

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 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 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." 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," 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)." 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).

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

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, 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). 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 OPA information. Therefore, the FAH strongly supports more meaningful OPA 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;
- 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;
- 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. In these cases, the No Surprises Act does not permit delay in the benefit determination itself – thus, if the plan were to cite noncoverage 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(a0(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,