



Charles N. Kahn III
President and CEO

December 6, 2021

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

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

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

Re: Requirements Related to Surprise Billing; Part II; CMS-9908-IFC; 86 Fed. Reg. 55,980 (Oct. 7, 2021)

Dear Secretaries Becerra, Yellen and Walsh:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services. These tax-paying hospitals account for nearly 20 percent of U.S. hospitals and serve their communities proudly while providing high-quality health care to their patients.

The FAH appreciates the opportunity to submit comments to the Office of Personnel Management, Department of the Treasury, Department of Labor, and Department of Health and Human Services (HHS), regarding their interim final rules, Requirements Related to Surprise Billing; Part II (IFR), published in the Federal Register (86 Fed. Reg. 55,980) on October 7, 2021. The FAH and its members strongly support the *No Surprises Act*, which first and foremost ensures that patients have in-network coverage and cost-sharing obligations in circumstances where the patient has no reasonable control over the network status of the facility or health care providers administering care. The FAH has maintained that surprise medical bills of all types (including those that result from improper payer denials or limitations on coverage) burden our health care delivery system and should be eliminated in a manner that preserves market negotiation of network rates between health plans and providers, consistent with Congress’s intent.

The FAH, however, is deeply concerned that the IFR improperly overrides the congressional compromise contained in the *No Surprises Act* by imposing a presumption that the qualified payment amount (QPA) is the appropriate out-of-network rate for an item or service and generally seeking to ensure that the Federal independent dispute resolution (IDR) process produces predictable outcomes that will reduce the use of the Federal IDR process. Congressional committees spent two years consulting with stakeholders on surprise billing issues, weighing policy considerations, and reaching an ultimate compromise that protects the consumer from surprise bills and financial uncertainty through the use of median contracted rate data while establishing the need for an independent process that balances the interests of providers, facilities, plans, and issuers in resolving payment disputes through a Federal IDR process that considers the full range of facts and circumstances presented by the parties (excluding three prohibited factors). As noted in the December 11, 2020, press release announcing the congressional compromise, the *No Surprises Act* “takes patients out of the middle, and allows health care providers and insurers to resolve payment disputes without involving the patient” in an IDR process where the independent arbiter “is required to consider the median in-network rate, information related to the training and experience of the provider, the market share of the parties, previous contracting history between the parties, complexity of the services provided, and any other information submitted by the parties.”¹ Moreover, the *No Surprises Act* excluded measures, including minimum claim thresholds, that would have reduced the use of the Federal IDR process. Against this backdrop, HHS, the Department of Treasury, and the Department of Labor (collectively the “Departments”) lack the authority to impose a presumption that the QPA is the appropriate out-of-network rate and to otherwise transform IDR effectively into a rate-setting process.

¹ House Committee on Energy & Commerce, Press Release, Congressional Committee Leaders Announce Surprise Billing Agreement (Dec. 11, 2020), at <https://energycommerce.house.gov/newsroom/press-releases/congressional-committee-leaders-announce-surprise-billing-agreement>.

WAIVER OF PROPOSED RULEMAKING (Part VII)

The FAH strongly disagrees with the Departments’ assertion of good cause for promulgating the regulations set forth in the IFR without the benefit of notice and comment procedures. As the Departments concede, the statutory effective dates at issue “may have allowed for the regulations, if promulgated with the full notice and comment rulemaking process, to be applicable in time for the applicability date of the provisions” in the statute.² This is certainly true—the *No Surprises Act* was enacted on December 27, 2020, and Congress directed the Departments to issue regulations implementing the IDR process by December 27, 2021, such that the Departments had an entire year within which to finalize regulations establishing the IDR process. The Departments’ assertion that notice and comment procedures were impracticable, unnecessary, or contrary to the public interest is meritless where Congress provided ample time for notice-and-comment rulemaking and notice-and-comment rulemaking would have provided a critical opportunity for the Departments to receive needed stakeholder input on proposals and alternatives.

Moreover, the Departments provide no rationale as to why the Departments had good cause to promulgate regulations that go beyond the *establishment* of the IDR process pursuant to IRC § 9816(c)(2)(A), 29 U.S.C. § 1185e(c)(2)(A), and 42 U.S.C. § 300gg-111(c)(2)(A). Congress only required the Departments to “establish by regulation one [IDR] process” used to resolve the amount of payment for the item or service through a certified IDR entity’s determination made “in accordance with” the statute (including subsection (c)(5)).³ Congress itself crafted the rules governing how certified IDR entities must evaluate and choose among the parties’ offers, leaving the Departments to design the process for certifying IDR entities, build a process for assigning disputes to certified IDR entities, and otherwise create the infrastructure for the IDR process. Even if the Departments have authority to alter or limit the certified IDR entity’s consideration of factors in IDR (a point the FAH does not concede), there was no good cause for doing so without notice-and-comment rulemaking. Rather, the Departments were free to leave certified IDR entities to evaluate permissible factors and circumstances pursuant to statute while obtaining stakeholder feedback on any substantive proposals concerning determination of the payment amount.⁴

² 86 Fed. Reg. at 56,043-44.

³ IRC § 9816(c)(2)(A), 29 U.S.C. § 1185e(c)(2)(A), and 42 U.S.C. § 300gg-111(c)(2)(A).

⁴ It is also worth noting that qualified IDR items and services will not begin to be submitted to the Federal IDR process until March of 2022 because an item or service furnished after January 1, 2022, must first be billed to the plan or issuer, paid or denied by the plan or issuer, submitted for open negotiations within 30 days, and negotiated during a 30-day period before the initiation of IDR. It was therefore neither impracticable nor contrary to the public interest for the Departments to establish the IDR process by regulation pursuant to the statutory deadline while separately undertaking notice-and-comment rulemaking on substantive elements of the payment determination.

INDEPENDENT DISPUTE RESOLUTION PROCESS
(Part III; 26 C.F.R. § 54.9816-8t, 29 C.F.R. § 2590.716-8, 45 C.F.R. § 149.510)

IDR Payment Determination and QPA Presumption (Part III.D.4.ii; Subsection (c)(4))

The FAH strongly opposes the Departments’ creation of a presumption that the QPA is the appropriate payment amount for qualified IDR items and services because the presumption is inconsistent with the statute’s text and purpose, will result in certified IDR entities selecting payment amounts that do not best represent the value of the qualified IDR item or service, undermines the open negotiation process set by statute, and risks spillover effects that harm patients without offsetting benefits. With the *No Surprises Act*, Congress created a neutral IDR process to arbitrate provider-payer disputes about the appropriate rate for out-of-network items or services. Congress spelled out a list of factors that the IDR entity *must* consider to determine the appropriate payment rate and charged the Departments with issuing regulations for the IDR process “in accordance with . . . the . . . provisions” of the Act. The *No Surprises Act*, however, does not permit the Departments to limit or eliminate an IDR entity’s consideration of permissible factors and circumstances presented by the parties during IDR. But the IFR does just that by requiring IDR entities to prioritize one factor—the QPA—in selecting an offer as the out-of-network rate, except upon a showing of credible information that clearly demonstrates the QPA is materially different from the appropriate out-of-network rate. The loss of the neutral process created by statute risks harms in the form of market disruptions, narrowed provider networks, and reduced access to care, particularly in underserved communities.

The QPA Presumption is Contrary to Law

During the negotiation of the *No Surprises Act*, early iterations of surprise billing legislative proposals included provisions that approached rate-setting or otherwise limited access to a dispute resolution process. In the final bill, which followed two years of bipartisan and bicameral deliberations, Congress responded to broad-based concerns that a dispute resolution process tantamount to rate-setting would disrupt the health care market, skew managed care negotiations, and risk patient harms while still providing for the quick resolution of patient cost-sharing obligations. It did so by adopting two separate amounts: (1) the “recognized amount,” which is based on the QPA and is used to expeditiously determine the patient’s cost-sharing obligations and (2) the “out-of-network rate,” which is the final payment amount determined in open negotiations or in IDR based on all of the relevant facts and circumstances of which the QPA is only one.⁵

In furtherance of this approach, the statute sets forth fairly detailed rules for calculating the QPA so that the recognized amount can be readily ascertained and the patient’s cost-sharing obligations promptly finalized. Once the patient’s obligation is resolved, if the provider or facility and plan or issuer disagree on the appropriate amount of total payment, they can proceed to a more nuanced and fulsome evaluation of the appropriate payment amount in open negotiations. Then, if necessary, the parties can obtain a determination of the payment amount at

⁵ These amounts differ in states that have in effect specified state laws or an All-Payer Model Agreement.

IDR based on all the facts and circumstances properly presented. These facts and circumstances include, but are not restricted to, the QPA. The certified IDR entity “shall consider” each of the following: the QPA, “information on any circumstances” listed in subsection (c)(5)(C)(ii), “such information as requested” by the certified IDR entity, and “any additional information” submitted by a party and relating to a party’s offer.⁶ Importantly, the statute does not say that the QPA takes primacy over any of the other circumstances to be considered.

Unlike the statute, however, the IFR requires the certified IDR entity to default to the QPA, unless the parties submit “credible information” that “clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate.”⁷ The Departments explain that the regulations make the QPA the “primary factor the certified IDR entity will always consider” and that they do not require the IDR entity “to consider all factors equally.”⁸ Furthermore, the rulemaking preamble says that making the QPA the primary factor will lead to out-of-network services usually being paid in an amount that is close to the QPA.⁹

The Departments assert that this QPA presumption represents the “best interpretation” of the statute, but fail to identify any statutory language that suggests the QPA is to be given any greater weight than information on any other circumstances and factors that can be presented by the parties. Instead, the Departments argue that, when identifying the information that the certified IDR entity is required to consider, Congress listed the QPA first in a subclause separate from the other information that must be considered. This portion of the statute reads as follows:

In determining which offer is the payment to be applied pursuant to this paragraph, the certified IDR entity, with respect to the determination for a qualified IDR item or service shall consider-

(I) the qualifying payment amounts (as defined in subsection (a)(3)(E)) for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR item or service; and

(II) subject to subparagraph (D) [prohibiting consideration of three specified factors], information on any circumstance described in clause (ii), such information as requested [by the certified IDR entity] in subparagraph (B)(i)(II),

⁶ IRC § 9816(c)(5)(C)(i), 29 U.S.C. § 1185e(c)(5)(C)(i), and 42 U.S.C. § 300gg-111(c)(5)(C)(i). The *No Surprises Act*, however, prohibits consideration of certain factors—usual and customary charges, the amount that would have been billed in the absence of the balance billing prohibitions, and public payor rates. IRC § 9816(c)(5)(D), 29 U.S.C. § 1185e(c)(5)(D), and 42 U.S.C. § 300gg-111(c)(5)(D).

⁷ 26 C.F.R. § 54.9816-8T(c)(4)(ii)(A), 29 C.F.R. § 2590.716-8(c)(4)(ii)(A), 45 C.F.R. § 149.510(c)(4)(ii)(A).

⁸ 86 Fed. Reg. 55,980, 56,061 (Oct. 7, 2021).

⁹ *Id.*

and any additional information provided [with a party's submission] in subparagraph (B)(ii).¹⁰

This organization does not suggest any intent to prioritize one consideration over another in the many varied disputes that will be submitted for IDR. The same instruction (“the certified IDR entity . . . shall consider”) applies uniformly to all of these permissible considerations. In addition, using a separate subclause to address the QPA was a logical drafting choice because the QPA is not otherwise referenced in subsection (c)(5) and needed to be further specified by reference to the applicable year, items and services, and geographic region. Moreover, the remaining categories of information (each of which is further detailed elsewhere in subsection (c)(5)) were sensibly grouped together to facilitate making each “subject to subparagraph (D),” which prohibits the consideration of three particular factors. Because the QPA is not one of the three factors that the certified IDR entity is prohibited from considering under subparagraph (D), no reference to subparagraph (D) was required in connection with the QPA.

The Departments also assert that the “detailed rules for calculating the QPA” suggest “that an accurate and clear calculation of the QPA is integral to the application of consumer cost sharing and to the certified IDR entity’s determination of the out-of-network rate.”¹¹ As explained above, however, these detailed rules simply reflect that the QPA must be readily ascertained in order to determine the recognized amount and limit the patient’s cost-sharing obligations. This detail does not suggest that the QPA is of special importance in determining the out-of-network rate. Instead, the statute crafted a totality of the circumstances approach to determining the out-of-network rate, which is a test familiar to adjudicators and arbitrators, and only listed the QPA as one of the many factors that the certified IDR entity “shall consider.” Moreover, contrary to the Department’s contention, the fact that the “recognized amount” is generally based on the QPA does not indicate that the QPA is “a reasonable out-of-network rate.”¹² Congress separately defined the recognized amount (based on the QPA) and the out-of-network rate (based on the totality of circumstances, when determined in IDR) indicating that Congress *rejected* the adoption of the QPA as a benchmark or a presumptive out-of-network rate.

The other statutory language identified in the IFR is similarly unavailing. The references to the QPA in connection with reporting requirements in subsection (c)(7) reflect nothing more than an interest in standardizing reported data so that information on payment determinations can be more readily digested. And the QPA audit requirements under subsection (a)(2) simply establish necessary regulatory oversight to ensure that plans and issuers do not game the QPA and mislead consumers, providers, facilities, and certified IDR entities by applying a non-compliant QPA.

The plain language, statutory context and structure, and legislative history, thus all demonstrate that Congress intended and required certified IDR entities to consider the totality of

¹⁰ IRC § 9816(c)(5)(C)(i), 29 U.S.C. § 1185e(c)(5)(C)(i), and 42 U.S.C. § 300gg-111(c)(5)(C)(i).

¹¹ 86 Fed. Reg. at 55,996.

¹² *Id.*

circumstances (excluding only the three specified, prohibited considerations) in choosing between the two parties' offers. The IFR's QPA presumption and its limitation on consideration of the other factors listed in the statute are incompatible with this statutory design and should be removed from the Departments' regulations. This conclusion has been confirmed in recent correspondence between members of Congress and the Departments. On November 5, 2021, more than 150 members of Congress object to the QPA presumption, concluding that "the parameters of the IDR process in the IFR . . . do not reflect the way the law was written, do not reflect a policy that could have passed Congress, and do not create a balanced process to settle payment disputes."¹³ Likewise, House Ways & Means Committee Chair Richard Neal (D-MA) and Ranking Member Kevin Brady (R-TX) concluded that the IFR's QPA presumption "strays from the No Surprises Act in favor of an approach that Congress *did not* enact in the final law" and confirms that the statute "directs the arbiter to consider all of the factors without giving preference or priority to any one factor."¹⁴ The final legislation "is the express result of substantial negotiation and deliberation among th[e] Committees of jurisdiction, and reflects Congress's intent to design an IDR process that does not become a de facto benchmark."¹⁵ ***Because the Departments cannot adopt, by regulation, a policy alternative that Congress rejected, the FAH urges the Departments to rescind the QPA presumption in favor of the totality of the circumstances approach mandated by statute.***

Policy Considerations Do Not Support the QPA Presumption

The policy considerations cited by the Departments in connection with the QPA presumption are similarly inconsistent with the statute. The Departments argue that the QPA presumption will "increase the predictability of the IDR outcomes" and "promote efficiency and predictability in the Federal IDR process."¹⁶ But nothing in the statute suggests any legislative intent to foster predictability in the IDR process for resolving payer and provider disputes. In fact, predictability is fundamentally inconsistent with the totality of the circumstances IDR design adopted by Congress.

Moreover, predictability is not an inherent good—rather, predictable IDR outcomes are akin to rate-setting, a policy rejected by Congress due to the distinct market and consumer harms of rate-setting. With a predictable IDR process that is tied to median in-network rates, plans and issuers have less of an incentive to negotiate in good faith with providers and facilities. Congress, however, endeavored to preserve meaningful payer-provider rate negotiations, as demonstrated by the statutory requirement that certified IDR entities consider the parties' good

¹³ Thomas R. Souzzi, Member of Congress, et al., Ltr. to Secretary Becerra, Secretary Walsh, and Secretary Yellen (Nov. 6, 2021), *available at* https://wenstrup.house.gov/uploadedfiles/2021.11.05_no_surprises_act_letter.pdf.

¹⁴ Richard E. Neal, Chairman & Kevin Brady, Ranking Member, Committee on Ways and Means, Ltr. to Secretary Becerra, Secretary Walsh, and Secretary Yellen (Oct. 4, 2021).

¹⁵ *Id.*

¹⁶ *Id.*

faith efforts (or the lack thereof) to enter into an in-network agreement.¹⁷ As a consequence of predictability in IDR, plans and issuers may seek to terminate or decline to renew provider agreements. In fact, providers and facilities have reported that payers have already begun to threaten termination of managed care agreements,¹⁸ a step that will reduce patients' options for in-network care. As noted in a letter from over 150 members of Congress from both parties, the IDR process set forth in the IFR "could incentivize insurance companies to set artificially low payment rates, which would narrow provider networks and jeopardize patient access to care – the exact opposite of the goal of the law. It could also have a broad impact on reimbursement for in-network services, which could exacerbate existing health disparities and patient access issues in rural and urban underserved communities."¹⁹

Predictable IDR outcomes are also inconsistent with a meaningful open negotiation process. Congress requires that payment disputes proceed through open negotiation before submission to IDR.²⁰ This process, however, becomes nothing more than an empty exercise and 30-day waiting period if a predictable IDR process eliminates issuers' and plans' incentive to negotiate in good faith. In Virginia, the Commissioner of Insurance recently admonished issuers that the failure to adjust offers during negotiations under Virginia's surprise billing law suggests the failure to negotiate in good faith: "We have observed that in certain disputes between providers and carriers, there is no difference between a carrier's initial allowed amount offer and the offer made following the good faith negotiation period. This strongly suggests that no good faith negotiations between the parties have occurred. The arbitration process is intended only as a last alternative, and only after a concerted effort has been made by both parties to reach agreement on a commercially reasonable payment amount."²¹ Because the QPA presumption creates predictability that may *discourage* plans and issuers from negotiating in good faith, the policy does not in fact "encourage parties to reach an agreement outside of the Federal IDR process" despite the IFR's assertion to the contrary.²²

Along similar lines, the FAH opposes the provision of guidance to certified IDR entities on their consideration of permissible information submitted by the parties. The IFR includes a

¹⁷ IRC § 9816(c)(5)(C)(ii)(V), 29 U.S.C. § 1185e(c)(5)(C)(ii)(V), and 42 U.S.C. § 300gg-111(c)(5)(C)(ii)(V).

¹⁸ *E.g.*, American Society of Anesthesiologists, BlueCross BlueShield of North Carolina Abuses No Surprises Act Regulations to Manipulate the Market Before Law Takes Effect (Nov. 22, 2021), at <https://www.newswise.com/politics/bluecross-blueshield-of-north-carolina-abuses-no-surprises-act-regulations-to-manipulate-the-market-before-law-takes-effect>.

¹⁹ Thomas R. Souzzi, Member of Congress, et al., Ltr. to Secretary Becerra, Secretary Walsh, and Secretary Yellen (Nov. 6, 2021), *available at* https://wenstrup.house.gov/uploadedfiles/2021.11.05_no_surprises_act_letter.pdf.

²⁰ IRC § 9816(c)(1), 29 U.S.C. § 1185e(c)(1), and 42 U.S.C. § 300gg-111(c)(1).

²¹ Va. Comm'r Ins., Admin Ltr. 2021-04, Compliance with Virginia's Balance Billing Claims (Nov. 22, 2021), at <https://scc.virginia.gov/getattachment/0d032dd2-8cbf-4446-87b0-06db15cda57c/21-04.pdf>.

²² 86 Fed. Reg. at 55,996.

number of examples, instructing certified IDR entities as to how they should consider particular facts and circumstances and indicates the Departments' intent "to provide additional guidance to certified IDR entities as necessary to clarify how the allowable factors should be considered."²³ The parties to IDR are sophisticated actors, well equipped to present their arguments as to how particular circumstances are relevant to the payment determination in the unique facts of an individual case. Guidance to the certified IDR entities inappropriately limits the totality of the circumstances inquiry mandated by statute and limits the value of the IDR process created by Congress.

In light of the foregoing legal and policy concerns, the FAH strongly urges the Departments to repeal the following provisions of 26 C.F.R. § 54.9816-8T, 29 C.F.R. § 2590.716-8, and 45 C.F.R. § 149.510: subsection (a)(2)(viii) (defining "material difference"); the second sentence of subsection (c)(4)(ii)(A) (creating the QPA presumption); the final sentence of subsection (c)(4)(iii)(C) (limiting consideration of additional information); subsection (c)(4)(iv) (setting forth examples limiting consideration of additional information); and subsection (c)(4)(vi)(B) (requiring additional written explanation where the certified IDR entity selects the offer that is not closest to the QPA).

IDR Deadlines and "Business Days" (Parts III.B & III.D.9)

The FAH appreciates the Departments' responsiveness to stakeholder concerns regarding key deadlines in the IDR process. The deadlines set forth in the *No Surprises Act* would be impractical and operationally burdensome if uniformly interpreted as calendar day deadlines, and *the Departments' decision to interpret many of the references to "days" in the statute as references to "business days" helps to facilitate a more fair and efficient IDR process*. The FAH, therefore, supports the Departments' use of "business day" deadlines for many key deadlines in the implementing regulations.

The FAH further urges the Departments to exercise their discretion under subsection (c)(9) of the respective statutes²⁴ to modify deadlines and other temporal requirements as necessary and appropriate due to extenuating circumstances. The implementing regulations properly contemplate extensions of deadlines to address delays due to matters beyond the control of the parties or for good cause. In preambular language, the Departments give the example of a request for extension of a deadline (other than the time period for payment) due to a natural disaster, but this is presented as an illustrative example that does not limit the range of extenuating circumstances that may warrant an extension of time. The FAH believes that circumstances beyond the control of the parties or good cause for an extension may exist in a wide range of situations that include (but are not limited to) the plan's or issuer's failure to provide information about the QPA,²⁵ technical issues that delayed or prevented a notice or

²³ 26 C.F.R. § 54.9816-8T(c)(4)(iv), 29 C.F.R. § 2590.716-8(c)(4)(iv), 45 C.F.R. § 149.510(c)(4)(iv) (setting forth examples); 86 Fed. Reg. at 55,998 (addressing future guidance).

²⁴ IRC § 9816(c)(9); 29 U.S.C. § 1185e(c)(9); 42 U.S.C. § 300gg-111(c)(9).

²⁵ The plan or issuer is required to provide certain information regarding the QPA with its initial payment or denial of payment and upon request by the provider or facility. 26 C.F.R. 54.9816-6T(d), 29 C.F.R. § 2590.716-6(d), 45 C.F.R. 149.140(d). As detailed further in the

submission, the parties' agreement to continue settlement discussions, illness of key personnel, and clerical errors.

In addition, the FAH urges the Departments to further exercise their authority under subsection (c)(9) by automatically tolling the deadline for commencing open negotiations and the deadline for submitting a notice initiating the Federal IDR process in cases where a dispute concerning medical necessity, denial of coverage, or coding for the item(s) or service(s) at issue are pending. As the Departments note, it is not the role of a certified IDR entity "to make determinations of medical necessity[] or review denials of coverage."²⁶ Rather, the IDR process is focused on determining the appropriate amount of payment for a qualified IDR item or service. Pending disputes regarding medical necessity, denials, and downcoding must be appropriately resolved prior to IDR, whether through internal or external appeals processes or otherwise, so that the parties and IDR entity have a common understanding of the items and services for which payment is owed. This is especially important given the increasing prevalence of these payer practices. Likewise, the open negotiation period is more likely to produce meaningful discussions of the appropriate payment amount for an item or service if disputes regarding threshold issues (medical necessity, denials, and coding) have been resolved first. The FAH, therefore, strongly urges the Departments to add a provision that automatically tolls the deadlines for the open negotiation notice and notice of IDR initiation until the resolution of any such appeal or dispute.

Open Negotiation (Part III.C.1)

Good Faith Negotiations. The FAH believes that meaningful negotiations between providers or facilities and plans or issuers is critical to ensuring that open negotiations are not futile exercises and to avoiding unnecessary IDR proceedings. To this end, the FAH urges the Departments to amend the regulations to do more than "encourage parties to negotiate in good faith during" the open negotiation period.²⁷ ***Each party should instead be required to negotiate in good faith during the open negotiation period, including by responding in a timely fashion to all requests for information regarding the calculation of the QPA and other facts and circumstances relevant to the appropriate payment amount.*** Such a good faith requirement should be appropriately enforced by HHS or State regulators, and the IDR entity should consider

FAH's September 7, 2021 letter to the Departments (Attachment A, available at <https://www.fah.org/wp-content/uploads/2021/09/FAH-Comments-Surprise-Billing-Part-One-FINAL.pdf>), the FAH continues to strongly urge the Departments to significantly expand the range of information that is shared with facilities and providers and to ensure that information is provided at the time of payment, without the need for a provider request. Transparency around the determination of the QPA is critically important to a fair and efficient IDR process, and a plan's or issuer's failure to provide information regarding the QPA calculation and supporting data should constitute good cause for delay of any provider or facility deadlines to allow sufficient time for such data to be provided and discussed in open negotiations.

²⁶ 86 Fed. Reg. at 55,996.

²⁷ 86 Fed. Reg. at 55,991.

information regarding a party's failure to negotiate in good faith when making its payment determination.

Waiver of Challenge to Open Negotiation Notice. Although the IFR properly provides that the certified IDR entity's payment determination "shall be binding upon the parties involved" except in cases of fraud or misrepresentation,²⁸ the Departments suggest that a payment dispute could proceed through open negotiations and the entire Federal IDR process, but result in an "unenforceable" payment determination if the open negotiation notice was not properly provided to the other party.²⁹ ***The FAH strongly opposes the suggestion that an IDR entity's payment determination could be subject to such a collateral challenge.*** Rather, if a party participates in open negotiations and participates in the IDR process, any challenge that party has to the sufficiency of the open negotiation notice is waived by its participation in the process. And, to the extent that a notice of open negotiation is defective, the party impacted should be permitted to raise any un-waived challenge to the sufficiency of the notice only if it can establish that it would be prejudiced by treating the notice as sufficient. Once the parties have engaged in the open negotiation and IDR process, it would be inequitable and inefficient to permit the parties to subsequently challenge the sufficiency of notice. And any challenge after the certified IDR entity makes its payment determination is plainly impermissible under the statutory and regulatory provisions establishing that payment determinations are binding.

Treatment of Batched Items and Services (Part III.D.3; Subsection (c)(3))

The appropriate batching of items and services for IDR serve critical efficiency and cost reduction purposes, allowing plans, issuers, providers, and facilities to obtain a determination of the out-of-network rate for related items and services in a single IDR proceeding. The FAH supports the Departments' acknowledgment that it is appropriate to use an alternative period for batching items and services for which IDR is delayed due to the 90-calendar-day suspension period, but requests technical revisions to the alternative period provision and requests that the Departments amend the other conditions for batching items and services to facilitate broader batching of qualified IDR items or services.

Alternative Period for Items and Services Subject to 90-Day Suspension Period. As the Departments acknowledge, the 30-day period for batching should be extended for cases where initiation of IDR is delayed due to the 90-day cooling off period. As currently worded, however, the implementing regulation for this alternative batching period only applies to items and services "furnished within . . . the same 90-calendar-day period under paragraph (c)(4)(vi)(B)

²⁸ 26 C.F.R. § 54.9816-8T(c)(4)(vii)(A), 29 C.F.R. § 2590.716-8(c)(4)(vii)(A), 45 C.F.R. § 149.510(c)(4)(vii)(A); *see also* IRC § 9816(c)(5)(E)(i), 29 U.S.C. § 1185e(c)(5)(E)(i), 42 U.S.C. § 300gg-111(c)(5)(E)(i).

²⁹ 86 Fed. Reg. at 55,990 ("The Departments caution that if the open negotiation notice is not properly provided to the other party (and no reasonable measures have been taken to ensure actual notice has been provided), the Departments may determine that the 30-business-day open negotiation period has not begun. In such case, any subsequent payment determination from a certified IDR entity may be unenforceable due to the failure of the party sending the open negotiation notice to meet the open negotiation requirement of these interim final rules.").

[sic] of this section.”³⁰ The 90-day suspension period under paragraph (c)(4)(cii)(B), however, refers to a period during which items and services cannot be submitted for IDR. The items and services impacted by the 90-day suspension period will generally have been furnished prior to the start of that 90-day suspension period. In order for an item or service to be subject to the suspension period, the day that is four business days after the 30-business-day open negotiation period must fall within the 90-calendar-day suspension period. Because the plan or issuer has 30 calendar days to make payment after receipt of the bill for items or services,³¹ the parties have 30 business days to initiate an open negotiation period, and the open negotiation period is itself 30 business days, even in the (unlikely) event that the claim was submitted on the same day the item or service was furnished, the item or service would not be furnished during the 90-day suspension period. It is the FAH’s understanding, however, that the Departments intend for the alternative period to apply to all items and services for which the initiation of IDR is delayed due to the suspension period and that the language of the current regulation is a scrivener’s error. Therefore, consistent with this intent, the FAH urges the Departments to amend paragraph (c)(3)(i)(D) to read as follows:

All the qualified IDR items and services were furnished within the same 30-business-day period, or all of the qualified IDR items and services are subject to the same 90-calendar-day period under paragraph (c)(4)(~~vi~~)(vii)(B) of this section, as applicable.

Bundled Payments. The IFR also contemplates that qualified IDR items and service may be billed “as part of a bundled payment arrangement” or that a plan or issuer may “make[] or den[y] an initial payment as a bundled payment,” permitting the qualified IDR items and services to be submitted as part of one payment determination in these cases.³² The reference to “bundled payment arrangements” in this provision is unclear because IDR is only available where the facility or provider and plan or issuer do not have a direct or indirect contractual relationship with respect to the furnishing of the items or services at issue (and thus, no payment arrangement exists).³³ And the Departments’ regulations require that the QPA be calculated separately for each item and service, even where the plan or issuer uses bundling or capitation for in-network claims.³⁴ As such, it is unclear when a qualified IDR item or service could properly be billed “as

³⁰ 26 C.F.R. § 54.9816-8T(c)(3)(i)(D), 29 C.F.R. § 2590.716-8(c)(3)(i)(D), 45 C.F.R. 149.510(c)(3)(i)(D).

³¹ 26 C.F.R. § 54.9816-4T(b)(iv)(A), 29 C.F.R. § 2590.716-4(b)(iv)(A), 45 C.F.R. § 149.110(b)(iv)(A).

³² 26 C.F.R. § 54.9816-8T(c)(3)(ii), 29 C.F.R. § 2590.716-8(c)(3)(ii), 45 C.F.R. 149.510(c)(3)(ii).

³³ 26 C.F.R. § 54.9816-3T, 29 C.F.R. § 2590.716-3, 45 C.F.R. 149.30 (defining “nonparticipating emergency facility” and “nonparticipating provider”).

³⁴ 26 C.F.R. § 54.9816-6T(b)(2)(iii), 29 C.F.R. § 2590.716-6(b)(2)(iii), 45 C.F.R. 149.140(b)(2)(iii) (“In calculating the median contracted rate, a plan or issuer must: . . . (iii) In the case of payments made by a plan or issuer that are not on a fee-for-service basis (such as bundled or capitation payments), calculate a median contracted rate for each item or service using the underlying fee schedule rates for the relevant items or services. If the plan or issuer

part of a bundled payment arrangement” or paid or denied as a bundled payment and then submitted to the Federal IDR process.

It is the FAH’s understanding that payment disputes involving each item and service included on a bill for a single encounter would be considered in a single IDR proceeding in every instance, regardless of whether the plan or issuer uses bundled payments when paying in-network claims for such items or services. Plainly, these cases involve the same facility, the same plan or issuer, and items and services related to treatment of the same condition because there is a single episode of care and a single patient. There is no policy rationale that would support separating payment disputes for these items and services into distinct IDR proceedings, and the IFR does not present any such rationale or otherwise discuss an intent to separate IDR proceedings involving items and services furnished by a single facility during a single encounter to the same patient. Therefore, the regulation should—consistent with the statute—be read to automatically group all such items and services into a single IDR proceeding that would be subject to the certified IDR entity fee for a single determination (or, if properly batched with items and services furnished during a separate encounter, subject to the fee for batched determinations).

The FAH, therefore, urges the Departments to amend paragraph (c)(3)(ii) of their regulations as follows:

(ii) ~~*Treatment of bundled payment arrangements—Considerations of Items and Services in a Single Encounter.*~~ In the case of qualified IDR items and services ~~billed furnished to a participant or beneficiary~~ by a provider, facility, or provider of air ambulance services as part of a bundled payment arrangement, or where a plan makes or denies an initial payment as a bundled payment, ~~the in an encounter, such~~ qualified IDR items and services ~~may submitted to the Federal IDR process should~~ be submitted as part of one payment determination. ~~Bundled payment arrangements—Items and services~~ submitted under this paragraph (c)(3)(ii) are subject to the ~~rules for batched determinations set forth in paragraph (e)(3)(i) of this section and the certified IDR entity fee for single determinations as set forth in paragraph (e)(2)(vii) of this section.~~

The foregoing amendment would comport with the plain text of the statute and avoid the inappropriate and unexplained separation of items and services for a single patient by a single provider or facility in a single encounter into multiple IDR proceedings. To the extent this recommendation is inconsistent with the Departments’ intent, the FAH requests that the Departments provide stakeholders with an explanation and an opportunity to provide further comment on such explanation.

Treatment of a Similar Condition. The FAH opposes the Departments’ use of a code-level approach to determining whether items and services are sufficiently similar for purposes of batching. Congress contemplated broader batching, instructing that joint consideration may be

does not have an underlying fee schedule rate for the item or service, it must use the derived amount to calculate the median contracted rate.”)

appropriate if the “items and services are related to the treatment of a similar condition.”³⁵ The IFR, however, only permits batching if the items and services themselves are similar (e.g., “billed under the same service code, or a comparable code under a different procedural coding system”). Under this approach, two electrocardiograms administered in the emergency department to two patients could be batched, but it appears that all of the emergency services furnished to two patients that present with heart failure could not be batched if any of the particular items and services furnished differ—notwithstanding the fact that each item and service is plainly related to treatment of a similar condition. This approach is inappropriately restrictive, unnecessarily frustrating the efficient resolution of payment disputes. Moreover, it is inconsistent with the statutory language which focuses on the underlying condition being treated (“related to the treatment of a similar condition”) rather than the particular items and services at issue and the codes for those items and services. The FAH urges the Departments to amend the batching regulations to focus on whether items and services are “related to the treatment of a similar condition.” Moreover, the FAH supports a broad construction of this provision that treats, for example, all trauma care items and services as related to treatment of a similar condition. Such an approach is consistent with the statutory focus on encouraging efficiency and minimizing costs through appropriate batching.

Same Provider or Facility and Same Issuer or Plan. In addition, the FAH urges the Departments to amend the “same provider or facility” and “same issuer or plan” conditions for batching items or services to address affiliates and entities under common ownership or control. A group of facilities under common ownership or control should be permitted to batch items and services related to the treatment of a similar condition where the same plan or issuer is responsible for payment. A single health system may include hospitals with different National Provider Identifiers and Tax Identification Numbers, and permitting health systems to batch claims for their hospitals will promote efficiency and reduce costs, similar to batching for providers in the same group of providers. And, because issuers under common ownership or control frequently apply uniform payment practices, a facility should be permitted to batch items and services related to the treatment of a similar condition where the issuers responsible for payment are under common ownership or control. Likewise, in the case of a group health plan administered by an issuer’s affiliate, a facility should have the flexibility to batch items and services related to the treatment of a similar condition where the entities responsible for payment are group health plans administered by entities under common ownership or control and issuers that are affiliates of or share common ownership or control with the entities administering the group health plans.

Amending the conditions for batching to promote greater flexibility will avert having an excessive number of IDR initiations for a very limited set of services and would help minimize IDR backlogs that could otherwise frustrate the efficient resolution of disputes.

³⁵ 42 U.S.C. § 300gg-111(c)(3)(A)(iii).

Certified IDR Entities, Conflicts of Interests, Denial and Revocation of Certification (Parts III.A., III.D.1, III.D.5, III.D.6)

Conflicts of Interest. The careful certification and auditing of IDR entities to ensure that each is free of conflicts of interest, has sufficient knowledge and expertise, and has adequate staff is critical to the Federal IDR process operating in a fair, impartial, competent, and efficient manner. With respect to conflicts of interest, the FAH appreciates the Departments acknowledgement that issuers of short-term, limited duration insurance and their affiliates and subsidiaries have impermissible conflicts of interest, as do affiliates and subsidiaries of trade associations representing plans, issuers, providers, and facilities. ***The FAH, however, urges the Departments to refine and strengthen the conflict of interest requirements for IDR entities by treating all health plan administrators and their affiliates as conflicted and establishing an adequate lookback period for familial, financial, or professional relationships with a party.*** Just as an affiliate or subsidiary of a group health plan or health insurance issuer has an impermissible conflict of interest, so too does an affiliate or subsidiary of a health plan administrator.

In addition, the FAH urges the Departments to amend subsection (a)(2)(iv)(d) to address recent material familial, financial, or professional relationships with parties. As the Departments implicitly acknowledge with the creation of a 1-year lookback period for impermissible relationships under subsection (c)(1)(ii)(C), recent material familial, financial, or professional relationships can impact a decisionmaker’s independence and impartiality. The FAH believes that the 1-year lookback period for personnel assigned to a payment determination should be applied to the entire certified IDR entity and that the lookback period should also be extended to at least 2 years. An entity or an individual that has had a material financial relationship with a party for years or decades would be unlikely to approach disputes involving such parties in an impartial manner one year later, and the use of a 1-year restriction on aiding or advising on trade or treaty negotiations under 18 U.S.C. § 207(b) does not suggest that a 1-year restriction is sufficient to avoid conflicts of interest. Congress has separately used a 2-year lookback period for State survey teams, prohibiting a State from using as a member of a survey team “an individual who is serving (or has served within the previous 2 years) as a member of the staff of, or as a consultant to, the facility surveyed . . .”³⁶ To effectuate the expanded lookback period and apply a lookback period to certified IDR entities, the FAH urges the Departments to amend subsection (c)(1)(ii)(C) to change “1 year” to “2 years” and to amend the beginning of subsection (a)(2)(iv)(d) as follows: “A certified IDR entity, that has (or, in the past 2 years, has had), or that has any personnel, contractors, or subcontractors assigned to a determination who have (or, in the past 2 years, have had)”

Public Information. The Departments seek comment on whether additional information about certified IDR entities should be made public, noting that the Federal IDR portal will include a list of certified IDR entities, including basic information about the entity (e.g., contact information, certified IDR entity numbers, websites, and service areas) and its fees. The FAH urges the Departments to expand the information provided on the portal to provide data on any petitions for denial or revocation of IDR entity certification, including the number of petitions

³⁶ 42 U.S.C. §§ 1395i-3(g)(2)(E)(ii), 1396r(g)(2)(E)(ii).

submitted and the type of submitter (*e.g.*, providers, facilities, issuers, plans, and others) and historical data on the number of payment determinations made by the qualified IDR entity each calendar quarter.

Denials and Revocations. In cases where an IDR entity is not appropriate for new or continued certification, the certification and revocation process must ensure that the IDR entity's certification is denied or revoked through an appropriately transparent process. The FAH urges the Departments to revise their denial and revocation regulations to address additional substantive bases for revocation, improve processes, and provide appropriate transparency. First, ***the FAH recommends revising subsection (e)(6)(ii) to expressly provide that certification may be revoked if, in conducting payment determinations, "the IDR entity has failed to meet the standards that applied to those determinations or review, including standards of independence and impartiality."*** This language is currently found in subsection (e)(6)(i)(D) as a basis for denying certification, and the omission of similar language from the list of bases for revocation of certification is inconsistent with the critical importance of independence and impartiality.

From a procedural standpoint, the IDR process offers providers, facilities, plans, issuers, and individuals only a narrow opportunity to petition for denial or revocation of IDR entity certification. Although Congress mandated that the certification process "ensure" that these entities and individuals "may petition for denial of a certification or a revocation of a certification," the IFR only provides a 5-business-day window during which a petition for denial can be submitted. In contrast, the IDR entity is given 10 business days to respond to a petition. It is unlikely that a 5-business-day period will be sufficient for individuals and entities to become aware of a pending application for certification and to prepare and submit a petition, and the application of such a brief petition period cuts against the statutory requirement to "ensure" individuals, providers, facilities, plans, and issuers may petition for denial of a certification. ***Instead, the FAH recommends a period of 15 business days for petitions to deny certification.***

Finally, the FAH urges the Departments to foster transparency in the certification and revocation process by providing notice to individuals, providers, facilities, plans, and issuers potentially impacted by denials or revocations. At present, the regulations do not provide notice to petitioning individuals and entities on the outcome of their petition and do not provide notice to the parties to a pending IDR matter of a revocation. If an individual or an entity petitions for denial of certification, that individual or entity should thereafter receive notification of the Secretary's finding regarding the adequacy of the petition and, if the petition is adequate, should receive a copy of the Departments' decision as to denial or revocation as well as any further decision following appeal. With respect to revocations, the IFR provides that the certified IDR entity may continue to work on previously assigned determinations through the end of the 30-business-day appeal period after revocation and does not provide any process for notifying the parties to any pending payment determinations assigned to the certified IDR entity of the revocation proceedings. The absence of a notice process for parties may result in providers, facilities, plans, and issuers unwittingly proceeding in a payment determination with a certified IDR entity that does not comply with the requirements of subsection (e). Instead, the parties to any pending payment determination involving a certified IDR entity that is the subject of a petition for revocation should, at a minimum, receive written notice of revocation within one business day of the decision and receive notice of any final revocation within one business day

following any appeal. Upon receipt of such notice, a party to a payment determination pending before the certified IDR entity should be provided a brief window within which to seek reassignment to another certified IDR entity. The FAH recommends the foregoing changes to the denial and revocation process to promote and preserve the integrity of the Federal IDR program.

Submission of Offers (Part III.D.4.i; Subsection (c)(4)(i))

The IFR sets forth the types of information that must be included with each party's offer submitted to the certified IDR entity, providing the parties with the flexibility to submit any information relating to an offer as long as the submission does not include information on factors described in paragraph (c)(4)(v). Under the IFR, a facility must include information regarding the number of facility employees in its submission, and the Departments seek comment on reporting whether additional guidance is necessary to account for the variety of methods of staffing that may be used by facilities. ***The FAH recommends that the Departments amend this provision to instead require submission of the facility bed count as a readily ascertainable and common metric of facility size.*** As the Departments acknowledge, differences in staffing models introduce variability in the number of facility employees, and this variability is addressed by instead focusing on bed counts.

SCOPE OF CLAIMS ELIGIBLE FOR EXTERNAL REVIEW

(Part IV.A, 26 C.F.R. § 54.9815-2719T, 29 C.F.R. § 2590.715-2719, 45 C.F.R. § 147.136)

The *No Surprises Act* requires that the external review process apply with respect to any adverse determination by a plan or issuer. Because the statute does not distinguish between grandfathered and non-grandfathered plans, the FAH supports the IFR's extension of external review requirements to grandfathered plans for adverse benefit determinations involving items and services covered by the *No Surprises Act*. The IFR also amends the scope of claims eligible for external review to include adverse benefit determinations related to compliance with the surprise billing and cost-sharing protections under the *No Surprises Act*. ***Although the FAH supports of the expansion of external review under the No Surprises Act, the FAH is concerned with the Departments' addition of examples that pertain to provider and facility actions rather than the plan's or issuer's compliance with surprise billing and cost-sharing protections.*** For example, newly added Example 6 addresses whether a claim was coded correctly, consistent with the treatment the individual received. The provider and facility assigned codes that accurately capture the items and services furnished, and the coding of a claim is not an adverse benefit determination. Any concerns regarding the coding of a claim are appropriately directed to the provider or facility and are not proper subjects of external review. In addition, new Example 5 relates to the provider's or facility's satisfaction of notice and consent requirements. Notice and consent is a provider or facility function, and a provider's or facility's (non)compliance with the notice-and-consent requirements is not an adverse benefit determination subject to external review. Therefore, the FAH urges the Departments to amend the external review regulations to remove Examples 5 and 6 and to confirm that external review is limited to adverse benefit determinations.

GOOD FAITH ESTIMATE
(Part VI.A; 45 C.F.R. § 149.610)

Delayed Implementation & Enforcement

The FAH supports the Departments' decision to delay the issuance of implementing regulations and defer enforcement of the requirement under PHS Act section 2799B-6(2)(A) that providers and facilities provide a good faith estimate for individuals enrolled in health plan or coverage and seeking to submit a claim for scheduled items or services to their plan or coverage. Implementation of this requirement involves overcoming technical challenges to facilitate the data transfers and will require additional time and stakeholder input. The FAH appreciates the Departments' responsiveness to stakeholder input on this issue and their commitment to undertake future notice and comment rulemaking to implement this provision, which will provide a critical further opportunity for provider and facility input, particularly on any operational and technological considerations with any proposed regulations.

The FAH likewise appreciates HHS' decision to defer enforcement of the requirement that a good faith estimate include expected charges from co-providers or co-facilities. Providers and facilities do not currently have systems and processes for identifying co-providers and co-facilities at the time of a request, let alone to receive and provide the required information from co-providers and co-facilities. It is therefore appropriate for HHS to exercise its enforcement discretion with respect to the inclusion of other providers and facilities on the good faith estimate, and the FAH urges HHS to extend the period of deferred enforcement beyond one year to the extent additional implementation time is necessary to address critical technological and operational barriers to compliance.

Coverage Assistance and Financial Agreements

The FAH is concerned that the IFR makes no reference to the availability of health care coverage, financial assistance, or payer-provider financial agreements. The good faith estimate process should be harmonized with other hospital activities focused on coverage, financial assistance, and financial planning in order to minimize the risk of harm. If a good faith estimate is provided prior to a review of patient eligibility for coverage or financial assistance, the good faith estimate may overstate the cost of care and discourage patients from receiving necessary and timely care.

When a patient presents to a hospital as uninsured, the hospital typically assists the patient in identifying available coverage. This process may result in the hospital determining the patient to be presumptively eligible for Medicaid pursuant to 42 C.F.R. § 435.1110, the patient otherwise enrolling in Medicaid or another Federal health care program, the patient enrolling in individual health insurance coverage with premium assistance tax credits through the Exchange, or the patient enrolling in COBRA continuation coverage or other coverage. Where a hospital is able to assist the patient in securing coverage, not only is the patient's financial responsibility for hospital items and services reduced or eliminated, but the patient will also enjoy the improved financial security and wellbeing that comes with prospective healthcare coverage. Patients with health care coverage are more likely to fill needed prescriptions and return for follow-up care,

improving their recovery. While the process for determining the patient's eligibility for coverage is proceeding, the hospital should not be required to prepare and deliver a good faith estimate that may not be relevant to the patient in light of his or her ultimate coverage and that may dissuade the patient from pursuing needed treatment. ***As such, the FAH urges HHS to explicitly provide that a facility that is actively assessing an uninsured or underinsured individual's eligibility for and assisting with enrollment in health care coverage is not required to provide a good faith estimate to such individual unless and until the patient is determined to be ineligible for coverage.***

With respect to an uninsured patient that declines or is ineligible for coverage, a hospital may enter into a single case agreement directly with the patient that provides for prepayment of items and services or uses a defined payment plan, after application of any available financial assistance program. In such cases, the financial agreement between the hospital and patient will govern and limit the patient's financial liability. The provision of a separate good faith estimate, including an itemized list of items and services, would be unnecessarily burdensome where such an agreement is in place, and the FAH urges HHS to deem a binding prepayment or defined payment plan agreement as satisfying the good faith estimate requirements.

Scheduling or Requesting a Good Faith Estimate from a Hospital

The IFR defines a convening provider or facility as the entity that is or would be responsible for scheduling an item or service and requires that the convening provider or facility collect information and prepare a good faith estimate upon scheduling an item or service. ***It is the FAH's understanding that "scheduling" involves affirmatively booking facilities for a particular date and time and that hospitals would not typically serve as convening facilities because the hospital generally is not responsible for scheduling items or services.*** For example, hospitals might use provider-direct scheduling systems that allow providers to schedule procedures and appointments in available time slots. Although hospital information systems might be used to facilitate the provider's scheduling of a service, the hospital in these cases does not schedule any item or service and would not be a convening provider responsible for providing a good faith estimate. In other cases, the hospital might undertake preliminary information gathering or administrative tasks (*e.g.*, pre-registration) that are designed to facilitate the patient's future registration but do not involve booking hospital facilities for a particular date and time. These activities likewise do not constitute scheduling, and the FAH understands that good faith estimate requirements are not triggered by pre-registration or similar non-scheduling activities. In sum, because hospitals are generally not responsible for scheduling items or services for uninsured or self-pay individuals, the FAH understands that hospitals will largely be considered co-facilities subject only to the requirements of subsections (b)(2) and (d).

Under 45 C.F.R. § 149.610(b)(2)(iv), if an uninsured or self-pay individual separately schedules or requests a good faith estimate from a co-facility, that facility is considered a convening facility for such item or service. ***The FAH opposes the imposition of this requirement, which will unnecessarily and inappropriately burden co-facilities that are not responsible for scheduling and risk the provision of unreliable good faith estimates that are limited by the information available to the co-facility.*** Even if the individual scheduling or requesting a good faith estimate from the co-facility is able to provide appropriate diagnostic

codes and identify the relevant items and services, the co-facility would not generally be in a position to identify co-providers and co-facilities who are reasonably expected to provide items or services in conjunction with and support of the primary item or service or to identify anticipated items and services that will require separate scheduling. It is inappropriate to impose convening provider or convening facility obligations on a facility or provider that is not responsible for scheduling, and the FAH urges amending the regulation to permit a co-provider or co-facility to refer the patient to their treating physician or surgeon or other convening provider or facility to schedule the service or request a good faith estimate.

In the interim and at a minimum, the FAH urges a narrow construction of this provision to ensure that a scheduling inquiry or request to a co-facility that does not include the information necessary for preparation of a good faith estimate does not constitute the separate scheduling or requesting of a good faith estimate under subsection (b)(2)(iv). If the inquiring individual does not provide the threshold information regarding, for example, the identity of the patient's anticipated surgeon or admitting physician, the patient's diagnosis codes, and the items and services to be furnished, the co-facility would not have the basic information necessary to provide good faith estimate information for its own items and services, let alone sufficient information to enable the co-facility to perform the responsibilities of a convening provider. In order to be effective, a request must be accompanied by the information reasonably necessary to provide the good faith estimate.

Similarly, the FAH urges HHS to amend or narrow subsection (b)(1)(iv), which states that convening providers and convening facilities "shall consider any discussion or inquiry regarding the potential costs of items or services under consideration as a request for a good faith estimate." This provision assumes that the convening provider or convening facility is in an active treatment relationship with the requesting individual in which particular recommended treatments or procedures are being discussed. Outside of this context, however, the convening provider or convening facility would not have sufficient information to provide the information in a good faith estimate with any reliability. ***As such, a request to a convening provider or convening facility should only be effective to trigger the preparation of a good faith estimate if the convening provider or convening facility has sufficient information concerning the individual's condition and care to enable the identification of co-providers and co-facilities and to otherwise reliably compile the information specified in subsection (c)(1).*** Such information might be derived from a treatment relationship with the requesting individual or might be provided directly by the requesting individual.

Patient Medical Record

The FAH opposes the requirement under 45 C.F.R. § 149.610(f)(1) that the good faith estimate be included in the patient's medical record. The statute makes no reference to inclusion of the good faith estimate in the medical record, and the IFR does not provide any rationale for this requirement. Facilities commonly maintain billing records separate from the medical record, and it is impractical and unnecessarily burdensome to mandate that the good faith estimate be maintained differently from other billing records.

Oral Notice of Availability of Good Faith Estimate

Subsection (b)(1)(iii)(B) requires a convening provider to “orally” provide notice of the availability of a good faith estimate when scheduling an item or service or when questions about the cost of items or services occur. This provision assumes that scheduling or the submission of cost-related questions will occur in an in-person or telephonic basis when oral notice would be feasible and appropriate, but in some cases, a convening provider may only interact with an individual through electronic communications when scheduling an item or service or fielding questions regarding costs. *The FAH, therefore, understands subsection (b)(1)(iii)(B) to be most logically read as only applying in the course of in-person or telephonic interactions and urges HHS to so clarify.*

The IFR Understates the Burdens Associated with the Good Faith Estimate Requirement

The good faith estimate requirements set forth in section 149.610 are extraordinarily burdensome and will be unduly costly to providers and facilities. The FAH expects that convening providers, convening facilities, co-providers, and co-facilities will incur costs connected with the provision of good faith estimates to the uninsured and self-pay individuals that far exceed CMS’ estimate of only \$356.7 million dollars. In calculating this estimate, HHS assumed that only 3,498,942 good faith estimates would be provided annually under section 149.610. This number, however, is based on the number of nonemergency elective procedures performed annually, multiplied by the uninsured rate (9.2%), reduced by 30% due to uninsured individuals being more likely to forego elective procedures, and increased by 5% to account for situations where a good faith estimate is provided but the uninsured patient does not undergo the procedure.³⁷ This calculation includes a number of unsupported assumptions that improperly understate the projected number of good faith estimates:

- First, the initial number of nonemergency elective procedures estimated by HHS is based on data on the number of elective procedures furnished in inpatient hospitals and ambulatory surgery centers.³⁸ The good faith estimate requirement, however, is not limited to inpatient hospital and ambulatory surgery center procedures—it applies to items and services more broadly, including those furnished by other facilities and by other providers.
- Second, HHS projects that a significant number of uninsured individuals “will forego elective procedures because of costs” without first obtaining a good faith estimate. Even if HHS’ unexplained assumption regarding the number that will forego care is correct, it is unreasonable to anticipate that these individuals will not discuss or inquire regarding the potential costs of items or services under consideration before choosing to forego care.

³⁷ 86 Fed. Reg. 56,080 n.282.

³⁸ Squitieri, Lee et al. “Resuming Elective Surgery during Covid-19: Can Inpatient Hospitals Collaborate with Ambulatory Surgery Centers?.” *Plastic and reconstructive surgery. Global open* vol. 9,2 e3442. 18 Feb. 2021, doi:10.1097/GOX.0000000000003442.

- Third, HHS projects that uninsured individuals will not shop around and obtain good faith estimates from multiple facilities and providers. The assumption of a one-to-one relationship between procedures and good faith estimates is wholly unexplained and irrational.
- Finally, the calculation does not include any good faith estimates provided to insured individuals who request a good faith estimate as a self-pay patient. A growing portion of the population is covered under high deductible health plans, and individuals with significant deductible obligations may choose to evaluate the costs of proceeding on a self-pay basis, particularly toward the end of a benefit period.

In addition, HHS' analysis of burden assumes that a business operations specialist will be able to generate a good faith estimate without any input from clinicians or other staff. Producing good faith estimates requires, *inter alia*, identifying the co-providers and co-facilities reasonably expected to provide items and services in conjunction with the primary item or service, preparing an itemized list of items and services reasonably expected to be furnished, and listing items or services that will require separate scheduling and that are expected to occur before or following the expected period of care.

In light of the foregoing erroneous and unsupported assumptions, the burden estimate set forth in the IFR does not satisfy the requirements of section 3506(c)(1)(A)(iv) of the Paperwork Reduction Act. HHS is required to evaluate fairly whether proposed collections of information should be approved and to review "a specific, objectively supported estimate of burden," but the burden described in the IFR significantly understates the burden imposed on providers and facilities in connection with the provision of good faith estimates to uninsured and self-pay individuals.

PATIENT-PROVIDER DISPUTE RESOLUTION PROCESS

(Part VI.B; 45 C.F.R. § 149.620)

The FAH strongly opposes the IFR's definition of the term "substantially in excess" to mean an amount that is \$400 more than the total amount of expected charges for the facility of provider. The threshold for billed charges being substantially in excess of the good faith estimate should appropriately vary based on the amount of the good faith estimate because the extent to which a patient anticipates variation in costs directly relates to the amount of estimated costs. A patient planning for a procedure that carries with it a good faith estimate of \$20,000 has significantly different expectations compared to a patient undergoing a \$2,000 procedure or a \$200 procedure. Likewise, from the provider or facility perspective, reasonably estimating expenses for high-dollar procedures carries with it greater risk as there is a wider range of unforeseen circumstances and variations in care that could cause the final billed charges to vary from the good faith estimate. ***Therefore, a percentage-based approach to determining when billed charges are "substantially in excess" of the good faith estimate is more consistent with both parties' reasonable expectations of variation in billed charges, as compared to a flat dollar amount.***

The FAH is also concerned that HHS' use of a flat dollar amount to define billed charges that are substantially in excess of a good faith estimate may also have unintended consequences that adversely impact uninsured and self-pay patients. Providers and facilities, in the face of such a rule, may seek to mitigate their risks by providing higher good faith estimates, particularly for procedures that have greater variability in billed charges. And, in some cases, the burdens of the good faith estimate requirements and the patient-provider dispute resolution process alongside existing collection risks and administrative costs may result in some providers or facilities declining to provide particular services on a self-pay basis.

Finally, the FAH urges the Departments to focus on medical experience when certifying dispute resolution entities as Selected Dispute Resolution (SDR) entities. SDR entities are primarily charged with assessing whether the additional billed charges not reflected in the good faith estimate "reflect[] 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."³⁹ Assessing and evaluating the information presented by providers and facilities on medical necessity and foreseeability will necessitate medical expertise in the specialties relevant to that patient's care. In recognition of this role, the FAH urges the Departments to require that SDR entities have qualified, clinical personnel in a range of specialties.

The FAH appreciates the opportunity to weigh in on the IDR provisions for implementation under the *No Surprises Act*. We look forward to continued engagement with you to protect patients from surprise medical bills and ensure a fair and operationally feasible process for payments to out-of-network providers. Should you have any questions or follow up, please do not hesitate to reach out to me or a member of my staff at 202-624-1534.

Sincerely,



³⁹ 45 C.F.R. 149.620(f)(2)(i)(C), (3)(i), (3)(iii)(2)-(3), & (3)(iii)(B).



ATTACHMENT A

Charles N. Kahn III
President and CEO

September 7, 2021

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

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

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

Re: Requirements Related to Surprise Billing; Part I; CMS-9909-IFC; 86 Fed. Reg. 36,872 (July 13, 2021)

Dear Secretaries Becerra, Yellen and Walsh:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services. These tax-paying hospitals account for nearly 20 percent of U.S. hospitals and serve their communities proudly while providing high-quality health care to their patients.

The FAH appreciates the opportunity to submit comments to the Office of Personnel Management, Department of the Treasury, Department of Labor, and Department of Health and Human Services, regarding their interim final rules, Requirements Related to Surprise Billing; Part I (IFR), published in the Federal Register (86 Fed. Reg. 36,872) on July 13, 2021. The FAH and its members strongly support the *No Surprises Act*, which first and foremost ensures that patients have in-network coverage and cost-sharing obligations in circumstances where the patient has no reasonable control over the network status of the facility or health care providers

administering care. Surprise medical bills – including those that result from improper payer denials or limitations on coverage – burden our health care delivery system and should be eliminated in a manner that preserves market negotiation of network rates between health plans and providers, consistent with Congress’s intent.

Emergency Services and Addressing Unfair and Abusive Payer Practices (Part III.B.1.i)

The FAH appreciates the Departments’ recognition that plans and issuers have deployed a range of unfair payment practices and abuses to inappropriately deny coverage of emergency services. As one example, some plans may violate the *Affordable Care Act’s* (ACA) patient protections by making an initial coverage determination based on final diagnosis codes and then applying the prudent layperson standard only if the participant, beneficiary, or enrollee appeals or seeks further consideration of the claim. Other plans or issuers may inappropriately require “sudden onset” of the emergency medical condition or impose a time limit between the onset of symptoms and the patient’s presentation at the emergency department. ***The FAH supports the Departments’ explicit admonishment that plans and issuers have been and continue to be prohibited from limiting what constitutes an emergency medical condition on the basis of diagnosis codes, requiring “sudden onset” of an emergency medical condition, imposing a temporal limitation on seeking care for an emergency medical condition, and applying general plan exclusions to deny coverage for emergency services.*** Rather, the ACA and the *No Surprises Act* both make it clear that the determination of whether an emergency medical condition exists must use the prudent layperson standard, which necessitates an assessment of all pertinent documentation with a focus on the presenting symptoms. Moreover, general plan exclusions cannot be applied to deny coverage for emergency services.

There are many other unfair and abusive plan practices that result in surprise bills for patients and/or burden providers and facilities with underpayments and disputes, including: inappropriate plan denials based on general plan exclusions and otherwise, down-coding and reclassifications; extended observation care; delayed credentialing to avoid payment; and reference pricing-based plans that operate without a network. These abuses are well known—for example, the HHS Office of the Inspector General concluded that Medicare Advantage Organizations (MAOs) overturned 75 percent of their own denials from 2014 – 2016 and that independent reviewers at higher levels of review overturned additional denials “in favor of beneficiaries and providers.”¹ These overturn rates raise concerns that “some beneficiaries and providers may not be getting services and payment that MAOs are required to provide.” These activities impose inappropriate burdens on patients receiving and providers or facilities furnishing both in-network and out-of-network services, and, in the context of emergency services, generate surprise bills, cause patients to forego seeking emergency services, and burden emergency facilities and providers with unnecessary disputes and administrative burdens. ***Therefore, the FAH urges the Departments to expand their oversight of plans and issuers to prevent and address unlawful and abusive plan practices.***

¹ *Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials*, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL (Sept. 2018) at p. 2.

The FAH also supports the IFR’s explicit confirmation that pre-stabilization services are emergency services for purposes of coverage and benefits. However, the FAH maintains that the ACA’s patient protections for emergency services also properly extend to pre-stabilization services that are furnished following a good faith admission but before the patient is stabilized. Although Medicare regulations provide that a facility has satisfied its obligations under the Emergency Medical Treatment and Active Labor Act (EMTALA) when it admits a patient “as an inpatient in good faith in order to stabilize the emergency medical condition,” it does not follow that a plan or issuer satisfies its ACA coverage obligations with respect to emergency services by limiting coverage to items and services furnished after an inpatient admission. Such an interpretation is inconsistent with Congress’s intent to ensure meaningful coverage for emergency services because it leaves the patient unprotected for pre-stabilization emergency services (e.g., inpatient treatment in a burn unit) – which are, in many cases, the most costly portion of the patient’s emergency services. The EMTALA regulation concerning good faith admissions was adopted based on HHS’s determination that hospital inpatients are protected by other laws such that the continuation of EMTALA obligations after an inpatient admission is unnecessary. From a coverage standpoint, however, other laws do not adequately protect the patient from improper coverage limitations when he or she is admitted as an inpatient prior to stabilization. Therefore, the rationale underlying the exception at 42 C.F.R. § 489.24(d)(2) is simply inapplicable to the patient protections under the ACA. Congress has made its intent on this point explicit in the *No Surprises Act* by confirming that the protection for emergency services apply “regardless of the department of the hospital in which the further medical examination and treatment is furnished,” ***but the FAH maintains that the ACA’s protections similarly apply to pre-stabilization services furnished following an inpatient admission, and the application of out-of-network cost-sharing obligations or the imposition of prior authorization requirements for these pre-stabilization services have been unlawful since the effective date of the ACA’s patient protections.***

Post-Stabilization Services (III.B.1.ii, 45 C.F.R. § 149.410(b)(1))

The Departments request comments on the definition of “reasonable travel distance” in the context of requirements that must be met before post-stabilization services cease to be emergency services.² ***The FAH recommends that the provider charged with determining whether the patient is able to travel to an available participating provider or facility – the attending emergency physician or treating provider – be given discretion to assess what constitutes a “reasonable travel distance” in light of all the facts and circumstances.*** A variety of factors could influence whether another facility is within a “reasonable travel distance,” including traffic, weather, and other route conditions. Given the range of factors that could come into play in individual cases, the FAH supports allowing providers to assess what is a reasonable travel distance in each individual case.

State Law Interactions with ERISA—Opt-In Statutes (III.B.2.iv.a)

The FAH appreciates the Departments’ recognition that some state surprise billing laws permit self-insured, ERISA-covered plans to voluntarily opt-in to the state law method for

² 86 Fed. Reg. at p. 36,881.

determining the cost-sharing amount or total amount payable for certain out-of-network services, but urges the Departments to require public disclosures of these elections. The IFR requires a self-insured plan that has chosen to opt in to such a state law to prominently display information about this election in its plan materials describing the coverage of out-of-network services. Because health care providers often do not have access to the self-insured plan’s plan materials, the FAH urges the Departments to also require the plan to display this information to the public (e.g., on a public website).

Non-Emergency Services Performed by Nonparticipating Providers at Participating Health Care Facilities (Part III.B.1.iii & iv)

The FAH urges the Departments to address plan delays in credentialing individual providers in contracted medical groups because these practices result in providers being inappropriately treated by the plan as nonparticipating providers. When a new provider joins a contracted medical group, the plan may not consider the new provider to be a participating provider unless and until the provider is credentialed, and the plan often declines to make the credentialing determination effective retroactive to the date of application. In some cases, the credentialing process is unduly delayed resulting in a period of months during which the provider is treating patients at a health care facility but is treated as a nonparticipating provider despite his or her medical group’s contract with the plan or issuer. Under the *No Surprises Act*, a nonparticipating provider lacks a direct or indirect contractual relationship with the plan or issuer, and the statute and IFR make no reference to whether the plan has credentialed the provider. *The FAH requests that the Departments address plans’ and issuers’ use of certification delays to treat providers as nonparticipating by requiring that credentialing determinations be made retroactive to the date the credentialing application was completed.*

Methodology for Calculating the Qualifying Payment Amount—Median Contracted Rate (III.B.2.vi.a, 45 C.F.R. § 149.140(a)(16))

Contracted Rate & Rental networks (45 C.F.R. § 149.140(a)(1))

The FAH supports the definition of “contracted rate” promulgated by the Departments, including the Departments’ confirmation that the contract rates accessed by plans and issuers through rental network agreements constitute “contracted rates” for purposes of the calculation of the qualifying payment amount (QPA). Rental network rates are “contracted rates recognized by the plan or issuer,”³ and the FAH therefore agrees with the Departments that the contracted rates between providers and the entity managing the provider network on behalf of a plan or issuer should be treated as the plan’s or issuer’s contracted rates for calculating the QPA.

Insurance Market—Self-Insured Plans (45 C.F.R. § 149.140(a)(8)(iv))

Under the IFR, sponsors of self-insured group health plans can choose to allow their third-party administrators to determine the sponsor’s QPA by calculating the median contracted rate using the contracted rates recognized by all self-insured group health plans administered by

³ Internal Revenue Code § 9816(a)(3)(E), ERISA § 716(a)(3)(E), PHS Act § 2799A-1(a)(3)(E).

the third-party administrator rather than determining the QPA by only referencing those of the particular plan sponsor. ***The FAH opposes conferring this discretion on plans because it creates inappropriate opportunities for gaming and abuse.*** By statute, the QPA is defined as “the median of the contracted rates recognized by the plan or issuer, respectively (determined with respect to all such plans of such sponsor or all such coverage offered by such issuer that are offered within the same insurance market . . . as the plan or coverage).”⁴ The statute does not allow for a plan (directly or through its third-party administrator) to consider rates that are not recognized by the plan, even if such rates might be recognized by other plans that share a third-party administrator with the plan. The IFR notes a concern that limiting self-insured group health plans to their own recognized rates will cause there to be more instances where the plan lacks sufficient information to calculate a median contracted rate, but Congress has already addressed the circumstances involving insufficient information – in these cases, the QPA is determined through use of an eligible database. It is inappropriate for a self-insured group health plan to opt out of this statutory process by looking to the rates recognized by other plans administered by the same third-party administrator.

Geographic Regions (45 C.F.R. § 149.140(a)(7)(i))

By statute, the QPA must be calculated for the geographic region in which the item or service is furnished. The FAH supports defining a geographic region for services other than air ambulance as one region for each metropolitan statistical area (MSA) in a state and one region consisting of all other portions of the state. The FAH, however, opposes the use of alternative, broader definitions of the geographic region for plans and issuers that do not have contracted providers in the MSA where the item or service is furnished (or, in the case of a rural provider, in any portion of the state that is not in an MSA). To put it simply, if a plan or issuer does not contract with providers in the geographic region as described in subsection (a)(7)(i)(A), the plan or issuer does not have sufficient information on contracted rates in the geographic region where the services were furnished and should instead use appropriate data for that actual geographic region.

Congress spoke to the approach that issuers and plans must take when they have insufficient information, and that approach ensures that the QPA is always based on *actual data from the particular geographic region where services were furnished*.⁵ Applying data from neighboring geographic regions under subsection (a)(7)(i)(B) and (C) of the QPA methodology regulations conflicts with the statutory scheme adopted by Congress. Moreover, requiring plans and issuers that do not contract in the area where services are furnished to use data from other parts of the state or census division in lieu of relying on an eligible database with actual local rate data risks patient cost-sharing obligations being set based on anomalous or non-representative data. In some cases, this will artificially depress the QPA, and in others, it will inflate the QPA (e.g., where a plan or issuer contracts with providers in a higher cost MSA in the state or census division). These risks are unnecessary where plans and issuers can readily use the insufficient information process to calculate a QPA that is actually valid for the geographic region where the

⁴ Internal Revenue Code § 9816(a)(3)(E)(i)(I), ERISA § 716(a)(3)(E)(i)(I), PHS Act § 2799A-1(a)(3)(E)(i)(I).

⁵ Internal Revenue Code § 9816(a)(3)(E), ERISA § 716(a)(3)(E), PHS Act § 2799A-1(a)(3)(E).

patient received care. *The FAH, therefore, urges the Department to amend subsection (a)(7)(i) to eliminate clauses (B) and (C).*

Methodology for Calculating the Qualifying Payment Amount—Cases with Insufficient Information (III.B.2.vi.d, p. 36895)

Eligible Databases (45 C.F.R. § 149.140(a)(3), (c)(3)(i))

If a plan or issuer does not have sufficient information to calculate a median contracted rate, the QPA is determined through the use of an eligible database for items and services furnished during 2022, or (in the case of a newly covered item or service) during the first coverage year for that item or service with respect to the plan or coverage. The impartiality and quality of the database are critical to ensuring that payments are made based on reliable data that reflects actual contracted rates in the same insurance market for the same or a similar item or service that is furnished by a provider in the same or similar specialty and provided in the geographic region in which the item or service is furnished. *The FAH, therefore, urges the Departments to refine and strengthen the conflict of interest requirements for eligible databases and to require the consistent use of databases appropriate to the items and services and geographic region at issue, as discussed further below.*

Conflict of Interests. Under the IFR, plans and issuers are permitted to use third-party databases as an alternative to state all-payer claims databases if conflict of interest requirements are met. These conflict of interest requirements address relationships with health insurance issuers and health care providers, facilities,⁶ or providers of air ambulance services and relationships with members of the same controlled group as or under common control with any such entity. *The FAH, however, urges the Departments to instead create a process by which the Departments will evaluate and determine which third-party databases are free of conflicts of interests.* Leaving it to issuers and plans to decide, in the first instance, whether a particular database is free of conflicts of interests creates the risk that issuers and plans will inappropriately rely on databases that either have conflicts of interests of a nature not specifically addressed by the IFR or that fail to disclose conflict of interest issues to the issuer or plan. Formal certification of databases as free of conflicts of interests by the Departments will ease the administrative burden on plans and issuers and avoid unnecessary disputes concerning the use of particular databases.

In addition, with respect to the particular conflicts of interest addressed by the IFR, the FAH urges the Departments to also address conflicts of interests created by trade association involvement and minority ownership by prohibited entities. With respect to trade associations, the FAH urges the Departments to prohibit the use of databases owned or controlled by any trade association whose membership consists of health insurance issuers, third party administrators,

⁶ Although the IFR’s “eligible databases” references affiliation, ownership, or control by a “facility,” the FAH understands this as referencing only health care facilities as defined in the IFR. Databases are only used to determine the QPA for nonparticipating emergency facilities and for certain professional services furnished in health care facilities, and any other facility type would be uninterested in the data used to calculate the QPA.

health plan sponsors, health care providers, health care facilities, or providers of air ambulance services. These trade association relationships create conflicts of interests for the administration of the database that compromise the reliability of the data for calculation of the QPA. In addition, with respect to ownership interests, the FAH urges the Departments to evaluate ownership interests in the aggregate for all health insurance issuers and their affiliates because small ownership interests spread among a group of similarly aligned entities could create a conflict of interest that is not evident from an evaluation of each ownership interest independently. Moreover, the threshold for a prohibited ownership interest should include minority ownership interests for all health insurance issuers and their affiliates.

Sufficiency of State All-Payer Claims Database Information. It is also critically important that eligible databases have sufficient data reflecting allowed amounts paid to health care providers or facilities for relevant services furnished in the applicable geographic region. At present, the IFR addresses many of these requirements for other third-party databases in subparagraph (ii)(B) and (C) of the definition of “eligible databases,” but it does not impose these requirements on state all-payer claims databases. Although most state all-payer claims databases would satisfy these requirements with respect to items and services furnished within the state, it is inappropriate to treat all state all-payer claims databases as categorically containing sufficient information in all cases. Certainly, it would be inappropriate to use one state’s all-payer claims database for items or services furnished in another state, or to use a database that fails to distinguish between governmental and commercial payers. As such, the FAH urges the Departments to apply the requirements in subparagraphs (ii)(B) and (C) to state all-payer claims databases.

Consistency in Databases Used. The FAH is concerned that the IFR appears to contemplate a plan or issuer changing databases for the same item or service in a geographic region from one year to another. In subsequent years (before the first sufficient information year), an issuer or plan is required to use the QPA from 2022 (or the QPA from the first coverage year for a newly covered item or service), increased by the percentage increase in the consumer price index for all urban consumers (CPI-U).⁷ As such, there should be no need – or opportunity – for a plan or issuer to use a different database from year to year. The FAH therefore urges the Department to remove “furnished through the last day of the calendar year” from subsection (c)(3)(ii) of their regulations.

The IFR also permits plans and issuers to select a different database for some items or services, provided that the basis for that selection is one or more factors not directly related to the rate of those items or services (such as the sufficiency of the data for those items or services). It is the FAH’s view that it would be very unusual for a plan or issuer to have a legitimate need to change the database used to determine the QPA for any facility items and services other than for reasons of the database’s geographic coverage. ***As such, the FAH urges the Departments to require that issuers and plans use the same database to determine the QPA for facility items or services in a geographic region. Moreover, where the QPA is derived from data in an eligible database, the plan or issuer should be required to disclose to the provider or facility the***

⁷ Internal Revenue Code § 9816(a)(3)(E)(iii)(II); ERISA § 716(a)(3)(E)(iii)(II); PHS Act § 2799A-1(a)(3)(E)(iii)(II); 26 C.F.R. § 54.9186-6T(c)(3)(ii); 29 C.F.R. § 2590.716-6(c)(3)(ii); 45 C.F.R. § 149.140(c)(3)(ii).

eligible database used as well as any other eligible database(s) that the issuer or plan uses to determine the QPA for other items or services in the geographic region at issue. Such transparency is critical to ensure compliance with the IFR's consistency requirement and prevent abuse.

New Service Codes (45 C.F.R. § 149.140(c)(4))

Recognizing that the creation of new service codes over time may necessitate application of a different QPA methodology when neither the provider's contracts nor eligible databases contain sufficient data concerning the new service code, the IFR creates a process by which the QPA can be calculated by using the QPA for a reasonably related service code as a benchmark. ***The FAH urges the Departments to ensure transparency and consistency when plans and issuers use the benchmark and relativity methodology to calculate the QPA for a new service code.*** First, the plan or issuer should be required to use the same reasonably related service code to calculate the QPA for a particular new service code in all instances to reduce the risk of gaming and abuse by changing the reasonably related service codes in different markets. It would, for example, be improper for a plan and issuer to use one reasonably related service code to determine the QPA for a new service code in one market but then use a different reasonably related service code to manipulate the QPA for the new service code in another market. ***Therefore, the FAH urges the Departments to require plans and issuers to use a single benchmark code and consistent methodology for determining the QPA of each new service code.***

Once the reasonably related service code is selected, in most cases, the plan or issuer will determine the ratio between the Medicare payment rate for the new service code and Medicare payment rate for the reasonably related service code and then convert the QPA for the reasonably related service code to a QPA for the new service code. Although Medicare payment rates are not useful benchmarks for the commercial market, the FAH supports the use of a relativity ratio based on Medicare rates – which are readily ascertainable and available to all parties – in the relatively rare instance where sufficient data concerning commercial rates for the new service code is not yet available. But, in instances where there is no Medicare payment rate for the new service code, the plan or issuer's reimbursement rate for the new service code is compared to the plan or issuer's reimbursement for the related service code (the relativity ratio), and that relativity ratio is used to convert the QPA for the related service code to a QPA for the new service code. The IFR does not establish a method to calculate the relativity ratio, but the Departments expect that plans and issuers will use a reasonable method. ***The FAH urges the Departments to expand transparency requirements related to the QPA calculation for new service codes to ensure that facilities and providers are provided with adequate information concerning the full QPA methodology used for a new service code.*** This would include sharing not only the reasonably related service code used, but also the QPA for the reasonably related service code, the relativity ratio used, and the data used to calculate the relativity ratio. And, in circumstances where Medicare rates are not available, this information should also include the reasonable method used by the plan or issuer, which should be uniform and consistent across markets. Because the use of a reasonably related service code to calculate the QPA should be rare and plans and issuers should apply a consistent methodology in each case, it would not be

unduly burdensome for plans and issuers to compile this information and then share it with each provider or facility that receives payment for the new service code.

Information to be Shared About the QPA (III.B.2.vi.e, 45 C.F.R. § 149.140(d))

The FAH strongly supports the transparent and meaningful disclosure of information relating to the calculation of the QPA. Providing this information with claims payment will aid in preventing abusive practices, ensuring appropriate payment, and promoting the efficient resolution or avoidance of payment disputes. *The FAH, however, urges the Departments to significantly expand the range of information that is shared with facilities and providers and ensure that information is provided in the normal course, without the need for a provider request.* First, the information set forth in subsection (d)(2) should be provided with claims payment rather than by request. The plan or issuer and provider or facility have only 30 days to engage in negotiations, and this limited time frame means that information not provided with the payment will have limited utility in aiding meaningful negotiations or informing the decision to initiate IDR. Moreover, plans and issuers will need to have this information compiled and readily available in order to timely provide it in response to provider or facility requests, so providing the information in the normal course would not meaningfully increase the administrative burden on plans and issuers. Finally, because the QPA is generally calculated for a single reference year (2019) and then indexed, much of the information that should be disclosed will remain unchanged from year to year, further reducing the burden of sharing this additional QPA information. *Therefore, the FAH strongly supports more meaningful QPA transparency through a requirement that plans and issuers provide all QPA information (including the information set forth in subsection (d)(2)) to providers and facilities at the time of payment.*

In addition to providing the QPA data set forth in subsection (d)(1) and (d)(2) with payment, the plan or issuer should also provide methodological details concerning the calculation of the QPA, including the following particular pieces of information:

- (1) the number of contracted rates that were used to determine the median contracted rate;
- (2) the list of particular providers or facilities whose contracted rates were used to determine the median;
- (3) in cases where an eligible database was used to calculate the QPA under subsection (c)(3)(i) or (ii), the list of each eligible database that the plan or issuer has used to determine any QPA for items or services furnished in the state since January 1, 2021;
- (4) in cases where the QPA for a new service code is determined under subsection (c)(4)(i) or (ii), the QPA for the reasonably related service code, the relativity ratio calculated by the plan or issuer, and the data used to calculate the relativity ratio;
- (5) in cases where the QPA for a new service code is determined without using Medicare payment rate information under subsection (c)(4)(i)(B) (or updated under subsection (c)(4)(ii)), an explanation of the reasonable method used by the plan or issuer, which should be uniform and consistent across markets.

Plans and issuers are already required to consider the foregoing information in order to accurately determine the QPA, so compiling and sharing this information with providers and facilities with claims payment is not unduly burdensome. Moreover, in most cases, the burden is reduced because this information will not change from year-to-year and thus can be compiled when the QPA is initially determined and then shared each time that QPA is used.

Finally, where the plan or issuer uses a reasonably related service code to determine the QPA for a new service code, negotiations and IDR may be materially aided by information concerning other reasonably related service codes. *As such, the FAH urges the Departments to require plans and issuers, within 10 days of a request, to share with a requesting provider or facility the QPA for up to five alternative reasonably related service codes designated by the provider or facility and, where Medicare has not established a Medicare payment rate for the new service code, the relativity ratio for each of these alternative reasonably related service codes.* This additional information will ensure accountability and reduce the potential for gaming and abuse in the rare instances where a reasonably related service code is used to calculate the QPA, and the prompt sharing of this information may promote prompt resolution of disputes, whether through negotiation or IDR.

Health Plan Audits (Part III.B.2.vi.f., 45 C.F.R. § 149.140(f))

Under the IFR, the Departments will use HHS's existing enforcement procedures to ensure health plan compliance under the *No Surprises Act*, and HHS intends to amend its enforcement regulations through future notice and comment rulemaking to reflect the amendments made to the *Public Health Service (PHS) Act* by the *No Surprises Act*. Although the FAH supports using existing jurisdiction and processes to ensure health plans and issuers comply with the *No Surprises Act*, the FAH does not believe that these existing enforcement procedures satisfy the statutory audit requirement set forth in section 9816(a)(2) of the Internal Revenue Code and section 2799A-1(a)(2) of the PHS Act. The FAH supports strong and continued governmental oversight of plans and issuers, including through the use of regular and meaningful governmental audits and reporting. Such oversight will promote the processing of out-of-network claims in good faith, protect patients, minimize disputes and gamesmanship, and reduce the transaction cost associated with securing payment for out-of-network emergency services. The FAH urges the Departments to develop standards for enforcement and complaint investigation by state regulators, to develop audit standards for states to audit and annually report on plan and issuer compliance with QPA requirements, and develop and implement federal audit processes and procedures that will be applied to audit and annually report on plan and issuer compliance in states that do not undertake appropriate auditing. Consistent with the *No Surprises Act*, these audit processes should include the routine auditing of a sample of plans and issuers, as well as auditing following any complaints or information concerning compliance with QPA requirements.

Additional Plan and Issuer Requirements Regarding Making Initial Payments or Providing Notice of Denial (Part III.B.3, 45 C.F.R. §§ 149.110(b)(3)(iv), 149.120(c))

No Minimum Payment Rate. The Departments seek comment on whether to set a minimum payment rate or methodology for a minimum initial payment in future rulemaking.

The FAH strongly opposes a minimum payment amount because it would upset the statutory scheme established by Congress and involve unnecessary and inappropriate rate-setting activities. During Congress’s consideration of various pieces of legislation addressing surprise billing and coverage, legislators explicitly considered approaches that would have involved automatic payment of an initial or interim payment amount that could then be negotiated or further determined in IDR. Congress, however, rejected this approach in the *No Surprises Act* and instead required the determination of the QPA, which is used to determine the recognized amount for patient cost-sharing and as a factor in IDR in situations where a specified state law does not apply. This approach appropriately protects the patient by ensuring the swift resolution of the patient’s cost-sharing obligation, while avoiding direct or indirect provider and facility rate-setting. Following Congress’s rejection of an initial or minimum payment rate, the Departments lack statutory authority to adopt such a rate.

Notice of Denial of Payment. The *No Surprises Act* establishes 30 calendar days as the maximum time that a plan or issuer has to make payment on a claim for out-of-network emergency services or out-of-network provider services at an in-network facility.⁸ In adopting this prompt payment requirement, however, Congress did not create an exemption from or preempt other laws that may establish more rigorous benefit determination or payment deadlines. ***The FAH, therefore, requests that the Departments confirm that, where other laws impose more rigorous temporal requirements, neither the IFR nor the No Surprises Act override or preempt those laws.*** By way of example, the Departments note that ERISA requires that a benefit determination must be made within 15 days of receipt of any additional information requested by the plan in situations where the plan could not make a benefit determination based on the information originally submitted with the claim.⁹ In these cases, the *No Surprises Act* does not permit delay in the benefit determination itself – thus, if the plan were to cite non-coverage or a limitation on benefits as the basis for the denial of payment, that adverse benefit determination would still be subject to the 15-day ERISA deadline, notwithstanding the IFR’s 30-day deadline for transmitting the notice of denial of payment. On the other hand, where a state law provides a less rigorous prompt payment requirement (*e.g.*, 30 *working* days following receipt of a clean claim), the issuer would still be required to send payment or a notice of denial of payment within 30 calendar days under the *No Surprises Act* and the IFR.

Surprise Billing Complaint Process (Parts III.B.4 and IV.A.4, 45 C.F.R. § 149.150)

The FAH strongly supports the IFR’s extension of the complaints process to the full range of consumer protections, coverage, claims processing, and payment requirements that apply to group health plans and health insurance issuers under the *No Surprises Act*. Although Congress only expressly directed the Departments to establish a process to receive complaints regarding compliance with requirements regarding the determination and application of the QPA,¹⁰ a broader complaint process is appropriate to promote plan and issuer compliance with

⁸ Internal Revenue Code § 9816(a)(1)(C)(iv)(I), (b)(1)(C); ERISA § 716(a)(1)(C)(iv)(I), (b)(1)(C); PHS Act § 2799A-1(a)(1)(C)(iv)(I), (b)(1)(C).

⁹ 86 Fed. Reg. at 36,901.

¹⁰ Internal Revenue Code § 9816(a)(2)(B)(iv), ERISA § 716(a)(2)(B)(iv), and PHS Act § 2799A-1(a)(2)(B)(iv).

the *No Surprises Act* and to further protect consumers. By way of example, restricting the complaint process to QPA issues would inappropriately filter out complaints concerning the improper imposition of prior authorization requirements for emergency services, to the detriment of providers, facilities, and consumers.

Exceptions to Balance Billing Civil Monetary Penalties (Part IV.A.1)

The IFR indicates that HHS intends to address the imposition of civil monetary penalties and appropriate exceptions in future rulemaking. Such future rulemaking will, in particular, address the exception for a facility or provider that did not knowingly violate, should not have reasonably known that it violated the balance billing requirements, and withdrew the violating bill within 30 days of the violation. ***The FAH strongly recommends clarifying in future rulemaking that the trigger date for 30-day timeframe is the date the provider becomes aware of the balance billing violation.*** In adopting this exception, Congress recognized that it would be inappropriate to impose a civil monetary penalty on a provider that neither knew nor should have known of the violation at the time of billing and promptly rectifies the violation upon learning of the violation. ***In addition, the FAH recommends the creation of a presumption that a facility or provider neither knew nor should have known of the balance billing violation when the facility or provider acts in conformity with the plan’s or issuer’s explanation of benefits (EOB).*** Providers and facilities should be permitted to reasonably rely on the information provided by the plan or issuer in the EOB when billing patients, and it would be inappropriate for providers and facilities to face civil monetary penalties when the violation resulted from reliance on (mis)information contained in an EOB and corrective action is taken once the error comes to light.

The FAH appreciates the opportunity to weigh in on these initial areas for implementation under the *No Surprises Act*. We look forward to continued engagement with you to protect patients from surprise medical bills and ensure a fair and operationally feasible process for payments to OON providers. If you have any questions or wish to speak further, please do not hesitate to reach out to me or a member of my staff at 202-624-1534.

Sincerely,

