on the health plan's identification of plan type (ERISA, non-ERISA, "specified state law," etc.). In addition to this information being clearly displayed on a patient's insurance card, pathologists would need this information as well on communications such as the explanation of benefits statement. Of course, the earlier received and more accessible this information is, the more prepared providers will be for helping the patient and making decisions regarding the IDR process.

Enforcement

Finally, the CAP strongly believes inadequate insurer networks are the root cause of surprise bills. Without adequate networks of contracted physicians, a patient cannot be properly guarded against out-of-network health care at an in-network facility. Simply put, if there are more in-network providers to begin with, there will be fewer patients receiving surprise bills. Thus, the CAP appreciates the inclusion of language that directs the GAO to study network adequacy and hopes that the agency will consider additional proposals to address this issue in the future, especially as we are better able to evaluate the implementation and success of the *No Surprises Act*.

As we outlined above, strong regulations are needed to prevent health plan manipulation and gaming that harms patients (and which is already happening), while ensuring robust oversight and audit/complaint processes for an equitable and balanced system to fairly resolve payment disputes between providers and health plans.

Summary

The CAP appreciates the hard work already put forward to address this issue, as well as the opportunity to continue to provide our recommendations on finding 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.

Sincerely,

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